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Engineering biological diversity: the international governance of synthetic biology, gene drives, and de-extinction for conservation☆

Jesse L Reynolds[1,2]

In the face of insufficient progress in conserving and restoring biodiversity, the *in situ* use of advanced genetic modification, gene drives, and other biotechnologies for conservation purposes are being considered, researched, and developed. This paper introduces the methods, applications, environmental risks, and social challenges of 'conservationist synthetic biology'; reviews existing governance, with an emphasis on international instruments, institutions, and processes; and offers observations of the politics of developing further governance. The most important multilateral environmental agreement is the Convention on Biological Diversity. Governance of such conservationist synthetic biology is vital but gaps remain. The further development of governance is a political process, and conservationist synthetic biology has a political landscape that is atypical for emerging technologies.

Addresses
[1] Emmett Institute on Climate Change and the Environment, University of California, Los Angeles School of Law, 385 Charles E. Young Drive East, Los Angeles, CA 90095, USA
[2] Utrecht Centre for Water, Oceans and Sustainability Law, Utrecht University School of Law, Newtonlaan 201, 3584 BH Utrecht, The Netherlands

Corresponding author: Reynolds, Jesse L (j.l.reynolds@uu.nl)

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Introduction

Halting biological diversity ('biodiversity') loss is a leading sustainability challenge, but decades of efforts have been disappointing. For some threatened species, non-technological means such as habitat protection are insufficient due to the species' conservation status or the nature of their threats. Consequently, some scientists are researching and developing techniques to genetically modify species *in situ* (that is, in the wild) to conserve and restore biodiversity. Under the concept of 'synthetic biology,' some of these could improve ecosystem integrity, function, and resilience; fulfill ethical obligations; satisfy legal duties; and increase public support for conservation. Yet they also pose environmental risks and social challenges. The most recent *Frontiers* report from the UN Environment Programme identifies *in situ* synthetic biology among its five 'Emerging Issues of Environmental Concern' [1••]. This paper introduces the methods, applications, environmental risks, and social challenges of what I call 'conservationist synthetic biology'; reviews existing governance; and offers observations of the politics of developing further governance.

Conservationist synthetic biology

Conservationist synthetic biology has a historical lineage. Humans have genetically altered wild species for millennia – for example, through the selective pressures of hunting – and bred them to help restore ecosystems for decades. Although transgenic biotechnologies raised the possibility of intentionally genetically modifying *in situ* populations [2] (meaning the interbreeding members of a species' that typically live in a geographic place), it was not until the more precise, faster, and less costly CRISPR-based methods in the 2010s that doing so became feasible [3–6,7••,8].

Advanced biotechnological techniques are sometimes called 'synthetic biology' (see Figure 1), although this phrase's meaning seems indistinct from modern biotechnology. Genetic modification is a category therein. A specific subcategory of genetic modification would use gene drives, 'systems of biased inheritance in which the ability of a genetic element to pass from a parent to its offspring . . . is enhanced' [9]. In contrast to typical sexual reproduction in which a parent transmits a given gene to about half its offspring, a gene drive causes an associated gene to be transmitted to (nearly) all offspring. Gene drives are effective only in sexually reproducing species that have a short life cycle. Engineered gene drives (henceforth simply 'gene drives') empower humans to genetically modify an entire *in situ* population by introducing a small number of gene drive organisms (GDOs). Most interest in gene drives has been in

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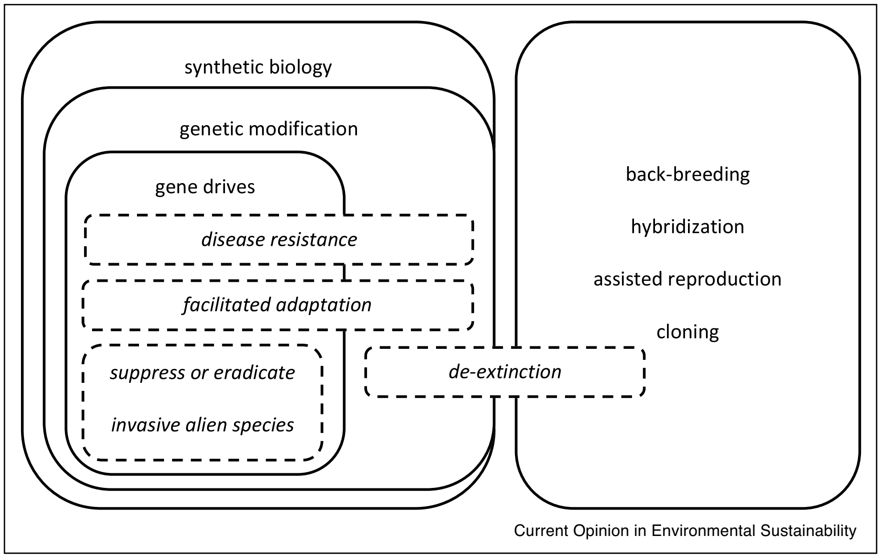
Figure 1



Techniques (solid lines, plain text) and applications (dashed lines, italicized text) of conservationist synthetic biology.

reducing the size of a population or extinguishing it entirely, which could be achieved by causing most or all offspring to be male or members of one sex to be infertile.

These synthetic biology techniques have four conservatist applications. First, genetic modification could confer disease resistance to a threatened species (here including endangered ones). For example, the American chestnut tree could be made resistant to the fungal blight that has nearly caused its extinction [10]. Second, in 'facilitated adaptation,' genetic modification could increase threatened species' resilience, such as against anthropogenic climate change. Corals in Australia's Great Barrier Reef could be modified to withstand warmer and more acidic marine water, both of which are due to elevated atmospheric concentrations of greenhouse gases [11•]. Although GDOs could be used toward these first two applications, such a powerful technology would generally be unnecessary. Instead, in these cases, organisms whose genomes have been modified through 'typical' (that is, without gene drives) biotechnology could have sufficient reproductive advantage relative to the unmodified *in situ* populations to enable the gene and trait to propagate and perhaps dominate [7••]. Third, gene drives could suppress or eradicate populations of invasive alien species, a leading direct driver of biodiversity loss. This is particularly appealing on islands, which are vulnerable to invasive species and could better contain a gene drive [12,13•]. Fourth, biotechnological methods could revive locally, functionally, or globally extinct species, or at least analogs thereof, and reintroduce them *in situ* [14]. This could use 'typical' genetic modification as well as selectively breeding similar species through back-breeding and hybridization, assisted reproduction, cloning, and genetic modification. Scientists are researching whether the quagga, heath hen, passenger pigeon, and others could be returned.

Environmental risks and social challenges

Conservationist synthetic biology poses environmental risks and social challenges. The former vary by technique. Genetic modification could affect the species in unexpected ways or spread beyond the target population or species, for example via horizontal gene flow or hybridization [15]. The novel organisms could adversely affect ecosystems as well. Although scientists would hopefully research risks before using genetically modified organisms *in situ* for conservation purposes, accidental release is possible. Gene drives' potential impact relative to effort of intervention amplifies concern [16]. In fact, some researchers state that GDOs should only be placed *in situ* when the intention is to internationally affect most or all populations of the target species [12,17]. De-extinction's environmental risks could, in addition to those of any genetic modification used, resemble those of an invasive alien one [18,19•,20]. This is because the ecosystems into which such a species would be reintroduced have changed significantly. What the revived species would consume, what would consume it, and with which other species it would compete would be partially uncertain. Furthermore, a revived species could pose disease risks, including to humans [19•].

'Social challenges' encompass diverse social, political, legal, economic, and ethical concerns. Some can be better understood as socially mediated environmental risks. Conservationist synthetic biology could undermine efforts to conserve biodiversity through primary, widely preferred means such as habitat protection, perhaps by consuming limited financial and other resources [19•,21,22••]. Some techniques may be able to be used maliciously, as in an agricultural pest or disease-transmitting insect equipped with a gene drive [23]. Other social challenges are unrelated to environmental risks. Modified or de-extinguished animals may suffer [24]. The introduction of genetically modified or revived organisms could have negative economic impacts, such as reduced tourism or competition with valuable other species [25]. Furthermore, many (seemingly) unmodified species and ecosystems have significant nonuse value, even to those who live elsewhere. Related to this are ethical issues concerning hubris [22••,26], implications for human–nature relationships [18], and potentially excessive optimism in technology [19•]. It is unclear who has the legitimate authority to biotechnologically intervene for conservation purposes [27], pointing toward questions of whom must be consulted or who must give consent [28], intellectual property [29], and private actors' decision-making [30]. Throughout this, perceptions of conservationist synthetic biology are likely to be subjective and divergent from experts' views [19•,31,32], as they have the characteristics – for example, invisible, out of one's control, and dreadful – of phenomena where lay views differ from those of experts [33].

Existing governance

The high-stakes combination of potential to conserve and restore biodiversity, environmental risks, and social challenges imply the importance of governance for conservationist synthetic biology. Many observers understandably look toward national, subnational, and European Union law as primary sources of governance. These emerging biotechnologies would be regulated by numerous existing provisions concerning, among other things, endangered species, habitat protection, 'traditional' genetically modified organisms, veterinary medicine, animal welfare, biosafety, toxins, and intellectual property [11•,30,34]. However, conservationist synthetic biology will pose legal uncertainties and challenges. For example, would a formerly extinct species be considered native or invasive [35]? A few countries – such as Brazil, The Netherlands, and Uganda – have developed laws, administrative regulations, and/or guidelines that are at least partially specific to conservationist synthetic biology [36].

Because researchers, materials, knowledge, and impacts will cross jurisdictional borders, governance will need to be – to some degree – international [37]. Under the customary international law of transboundary harm, states are obligated to take steps to prevent harm arising from activities within their jurisdiction or under their control that pose a significant transboundary risk. Specifically, states are to practice due diligence by – among other things – requiring the activity's authorization, assessing environmental impacts, notifying and cooperating in good faith with potentially affected states, and informing the public.

The most important multilateral agreement for conservationist synthetic biology is the Convention on Biological Diversity (CBD) regime [38–40]. The framework CBD has near-universal membership – only the United States has not ratified it – and has the conservation of biological diversity among its objectives (Article 1). The CBD parties have numerous obligations toward which conservationist synthetic biology techniques could contribute (e.g. Article 8). At the same time, these techniques could cause adverse impacts on biodiversity, which parties are to take steps to reduce (Article 14). The CBD also obligates parties to promote research that contributes to biodiversity conservation, to promote and cooperate in the use of scientific advances in biodiversity, and to transfer relevant technologies to other parties (Articles 12, 16). Finally, this agreement has specific provisions for biotechnology in general and for 'living modified organisms' (LMOs). For the latter, these countries are to regulate, manage, or control the risks associated with those that are likely to have adverse environmental impacts that could affect biodiversity conservation, taking also into account the risks to human health (Article 8(g)).

The CBD's Cartagena Protocol on Biosafety strives for the safe transboundary transfer, handling, and use of LMOs that could have adverse effects on biodiversity (Article 1). Although the Protocol defines LMO (Article 3 (g)), it is unclear whether all synthetic biology organisms would qualify as such. Regardless of whether they would, the Protocol elaborates on the mechanisms, measures and strategies to manage LMOs' risk. Parties that intend to export LMOs must obtain importing parties' advanced informed agreement (Articles 7–12). Those countries that have ratified the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress are obligated to provide response measures (Article 5) and for civil liability (Article 12) for significant damage to biological diversity that results from LMOs' transboundary movement, taking also into account risks to human health.

The CBD's biennial Conferences of Parties (COPs) have issued several decisions regarding synthetic biology. The first merely invites countries to submit relevant information and to apply the precautionary approach to the field release of living synthetic biology organisms (Decision X/13, 2010). The 2014 COP decision established an Ad Hoc Technical Expert Group, which contains representatives of countries, other intergovernmental organizations, nongovernmental organizations, researchers, and industry (Decision XII/24, 2014). This decision also urges states to take five specific actions concerning synthetic biology:

have risk assessment and management procedures in place for any environmental release, approve field trials only after risk assessments, carry out scientific assessments regarding potential biodiversity effects, encourage research into synthetic biology's positive and negative biodiversity impacts, and cooperate in building capacity in developing countries. At the subsequent COP, the parties offered an operational definition of synthetic biology, although this clarified little. They also further encouraged countries to facilitate public and multi-stakeholder dialogues and awareness-raising activities and to cooperate in developing guidance and building capacity (Decision XIII/17, 2016). Finally, the 2018 CBD COP decision dedicated particular attention to GDOs, calling for additional research, a precautionary approach, and conditions limiting GDOs' release into the environment (Decision 14/19, 2018). These conditions include risk assessment, risk management, and possibly some involvement of the public in decision-making. Further action is expected at the next COP.

Looking beyond the CBD, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) aims to protect the survival of listed species from being further threatened by international trade. Although this could include de-extinguished species [38] or (improbably) other synthetic biology organisms, the likely candidate species for these interventions are not listed in CITES' Appendices: the former because they went extinct before CITES's development and the latter because they are not threatened. Regardless, CITES has exceptions for personally owned organisms and for scientists or scientific institutions (Article VII). Furthermore, it protects to a lesser degree captive-bred organisms, clearly encompassing de-extinguished species.

International bioweapons-environmental and environmental weapons law would regulate the possible hostile use of conservationist synthetic biology organisms, products, and techniques. The UN Biological Weapons Convention requires countries to prohibit bioweapons. Likewise, the Environmental Modification Convention (ENMOD) does so for the hostile or military use of environmental modification – which would include many of the biotechnologies discussed here – that would have widespread, long-lasting or severe effects (Article II). ENMOD parties also commit to facilitate information exchange on peaceful environmental modification (Article III.2).

Because governance is broader than law, one should look beyond legal mechanisms and institutions. The International Union for Conservation of Nature (IUCN) is a hybrid intergovernmental and nongovernmental organization. In 2016, an IUCN task force finalized 'Guiding Principles on Creating Proxies of Extinct Species for Conservation Benefit' [21]. These reject the possibility that 'extinct species . . . can be resurrected in their genetic, behavioural and physiological entirety,' but instead that they can be only approximated. The guidelines offer authoritative advice regarding a need to expect conservation benefit, the selection of candidate species, and the release and management of proxy species. That same year, the IUCN initiated a process toward developing similar guidance for synthetic biology and gene drives (WCC-2016-Res-086). The outcome is expected at the IUCN's next Congress, scheduled for 2021.

Finally, some synthetic biology researchers and experts have developed high-level principles and other self-governance mechanisms for conservationist synthetic biology, especially in the more controversial case of gene drives [30,41]. One set of principles is derived from a US National Academies report and endorsed by multiple organizations and scientists. These call for 'the sponsors and supporters of gene drive research [to] advance quality science to promote the public good; promote stewardship, safety, and good governance; engage thoughtfully with affected communities, stakeholders, and publics; [and] foster opportunities to strengthen capacity and education' [42]. Gene drive researcher Kevin Esvelt proposes that a nonprofit organization manage relevant intellectual property, making access conditional on compliance with norms of responsible research [43]. More generally, scientists and other experts are focused primarily on public engagement and consultation [13•,28,32,44,45].

Conclusion: the politics of developing governance

The emerging technologies of conservationist synthetic biology present high-stakes risk-risk tradeoffs, with substantial potentials to further sustainability and to cause environmental harm. Governance is vital, but existing mechanisms, institutions, and processes have gaps. The further development of governance is a political process.

Although critics often frame emerging technologies as being hyped by firms and boosters, this is not the case with conservationist synthetic biology. Those who advocate for its research and development seem to do so despondently [3,19•] and emphasize caution over speed [12]. Furthermore, few to no business interests are promoting the endeavors. This is likely a consequence of these biotechnologies' largely nonexcludable character, in which their effects cannot be limited to those who pay for the services [46]. Consequently, there is little potential for profit in providing such public goods (in the economic meaning, not the normative one).

Emerging technologies are sometimes resisted by environmentalists. However, given conservationist synthetic biology's applications and potential as well as the insufficient progress in conserving biodiversity, opposition may be diffused. Ultimately, conservationist synthetic biology cuts right to the heart of environmentalism's meaning [47]. Contemporary environmentalism arose in part as a reaction to powerful new technologies – think of DDT and nuclear power – that were seen as hierarchical, hubristic, and dangerous. This is evident both in the movement's founding texts, where environmental impact is purported to be proportional to technological development [48], and in its less widely read but influential intellectual foundations [49]. Yet technologies do not necessarily increase environmental impact per unit of consumption; in fact, they often decrease it. In a persistent echo of the movement's 'small is beautiful' legacy, many environmentalists seem quick to embrace technological opportunities when they are decentralized, visible, relatively familiar, and in consumers' control, such as solar panels, insulation, and electric cars, while resisting those that are centralized, invisible, relatively unfamiliar, and in others' control, such as nuclear power, climate geoengineering, and biotechnology. Whether we proceed with technologies are, to a degree, political decisions. At the same time, whether we can expect to conserve biodiversity while also ensuring the economic development of the world's peoples with existing decentralized technologies is largely a question of experts' assessments. The evidence to date is not encouraging.

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