

Emerging Technologies in Biodiversity Governance: Gaps and Opportunities for Transformative Governance

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7.1 Introduction

Emerging technologies potentially have far-reaching impacts on the conservation, as well as the sustainable and equitable use, of biodiversity. Simultaneously, biodiversity itself increasingly serves as an input or source material for novel technological applications. In this chapter, we assess the relationship between the regime of the Convention on Biological Diversity (CBD, or “the Convention”) and the governance of three sets of emerging technologies: geoengineering, synthetic biology and gene drives, as well as bioinformatics. The linkages between biodiversity and technology go beyond these cases, with, for example, geographic information systems, satellite imagery or possibly even blockchain technology playing potentially important roles for implementing the CBD’s objectives. Here, however, we focus on technologies that have been subject to extensive debate and rulemaking activity under the CBD.

First, geoengineering, that is, the “deliberate intervention[s] in the planetary environment of a nature and scale intended to counteract anthropogenic climate change and its impacts” (Williamson and Bodle, 2016: 8), includes both carbon dioxide removal and solar radiation management (or modification) techniques. Geoengineering techniques could mitigate climate change and its impacts on biodiversity but could also cause harmful effects. Assessing these benefits and risks is complicated by great uncertainty as well as normative and political contestation. Second, synthetic biology applications, including so-called gene drives, fall within the scope of biotechnology as defined by the CBD: “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use” (CBD, Art. 2). Such applications may have positive impacts on the conservation and sustainable use of biodiversity (and, possibly, the fair and equitable sharing of benefits arising out the utilization of genetic resources); yet they also imply diverse and potentially severe biosafety risks, as well as possibly problematic socioeconomic impacts (SCBD, 2015: 39–40). Third, bioinformatics allows for the extraction of digital sequence information (DSI), that is, the genetic information that is

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derived from genetic resources. DSI is increasingly used in basic and applied research, replacing the need for access to “physical” genetic resources. While DSI has the potential to facilitate research on genetic resources, its use poses challenges with regard to the CBD’s objective of fair and equitable benefit-sharing (Tsioumani, 2020: 24).

The Convention facilitates political, technical and scientific deliberation on biodiversity-related technologies and partially provides for their regulation. This takes place through technical guidance, legally binding international rules under the Convention and its protocols, as well as different layers of governing body decisions. These two general functions are essential to implementing the CBD’s objectives. Regarding facilitating deliberation and cooperation, the Convention created a standing Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) to assist the Conference of the Parties (COP). The Convention also provides for access to and transfer of technology (Art. 16), exchange of information including research results (Art. 17) and scientific and technical cooperation (Art. 18) as means toward bridging capacity asymmetries in achieving its objectives. Aichi Target 19 under the Strategic Plan for Biodiversity 2011–2020 holds that by 2020, “technologies relating to biodiversity, its values, functioning, status and trends, and the consequences of its loss, are improved, widely shared and transferred, and applied.” With respect to regulation, the preambular text of the CBD, the Cartagena Protocol on Biosafety and a host of COP decisions refer to the precautionary approach, thus acknowledging its applicability in regard to relevant technological issues. The customary rule of transboundary environmental harm, enshrined in CBD Article 3, applies to technologies and activities in general that may “cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.” Environmental impact assessment, mandated under Article 14, bears relevance for technological projects “that are likely to have significant adverse impacts” on biodiversity.

The CBD regime has responded relatively quickly to specific emerging technological opportunities and challenges: through publication of technical reports, deliberations at COP and SBSTTA meetings and the creation of various consultation processes and ad hoc technical expert groups (AHTEGs). This has led to diverse COP decisions on a broad range of technological issues, as well as the adoption of a series of guidelines on both methodological and substantive aspects of governing technological change. In addition, rules have been put in place for the systematic monitoring of technological developments relating to biodiversity conservation and sustainable use, with SBSTTA being mandated to “[i]dentify new and emerging issues relating to the conservation and sustainable use of biodiversity” (Decision VIII/10). However, none of the technologies we discuss in this chapter has been classified as such as of yet.

The following three sections map the rules, institutional responses and regulatory gaps with regard to climate-related geoengineering; synthetic biology, including gene drives; and bioinformatics and DSI. In the conclusions, we assess the extent to which governance of those technologies under the CBD regime can support transformative change in order to address indirect drivers of biodiversity loss (see Chapter 1). While the CBD seems reasonably effective and appropriate in most of those regards, we point out that adaptation is limited to soft-law governing body decisions as well as technical guidance, limiting its

efficacy for mitigating risks or capturing potential benefits associated with technological change. This raises questions regarding the effectiveness and stringency of technology regulation within the context of the CBD's Post-2020 Global Biodiversity Framework, which, at the time of writing, contracting parties are expected to adopt in 2022.

7.2 Climate-Related Geoengineering

Anthropogenic climate change is closely related to the CBD's goals, especially the conservation of biological diversity (Bellard et al., 2012). The Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services estimates that climate change is the third most impactful direct driver of biodiversity loss (IPBES, 2019), and deleterious effects are expected to increase as the climate further changes. However, it is not only climate change that could have impacts on biodiversity but also our responses to mitigate it, including through two sets of technology that are often collectively referred to as "geoengineering." In recent years, it has become increasingly evident that greenhouse gas emissions reductions in line with the relevant international agreements will likely be insufficient for limiting global warming to 2°C above preindustrial levels. Decision-makers, climate modelers and other scientists began to turn to anthropogenic activities and technologies that would remove carbon dioxide from the atmosphere and durably sequester it for long timescales. Such carbon dioxide removal (CDR) techniques are diverse, and some hold the potential to significantly reduce net emissions and atmospheric concentrations of CO₂ (The Royal Society, Royal Academy of Engineering, 2018). Proposed CDR techniques include: (1) bioenergy with carbon capture and sequestration (BECCS), in which plants are grown and burnt to produce energy, with the resulting CO₂ captured and stored; (2) direct air capture (DAC), in which CO₂ is captured from ambient air, and stored; (3) enhanced weathering, in which minerals are processed to accelerate natural chemical CO₂ sequestration; and (4) ocean fertilization, in which nutrients are added to accelerate natural marine biological CO₂ sequestration. CDR could make ambitious climate change targets more achievable, could later compensate for initially exceeding emissions limits, and appears essential to meeting internationally agreed-upon climate change goals. Indeed, the favorable scenarios of the Intergovernmental Panel on Climate Change (IPCC) assume very large-scale BECCS (IPCC, 2018). The 2015 Paris Agreement implicitly endorses this technique (Articles 4.1, 5). Likewise, some states have implicitly committed to them through "net zero" emissions targets (Darby, 2019). At the same time, these techniques pose environmental risks and social challenges. Furthermore, CDR techniques affect atmospheric concentrations only slowly, are relatively expensive and are unlikely to be available at scale in the short term.

In addition to CDR, the other form of geoengineering is a set of technological responses to climate change referred to as solar radiation modification (SRM), which would intentionally modify the Earth's shortwave radiative budget with the aim of reducing climate change (IPCC, 2018: 558). Models indicate that at least some approaches could reduce climate change effectively, rapidly, reversibly and at low direct financial cost (National

Research Council, 2015). The leading proposal would replicate volcanoes' natural cooling effect by injecting aerosols into the stratosphere. Another proposal is to spray seawater as a fine mist, the droplets of which would, after evaporation, brighten low-lying marine clouds. Like CDR, SRM could reduce climate change but poses environmental risks and social challenges. As it is presently understood, SRM is necessarily global, which points to issues of international decision-making that are further complicated by its low resource requirements which, in principle, might allow for its deployment by smaller clubs or even single countries. Among the social challenges are a need for long maintenance and only gradual phase-down, displacing emissions cuts, claims of blame and demands for compensation for harm, and biasing future decision-making through sociotechnical lock-in (Reynolds, 2019).

Although geoengineering is typically envisioned as a means to reduce global climate change, it could be done in ways that have local effects. This is particularly salient with respect to biodiversity, which is unevenly distributed and mostly concentrated in hotspots. These might constitute priority areas for local deployment. Consider coral reefs, which are among the most biodiverse and threatened ecosystems. Coral reefs face the double threat of warmer marine waters and ocean acidification due to dissolved CO₂, both of which result in coral bleaching. Ocean alkalization, a marine CDR method akin to enhanced weathering, may be able to locally prevent and reduce ocean acidification (Feng [冯玉铭] *et al.*, 2016). Local SRM through marine cloud brightening or biodegradable ocean surface films could protect corals by locally limiting warming during heat waves (McDonald *et al.*, 2019).

Geoengineering's effects are uncertain. At a gross level, if a technology were to reduce climate change, then it would also reduce climatic impacts on biodiversity. This general claim is subject to a number of qualifications. First, geoengineering would have secondary effects, some of which would be negative. For CDR, these are relatively local, whereas the benefits of reduced atmospheric CO₂ would be global. In order to substantially reduce atmospheric CO₂ concentrations, BECCS would require vast amounts of arable land, which could reduce natural habitat, especially in (sub)tropical regions (Stoy *et al.*, 2018). BECCS and DAC need storage, which could leak, posing risks to species and ecosystems. Enhanced weathering involves large-scale excavation, transportation and processing, and could adversely affect ocean chemistry. Ocean fertilization alters marine ecosystems in uncertain ways (Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection, 2019). For SRM, impacts would be geographically distant or global. It would compensate changes to temperature and precipitation differently, imperfectly and heterogeneously. Stratospheric aerosol injection could slow the recovery of the protective stratospheric ozone layer. Other environmental risks remain unknown. A second qualification is that geoengineering's positive and negative impacts on biodiversity would be socially mediated. Although it could be used rationally to reduce climate change, it – especially SRM – might be poorly implemented. In that case, it could be deployed too rapidly or at too high of an intensity, or it could be stopped too suddenly (but see Rabitz, 2019a; Trisos *et al.*, 2018). Similarly, BECCS could be scaled-up carefully, with relatively little biodiversity impact, or haphazardly. Third and finally, much remains unknown. Research to date has been limited, especially on SRM and on biodiversity impacts (McCormack *et al.*, 2016).

Given the CBD's broad scope and geoengineering's potential to help conserve or potentially harm biodiversity, it is unsurprising that the Convention's bodies have engaged with the governance of geoengineering. However, the path that it took there has been somewhat reactive and arguably suboptimal. The catalyst for action was commercial firms' plans to undertake ocean fertilization, which at the time seemed to some observers to have substantial potential to remove CO₂. In response to agitation by some nongovernmental organizations and "in accordance with the precautionary approach," in 2008 the COP requested that states not allow ocean fertilization activities until there is "adequate scientific basis on which to justify such activities . . . and a global, transparent and effective control and regulatory mechanism," and even then, only if they are noncommercial, scientific, subject to prior environmental impact assessment and "strictly controlled" (Decision IX/16.C). Although, as a COP decision, this statement is necessarily nonbinding, it appears to have contributed to the subsequent halt of legitimate, noncommercial ocean fertilization research, which had been occurring for about a decade (Williamson et al., 2012). The Parties to the London Convention and London Protocol, which regulate marine dumping, issued similar decisions on ocean fertilization in 2008 and 2010 (Resolutions LC- LP.1 and LC- LP.2). Parties to the latter agreement also approved an amendment that, when and if it comes into effect, would regulate marine geoengineering more broadly, although low ratification numbers indicate that this is unlikely to happen in the short term (Resolution LP.4[8]).

Since then, the CBD COPs have adopted three decisions regarding geoengineering. The first of these, in 2010, expanded the ocean fertilization decision to apply to geoengineering more broadly (Decision X/33.8[w]). In this, the COP invited Parties and other governments to consider not allowing any "climate-related geo-engineering activities that may affect biodiversity unless three criteria are met: a) 'science based, global, transparent and effective control and regulatory mechanisms'; b) an 'adequate scientific basis'; and c) 'appropriate consideration of the associated risks for the environment and biodiversity and associated social, economic and cultural impacts'." This decision has received significant attention. Some journalists and activists call it a moratorium or even a ban (e.g. Tollefson, 2010). However, that is an incorrect description (Reynolds et al., 2016). The COP does not have the authority to issue rules that are binding under international law. The text here uses particularly qualified language, in which it merely "invites" states to "consider the guidance." Both CBD reports on the topic call the decision "a comprehensive non-binding normative framework" (SCBD, 2012: 106; Williamson and Bodle, 2016: 144). Finally, its reference to being "in accordance with [. . .] Article 14" suggests that the decision is further limited to climate-related geoengineering activities that are likely to have *significant adverse* effects on biological diversity. In the absence of threshold criteria, it remains unclear beyond which point an activity would be classified as causing such effects.

In 2012, the Parties issued a decision on climate-related geoengineering. This, however, added little substance, only noting that no single geoengineering approach "meets basic criteria for effectiveness, safety and affordability," that significant knowledge gaps remain, and "the lack of science-based, global, transparent and effective control and regulatory mechanisms for climate-related geoengineering" (Decision XI/20). Somewhat more substantive was Decision XIII/14 of 2016, which "notes that more transdisciplinary research

and sharing of knowledge . . . is needed in order to better understand the impacts of climate-related geoengineering on biodiversity and ecosystem functions and services, socio-economic, cultural and ethical issues and regulatory options.” Finally, the Secretariat of the CBD has commissioned and published two major reports on geoengineering with respect to the Convention (SCBD, 2012; Williamson and Bodle, 2016).

These COP decisions are important to the global governance of geoengineering, as they remain the only explicit statements from the international community regarding geoengineering in general (notably, the UN Environment Assembly was unable to reach a consensus in a 2019 discussion). Although the Parties to the London Convention and London Protocol, as well as the International Maritime Organization, have since 2008 largely assumed the international governance of ocean fertilization, the CBD’s 2010 and 2016 decisions offer significant guidance in a domain that arguably lacks it. They express caution, calling on states to ensure that geoengineering activities beyond a certain expected magnitude of impact do not take place until particular criteria are satisfied. At the same time, important ambiguities persist. Are “small scale scientific research studies that would be conducted in a controlled setting” limited to indoor activities, or could they include low-risk and/or well-contained outdoor experiments? And given that geoengineering could reduce dangerous climate change, that it poses its own threats of significant reduction or loss of biological diversity and that full scientific certainty is lacking, what are the implications of anticipatory governance for decision-making under uncertainty? Furthermore, the 2016 COP decision and report have important implications for the global governance of biodiversity: that large-scale interventions in natural systems, such as climate geoengineering, have the potential to help conserve biodiversity and that more research is consequently needed. Furthermore, the COP decisions push the boundary of the CBD’s scope, engendering real and potential conflict with other international legal institutions such as the London Convention and London Protocol, and the UN Framework Convention on Climate Change (UNFCCC) (see van Asselt, 2014).

Geoengineering activities, including those that may affect biodiversity, are governed by several legal and nonlegal mechanisms beyond the CBD, including the UNFCCC, the UN Convention on the Law of the Sea, the Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques, and the London Convention and London Protocol (Reynolds, 2019). However, almost all of these were developed without geoengineering in mind and do not explicitly reference geoengineering and/or biodiversity. Exceptions in both regards are the above-noted resolutions on ocean fertilization and amendment on marine geoengineering that the Parties to the London Convention and London Protocol have approved. The frameworks under the 2010 resolution and 2013 amendment include assessing potential impacts on marine ecosystems, and the resolution explicitly refers to biodiversity.

7.3 Synthetic Biology and Gene Drives

Synthetic biology comprises a broad variety of technologies that are at different stages of the research and development pipeline and that differ widely in terms of their practicability

as well as potential benefits and risks for biodiversity. Work under the Convention is guided, for the time being, by a 2016 operational definition developed by the AHTEG on synthetic biology but not endorsed by the COP, which defines synthetic biology as “a further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems” (Decision XIII/17; Keiper and Atanassova, 2020). How this differs from “traditional” biotechnology, such as defined under CBD Article 2, is not clear. Regardless, this includes, for instance, approaches for the computer-based design of genomes, the synthesis of DNA nucleobases that do not exist in the known universe and the deliberate engineering of metabolic pathways within cells (SCBD, 2015). Current and near-term commercial and industrial applications of synthetic biology aim mainly at creating microorganisms that synthesize products for fuels, pharmaceuticals, chemicals, flavorings and fragrances (El Karoui et al., 2019). Potential positive impacts may include pollution control through microorganisms designed for bioremediation and reduction of overharvesting of threatened wild species through development of synthesized products (SCBD, 2015). Synthetic biology may also serve a role in enhancing the resilience of agricultural systems by developing crops with improved resistance to environmental stress, chemical pollution, pesticides and fertilizers. One – currently hypothetical – application of synthetic biology of relevance to biodiversity conservation is de-extinction: the cloning of extinct species by grafting ancestor DNA onto the genome of existing species with a similar genetic profile (Church and Regis, 2014). As the history of agricultural biotechnology suggests a pattern of overpromising and underdelivering on the supposed environmental benefits of genetic engineering, many of these claims may warrant skepticism. What sets the case of synthetic biology and gene drives apart from the debate on agricultural biotechnology during the 1990s is that, at least for the time being, a significant amount of research and development is being carried out in the public and philanthropic sectors rather than in the for-profit private sector. Patent activity remains relatively limited (Oldham and Hall, 2018). In addition, as synthetic biology technologies become less expensive and more widely accessible, several small-scale, publicly accessible community laboratories, do-it-yourself and open science collaborations are emerging that may lead to a democratization of science (Laird and Wynberg, 2018).

However, the release (including from small-scale, “do-it-yourself biology”) of organisms created via synthetic biology may raise environmental concerns in regard to biosafety, as well security, socioeconomic and ethical issues. Biosafety issues include, for example, the potential for survival, persistence and transfer of genetic material to other microorganisms, possible negative effects on nontarget organisms and transfer of genetic material to wild populations. Indirect negative impacts could arise from the increase in the utilization of biomass required for synthetic biology applications. Security considerations arise from the potential malicious or accidental use of synthetic biology applications. Socioeconomic considerations relate to potential impacts on community livelihoods in developing countries where traditional crops and other natural resources are replaced. Ethical concerns relate to the socially accepted level of

uncertainty and predictability of its impacts and the threshold between the modification of existing organisms and the creation of new ones (SCBD, 2015). More fundamentally, transformative change may also entail deeper ethical concerns regarding the very creation of artificial life or the genetic modification of entire species.

As a specific set of emerging technologies, gene drives are conceptually easier to pin down. These are often understood as “systems of biased inheritance in which the ability of a genetic element to pass from a parent to its offspring through sexual reproduction is enhanced” (National Academies of Sciences, Engineering, and Medicine, 2016: 1). Within the CBD process, gene drives have generally been considered part of the broader issue of synthetic biology. From a technical perspective, however, gene drives are based on techniques for genome editing, such as CRISPR/Cas9, that are already firmly established in the contemporary life sciences and, while falling within the broad definition of “biotechnology” in the Convention’s Article 2, do not necessarily fall within the operational definition of “synthetic biology” (Esvelt *et al.*, 2014). By increasing the probability with which genetic traits are passed on to later generations, gene drives offer the possibility of rapidly and efficiently modifying the genetic profile of entire target populations (meaning the interbreeding members of a species that typically live in a geographic place) of sexually reproducing organisms with short gestation cycles (Esvelt *et al.*, 2014). A major motivation for the development of gene drives is the control of disease vectors such as mosquitoes. However, they are also under discussion as a tool for combating invasive alien species, which is a crosscutting issue under the CBD (Leitschuh *et al.*, 2018). Examples of such species include rats and other rodents, as well as organisms such as certain mussels, jellyfish and sea stars that have been introduced into vulnerable marine ecosystems through ballast water tanks. At the same time, the rapid environmental diffusion of gene drives, the potential of unforeseen effects on target species and ecosystems, the possibility for the introduction of new diseases through the replacement of the population of the original disease vector by another vector species, unpredicted mutations in the drive or unintended off-target effects raise serious biosafety questions (SCBD, 2015). Thus, while synthetic biology and gene drives could potentially contribute to the CBD’s objectives of conservation and sustainable use by protecting or restoring ecosystems, or by reducing anthropogenic pressures from agricultural practices, they also pose novel and unpredictable risks and regulatory challenges.

The CBD COP started addressing synthetic biology and gene drives as a recurring agenda item in 2014. Yet by 2010, COP decision X/37 on biofuels and biodiversity urges Parties and non-Parties to apply precaution regarding “the field release of synthetic life, cell or genome into the environment.” Decision XII/24 of 2014, which addresses synthetic biology in general but does not cover gene drives, urges Parties to take a precautionary approach, including by having “effective risk assessment and management procedures” or other types of regulation in place prior to any deliberate release. That decision also installed an AHTEG for collecting and synthesizing different stakeholder perspectives, for identifying existing regulatory gaps and for elaborating the operational definition of synthetic biology quoted above. Decision XIII/17 of 2016 notes the future need for developing new approaches to assessing the risks associated with synthetic biology; notes that some

organisms produced through synthetic biology may fall outside the functional scope of the CBD and the Cartagena Protocol; and invites Parties to engage in further stakeholder consultations, research and knowledge synthesis for identifying potential biodiversity-related risks and benefits of synthetic biology. In that decision, the COP for the first time engages with gene drives, noting that they may fall within the category of synthetic biology, and thus may partially fall within the scope of the earlier decision XII/24. In 2018, the COP finally agreed on the need for systematic monitoring and horizon-scanning for technological developments in synthetic biology, under decision XIV/19. This decision for the first time provided more specific guidance in regard to gene drives, calling upon Parties and non-Parties to require “[s]cientifically-sound case-by-case risk assessment” as well as adequate risk management procedures prior to a deliberate release.

The primary barrier to the effective governance of synthetic biology and gene drives under the CBD framework is the stark contrast in perceptions of the Parties of the associated risks and benefits, as well as their distribution. Reminiscent of CBD debates in the 1990s with regard to modern biotechnology and LMOs, the highly politicized deliberations reflect different understandings of technology, perceptions of environmental risk and precaution, expectations regarding benefits (including commercial ones), and scientific and regulatory capacities to assess associated risks (Reynolds, 2020). At the same time, an important difference between past biotechnology debates and the current ones regarding gene drives is that, while private firms were developing and advocating for the former, they are absent from the latter, presumably due to insufficient commercialization perspectives (Mitchell et al., 2018). While there is general consensus among Parties that the use of those technologies should be subject to the precautionary approach (see CBD preamble, recital 9), how exactly precautions would be *operationalized* is a matter of ongoing dispute. Bracketed text in SBSTTA recommendation 22/3 of July 2018 – later rejected by the COP – illustrates this divergence of views: Whereas some Parties prefer precaution regarding the *extent and timeframe of the release* of gene drives, others, such as Bolivia at the time, interpret precaution as implying *refraining* from such releases (ENB, 2018a). To some extent, the debate revolves around questions of regulation of synthetic biology as an inherently risky new and emerging technology versus case-by-case assessment of its products and applications, or even prohibition of environmental releases until further knowledge is available.

Regardless of the merits of any of these approaches, nonuniversal participation in the CBD and, particularly, the Cartagena Protocol poses additional challenges and creates the risk of jurisdiction-shopping. Notably, the USA is neither a party to the Convention nor to the Cartagena Protocol, and some of the countries with strong biotechnology industries, such as Argentina, Australia and Canada, are not parties to the Protocol. Addressing this issue under both the Convention and the Protocol thus poses challenges for effective decision-making because of their different memberships. Regulating or even prohibiting environmental releases of gene drives and organisms produced via synthetic biology may generate incentives for operators to carry out such releases in jurisdictions where regulatory standards are less restrictive. Especially regarding initial, small-scale field testing that might only entail limited transboundary effects, the insufficient geographic coverage of the CBD regime severely limits the scope for effective international regulation (Rabitz, 2019b).

Beyond the CBD regime, a range of other international institutions potentially bear relevance for the governance of synthetic biology and gene drives. The WHO has developed a Guidance Framework for Testing of Genetically Modified Mosquitoes, incorporating cost–benefit analysis and precaution. The Review Conferences of the Biological Weapons and Toxins Convention have, in recent years, started considering the biosecurity implications of both synthetic biology and gene drives. Other institutions may be relevant without necessarily addressing either technology directly. International patent law might matter to the extent that the patent protection of first-generation gene drive organisms might extend to their progeny. The use of synthetic biology in the food sector would likely create a role for the World Trade Organization’s Agreement on Sanitary and Phytosanitary Measures as well as the Codex Alimentarius Commission. Yet in all those cases, the governance implications of synthetic biology and gene drives are even less clear than they are for the CBD regime.

7.4 Bioinformatics and Digital Sequence Information

Synthetic biology applications have largely become possible due to advances in bioinformatics, an interdisciplinary field of knowledge that develops and uses methods and software tools to extract knowledge from biological material. It includes the collection, storage, retrieval, manipulation and modelling of data from biological resources for analysis, visualization or prediction through the development of algorithms and software. Bioinformatics tools allow for generating and analyzing large quantities of genotypic, phenotypic and environmental data. Techniques for high-efficiency genomic sequencing have been followed by methods for measuring the current molecular state of cells and organisms, for predicting classical phenotypes in an automated manner and even for reengineering the content and function of living systems. These technologies have led to the rapid generation of large amounts of data describing biological systems, and the analysis and interpretation of these data using statistical and computational expertise (Can, 2014; Diniz and Canduri, 2017).

Developments in bioinformatics pose challenges for access and benefit-sharing (ABS) frameworks. This includes the CBD and its Nagoya Protocol on ABS, which aim to ensure that users of genetic resources share (commercial and other) benefits that arise from utilization. They result in what is described as the “dematerialization” of genetic resources, suggesting that “the information and knowledge content of genetic material [could increasingly be] extracted, processed and exchanged in its own right, detached from the physical exchange of the . . . genetic material” (Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture, 2013).

Within the CBD, the term DSI is understood to refer to nucleic acid sequence reads and the associated data, and information on the sequence assembly, its annotation and genetic mapping, describing whole genomes, individual genes or fragments thereof, barcodes, information on gene expression, and behavioral data, among others (Convention on Biological Diversity, 2018). The origin of debates on DSI can be traced to the report of

the 2015 meeting of the AHTEG on synthetic biology. Participating experts identified potential adverse effects of synthetic biology for the CBD objective of fair and equitable benefit-sharing, including inappropriate access without benefit-sharing due to the use of DSI, and a “shift in the understanding of what constitutes a genetic resource” (Convention on Biological Diversity, 2015: 10). As explored below, such a shift in understanding lies at the heart of the highly polarized debate on DSI (see also Keiper and Atanassova, 2020).

The issue of regulation of DSI-use has also arisen in ABS-related processes beyond the CBD and the Nagoya Protocol, including the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the Pandemic Influenza Preparedness Framework for access to vaccines and other benefits (PIP Framework) under the WHO, and the ongoing negotiations under the UN Convention on the Law of the Sea on marine biodiversity beyond the limits of national jurisdiction (BBNJ), albeit with differing terminologies and varying political progress. While significant advances in deliberations have been made under the PIP Framework, DSI turned out to be a deal-breaker for efforts at reforming the ITPGRFA’s Multilateral System, leading to the collapse of six years of negotiations at the end of 2019 (ENB, 2019; Tsioumani, 2020).

The availability and easy exchange of large amounts of sequence data have the potential to facilitate research on genetic resources, especially for actors in developed countries who have the capacities to analyse and use such data. At the same time, it poses two main regulatory issues: the possibility of appropriation of genetic sequence data, including data placed in the public domain, through intellectual property rights (IPRs), in particular patents; and the question of value generation from the use of such data, and related benefit-sharing obligations (Laird and Wynberg, 2018; Welch et al., 2017). Opinions diverge in particular as to whether and how its utilization should give rise to benefit-sharing obligations supporting the CBD’s objective of fair and equitable benefit-sharing, which is intended to incentivize nature conservation, provide the financial and other means for doing so, and inject fairness and equity in bio-based research and development (Morgera, 2016; Tsioumani, 2018). The latter question further involves a series of legal interpretation issues concerning the scope of the CBD and the Nagoya Protocol, and implementation concerns involving the identification of users and monitoring/tracking of uses of such data. These issues will be briefly addressed below, in turn. Additional normative questions arise with regard to benefit-sharing from the utilization of human genetic resources which, however, fall outside the scope of the CBD and thus this chapter.

As evidenced from several open-access registries and projects, the synthetic biology community – which brings together most DSI users – has a strong open source sharing ethos and encourages the release of genomic and other datasets as public goods (Tsioumani et al., 2016). At the same time, as in all technological fields, researchers tend to patent research tools and sequences strategically, with clear commercial applications (Welch et al., 2017). As patent law is territorial in nature, and legal debates on social and moral concerns regarding patent eligibility of genetic sequences continue to rage in several jurisdictions, the patent landscape varies around the globe (Nuffield Council on Bioethics, 2002). In the United States, the 2013 Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics* held that DNA segments and the information they encode are not patent-eligible simply

because they have been isolated from surrounding genetic material, thus reversing years of prior jurisprudence and confirming a shift in the broad scope of the patentability of genetic sequences. Under the EU's Biotechnology Directive (98/44/EC), biological material that is isolated from its natural environment or produced by means of a technical process may be the subject of an invention, even if it previously occurred in nature. The European Court of Justice subsequently clarified, in *Monsanto Technology v. Cefetra BV*, that, in order to meet the requirements for patent eligibility, the "functionality" of the genetic sequence must be disclosed in the patent application. Developing countries have also sought to set their own standards. Brazil, for instance, excludes living beings or biological materials found in nature from patentability, even if isolated, and this includes the genome or germplasm of any living being (Correa, 2014). Navigating the patent landscape is further complicated by the uncertainty generated by those patent applications that are still pending, resulting in an inability to locate the ownership of patents, as well as by the fees usually required for searching patent databases (Hope, 2004). Moreover, while ownership of a patent is usually a matter of public record, ownership of the rights transferred through licenses is not. Most jurisdictions do not impose a responsibility on licensees to disclose, making it almost impossible for a researcher to assemble all the licenses needed to proceed with their research (Jefferson, 2006). This complexity has devastating consequences for public sector researchers, particularly in developing countries. Adding the specificities of ABS legislation to the mix can only increase the degree of complexity and legal uncertainty, further restricting access to DSI.

Unrestricted access to DSI, in the form of public and open-access databases, can be considered an important form of nonmonetary benefit-sharing, as long as it is accompanied by capacity-building measures to ensure its fair and equitable use by actors in developed and developing countries alike. Nonmonetary benefit-sharing, via information exchange, capacity-building and technology transfer, may allow for an increase of endogenous research capacities for genetic resource utilization and thus assist in bridging the gap between developed and developing countries. However, in view of the increasing use of DSI in bio-based research and development, alongside potential restriction of its availability through IPRs, biodiversity-rich developing countries have been calling for the application of monetary benefit-sharing requirements to the use of DSI arising from genetic resources, according to the provisions of the CBD and the Nagoya Protocol. Debates have centered mainly around the interpretation of the scope of the CBD and the Protocol. At the time of writing, most developed countries oppose any benefit-sharing from DSI and argue that the CBD and the Nagoya Protocol have been developed to address exchanges of "material" resources. Their legal argumentation points to the definition of "genetic resources," as genetic "material" that contains "functional units of heredity" (CBD Art. 2 and Nagoya Protocol Art. 2). Therefore, exchanges of "immaterial" information such as DSI would fall outside the scope of the two instruments. In contrast, developing countries argue that letting DSI-use escape benefit-sharing obligations would make the Nagoya Protocol obsolete, and thus negate any progress toward the redistribution of benefits from countries that have the capacity to use genetic resources toward those that have stewarded them. In addition, developing countries hold that the use of DSI qualifies as "utilization" of genetic resources (Nagoya Protocol Art. 2), thus giving rise to benefit-sharing obligations. The issue attracted

more attention than any other item under negotiation at the 2018 meeting of the COP in Egypt and is expected to be central at the negotiations for a Post-2020 Global Biodiversity Framework. In fact, several countries from the global South declared that there will be no agreement on a Post-2020 Global Biodiversity Framework unless benefit-sharing from DSI-use is ensured (ENB, 2018b; 2019).

The CBD and Nagoya Protocol objective of fair and equitable benefit-sharing has opened new ground in environmental agreements with regard to the distribution of benefits of scientific progress. However, its implementation in the bilateral system of exchanges between providers and users of genetic resources envisaged by these instruments poses challenges, particularly with regard to the determination of the value of the genetic resource under consideration, the determination of benefits, the development of mutually agreed terms for benefit-sharing and their application in the context of an interlinked web of national laws and policies, and ensuring compliance by users (Morgera et al., 2014). These challenges are exacerbated in the case of DSI. Implementation concerns involve in particular the identification of the value of DSI, its origin and its user, as well as ensuring compliance by monitoring its use (Laird and Wynberg, 2018). Digitalization raises fundamental questions regarding the long-term viability of the bilateral approach to benefit-sharing under the CBD and the Nagoya Protocol. That said, a number of CBD Parties have already enacted benefit-sharing obligations from DSI-use as part of their domestic ABS measures, including, among others, Brazil, Malaysia and South Africa.

Despite the intense political controversies, COP decision 14/20 of 2018 established a science and policy-based process that is expected to shed light on many of the regulatory challenges related to DSI. The COP invited submission of views aiming to clarify the concept, including relevant terminology and scope, as well as submission of domestic ABS measures and benefit-sharing arrangements considering DSI. It further called for submission of information on capacity-building needs, and commissioned a series of peer-reviewed studies focused on some of the more technical issues explored above, including: the concept and scope of DSI; traceability; databases; and domestic ABS measures addressing benefit-sharing arising from DSI commercial and noncommercial use. In anticipation of deliberations in the CBD subsidiary bodies and the Working Group on the Post-2020 Framework, these studies informed the debates of the AHTEG established to address the issue. The AHTEG offered clarifications on the scope of DSI; options on terminology regarding categories of information that could be considered DSI; implications concerning traceability, use, exchange of information and ABS measures; and key areas for capacity-building (Convention on Biological Diversity, 2020).

7.5 Toward the Transformative Governance of Emerging Technologies

While our cases address different issues, all highlight the challenges the CBD regime faces in governing biodiversity-related technologies. In general, the CBD regime is relatively quick to pick up novel technological issues and to process them in an inclusive manner, based on high-quality scientific and technical expert advice. In the output dimension,

rulemaking has been limited to nonbinding (and frequently heavily qualified) COP decisions and assorted technical guidance. The rapid identification and addressing of governance gaps associated with novel technologies thus does not necessarily translate into strengthened international regulation. This appears linked to the Convention's broad scope and objectives, complex overlaps with other intergovernmental organizations, system of consensual and participatory decision-making, lack of compliance and enforcement mechanisms, and, crucially, frequently stark divergences in the regulatory preferences of its contracting parties.

To assess the extent to which the CBD can support transformative governance of biodiversity with respect to emerging technologies, we follow the criteria introduced in Chapter 1. The capacity of the CBD regime to *integrate* governance activities varies across our cases. For geoengineering, we witness an institutional division of labor with the London Convention / London Protocol (see Reynolds, 2018). On DSI, the parallel processes under the CBD, the WHO and the ITPGRFA are characterized by polycentric cross-institutional linkages, although debates focus more on the differences between them with regard to mandate, scope and objectives, rather than the need to address such implications in a systematic manner across sectors and processes. For synthetic biology and gene drives, the lack of rulemaking activities outside the CBD regime limits the scope for integration from the outset. At the same time, the CBD possesses a high degree of *inclusiveness*, illustrated by the establishment of an open-ended online forum on synthetic biology and stakeholder participation regarding DSI, including by representatives of Indigenous peoples and local communities, civil society, academia and research, and the private sector, as well as relevant international bodies. The CBD processes on DSI, as well as synthetic biology and gene drives, are also characterized by relatively strong *transdisciplinarity*, drawing on natural sciences, law and social sciences, as well as the knowledge of Indigenous peoples. In contrast, information uptake with regard to deliberations on geoengineering is less structured and arguably weak, with relevant COP decisions having been criticized as poorly informed (Sugiyama and Sugiyama, 2010). Regarding *adaptiveness*, all our cases are characterized by COP decisions that are vague, use heavily qualified language and fail to clarify important operational criteria. However, institutional adaptation to emerging technologies is a frequent challenge that is not necessarily specific to the CBD (Marchant et al., 2013). Finally, *anticipation* requires addressing the Collingridge dilemma, in which developing governance faces few barriers early on but too little is then known, while later on there is greater knowledge, but interests have arisen and legislation has ossified (Collingridge, 1980). From this perspective, governance responses under the CBD have indeed been anticipatory. This is most evident in the SBSTTA's mandate to identify "new and emerging issues." Also, in all three cases considered here, the CBD initiated governance processes in the very early stages of technological development. This may be a consequence of the relatively prominent position given to precaution in the CBD and in the COP's interpretation thereof. If anything, there is a reasonable argument that the CBD has engaged too early in these areas, before sufficient knowledge of potential technological impacts, limits and risks became available.

To conclude, it is important to keep in mind that the three technologies discussed above not only pose potential threats, but also offer potential benefits for the objectives of the CBD. DSI may either undermine effective benefit-sharing (by allowing users to shirk their obligations) or enhance utilization of genetic resources (by obviating the need for physical specimens), thus improving research on environmentally useful innovations as well as increasing the overall size of the “pie” from which benefits may subsequently be shared. Some proposals for geoengineering could arguably have adverse effects on biodiversity but equally have an important function for its conservation. Synthetic biology and gene drives create novel biosafety risks and could cause significant harm for species and ecosystems, yet may also contribute to the conservation objective by allowing for greater biological control of invasive alien species, pests and diseases.

Such technological solutions to environmental challenges are frequently critically referred to as “techno-fixes.” On one hand, they may enable overreliance on unproven, ineffective or unsafe technologies while displacing regulatory or socioeconomic solutions that could address root causes of biodiversity loss, such as habitat loss and alteration, pollution and overexploitation of species. Faith in technological solutions further can ignore the complexity of biological diversity and interdependence of living systems, which, coupled with lack of data and knowledge, can translate into uncertainties and even ignorance. On the other hand, the history of biodiversity governance demonstrates the limited efficacy of conventional solutions and the lack of sufficiently powerful political coalitions to address the root causes of biodiversity loss. History also suggests that technological evolution is, to a certain degree, inevitable and often faster than regulation. In addition, technologies can catalyze structural social, political and economic change, often in surprising ways. The emerging synthetic biology community, for instance, could be a source of great risk, although it may in the future also produce valuable social and institutional advancements in how the CBD and other bodies govern emerging biotechnologies, including through their open data and sharing ethos.

However, within the context of the CBD, interest constellations reflect differences in socioeconomic development and innovative capacity, as well as normative disputes over the role of technology in environmental governance. Shifting toward inclusive, effective and outcome-oriented technology regulation in the post-2020 era, together with the fair distribution of costs, risks and benefits of the technologies involved, is likely to be one of the main challenges of the CBD deliberations for the years to come. In this context, given the divergences in Parties’ priorities and interests and the realities of intergovernmental decision-making, it is doubtful that transformative governance of technology will originate in the realm of the CBD, or any other intergovernmental process; it will rather reflect and follow deep socioeconomic and behavioral changes.

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