

# Emerging Technologies in Biodiversity Governance: Gaps and Opportunities for Action

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## **Abstract**

Numerous emerging technologies have potentially far-reaching impacts on the conservation and sustainable use of biodiversity. Simultaneously, biodiversity increasingly serves as an input for novel technological applications. We assess the relationship between the Convention on Biological Diversity (CBD) regime and the governance of three sets of emerging technologies: climate-related geoengineering (carbon dioxide removal and solar radiation modification), synthetic biology (including gene drives), as well as bioinformatics and digital sequence information. We present an overview of these technologies' relevant applications, including potential positive and negative impacts on the CBD's objectives; explore the state of relevant deliberations under the CBD and other intergovernmental fora, including normative gaps and opportunities for action; and assess the extent to which governance of those technologies under the CBD regime can support transformative governance of technologies and biodiversity from the vantage points of adaptiveness, integration, anticipation, inclusion and information.

**Keywords:** Biodiversity; Technology; Biotechnology; Synthetic biology; Gene drives; Bioinformatics; Digital sequence information; Geoengineering; Solar radiation modification; Carbon dioxide removal

## **1. Introduction**

Numerous emerging technologies have potentially far-reaching impacts on the conservation and sustainable 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) and the governance of three sets of emerging technologies: geoengineering, synthetic biology, and bioinformatics. Although these three sets of technologies have been subject to extensive discussions under the CBD, the linkages between biodiversity and technology go far beyond these immediate cases.

First, geoengineering, that is, “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. The various proposals 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 gene drives and other recent biotechnological innovations, are under discussion as they 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). Synthetic biology applications may have positive impacts on the conservation and sustainable use of biodiversity, including for instance by designing micro-organisms for bioremediation; protecting, restoring, and reviving threatened or recently extinct species; and reducing or eradicating unwanted populations, such as of invasive alien species. At the same time, they carry diverse and potentially severe biosafety risks, such as potential negative effects on non-target organisms and transfer of genetic material to wild populations, as well as a range of unintended health and socio-economic impacts (SCBD, 2015: 39–40). Third, bioinformatics allows for extraction of digital sequence information (DSI), that is, the genetic information that is derived from genetic resources, and 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 for regulation, mainly regarding possibilities for misappropriation and escaping benefit-sharing obligations (Tsioumani, 2020: 24).

From the outset, the drafters of the CBD recognized the existence of links between technology and biodiversity, with the former creating opportunities for improved management of, but also posing challenges and carrying risks for, the latter. Scientific research may thus strengthen the knowledge base required for policy-making, while technological developments, such as geographic information systems, satellite imagery or blockchain technology may be used to improve implementation and monitoring. At the same time, new and emerging technologies, including for instance developments in biotechnology, may have unintended impacts on biodiversity, in view of the high degree of uncertainties regarding living systems (Erdelen and Richardson, 2019; Tittensor et al., 2014). Through legally-binding international rules under the Convention and its protocols, as well as different layers of “soft law”-style governing body decisions and technical guidance, the Convention facilitates deliberation and cooperation on and regulates technologies as they related to the CBD’s objectives. These two general functions are essential to meeting the CBD objectives, especially in developing countries. Regarding facilitating deliberation and cooperation, the Convention creates a standing Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) to assist the Conference of the Parties (COP); and 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 towards bridging capacity asymmetries in achieving the Convention’s objectives. Aichi Target 19 under the Strategic Plan for Biodiversity 2011–2020 holds that by that year, “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, as well as 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.

Compared to other intergovernmental organizations and bodies, 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 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. These include, for instance, the voluntary guidelines on biodiversity-inclusive impact assessment (Decision VIII/28) and guidance on risk assessment and management of living modified organisms (LMOs) under the Cartagena Protocol (Annex III of the Protocol and Decision BS-VIII/12). In addition, rules have been put in place for the systematic monitoring of technological developments relating to biodiversity conservation and sustainable use. The consolidated *modus operandi* of SBSTTA, adopted in 2006 (Decision VIII/10), mandates the SBSTTA to “[i]dentify new and emerging issues relating to the conservation and sustainable use of biodiversity”. Additional guidance on the formal procedures for doing so was adopted in 2008 (Decision IX/29), including a list of criteria related to, among others, new evidence of unexpected and significant impacts on biodiversity, the imminence of risk, the magnitude of actual and potential impact, and the absence or limited availability of tools to limit or mitigate the negative impacts. None of the technologies we discuss in this chapter has been classified as a “new and emerging issue”, although there is an ongoing, highly politicized, debate on whether synthetic biology and gene drives should be considered a “new and emerging issue” in accordance with the criteria above. Some parties, such as Norway, argue that synthetic biology should be classified as a new and emerging issue, due to the pace of technological developments, the potential impacts on the three CBD objectives, its cross-cutting nature, and depth of intervention (Royal Norwegian Ministry of Climate and Environment, 2019). Such classification would result in a dedicated stream of deliberations and possibly tools developed specifically for the governance of synthetic biology. Others, such as Australia, argue that risks associated with synthetic biology applications are not different from those associated with modern biotechnology and could be assessed and managed under the Cartagena Protocol (Submission by Australia, 2019). These parties consider synthetic biology an extension of modern biotechnology (ENB, 2018a; Keiper and Atanassova, 2020).

The following three sections map out the rules, institutional responses, and regulatory gaps in regard to climate-related geoengineering; synthetic biology, including gene drives; and bioinformatics, including DSI. In the conclusions, we assess the extent to which governance of

those technologies under the CBD regime can support transformative governance of technologies and biodiversity from the vantage points of adaptiveness, integration, anticipation, inclusion and information. While the CBD scores moderately to highly on most of those dimensions, we find 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.

## **2. Climate-related geoengineering**

Anthropogenic climate change is closely related to the CBD's goals, especially the conservation of biological diversity (Bellard et al., 2018). 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 prevent and reduce it. For example, so-called "ecosystem approaches" as well as reducing emissions from deforestation and forest degradation (REDD+) would help reduce net greenhouse gas emissions and facilitate adaptation but could reduce land available for the conservation of biodiversity. As early as the fifth CBD COP in 2000, the Parties recognized climate change's threats to biodiversity (Decisions V/3, V/4), and the climate-biodiversity nexus has received growing attention both within and beyond the CBD.

As responses to the growing threats of climate change and to the insufficiency of responses, scientists, policy-makers, and others have broadened the options. For example, in the late 1990s and early 2000s, vulnerable countries successfully pushed adaptation higher on the international agenda, and now both it and reducing greenhouse gas emissions are of equal importance there, at least in principle (Pielke Jr et al., 2007).

More relevant here are two sets of technology that are often collectively referred to as "geoengineering." It became increasingly evident in the lead-up to the 2015 Paris Agreement that emissions cuts could not keep global warming to well below 2°C above pre-industrial levels, as the Paris Agreement aims to do. 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 time scales. Such carbon dioxide removal (CDR, sometimes greenhouse gas removal or negative emission technologies) techniques are diverse, and some hold the potential to significantly reduce net emissions and atmospheric concentrations of carbon dioxide (National Research Council, 2015a; Royal Society and 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 carbon dioxide captured and stored; (2) direct air capture (DAC), in which carbon dioxide is captured from ambient air, and stored; (3) enhanced weathering, in which minerals are processed to accelerate natural chemical CO<sub>2</sub> sequestration; and (4) ocean fertilization, in which nutrients are added to accelerate natural marine biological CO<sub>2</sub> sequestration. Even relatively natural responses such as afforestation, reforestation, and managing soils to increase carbon sequestration could be CDR, depending on their scale. CDR could make ambitious climate change targets more achievable, could later compensate for initially exceeding emissions limits, and appear essential to meeting internationally agreed-upon climate change goals. Indeed, the favourable scenarios of the Intergovernmental Panel on Climate Change (IPCC) assume very large-scale BECCS (IPCC, 2018). The Paris Agreement implicitly endorses them (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 at diverse levels of technological readiness.

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, elsewhere solar radiation management, sunlight reflection methods, or solar geoengineering), which would intentionally modify the Earth’s shortwave radiative (that is, visible light) 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, 2015b). The feasible proposed technologies here are few. The leading proposal would replicate volcanoes’ natural cooling effect by injecting aerosols into the stratosphere. Another is to spray seawater as a fine mist whose droplets would, after evaporation, cause low-lying marine clouds to be brighter. Like CDR, SRM could reduce climate change while posing 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 high leverage. 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 socio-technical 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 highly unevenly distributed and concentrated in hotspots. Consider coral reefs, which are among the most biodiverse and threatened ecosystems. They face the double threat of warmer marine waters and ocean acidification due to the dissolution of carbon dioxide, 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). And 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 carbon dioxide would be global. In order to substantially reduce atmospheric carbon dioxide 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, likely leaving warm, cool, wet, and dry regions. 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, 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 of SRM and of impacts on biodiversity (McCormack et al., 2016).

Given the CBD's broad scope and geoengineering's potential to help conserve or potentially harm biodiversity, it should be 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 carbon dioxide. In response to agitation by some advocacy non-governmental 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 non-commercial, 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, non-commercial 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 (Resolutions LC- LP.1 and LC- LP.2), and those to the latter agreement approved an amendment that, when and if it comes into effect, would regulate marine geoengineering more broadly (Resolution LP.4(8)).

Since then, the CBD COPs have adopted three decisions regarding geoengineering. The first of these, in many ways, expanded the ocean fertilization one to apply to geoengineering more broadly (Decision X/33.8(w)). In this, the Parties invited countries 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."

The decision explicitly makes an exception for "small scale scientific research studies that would be conducted in a controlled setting" and that have been subjected to prior environmental



impact assessment. This decision has received significant attention. Some journalists and activists call it a moratorium or even a ban (e.g. Tollefson, 2010; Yusoff, 2013). 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 geo-engineering 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 climate geoengineering in general. (Notably, the UN Environment Assembly was unable to reach a consensus in a 2019 discussion, see The Economist, 2019). 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, how can the precautionary approach guide decision-making in high-stakes risk-risk trade-offs 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 (see van Asselt, 2014).

Geoengineering activities that may affect biodiversity would be governed by several legal and non-legal mechanisms beyond the CBD (Reynolds, 2019). However, almost all of these were developed without geoengineering in mind and do not explicitly reference 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 includes assessing potential impacts on marine ecosystems, and the resolution explicitly refers to biodiversity. More typical are the UN Framework Convention on Climate Change and its associated Paris Agreement, which would offer some guidance to the governance of geoengineering, especially CDR. The former's objectives include protecting ecosystems, while the latter's preamble highlights the importance of protecting biodiversity. Both obligate parties to conserve and enhance sinks and reservoirs of greenhouse gases.

### **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 an 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 micro-organisms that synthesise products for fuels, pharmaceuticals, chemicals, flavourings and fragrances (El Karoui et al., 2019). Potential positive impacts may include pollution control through micro-organisms designed for bioremediation and reduction of over-harvesting 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 such claims may warrant scepticism. 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 democratisation of science (Laird and Wynberg, 2018).

However, the deliberate release of organisms created via synthetic biology may raise environmental concerns in regard to biosafety, as well security-, socio-economic and ethical issues. Biosafety issues include, for example, the potential for survival, persistence and transfer of genetic material to other micro-organisms, possible toxic and other negative effects on non-target 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. Socio-economic 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).

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 that, by themselves, do not necessarily fall within the CBD’s working definition of synthetic biology rather than the definition of traditional biotechnology under the Convention’s Article 2 (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 (ibid.). A major motivation for the development of gene drives is the control of disease vectors such as mosquitoes. By knocking-out the ability of disease vectors to transmit viruses, or by directly programming them towards auto-extinction, gene drives hold great promise for improving public health, although it is unclear to what extent their cost-benefit ratio is more favourable than non-technological means such as improved healthcare and housing. As one tool for disease vector control, however, gene drives hold particular potential in developing and least-developed countries because insect-borne diseases are most common there (Champer et al., 2016). Gene drives are also under discussion as a tool for combating invasive alien species, which is a cross-cutting issue under the CBD (Leitschuh et al., 2018). This includes biological invasions through rodents or the introduction of invasive organisms 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 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 ongoing debates under the CBD and its Cartagena Protocol tend to focus on the biosafety risks that those technologies entail and on capacity and resource needs for regulators to assess and manage such risks. A key question is in how far the existing provisions of the CBD and the Cartagena Protocol possess regulatory gaps or could be used for the regulation of synthetic biology and gene drives. The applicability of rules under the CBD and its Cartagena Protocol principally hinges on the extent to which organisms modified through techniques of synthetic biology or gene drive systems classify as "living modified organisms" (LMOs). The Cartagena Protocol stipulates that an LMO is a "biological entity capable of transferring or replicating genetic material" which "possesses a novel combination of genetic material" that results from the application of "modern biotechnology" and overcomes "natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection" (Cartagena Protocol, Art. 3.g-i). Arguably, this does not cover every conceivable application of synthetic biology and gene drive systems (Rabitz, 2019b). However, while there is no consensus that gene drives necessarily classify as "synthetic biology", the CBD AHTEG has concluded "that most living organisms already developed or currently under research and development through techniques of synthetic biology, including organisms containing engineered gene drives, fall under the definition of LMOs as per the Cartagena Protocol" (Convention on Biological Diversity, 2019: para 19).

The CBD COP started addressing synthetic biology and gene drives as a recurring agenda item in 2014. Yet in 2010 already, 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, as well as for elaborating the operational definition of synthetic biology quoted above. Decision XIII/17 of 2016 notes the future need for developing new approaches 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 those 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 provides 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 contrasts in which parties perceive 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. While there is general consensus among parties that the use of those technologies should be subject to the precautionary approach, how exactly precaution 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, non-universal participation in the CBD and, particularly, the Cartagena Protocol, poses additional challenges and creates the risk of jurisdiction shopping. Notably, the USA is not a party to the Convention and some of the countries with strong biotechnology industries, such as Argentina, Australia and Canada, are not parties to the Cartagena 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 World Health Organization 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.

#### **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 analysing large quantities of genotypic, phenotypic and environmental data. Techniques for highly parallel 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 re-engineering 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; Carbonell et al., 2016; Diniz and Canduri, 2017).

Developments in bioinformatics pose challenges for access and benefit-sharing frameworks, including the CBD and its Nagoya Protocol on access and benefit-sharing. They result in what is described as “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). The item is coined as “digital sequence information” (DSI) in the CBD negotiations, although Parties have noted that it “may not be the most appropriate term and [...] is used as a placeholder until an alternative term is agreed upon (Decision 14/20). Technical work under the Convention has suggested that the term may 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 behavioural data, among others (Convention on Biological Diversity, 2018). The origin of debates on DSI can be traced in 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 on fair and equitable benefit-sharing, including inappropriate access without benefit-sharing due to the use of sequenced data, and a “shift in the understanding of what constitutes a genetic resource” (Convention on Biological Diversity, 2015: 10). As explored below, such shift in understanding lies at the heart of the highly polarized debates 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 World Health Organization (WHO), and the ongoing negotiations under the UN Convention on the Law of the Law on marine biodiversity beyond the limits of national jurisdiction (BBNJ), with differences in terminology: the term “genetic sequence data” is preferred in the ITPGRFA and the WHO, while the terms “resources in silico” and “digital sequence data” have been used in the BBNJ negotiations. Similarly, progress in addressing the issue varies. While significant advances in deliberations have been made under the PIP Framework on what has been identified as a key issue, there is no agreement for the time being to expand the scope of their standard material transfer



agreement to include benefit-sharing from the use of genetic sequence data. In the ITPGRFA realm, benefit-sharing from the use of genetic sequence data associated with plant genetic resources for food and agriculture in the Treaty's Multilateral System of ABS was identified as the deal breaker, leading to the collapse of six years of negotiations to enhance this System (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 (Welch et al., 2017; Laird and Wynberg, 2018). 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, as well as 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.

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 strategically patent research tools and sequences 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 US, the Supreme Court held in *Myriad* (*Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 2013) that DNA segments and the information they encode are not patent-eligible simply because they have been isolated from surrounding genetic material. With *Myriad*, the US Supreme Court reversed years of prior jurisprudence and confirmed a shift in the broad scope of patentability of genetic sequences. The EU position is different (Cole, 2015). The EU Biotechnology Directive

(98/44/EC) states that 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. However, as ruled by the European Court of Justice in *Monsanto Technology v. Cefetra BV* (C-428/08, 2010), in order to meet the requirements for patent eligibility, the “functionality” of the genetic sequence must be disclosed in the patent application (i.e. a DNA sequence alone, without any indication of what it does, is not a patentable invention). 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 even locate the ownership of patents, as well as by the fees usually required for searching patent databases (Hope, 2004). The obscurity is further exacerbated by the fact that, while ownership of the 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 her research (Jefferson, 2006). This multi-level 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 genetic sequence data.

Unrestricted access to DSI, in the form of public and open-access databases, can be considered an important form of non-monetary 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. Non-monetary benefit-sharing, via information exchange, capacity building and technology transfer may allow for 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 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 centred mainly around the interpretation of the scope of the CBD and the Protocol. Most developed countries oppose any benefit-sharing from DSI use and argue that the CBD and the Nagoya Protocol have been developed to address

exchanges of “material” resources; therefore exchanges of “immaterial” information such as DSI fall outside the scope of the two instruments. Their legal argumentation points to the definition of “genetic resources,” as genetic “material” “containing functional units of heredity” (CBD Art. 2 and Nagoya Protocol Art. 2). Supporting a teleological interpretation of the scope of the ABS provisions of the Convention and the Protocol, developing countries draw attention to fair and equitable benefit-sharing as the objective of the Nagoya Protocol and the third CBD objective. They argue that letting DSI use escape benefit-sharing obligations would result in making the Nagoya Protocol obsolete, and thus negate any progress towards redistribution of benefits of scientific progress from the countries that have the capacity to use the genetic resources towards those that have stewarded them. They further note that DSI should qualify 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 and 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. Its implementation however 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 (Access to Biological Resources and Benefit Sharing Act 2017), Malaysia (Access to Biological Resources and Benefit Sharing Act 2017), and South Africa (National Environmental Management: Biodiversity Act 2004, as amended in 2013).

Despite the intense political controversies, the COP decision adopted in 2018 (Decision 14/20) established a science and policy-based process which is expected to shed light on many of the regulatory challenges involved in DSI regulation. 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 non-commercial use. In anticipation of deliberations in the CBD subsidiary bodies and the Working Group on the post-2020 framework, these studies are expected to inform the debates of the AHTEG established to address the issue.

## **5. Towards transformative governance of emerging technologies**

While our cases address different issues, all highlight the challenges which 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, rule-making has been limited to non-binding (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 legal 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. In this concluding part, we synthesize our findings and consider the extent to which the CBD can support transformative governance of biodiversity with respect to emerging technologies. We do so from the vantage points of integration, inclusiveness and transparency, information, adaptation and anticipation.

*Integration.* The dispersion of regulatory authority over multiple international institutions is a broader trend in global environmental governance, with biodiversity-related technologies being no exception. This can cause institutional fragmentation, which requires the management of

potentially disruptive interactions and the demarcation of institutional spheres of authority, while also allowing the realization of inter-institutional synergy effects. The integrative capacity of the CBD regime varies across the three cases discussed above. The dearth of rule-making activities with regards to gene drives and synthetic biology outside the CBD regime (with the partial exception of the World Health Organization's work on genetically-modified mosquitoes) limits the scope for integration from the outset. For geoengineering, we witness – after early potential conflict – an institutional division of labour, with the CBD implicitly deferring to the London Convention / London Protocol regarding marine geoengineering (see Reynolds, 2018). The case of DSI, however, shows parallel efforts under the CBD regime, the World Health Organization as well as the Food and Agriculture Organization to come to terms with the implications of digitalization for access and benefit-sharing. So far, those processes 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.

The CBD processes highlight a relatively high degree of *inclusiveness and transparency*, which are considered – perhaps increasingly so – as essential characteristics of good governance, with regard to the democratic legitimacy of deliberations, the best possible outcomes, and improved implementation potential. This inclusiveness is illustrated, for instance, by the establishment of an open-ended accessible online forum on synthetic biology and the process for submission of views on DSI. In addition, both AHTEGs benefited from extensive stakeholder participation, including representatives of indigenous peoples and local communities, civil society, academia and research, and the private sector, as well as other international bodies addressing issues of relevance.

*Information.* The CBD processes can often benefit from a high degree and good quality of knowledge, including both relevant scientific information and indigenous peoples' inputs regarding other knowledge systems. The AHTEG on DSI for instance has been informed by a series of peer-reviewed studies addressing a range of conceptual, legal and implementation-related issues, concerning the concept and scope of DSI, existing databases, developments on traceability, and domestic legal and policy measures. The AHTEG and policy deliberations on synthetic biology are informed by an online forum, which addresses a broad range of issues, including the current state of knowledge, possible impact, and tools to support horizon scanning, monitoring, and assessing of the most recent technological developments requested by the COP. Still, CBD participants have indicated that the seemingly well-informed outcomes

of AHTEG discussions often fail to reach policy-oriented CBD bodies, noting that a gap still exists in translating the extensive scientific work into policy-relevant information. In contrast, information uptake with regard to deliberations on geoengineering is less structured and arguably weak. For example, both the COP decision on ocean fertilization and the expansive COP 10 decision have been criticized as poorly informed (IOC ad hoc Consultative Group on Ocean Fertilization, 2008; Sugiyama and Sugiyama, 2010; Parker, 2014).

Governance that is *adaptive* responds effectively to changing circumstances through the adoption of new rules or the amendment of existing ones. In the case of synthetic biology and gene drives, the CBD COP's decisions are vague and use heavily qualified language. Importantly, those decisions do not clarify the implications of the precautionary approach for deliberate environmental releases. Decisions on climate geoengineering are equally unspecific and fail to define important operational criteria, such as what would constitute an "adequate scientific basis" for considering the use of relevant technologies. In contrast, the governance of marine geoengineering under the London Convention / London Protocol sees a significantly more extensive and sophisticated set of rules, including for scientific assessments. For DSI, the question of whether or not sequence data is included within the CBD's definition of the term "genetic resources" remains as of yet unresolved, and no steps have been taken to clarify and close the existing governance gap. While it can be argued that the open-ended wording of CBD decisions aims at flexibility for implementation in different jurisdictions, lack of specific guidance may result in disadvantaging countries lacking national capacity to assess and regulate new technologies. Together, governance appears insufficiently adaptive, an aspect that may be the weakest link within this regulatory space. But ultimately, adapting is arguably the core challenge of both regulating emerging technologies as well as international law. After all, technologies often develop rapidly while governance mechanisms – especially legal instruments – are by design conservative and slow-moving (Marchant et al., 2013).

Finally, *anticipation* suggests that governance should develop chronologically upstream from technology and its impacts. In short, this calls for 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). With respect to this criterion, the discussions and development of the governance of emerging technologies and technological practices in the CBD and other regimes has indeed been anticipatory. In all three cases considered here, the COP and other institutions initiated processes toward governance well before they were used outdoors at substantial scale

or, with DSI, before the take-off of the use of digitalized genetic resources in the life sciences. 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 institutions have engaged too early in these areas, before sufficient knowledge of the technologies' and practices' potentials, limits, and risks and of states' interests is available.

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 undermine effective benefit-sharing or enhance access, 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 climate engineering 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 socio-economic solutions that could address root causes of biodiversity loss, such as habitat loss and alteration, pollution, and over-exploitation 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 catalyse structural social, political, and economic change, often in surprising ways. As an illustration, although the emerging synthetic biology community could be the source of great risk, it may also produce valuable social and institutional advancements. However, within the context of the CBD, interest constellations reflect differences in socio-economic development and innovative capacity, as well as normative disputes over the role of technology in environmental governance. Shifting towards 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.

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