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# SHIFTING VARIABLES IN REGULATING GENETIC RESOURCES: DEFINITION, LEGAL *STATUS* AND ACCESS

**Abstract:** This papers aims to investigate the implementation of Access and Benefit-Sharing (ABS) regimes by examining their key elements, i.e. the notion of 'genetic resources', their *legal status* and the concept of 'access'. The study will tackle the loopholes and inconsistencies of ABS rules, as stem from the inclusion of digital information sequences, and attention will mainly paid to the topic of dematerialisation of genetic resources and its relationship with the instances for the recognition of the right to seeds. The author concludes by noting that the debate is still in its infancy, but the importance of food security should leave considerable room for the engagement of peasants in the 'sustainable management', even with regard to data and digital sequence information. In conclusion it is stressed that ABS regimes should pursue fundamental objectives of sustainable use of genetic resources and contribute to human rights such as right to food and health.



## 1. — *Introduction.*

This paper deals with the implementation of Access and Benefit-Sharing (ABS) regimes by examining their key elements, namely the notion of 'genetic resources', their legal status and the concept of 'access'. Indeed, the application of said regimes is particularly challenging if these features are not correctly defined and understood.

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Genetic resources should be considered building blocks of life: they are the basis for improvement of agricultural crops and, today, they are incorporated in the value chain that leads to the production of many goods to meet emerging demands resulting from changing socioeconomic conditions (such as population growth, intensive agricultural production systems and spreading of new diseases)[(1)].

Despite the uses and global flow of the genetic materials, there is still lack of clarity concerning the subject matter as actually covered by international agreements and domestic ABS legislations. Notably, the question of what constitutes genetic resources, i.e. the object of access measures, has not been fully addressed. This definition issue is directly linked to the implementation and improvement of international and national legal regimes for said resources. Notwithstanding that the cardinal notion of sovereignty over natural resources is firmly established in international law[(2)], it is still highly problematic for States to exercise their power to regulate access to genetic resources[(3)]. Moreover, 'access' itself is a vague formula generating a number of questions and concerns: what is exactly meant by 'access'? And what are the rights and duties of States as subjects of international law, in relation to the acquisition of the genetic resources?

In this context, this paper firstly aims to provide an interpretation of the notion of 'genetic resources', examining its emergence within international treaties (notably the Convention on Biological Diversity and the Nagoya Protocol) and implementing legislations. Secondly, it will briefly explore the historical development of genetic resources' *legal status*, to then move to the new emerging challenges related to access. Thirdly, the last sections will tackle gaps and deficiencies as far as the elements previously described are

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(1) Commission On Genetic Resources For Food And Agriculture, *ABS Elements. Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture*, FAO, Rome, 2016, p. 7, available at *fao.org*.

(2) M. Gestri, *La gestione delle risorse naturali d'interesse generale per la comunità internazionale*, Torino, 1996, p. 67.

(3) In the present chapter the term 'State' is used in its meaning under international law, i.e. State as a subject of international law.

concerned. They will discuss the practical implications of a narrow or extensive understanding of the definition 'genetic resources', the fragmented exercise of sovereign rights over them and the loopholes and unresolved questions in ABS procedures.

2. — *A closer look at the notion of genetic resources.*

The notion of 'genetic resources' is at the very core of ABS mechanisms, whose effectiveness largely depends on its meaning. As a practical matter, it is fundamental for providers and users to be aware of which materials can be owned, controlled and transferred under applicable domestic and international regimes[(4)]. Furthermore, the understanding of genetic resources can directly influence what is meant by 'utilisation' of genetic material as covered by international and domestic legislations.

As noted by Schei and Tvedt: «Since the potential value and the level of knowledge regarding the functionality in biology change, the wording of the legally binding definition suggests being dynamic in the sense that it captures the evolving knowledge and (…) all biological material will be covered by this definition when its use captures either the actual or the potential value of the hereditary elements»[(5)].

The term 'resource' conveys the idea of something naturally occurring within States' jurisdiction, which may be used and manufactured along the industrial value chain to increase national wealth. There are, however, several examples of different ways in which the notion 'genetic resources' has been used in international arenas, prior to and after the Convention on Biological Diversity and as a consequence of the evolving scientific knowledge and technological advances. One should note that the definition 'genetic

(4) See W. Tvedt, T. Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*, IUCN, Gland-Bonn, 2007, p. 53.

(5) See J.P. Schei, W. Tvedt, *Genetic Resources in the CBD: the Wording, the Past, the Present and the Future*, UNEP/CBD/WG-ABS/9/INF/1, Fridtjof Nansen Institute, Oslo, 2010, p. 10, available at *cbd.int*.

resources' rests mainly in the text of the CBD, while the Conference of the Parties (COP) has maintained considerable discretion regarding the concept. Since its inclusion in the CBD, the formula has been introduced into international treaties, discussions, documents and domestic laws. Nevertheless, ABS transactions have not benefitted as expected from these normative trends because of its lack of consistency and the disarray concerning its extent.

The following sections will firstly trace the understanding of the concept 'genetic resources' and their legal regime within the framework of the CBD and the Nagoya Protocol, and then analyse the meaning of the notion of 'derivatives', whose inclusion in the ABS international regimes is still questioned.

### 2.1. – *Defining genetic resources.*

The Convention provides a packaged definition of 'genetic resources', linking this expression to those of 'genetic material' and 'biological resources'. It is therefore crucial to start with an overview of the interconnected definitions. Art. 2 of the CBD describes this construct as follows: 'Biological resources' include 'genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity'; 'Genetic material' means 'any material of plant, animal, microbial or other origin containing functional units of heredity'; 'Genetic resources' indicates 'genetic material of actual or potential value'.

Read together, the above definitions under art. 2 of the CBD seem to indicate that both biological resources and genetic resources rely on their 'actual or potential value' to humans. Indeed, it appears from art. 2 of the CBD that 'genetic resources are a subset of biological resources'[6], which differ

[6] According to UNEP, genetic resources include, for example, seeds, but also DNA (extracted from plants, animals or microbes) in the form of chromosomes, genes or plasmids, as well as any part thereof, such as the promoter region of a gene. See UNEP, *Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches*, UNEP/CBD/WG-ABS/7/2, Annex, § 3, available at *cbd.int*.

from the broader category of biological resources for containing 'functional units of heredity'. Yet the term 'functional units of heredity' has not been defined in the CBD. This is due to the fact that in the *travaux préparatoires* the political compromise prevailed, rather than a scientific approach[7].

In theory, the expression 'genetic resources' might include all genetic elements containing both DNA (deoxyribonucleic acid) and RNA (ribonucleic acid). Special weight to determine the meaning of the formula 'genetic resources' is to be paid to interpretation by subsequent legal and legislative action[8]. According to the literary meaning of art. 2, what clearly falls outside the concept of 'genetic resources', as conceived in the CBD, is any biological resources used as commodity in trade[9]. However, many scientific and political definitions are possible, which implies that the criterion of the ordinary meaning of the terms used is not helpful. Neither is helpful recourse to the preparatory work as a supplementary means of interpretation under art. 32 of the 1969 Vienna Convention on the Law of Treaties.

As far as the Nagoya Protocol is concerned, the *chapeau* of its art. 2 (dealing with 'Use of terms') clarifies that definitions under the CBD are applicable to it: as a result, the notion of 'genetic resources' as expressed in the CBD constitutes an integral part of the Protocol[10]. However, the Protocol seems to go beyond the definitions listed in the CBD, by including in art. 2 a reference to 'derivatives'. Furthermore, it defines 'utilisation

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[7] See W. Tvedt, T. Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*, cit., p. 54 ss.

[8] UN Convention on the Law of Treaties (Vienna, 1969), art. 31(3). For a thorough study on the role of subsequent agreements and subsequent practice as means of treaty interpretation within the framework of the rules on the interpretation of treaties set forth in arts. 31 and 32 of the 1969 Vienna Convention see International Law Commission, *Draft Conclusion on the Subsequent Agreements and Subsequent Practice in Relation to the Interpretation of Treaties, with Commentaries*, A/73/10, Part Two, 2018, pp. 17-50. Available at *legal.un.org*.

[9] According to art. 2, the Convention also does not include human genetic resources, although States may choose to regulate access to this material after having taken into account its bioethical implications.

[10] See Nagoya Protocol, art. 2.

of genetic resources' as «means to conduct research and development on the genetic and/or *biochemical composition of genetic resources*, including through the application of biotechnology as defined in article 2 of the Convention»[(11)]. While the issue of 'derivatives' will be examined in the following paragraph, it is worth here to briefly dwell upon the phrase 'biochemical composition of genetic resources'. This formula was introduced in the Nagoya Protocol as the result of a debate among parties on whether the term 'genetic resources', beyond referring to DNA, should also include: 1) genetic expression such as RNA, proteins and enzymes; and 2) any naturally occurring biochemical compounds which result from the cellular metabolism (i.e. resins or essential oils)[(12)]. Some commentators believe that reading art. 2(c), which mentions 'biochemical composition of the genetic resources', with the definition of derivatives, leads to a broader reach of the Nagoya Protocol provisions which, in the end, would cover all kind of biological materials[(13)].

2.2. – *Derivatives*.

Of all the possible types of materials susceptible to be regulated by ABS regimes, the most controversial are derivatives. The debate on 'derivatives' is crucial for its economic and commercial consequences. In sectors such as pharmaceuticals, food or cosmetics, many products contain unmodified genetic resources or come from those patterned on or incorporating manip-

(11) See Nagoya Protocol art. 2(c), italics added. On the point see E. Morgera, E. Tsioumani, M. Buck, *Unraveling the Nagoya Protocol. A Commentary on the Nagoya Protocol Access and Benefit-sharing to the Convention on Biological Diversity*, Leiden/Boston, 2014, p. 65.

(12) E. Morgera, E. Tsioumani, M. Buck, *Unraveling the Nagoya Protocol*, loc. cit. The authors also explain that while RNA, proteins and enzymes do not contain functional units of heredity but retain information from them, the naturally occurring compounds do neither cointain hereditary characters not information from them and they can be synthesized if the material is directly extracted from the biological sample.

(13) See G. Burton, *Implementation of the Nagoya Protocol in Juscanz Countries: The Unlikely Lot*, in E. Morgera, M. Buck, E. Tsioumani, *2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective. Implications for International Law and Implementing Challenges*, Leiden, 2013, p. 302.

ulated biochemical compounds and genes found in nature. As an example, the shikimic acid extracted from star anise, which is the raw material of Tamiflu (a medicine for flu treatment), is a derivative[14]. Is a compound synthesised artificially with reference to shikimic acid all the same a derivative? Is it regarded as an object of the Nagoya Protocol?

These questions lead to the consideration that it can be complicated to determine whether ABS procedures should apply to meta-extracts, fractions or essences obtained from plants, animals or other biological samples and finally used as excipients in industrial processes.

In the context of the CBD, 'derivatives' appeared in the definition of 'biotechnology'[15], but were not properly or clearly mentioned elsewhere in the text of the Convention. After its entry into force, some scholars had argued that «the benefit-sharing provisions of the Convention of Biological Diversity only apply to genetic material. Consequently, potentially valuable materials, such as biochemicals, sometimes (and confusingly) referred to as derivatives, are not covered by the access and benefit-sharing provisions of the Convention»[16].

The Bonn Guidelines, instead, related to derivatives in the context of prior informed consent[17] and mutually agreed-upon terms[18], without, however, defining them properly.

In 2008, the Conference of the Parties to the Convention on Biological Diversity (COP) decided to establish the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, in order to clarify the meaning of this term and its consequences in the ABS

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[14] See R. Kohsaka, *The Negotiating History of the Nagoya Protocol on ABS: Perspective from Japan*, 2012, p. 61, available at *ipaj.org*.

[15] CBD art. 2 defines 'biotechnology' as: «any technological application that uses biological systems, living organisms, or *derivatives* thereof, to make or modify products or processes for specific use» (emphasis added).

[16] See L. Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*, IUCN, Gland, Cambridge and Bonn, 1998, p. 35.

[17] See Bonn Guidelines, § 36 (1), available at *cbd.int*.

[18] *Ibid*., § 44 (1).

framework[19]. It confirmed that there was no common understanding of the concept and listed many different conceptions of derivatives[20]: «*a)* derivatives understood as the results of an organism's metabolism; *b)* derivatives understood as any result of human activity utilizing genetic resources; *c)* derivatives understood as information on genetic resources»[21]. According to the expert group, opinions also diverged regarding the possibility of having «derivatives that are genetic resources and derivatives that are not»[22]. Although no clear position emerged from the works of the expert group, it provided useful information regarding how domestic legislations addressed the issues of derivatives in relation to prior informed consent and mutually agreed terms[23].

Indeed, after Rio, governmental practice has been expansive in dealing with the material covered by the ABS regulations and a number of domestic laws included definitions of 'derivatives', 'by-product' and 'synthesised product'[24]. For instance, the Andean Pact Decision 391/1996 on 'Common Regime on Access to Genetic Resources' has included within its purview 'by-products', i.e. «a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings»[25]. Actually, the early drafts of the Decision extended the regulation to synthesised end-products from genetic resources but, in the end, the final version did not include them in the access regime[26].

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[19] See Decision IX/12, Annex II, B Expert Group on Concepts, Terms, Working Definitions and Sectoral Approaches. Some more information on the matter is available at *cbd.int*.

[20] See UNEP/CBD/WG-ABS/7/2/2, *Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches*, 2009, p. 9, available at *cbd.int*.

[21] *Ibid*., p. 9.

[22] *Ibid*., p. 10.

[23] *Ibid*., §§ 31-34, p. 11.

[24] For an overview see K. Kate, S. Laird, *Biodiversity and Business: Coming to terms with the "grand bargain"*, in *International Affairs*, 2000, p. 261 ss.

[25] See the Andean Pact Decison 391- Common Regime on Access to Genetic Resources, art. 1, available at *wipo.int*.

[26] See *Ibid*., p. 36.

Some years later, also the Seychelles in its 'Access to Genetic Resources and Benefit-Sharing Bill' (2005), referred to 'parts and components' of genetic resources to indicate «functional units of heredity, DNA sequences, chemical compounds, secondary metabolites, biochemicals and other similar materials and transcriptions or information describing any of the above in terms of structure or similar technical details»[27]. This provision was introduced to indicate that «any element of a genetic resource should be considered as a genetic resource in its own right and, therefore, the ownership and control, and any associated rights and obligations, also apply equally»[28].

Elsewhere, legislators use a broader definition to indicate what kind of material triggers users' obligations. Most notably, the recent Brazilian Law 13.123 (2015) utilizes the concept 'genetic heritage' to gather both genetic sequences and 'substances derived from the metabolism of these living beings'[29].

In such a context of puzzling inclusion of the term 'derivatives' within ABS domestic measures, the Nagoya Protocol not only has introduced the notion in its 'Use of terms' provision, but has also defined it. Pursuant to its art. 2, the word 'derivate' means 'a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain function units of heredity'[30]. What seems to remain at question is whether the ABS obligations should

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[27] Republic of Seychelles, Access to Genetic Resources and Benefit Sharing Bill, Supplementary scope definitions, Section 5.6. See J.R. Lewis-Lettington, D. Dogley, *Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005)*, International Plant Genetic Resources Institute, Rome, 2006, p. 19.

[28] *Ibid*., p. 20.

[29] Brazilian Law 13.123 effective on 17 November 2015. The Law repeals the former Brazilian Biodiversity Law (Provisional Measure 2.186, 2001), and its implementation is regulated by Decree 8772 of 11 May 2016, available at *planalto.gov.br*. See also M. Da Silva, D.R. De Oliveira, *The New Brazilian Legislation on Access to the Biodiversity Act (Law 13, 123/15 and Decree 8772/16),* in *Brazilian Journal of Microbiology*, 2018, pp. 1-4, available at *sciencedirect.com*.

[30] See Nagoya Protocol, art. 2(e).

be extended to derivatives or should be limited to genetic resources [31]. This mainly depends on the fact that, as the divergence about the inclusion of a specific reference to derivatives in the Protocol continued during the negotiation, especially between developing and industrialised Countries, the final compromise was to mention this term only in art. 2 (Definitions) eliminating all references to it in the operational provisions [32].

Moreover, one more question arises in cases concerning derivatives acquired without physical access to genetic resources, extracted and isolated from their natural habitat and available *ex situ* [33], the so-called 'isolated derivatives' [34]. For instance, once collected, the biochemical compounds of a resin produced by a plant may be extracted and isolated in the laboratory of a local university. The question is: what if a foreign researcher obtains access only to the isolated biochemical compounds collected, but not to the plant that produced the resin or to the resin itself? [35]. This hypothesis was discussed by the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, which highlighted that in these cases it is questioned whether derivatives would fall under the international regime; in any case, they «could be regarded as biological resources and therefore be subject to national sovereign rights and mutually agreed terms» [36].

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[31] T. Greiber, S. Moreno, M. Åhren, J.N. Carrasco, E.C. Kamau, J.C. Mediglia, M.J.Oliva, F.P. Welch, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit- Sharing*, in *IUCN Environmental Policy and Law Paper No. 83*, Gland, 2012, p. 70.

[32] However, this led to the indirect link between 'utilisation' and 'derivative' through the reference 'application of biotechnology' in the definition of 'utilisation'.

[33] According to the CBD, the expression 'ex-situ' conservation means 'the conservation of components of biological diversity outside their natural habitats'. See CBD art. 2.

[34] Cfr. T. Greiber, et al., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing*, cit., p. 67.

[35] Cfr. E. Morgera, E. Tsioumani, M. Buck, *Unraveling the Nagoya Protocol*, cit., p. 69.

[36] See UNEP/CBD/WG-ABS/7/2/2, *Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches*, cit., § 21, p. 10.

3. — *The legal status of genetic resources.*

Through history, the international community has adopted three main approaches concerning genetic resources: free access, common heritage of humankind and nations' sovereignty. The '*semina libera*' (i.e. free access) approach implied that any individual could freely access genetic resources all over the world, without requiring the consent of the territorial State, and export and freely use the collected samples for scientific, breeding or simply reproductive purposes[37].

In the 1980s, the FAO contributed to the spread of the opinion in the international community that plant genetic resources should be considered a 'Common Heritage of Mankind' (CHM), a notion that had been formerly applied in the context of the law of the seas (with regard to the mineral resources of the soil under the high sea). The CHM principle implied that these resources could not be appropriated by any single State and should be used according to solidaristic principles[38].

In the early 1990s, national sovereignty over genetic resources emerged as a principle of international law, and the 1992 CBD changed the previous understanding, by establishing that genetic resources fell under the territorial sovereignty of those individual States where they are found: States have the sovereign right to exploit them exclusively and the authority to enact laws regulating bioprospecting activities (i.e. access to genetic resources) within their borders[39].

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[37] See A. Fodella, *Recent Developments on Access and Benefit Aharing Relating to Genetic Resources (ABS) in International Law*, in C. Casonato, L. Busatta, S. Penasa, C. Piciocchi, M. Tomasi (eds.), *Il biodiritto e i suoi confini: definizioni, dialoghi, interazioni*, Quaderni della Facoltà di Giurisprudenza, (Università degli Studi di Trento) Trento, 2014, p. 96.

[38] See J.E. Noyes, *The Common Heritage of Mankind: Past, Present, and Future*, in *Denver Journal of International Law & Policy*, 2012, p. 447 ss.

[39] The move towards the application of States' sovereign rights was mainly motivated by dissatisfaction, particularly among developing Countries, about the increasing exploitation of genetic resources and their falling under control of foreign individuals or companies through the means of intellectual property rights, known as 'biopiracy'. See A. Zainol, L. Amin, F. Akpoviri, R. Ramli, *Biopiracy and States' Sovereignty over Their Biological Resources*, in

Sovereign rights of States are referred to in the Preamble of the CBD and twice in the text[40]. However, this peculiar emphasis on national sovereignty is balanced by duties: firstly, conservation of biodiversity is declared as a 'common concern'[41] to the entire international community. Secondly, nations are bound to create conditions that facilitate access to their genetic resources for environmentally sound uses by other parties, and not to impose restrictions that run counter to the objectives of the CBD[42].

Because the CBD limits these rights within States' borders, without allocating property rights over these resources, property law issues must be regulated by State legislative or administrative measures establishing the *legal status* of genetic resources[43]. However, it has been noted that sovereignty in the CBD «is recast in a modern perspective», in the sense that it does not imply an absolute territorial power and *jus excludendi alios* but embodies «a public authority to be exercised in a manner that is functional to the goals of sustainable utilization of the common good of biodiversity»[44].

As noted above, while recognising national sovereignty over genetic

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*African Journal of Biothechnology*, 2011, p. 12395 ss. Within the purview of what is generally termed 'biopiracy', the specific concept of 'misappropriation' has emerged. The term 'misappropriation' of genetic reosurces and traditional knowledge could be defined as the appropriation (and subsequent utilisation) of such resources and knowledge, which occurs in violation of the applicable domestic ABS legislation or regulatory requirements of a 'Party to the Protocol', for this definition see C. Chiarolla, *Biopiracy and the Role of Private International Law under the Nagoya Protocol*, in *IDDRI Working Paper*, 2012, p. 7, available at *iddri.org*.

[40] See CBD, arts. 3 and 15. The former recalls Principle 21 of the Stockholm Declaration, recognising that nations have sovereign right to exploit their own resources pursuant to their own environmental policies, the latter again reproduces the sovereign rights of States as a basis to determine access to genetic resources.

[41] On the replacement of the concept of 'common heritage of mankind' by 'common concern', see N.J. Schrijver, *Sovereignty over Natural Resources, Balancing Rights and Duties in an Interdependent World*, University of Groningen, 1995, p. 201 ss., available at *rug.nl*.

[42] See CBD, art. 15.2.

[43] See A. Smagadi, *National Measures on Access to Genetic Resources and Benefit Sharing – The Case of the Philipines*, in *Law Environmental and Development Journal*, 2005, p. 54.

[44] E. Morgera, E. Tsioumani, M. Buck, *Unraveling the Nagoya Protocol*, cit., p. XIII.

resources, international law leaves States free to determine the *legal status* of genetic resources that is «how they are treated in law at national and sub-national levels»[45]. Some observers have noticed that ideally the *legal status* of genetic resources should distinguish between rights over: *a)* an organism, a biological sample or its parts, including genetic material (physical entity); and *b)* the intangible informational component that is embodied in the sample[46]. Historically, until the intangible component of genetic resources has been described with sufficient specificity[47], legal approaches focused on the physical entity and the ownership over the biological resources was considered in terms of physical property.

Notwithstanding the development of international biodiversity law, it was evident that States faced difficulties in creating within their domestic legal orders workable frameworks to determine ownership, national rights and property over genetic resources. States adopted multiple approaches and applied concepts such as 'ownership', 'property' and 'control' differently: the ownership of genetic resources ranged «from a total state ownership as in Costa Rica and Ethiopia, to the apparent recognition of outright private ownership (…) for example Canada and Australia, and to *res nullius*»[48].

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[45] See UNEP/CBD/WG-ABS/5/5, *Report on the Legal Status of Genetic Resources in National Law, Including Law, Where Applicable, in a Selection of Countries*, 2007, Annex, available at *cbd.int*.

[46] See M.C. Correa, *Sovereign and Property Rights over Plant Genetic Resources*, Background Study Paper No. 2, FAO, 1994, Rome, p. 2 ss., available at *fao.org*.

[47] The importance of the informational side of the genetic material is well described by Vogel: 'Users are interested in the "natural information" teased out of the biological sample through research and development (R&D) and will obtain the input from the cheapest Provider' see H.J. Vogel, *On the Silver Jubilee of "Intellectual Property and Information Markets: Preliminaries to a New Conservation Policy*, in M.R. Muller, *Genetic Resource as Natural Information: Implications for the Convention on Biological Diversity and Nagoya Protocol*, London-New York, 2015, Foreword, p. XV.

[48] See UNEP/CBD/WG-ABS/5/5, *Report on the Legal Status of Genetic Resources in National Law, Including Law, Where Applicable, in a Selection of Countries*, cit., p. 3.

4. — *Access: the notion within and outside the Nagoya Protocol.*

One of the most difficult conceptual problem in the nowadays ABS regimes emerges when one asks: what is access? Even if one might think that the term 'access' has a clear and self-evident meaning, it has indeed assumed different meanings, especially after it was introduced in the wording of the CBD where it is completely undefined.

When the Rio Convention was negotiated, developing and developed States' parties proposed to link 'access' to 'benefit sharing', in order to make clear that access procedures were connected to the users' obligation to share equally benefits arising from utilisation of genetic resources. However, this linkage was rejected by some scholars who noticed that «there is no mandatory link between "access" and "benefit sharing" because thousands of people may obtain "access" (i.e. be allowed to collect samples), but only those who "utilize genetic resources" must engage in the benefit sharing»[(49)].

Some domestic statutes, adopted after the entry into force of the CBD, define access as consisting of either the physical acquisition of the genetic resource or its utilisation. For instance, The Andean Community Decision 391/1996 defines access «as the obtaining and use of genetic resources for purposes of research, biological prospecting, conservation, industrial application and commercial *use*, among others»[(50)]. According to the drafting of this provision, the obtaining of genetic resources and their utilisation are cumulatively considered within the *formula* of access. A slightly different *formula* is that of art. 2 of the Ethiopian Proclamation No. 482/2006 on Access to Genetic Resources and Community Knowledge and Community Right since it refers to access as «the collection, acquisition, transfer *or use* of genetic resources and/or community knowledge»[(51)].

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[(49)] See W. Tvedt, T. Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*, cit., p. 14.

[(50)] Andean Community Decision 391/1996 – Common Regime on Access to Genetic Resources, Title I, On the Definitions § 1, available at *wipo.int*.

[(51)] Ethiopian Proclamation to Provide for Access to Genetic Resources and Community Knowledge and Community Right No. 482/2006, Part One General Provision, § 2 (1) emphasis added, available at *cbd.int*.

Differently, the draft version of Section 6b of the Access and Benefit Sharing Policy of Bhutan provides that «access to genetic resources means the *utilization* of genetic resources from Bhutan irrespective of whether they are accessed *in situ* or *ex situ* for the purpose of conducting any research and/or development on the genetic and/or biochemical composition of genetic resources including through the application of biotechnology»[52].

Special attention should be also paid to the *African Model Legislation for the protection of the rights of local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources* which focuses on access as acquisition and not on utilisation of the material accessed. It refers to access as «the acquisition of biological resources, their derivatives, community knowledge, innovations, technologies, or practices as authorized by the National Competent Authority»[53].

The Nagoya Protocol provides international obligations, linking together administrative decisions on access (set out in domestic permits) and benefit-sharing agreements. Art. 6 establishes the Parties' rights and obligations in regulating access to genetic resources. Not only does it reaffirm the States' authority to determine access to resources under their jurisdiction, but it also establishes the principle of Prior Informed Consent (PIC) as a precondition for access[54], requiring mutually agreed terms (MATs) to be negotiated. As a result, the basic points of the Nagoya Protocol ABS seem to be clear from the outset: each State is entitled to authorise or deny access to genetic resources found in areas subject to its jurisdiction and may set conditions on access. Access is given in return for the sharing of benefits which arise from a certain kind of utilisation (i.e. research and development), which also include non-monetary benefits as technological transfer,

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[52] Draft of Access and Benefit Sharing Policy of Bhutan, 2014, § 6 (c) emphasis added, available at *moaf.gov.bt*. The above mentioned definition within the draft has been endorsed in the Access and Benefit Sharing Policy of Bhutan, 2015, p. 10, available at *absch.cbd.int*.

[53] See African Model Legislation on Access and Benefit Sharing, art. 2, Part II, available at *wipo.int*.

[54] See CBD, art. 15(4) and Nagoya Protocol, art. 6.

community improvement, jobs, sharing of research data and other advantages for the country of origin[55].

However, the Nagoya Protocol neither defines the expression 'access to genetic resources', nor the envisaged utilisations that users should indicate in access permits or licences. Within the wording of the Nagoya Protocol access is one of the main pillars of the ABS system; it operates as a precondition for the sharing of benefits arising from the utilisation of genetic material.

In light of the definition 'utilisation of genetic resources' and through the expression 'access for their utilization'[56], the term 'access' has been considered to be «the beginning of the conduct aimed at research and development in the jurisdiction of one Party on the genetic or biochemical composition of genetic resources that are provided by another Party»[57]. This has led to the idea that 'access' can be achieved through specific activities aiming to research and development and including collecting biological material in the wild, obtaining samples from gene banks or possibly getting digitalised information about genetic resources and their compositions.

The Regulation (EU) n. 511/2014, which has implemented the Nagoya Protocol in the European Union[58] and established a system to monitor users' due diligence obligations, defines access as «the acquisition of genetic resources and traditional knowledge (…) in a Party to the Protocol»[59]. It links this acquisition to the term access instead of that of utilisation, e.g. «research and development activities on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology»[60].

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[55] See Nagoya Protocol, arts. 6 and 5(4); Annex.

[56] See Nagoya Protocol, art. 6(1).

[57] See E. Morgera, E. Tsioumani, M. Buck, *Unraveling the Nagoya Protocol*, cit., p. 140.

[58] See V. Colcelli, *Information on Access and Benefit Sharing Regardiing the Utilisation of Genentic Resources Under the European Union Legal Regutaion*, in R. Arnold, R. Cippitani, V. Colcelli (eds.), *Genetic Information and Individual Rights*, Regensburg, 2018, pp. 80-95.

[59] See Regulation (EU) 511/2014, art. 3(3).

[60] Regulation (EU) 511/2014, art. 3(5). See European Commission, *Guidance document*

The Brazilian ABS Law 13.123 (2015) describes 'access' as research or technological development carried out on genetic heritage sample.[61] In so doing, the law seems to cover the kind of activities which are similarly included in the EU Regulation's term 'utilisation'[62]. The focus on utilisation as research and development is crucial within the Brazilian system when there is a change of intent in utilising genetic resources: if the specimens are initially accessed (acquired) for non-molecular research activities, they will be covered by Brazilian permits for export or transport, but researchers in foreign Countries will need to register access (for research and development purposes) when utilising the same or other specimens for molecular research[63].

Under the law of treaties, subsequent practice of contracting Parties is decisive to establish the meaning to be attached to ambiguous treaty provisions, like the Nagoya Protocol's notion of access. If it is consistent and reflects the common understanding of the parties as to the meaning of the treaty, it must be taken into account as an element of treaty interpretation as recently emphasized by the International Law Commission's report on the interpretation of treaties[64]. Nevertheless, the above mentioned and various *formulae* to define access within domestic legislations and in the EU Regulation 511/2014 reveal that States do not have (yet) reached a common view on how to frame the genetic resources' acquisition.

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*on the scope of application and core obligations of Regulation (EU) No. 511/2014*, 2016, p. 10, available at *eur-lex.europa.eu*.

[61] Literally Lei n. 13.123, art. 2, § VIII, Chapter I, defines 'acesso ao patrimônio genético' as «pesquisa ou desenvolvimento tecnológico realizato sobre amostra de patrimônio genético».

[62] See *Workhop Report: Utilization of Brazilian Genetic Resources in the EU- Understanding ABS Expectations and Legal Requirements*, Natural History Museum, London, 2016, p. 5, available at *embrapa.br*.

[63] See K. Davis, P. Holanda, *Monitoring Requirements of the Nagoya Protocol and New EU and Brazilian Legislation, and Existing Sectoral Workflow for the Tracking ABS Information: A Preliminary Analysis*, in *Background Paper for the Brazil ABS Workshop*, Brasilia, 2016, p. 22.

[64] See International Law Commission, *Draft Conclusion on the Subsequent Agreements and Subsequent Practice in Relation to the Interpretation of Treaties, with Commentaries*, A/73/10, Part Two, cit., p. 36.

4.1. – *The Tragedy of the Anti-commons and the specialized FAO regime for access to plant genetic resources for food and agriculture.*

The shift from the concept of '*common heritage*' to '*sovereign rights*', by giving rise to an enclosure of raw genetic material, has turned genetic resources into anti-commons[(65)]. As said, many States (especially in the Global South) have been asserting their sovereignty rights over genetic materials, as a response to biopiracy, by passing laws that restrict access to genetic materials within their territory. This has created artificial scarcity of a *per se* non-rivalrous resource, in other words an anti-commons situation susceptible to pose many problems for the conservation and improvement of genetic resources crucial for food security and public health. One should note that only the international flow of plant genetic resources can ensure adequate agro-biodiversity, which is in its turn indispensable to face changing environmental conditions and ultimately to guarantee global food security and the enjoyment of the fundamental right to food.

The International FAO Seed Treaty[(66)] represents a reaction to the rising tide of measures that extend private (by way of IPRs) or sovereign control over genetic resources, which seems inappropriate for food and agriculture[(67)]. The Seed Treaty recognizes that ABS for agriculture biodiversity must be treated differently from how is generally regulated under the CBD and the Nagoya Protocol, by providing an internationally agreed framework for the conservation and sustainable use for crop diversity[(68)]. *Ratione materiae*, it covers a subset of genetic resources of particular im-

(65) See M.A. Heller, *The Tragedy of the Anticommons: A Concise Introduction and Lexicon,* in *Modern Law Review*, 2013, p. 6 ss.

(66) Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA or Seed Treaty) adopted by the FAO in 2001 and entered into force in 2004.

(67) See M. Halewood, K. Nnadozie, *Giving Priority to the Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)*, in G. Tansey (ed.), *The Future Control of Food. A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security*, London-Sterling, 2008, p. 115.

(68) See C. Chiarolla, *Intellectual Property, Agriculture and Global Food Security: The Privatisation of Crop Diversity*, Cheltenham-Northampton, 2011, p. 7.

portance for agriculture, more precisely 35 crop *genera* and 29 forage species (Annex I), including wheat, rice, bananas, etc. In this respect, the Treaty should be considered as a *lex specialis*, whereas the CBD and the Nagoya Protocol provide the general framework for the protection and sustainable use of biodiversity.

It is arguable that the Treaty establishes a multilateral regime for the management of global commons indispensible for the enjoyment of the fundamental right to food. It establishes a Multilateral System to facilitate access to the specified list of plant genetic resources for food and agriculture, balanced by benefit-sharing obligations in the areas of information exchange, technology transfer, capacity building and commercial development. Contracting Parties, in the exercise of their sovereignty, provide (almost) free access to each others' plant genetic resources for research, conservation and breeding. Access to the materials included in the Multilateral System is supposed to be obtained without the possibility for the beneficiary to be granted IPRs over products or processes obtained by using the accessed resources, in order to maintain the *spirit of the commons*[(69)]. In case of grant of IPRs, based on a model Materials Transfer Agreement, the IPR holder has to pay part of the royalties to an international trust fund administered to the FAO to the benefit of farmers in the Global South. Although much attention has been paid to the Multilateral System's provisions, it is important to underline one other relevant element of the FAO Seed Treaty: the concept of '*farmers' rights*'[(70)], i.e. the rights of farmers to re-use, sell and exchange seeds obtained as part of their harvests. The recognition of farmers' rights highlights the tension between the stewardship approach (that is prevalent in the Treaty) and the ownership approach (that is prevalent in the Nagoya Protocol and in the TRIPs agreement).

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(69) See S. VEZZANI, *Le risorse fitogenetiche per l'alimentazione e l'agricoltura nel dibattito sui* global commons, in *Riv. crit. dir. priv.*, 2013, p. 433 ss.

(70) See L. PAOLONI, *Diritti degli agricoltori e tutela della biodiversità*, Torino, 2005, p. 11.

5. — *The temporal scope of the Nagoya Protocol.*

Within the Nagoya Protocol, there is some uncertainty concerning the temporal scope of the ABS regime and the triggering of users' obligations[71]. Indeed, it has been questioned whether obligations are triggered by utilisation or only when genetic resources are newly accessed. The solution to this question is of key importance: there are many cases where genetic resources have been physically accessed prior the entry into force of the Nagoya Protocol (on 12 October 2014), whose use has yet occurred or continued after the Treaty was entered into force. If ABS obligations are triggered at the time of access, the ongoing or new utilisation of resources accessed prior the Protocol's entering into force would be excluded from the scope of the Nagoya Protocol[72].

The question here under discussion is not about the non-retroactive application of the Protocol[73], but rather about when users' obligations arise. The temporal scope issue was one of the most contentious in the negotiations leading to the adoption of the Nagoya Protocol: most developing Countries proposed utilisation as the trigger for benefit-sharing obligations, whereas developed Countries and private companies opposed it[74].

The unclear wording of art. 2 does not solve the question of temporal scope; indeed, no specific provision was introduced because no compromise had been reached during the negotiations. However, the joint reading of

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[71] B. Lassen, et al., *The Two Words of Nagoya – ABS Legislation in the EU and Provider Countries: Discrepancies and How to Deal with Them*, Public Eye, Natural Justice, 2016, p. 7.

[72] See Berne Declaration and Natural Justice (eds.), *Access or Utilisation – What Triggers User Obligations? A Comment on the Draft Proposal of the European Commission on the Implementation of the Nagoya Protocol on Access and Benefit Sharing*, 2013, p. 4, available at *publiceye.ch*.

[73] See art. 28 of the Vienna Convention on the Law of Treaties which affirms the non-retroactivity of treaties: «Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party».

[74] See S.G. Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysis*, Ceblaw Brief, Malaya, 2011, p. 25.

arts. 2, 3 and 5(1) may suggest that the trigger for benefit sharing is utilisation rather than access[75]. According to this interpretation, new utilisations would lead to the application of the Protocol, regardless of whether the physical access took place before or after the Nagoya Protocol entered into force. This understanding could be considered in line with some domestic provisions, which are targeted towards the utilisation of genetic resources rather than access. For instance, both South Africa and India focus on the activities carried out in relation to genetic resources, as opposed to access, and designate utilisation as the trigger moment for ABS obligations. Some Countries have included express reference to genetic resources accessed before the entry into force of domestic law which requires access agreements[76]; some others have obtained the same result by defining access as also including utilisation[77]. To the contrary, other States have linked users' duties and obligations to bioprospecting activities, thus excluding from the scope of application of the domestic ABS regime all materials previously accessed[78].

Against this background, the EU regulations establish that PIC and MAT are needed only when new access to genetic resources has occurred after the Nagoya Protocol came into force for the Union and its member States. Thus, the European ABS Regulation covers acquisitions as of 12 October 2014 (the date when the Nagoya Protocol entered into force) and the Regulation is not applicable to genetic material whose utilisation occurs after 12 October 2014, but has been accessed prior that date[79]. In

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[75] See B. LASSEN, et al., *The Two Words of Nagoya – ABS Legislation in the EU and Provider Countries: Discrepancies and How to Deal with Them*, cit., p. 7.

[76] See e.g. Act No. 16/2016 of Zambia on Protection of Traditional Knowledge, Genetic Resources and Expression of Folklore, Section seventy-four, available at *www.ilo.org*.

[77] See e.g. Proclamation No. 482/2006 of Ethiopia on Access to Genetic Resources and Community Knowledge, and Community Rights, available at *cbd.int*. For a legal framework targed toward the utilisation see Biological Diversity Act of India, available at *nbaindia.org*.

[78] *Ibid.*, p. 19.

[79] See *Guidance on the EU ABS Regulation Implementing the Nagoya Protocol*, 2016, p. 9, available at *naturvardsverket.se*.

other words, a large number of genetic resources, that have been accessed from provider Countries and currently distributed through collections or utilised by companies, are excluded from ABS regulation in the EU framework.

The EU ABS framework that excludes from its scope the genetic resources which were physically accessed in the country of origin before the entry into force of the Nagoya Protocol, even if utilization takes place afterwards, does not take into account the position expressed by provider Countries, especially the African Group[80]. Moreover, the focus on physical access as the trigger for user obligations in the EU has risen a number of concerns because it appears to run counter to art. 15 of the CBD which requires the fair and equitable sharing of benefits arising from utilization and, mostly, it does not follow the preferable joint treading of arts. 2 and 5(1) of the Nagoya Protocol, according to which utilization is the triggers for benefit sharing[81].

6. — *Loopholes and controversial questions.*

The previous sections have analysed the novelty within the wording of international instruments which have introduced the notion of genetic resources, established the sovereignty rights of State over them and considered access as a pillar concept for the governance of genetic resources.

The analysis below aims at showing the new loopholes and the inconsistencies of ABS rules that stem from the inclusion of digital information sequences in the discourse of genetic resources.

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[80] For an analysis of the African Group contributions in international access and benefit sharing regime see B. Coolsaet, J.Pitsey, *Fair and Equitable Negotiations? African Influence and the International Access and Benefit-Sharing Regime*, in *Global Envirosnmental Politics*, 2015, p. 44.

[81] See Berne Declaration and Natural Justice (eds.), *Access or Utilisation – What Triggers User Obligations?*, cit., pp. 11-16.

6.1. – *Genetic resources and digital sequence information*.

The blurred outlines of the genetic resources notion, as explained before, need to be emphasized here in order to underline how the lack of clarity on this term is now concerning data, accessed on the Internet or through digital databases, which relate to genetic material. Indeed, the unfortunate drafting of the CBD and Nagoya Protocol does not explicitly address the application of computer science to genetic resources which facilitate the spread of digital information sequences. Nevertheless, information technology allows obtaining knowledge about genetic material without the need for access to biological samples. Thus, it is still much questioned if the transfer of digital sequence information should or should not be covered by the CBD and the Nagoya Protocol[82].

On the one hand, it has been said that the adjective 'functional' within the definition of 'derivative' [as a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if does not contain *functional* units of heredity][83] also refers to the information encapsulated in the DNA that can be transformed in a new, digital and 'functional' form[84]. On the other hand, it has been recommended to maintain a conceptual and definitional distinction between genetic material and data or information[85]. Opinions diverge both in the

[82] In Decision XIII/16, the Conference of the Parties (COP) requested the Executive Secretary to commission a fact-finding study to clarify terminology and concepts and to assess the extend and the terms and conditions of the use of digital sequence information on genetic resources in the text of the Convention and the Nagoya Protocol. See Secretary of the Convention on Biological Diversity United Nations Environment Programme, 'Call for Expressions of Interest Study on Digital Sequence Information on Genetic Resources, 24 April 2017, available at *cbd.int*.

[83] See Nagoya Protocol, art. 2(e) emphasis added.

[84] See J.P. Schei, W.M. Tvedt, *Genetic Resources in the CBD: the Wording, the Past, the Present and the Future*, cit., p. 20.

[85] See U.S. Submission on Digital Information on Genetic Resources, 18 August 2017 available at *cbd.int*. For an overwiev of the issues see also CBD/DSI/AHTEG/2018/1/4, *Outcomes of the Meeting of the Ad Hoc Technical Expert Group on Digital Sequence Information on*

doctrine and among States. Some of them have underlined that considering digital sequence information as genetic resources under the CBD and the Nagoya Protocol should lead to 'a renegotiation of the Convention and the Nagoya Protocol to redefine genetic material noting that information does not contain functional units of heredity or genes'[86].

As a matter of fact, this is not only a conceptual debate. Relevant economic interests are at stake: as scientific advances have shown, the utilisation of genetic resources does not originate merely from the physical acquisition of biological samples, but it rather comes out of the availability of digital information sequences. By making digital data freely available, online databases reduce the cost in research and development activities. In the near future, it might even be possible to reproduce living (micro-)organisms in laboratories without accessing biological samples, which might give rise to a new form of digital biopiracy[87].

The shifting pathway through nonphysical access to genetic resources is now a very current topic in the international arena. Several multilateral debates are underway in order to find regulatory mechanisms applicable to sequences data even outside the Convention and the Nagoya Protocol. These frameworks could include the Multilateral System of the FAO Seed Treaty[88], the WHO (in the context of the Pandemic Influenza Prepared-

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*Genetic Resources. Terminology and Different Types of Digital Sequence Information on Genetic Resources*, in *Report of the Ad Hoc Techical Expert Group on Digital Sequence Information on Genetic Resources, Annex*, 2018, p. 5., available at *cbd.int*.

[86] See Australian Submission on Digital Sequence Infromation on Genetic Resources, CBD Notification 2017-037, available at *cbd.int*.

[87] In 2014, the Startup Synthorx reported the creation of a bacterium with an expanded six-letter genetic alphabet, adding new bases X and Y to the standard G, A, T and C bases. Simultaneously, synthetic biology researchers have designed and produced a synthetic copy of thebaine, the opiate morphine precursor harvested from poppies for millennia, using yeast embedded with genetic sequence information from several plant species, a bacterium, and a rodent. See R.F. Service, *Modified Yeast Produce Opiates from Sugar*, in *Science*, 2015, p. 677, available at *science.sciencemag.org*.

[88] See FAO, *Enhancing the Functioning of the Multilateral System: Note by the Co-Chairs*, 10-12 October 2018, available at *www.fao.org*.

ness Framework)[89], the intergovernmental discussion concerning access to marine genetic resources beyond national jurisdiction[90] and the negotiation of the UN Declaration on the Rights of Peasants within the United Nations[91].

Many Countries and observers fear that allowing access to genetic information without Prior Informed Consent and in the absence of a Benefit Sharing agreement, the existing ABS regime would be undermined, unable to prevent biopiracy or misappropriation of genetic resources[92]. Many international provisions might go unheeded and be simply bypassed[93].

In the current discussions around this topic there have been conflicting views: some Countries and NGOs have recommended legally-binding decisions by international bodies to unequivocally require that digitalised sequence information are considered equivalent to its physical biological counterpart. They strongly believe that access and benefit sharing should

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[89] See World Health Organization, *Comments on the Draft Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources*, 2017, p. 2, available at *cbd.int*.

[90] See H. Harden-Davies, *Deep-sea Genetic Resources: New Frontiers for Science and Stewardship in Areas Beyond National Jurisdiction*, in *Deep – Sea Research Part 2: Topical Studies in Oceanography*, 2017, pp. 504-513. Also see, *Summary of the Firts Session of the Intergovernmental Conference on an International Legally Binding Insrument under the UN Convention on the Law of the Sea on Conservation and Sustainable Use of Marine Biodiversity of Areas Beyond National Jurisdiction (4-17 September 2018)*, in *Earth Negotiations Bulletin* 20 September 2018, pp. 2-9, available at *enb.iisd.org*.

[91] Recently, instances for the recognition of the right to seeds, right to biological diversity and right to the protection of plant genetic resources have resulted in the Draft Declaration on the Rights of Paesants and Other People Working in Rural Areas, proposed by civil society and representatives of paesants and other people working in rural regions. The document, which has been adopted in 2018 by the UN Human Rights Council, will be voted soon by the General Assembly. See Human Rights Council, *Report of the Open-Ended Intergovernemetal Working Group on a Draft United Nation Declaration on the Rights of Peasants and Other People Working in Rural Areas*, 2018, p. 58, available at *ohchr.org*.

[92] See Decision XIII/16, Digital Sequence Information on Genetic Resources, adopted by the Conference of the Parties to the Convention on Biolgical Diversity, 4-17 December 2016, Cancun, available at *cbd.int*.

[93] Namely, Convention on Biological Diversity and its 3rd objective, the Nagoya Protocol and the Fao Seed Treaty.

not only apply to the physical transfer of biological material, but also to sequence data[94]. On the opposite side, other States and stakeholders have questioned the falling of digital sequence information into the definition of genetic resources and have provided reasonable arguments for free access and the public domain use of data[95].

For instance, as concerns marine genetic resources China and the Holy See, opposed by Republic of Korea, Switzerland and Japan, favored applying an International legal binding instrument to marine genetic resources *in silico*[96]. Conversely the United States and Canada cautioned against including information under an ABS regime and concerned that this would lead to a reduction in data sharing and challenges in data tracking[97].

### 6.2. – *Open access, bounded openness and enclosure 3.0.*

The 'Rio' legal framework concerning access to genetic resources and benefit-sharing was drafted primarily with tangible genetic resources in mind and does not expressly address the rather different issue of sequences information. The use of term 'genetic material' in the CBD/Nagoya Protocol seems to suggest that intangibles do not fall within the scope of the above instruments. Indeed, the digital transfer of DNA sequences does not even require a Material Transfer Agreement, since no physical material is

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[94] See African Centre for Biodiversity (ABC), *Submission of Information on the Use of Digital Sequence Infomation on Genetic Resources for Food and Agriculture*, 2017, § 4, p. 3 ss., available at *cbd.int*.

[95] See G. Garrity, *The Emergence and Growth of Digital Sequence Information in Research and Development: Implications for the Conservation and Sustainable Use of Biodiversity, and Fair and Equitable Benefit-Sharing – A Fact Finding and Scoping Study Undertaken for the Secretariat of the Convention on Biological Diversity*, Society for Industrial Microbiology and Biotechnology, available at *cbd.int*.

[96] See, *Summary of the First Session of the Intergovernmental Conference on an International Legally Binding Insrument under the UN Convention on the Law of the Sea on Conservation and Sustainable Use of Marine Biodiversity of Areas Beyond National Jurisdiction (4-17 September 2018)*, in *Earth Negotiations Bulletin* 20 September 2018, cit., p. 4.

[97] *Ibid.*

transferred at all. This has led some researchers to argue that '[t]here are no restrictions on the use of our portal or the genome data'[(98)]. Many users, in order to avoid the obligation of benefit sharing, argue that no genetic material was accessed and thus they do not have any benefit-sharing obligation to the State of origin of the material from which the sequences have been isolated. May they use the freely accessed genetic information to realize new products and processes to be patented as inventions? This approach concerning digital genetic information "in silico" recalls the '*enclosure of the intangible commons of the mind*': a new state-created property rights that includes '*intellectual*' rather than '*real*'[(99)].

But there is more. While depriving State of origin of control over genetic materials, the sequencing of genetic data and their storage in databases may result in increasing the power of information technology companies (the 'giants of the web'), ensuring control over big data containing the very foundations of life[(100)]. In this connection a number of scholars have expressed strong criticisms regarding the phenomenon of the cloud and related copyright issues. It has been said that the cloud 'imposes a hierarchy to the web, centralizing capacities' and 'increase the ability of cloud players to control when, where and how users interact with the web'[(101)]. According to this view the cloud mechanism generates an Enclosure 3.0 characterized by a reduction of users' possibilities to participate in the Internet as creators, collaborators and sharers and they are potentially less in a position to control and influence the direction of the Internet. The discourse on 'biological open-source' arrangements and cloud models risks to renew the discourse dealing with dispossession on digital information

(98) See the Naked Mole-Rat Genome Resource available at *naked-mole-rat.org*.

(99) See J. Boyle, *The Second Enclosure Movement*, in *The Public Domain – Enclosing the Commons of the Mind*, Yale University Press, 2008, p. 42.

(100) See S. Rodotà, *Il mondo nella rete. Quali i diritti, quali i vincoli*, Bari, 2014, p. 27.

(101) See D. Lametti, *The Cloud: Boundless Digital Potential or Enclosure 3.0?*, in *Virginia Journal of Law & Technology*, 2012, p. 190 ss.

on genetic resources and disempowers the claim for repossession 'of seed sovereignty'[(102)].

Adopting a different perspective, some authors have suggested to depart from the sovereignty approach and to regulate access to genetic information differently from access to genetic materials, by adopting a 'bounded openness' approach[(103)]. In a *de jure condendo* perspective, it is suggested that genetic resources should continue to flow freely, but royalties on intellectual property over the value added would be distributed as an *ex post* utilization to the Countries of origin[(104)].

Other scholars, inspired by the 'free and open-source software' movement[(105)], have looked at the open-source and copyleft principles as a model for development of biological open-source practices: 'BioLinuxes'. These mechanisms should be modeled on a type of licence common to open-source arrangements in *software*. Applied to plant genetic resources, *copyleft* provisions would permit and encourage further development, improvement and recombination of the germplasm, but require that any lines or cultivars should be made available under 'General Public Licence for Plant Ger-

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(102) See J. Kloppenburg, *Re-Purposing the Master's Tools: The Open Sources Seed Initiative and the Struggle for Seed Sovereignty*, in *International Conference Paper Yale University*, September 14-15, 2013, pp. 2-25, available at *osseeds.org*.

(103) See J.H.Vogel, *On the Silver Jubilee of 'Intellectual Property and Information Markets: Preliminaries to a New Conservation Policy'*, in M.R. Muller, *Genetic Resources as Natural Information: Policy Implications for the Conservation on Biological Diversity*, Abingdon-New York, 2015, p. XVIII.

(104) For an example of mechanism based on the bounded openness policy see the Peruvian Society for Environmental Law's comment on the draft fact-finding and scoping study for the Secretariat of the Convention on Biological Diversity available at *cbd.int*.

(105) In order to escape the copyright and patent arrangements, sofware developers and hackers have created spaces in which they can develop content and code tha can be freely exchanged and built upon by others. The 'free and open source software' (FOSS) movement encompasses a considerable range of methods and organizations. What unifies these initiatives is to allow software users to create an enfoarceable legal framework that preserves access to the original sources code and to any subsequent modifications and derivatives.

mplasm' (GPLPG)[106]. No further restrictions for the use in subsequent breeding programs should be posed. This mechanism has been proposed for the seed sector in order to create a 'protected commons' for those millions of farmers who will freely share continuous access to a pool of plant germplasm. The 'BioLinux' solution has been seen also as a useful tool for achieving the civil society's goal of 'seed sovereignty'[107].

## 7. — *Conclusions.*

The above discussion has sought to highlight difficulties faced by ABS mechanisms. While ratification of international instruments was successful, the drafting and the enactment of implementing measures remain difficult, particularly at domestic and regional level, where States (and competent international organisations) are required to create necessary infrastructures for efficient and operative PIC/ABS/MATs. The chapter has emphasized that the discussion on the meaning of terms such as 'genetic resources', 'derivatives' and 'access' is not only a terminological one and rather involves scientific research, economic, political and social claims.

Particularly challenging is the regulation of access to genetic information stored in databases, which is creating a new divide between those who support unrestricted access to genetic data repositories and websites and those who question free access to that sources of information, by also em-

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[106] See J. Kloppenburg, *Impeding Dispossession, Enabling Repossession: Biological Open Source and Recovery of Seed Sovereignty*, in *Journal of Agrarian Change*, 2010, p. 377.

[107] *Ibid.*, p. 379. Lastly it is worth mentioning the increasing use of cloud platforms and the next-generation sequencing using Cloud BioLinux which offers an on demand solution for the bioinformatics comunity. This alternative model aims at helping smaller laboratories and institutes that do not have access to substantial computational resources and provides a platform for developing bioinformatics infrastructures on the cloud (K. Krampis, T. Booth, B. Tiwari, M. Bicak, D. Field, K. Nelson, *Cloud BioLinux: Pre-Configured and On-Demand Bioinformatics Computing for the Genomics Community*, in *BMC Bioinformatics*, 2012, p. 2 ss., available at *biomedcentral.com*.

phasizing that developing Countries may not possess sufficient research and infrastructure capacity to take advantages of such access.

The current debate on paradigm-shifting in regulating genetic resources is still in its infancy, and it is questionable whether open science and the free exchange of knowledge and human creativity will be put in the service of the public interest which lies behind the governance of genetic resources. However, what appears to be clear is that decisions at all levels of regulations should be made, bearing in mind the fundamental objectives of sustainable and efficient use of genetic resources, the need for sizeable contributions to right to food and health and the necessity of equitable and fair sharing of benefits.