4

Biotechnology

The genetic code which the cells of all living organisms contain constitutes the blueprint of life. This code amounts to no more than four letters that represent the four different nucleotides which together determine the surface structure of viruses just as they influence the nutrient content of rice corns or the metabolism of polar bears. The nucleotides contained in the coding region of a genome form triplets, so-called codons, each corresponding to a specific amino acid. Assembled inside cellular factories, multiple amino acids fold together into proteins, molecules which carry out a bewildering array of functions inside of an organism. This expression of genes in proteins means that genetic code corresponds to a variety of physical properties which may be useful or harmful, and that might be imitated, manipulated, removed, modulated, or expressed in foreign organisms. Many genes, in a sense, correspond to some physical function, yet we often might not know which functions precisely. In addition, various mechanisms regulate the ways in which a specific gene expresses itself, including environmental factors.

Genetic engineering is the manipulation of genetic sequences in order to induce some desirable phenotypic traits. This notably includes the insertion of transgenes – that is, foreign genetic material for creating phenotypes that lie beyond normal evolutionary boundaries. Insulin, for the treatment of diabetes, used to be extracted from the pancreas glands of pigs and cows via a difficult and expensive technical process. In what was the first major application of genetic engineering to the field of human medicine during the 1970s, *E. coli* bacteria were modified to express human insulin and thus allowed its mass production through bacterial cultures.[1] Transgenes in agriculture offered a novel method in commercial plant breeding, the most notable example being the *cry* genes of the *Bacillus thuringiensis*, inserted into staple crops such as potatoes and cotton in order to express an insecticidal toxin. More recently, various public and private scientific initiatives developed Golden Rice, genetically engineered to contain

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

large amounts of a Vitamin A precursor, which is intended to alleviate debilitating eye conditions that plague some developing countries due to pervasive nutritional deficiencies.[2] Unlike in the medical sphere, such agricultural applications of biotechnology tend to be extremely controversial. This is possibly due less to the potential risks of the technology itself than to associated developments such as the increasing stringency and coverage of intellectual property rights in plant breeding, as well as the drastic consolidation of corporate power in global agriculture during the past decades.[3] The impact and possible contentiousness of genetic engineering has only increased with the invention and global diffusion of novel techniques for genome editing. By far the most popular of these techniques, CRISPR/Cas9, mimics a genetic self-defence system which bacteria employ against viral attackers.[4] This system targets a specific site within a genome and then uses an endonuclease for cleaving it in two. This allows for the precise cutting of DNA double strands in order to remove specific genes or to insert new ones. By manipulating a cellular mechanism known as homology-directed repair, the cleaved double strands are subsequently joined together again. This technique can be metaphorically described as 'scissors and glue'. Being significantly more powerful than previous methods for genetic engineering, CRISPR/Cas9 has had transformative impacts on the life sciences, and even the global economy, in the past decade. At the same time, it also led to novel controversies, such as in novel plant breeding techniques and regarding germline editing for heritable changes in human genetics.[5]

Beyond such issues in genetic engineering, a potentially much more disruptive technological potential is in the area of synthetic biology. The term is notoriously difficult to define but broadly refers to the engineering and design of life as such rather than tinkering around with single genes. Under the Convention on Biological Diversity (CBD), the premier international body dealing with that issue, synthetic biology is tentatively and inconclusively defined 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'.[6] While this may be useful as a starting point, a more precise definition of synthetic biology remains elusive for the time being. This also means that it is quite challenging to specify what exactly connects the various actual and speculative technological applications that are loosely being referred to as instances of synthetic biology. Exemplifying the engineering philosophy behind synthetic biology, one major approach is the development of standardized biological parts, referred to as BioBricks, that can be assembled into customized genetic sequences.[7] Such sequences can then be inserted into other biological systems, such as *E. coli* bacteria, in order to produce user-specified effects. In a similar

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

manner, a team around the mercurial inventor and businessman Craig Venter recently developed a minimal bacterial genome containing no more than the bare essentials for life.[8] This bacterium, called JCV-syn3.0, contains less than 500 genes and could be a starting point for the development of stripped-down chassis organisms that allow users to plug in specific properties and functions at the genetic level. In a more radical approach to the artificial synthesis of life, Xenonucleic Acids (XNA) consist of nucleotides which are structurally different from the nucleotides occurring in nature.[9] Such additional synthetic nucleotides might eventually expand the alphabet of life which, in natural DNA, is limited to four nucleotides. With these and related applications, it is increasingly possible to synthesize life from anorganic chemical components, with such synthetic life potentially even supporting natural evolution.[10] In contrast, directed evolution is an approach often associated with synthetic biology which seeks to produce optimal proteins through artificial and high-speed evolutionary processes in the laboratory.[11] This method is currently being used in the production of a variety of commercial enzymes.[12] Another major technological possibility from a perspective of environmental sustainability is the recreation of extinct species, sometimes referred to as de-extinction.[13] This method is sometimes discussed in the context of the ongoing anthropogenic extinction event. However, without the possibility of simultaneously recreating the original natural environments of those species as well as their social structures and collective memories, it is an open question whether this method would not rather amount to the creation of *new* species rather than the re-creation of *extinct* ones. Regardless of whether or not any or all of these and related technological developments should properly be referred to as 'synthetic biology', they raise various issues from a perspective of environmental sustainability, in terms of both promises and perils.

Further confounding this vast technological panorama is the fusion between contemporary biotechnology and information technology. The identification of genetic functions, including for subsequent genetic engineering but also for a broad variety of other purposes, poses a significant data problem. The size of the genome differs between species. Some micro-organisms contain no more than 160,000 nucleotide base pairs with around 180 genes.[14] Humans have approximately 3 billion base pairs with maybe 30,000 genes, which roughly corresponds to 1 GB of data. Within any given species, genetic variation means different organisms will have slightly different genomes. Purposes as different as the analysis of human hereditary diseases or the identification of genes associated with drought tolerance in plants accordingly require significant amounts of data. These data, whether for humans, animals, plants, or microbes, contain myriad hidden patterns of gene–protein linkages, as well as of complex gene interactions, with revolutionary potential for the life sciences and modern medicine, but also for sustainability

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

science. They are amenable to novel computational methods under the wider umbrella terms of machine learning and big data.[15]

Extracting these data and making them accessible for commercial and non-commercial research alike involves two steps. The first is sequencing – that is, the reading out of the genetic information that are contained in the cells of a target species. This process used to be excruciatingly time-consuming. In the early 1970s, the sequencing of a bacterial virus proceeded at one base-pair per month, taking two years to complete.[16] Contemporary methods vary significantly in terms of speed, costs, efficiency, and accuracy.[17] Sanger sequencing, named after the British biochemist and double Nobel laureate Frederick Sanger, has historically been the dominant approach. While it remains in widespread use, it is limited to sequence reads of several hundred base pairs. As sequencing expanded in scope and scale, various methods that can handle larger reads have been developed. So-called shotgun sequencing randomly breaks down longer sequences into smaller parts, determines their respective base pairs, and then collates them to establish the full sequence. While this allows for the speedy reading of large genomic regions or even whole genomes, reassemblage can introduce challenges. For instance, as the shotgun fragments are reassembled based on matching ends, nucleotide sequences that frequently repeat across the genome can introduce uncertainties regarding where each fragment should be placed. Shotgun sequencing initially employed the Sanger method yet, from the late 1990s onward, a second generation of sequencing technologies emerged that centred on massively parallelized reads of short base-pair sequences and their subsequent assembly.[18] A third generation, still largely under development, allows for extraordinarily long reads, possibly in the range of hundreds of thousands of base pairs per instrument run.[19]

The second step is the collection and organization of sequence data in electronic databases, including public databases that provide open access for biomedical and other types of research. Stored sequence data is commonly annotated, for instance in order to point out regions that code for specific proteins.[20] By far the largest provider is the International Nucleotide Sequence Database Collaboration, a joint initiative by the DNA Data Bank of Japan, the European Bioinformatics Institute, and the National Center for Biotechnology Information in the United States. The data volumes to which these centres grant access stretches the limits of human imagination. The European Bioinformatics Institute, for instance, presently holds close to 400 petabytes (or 400 million gigabytes) of raw data. This institute also hosts the International Genome Sample Resource, which entails full genomic data for thousands of individuals, initially collected with the aim of characterizing human genetic variation within multiple populations.[21] Genbank, the primary database of the US National Center for Biotechnology Information, currently offers access to more than 230 million DNA sequences which jointly comprise

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

approximately 940 billion nucleotide bases. In addition, the centre holds 1.6 billion sequences amounting to more than 13 trillion bases in its Whole Genome Shotgun database. Beyond that, a variety of databases of a highly specialized nature exists. The Global Initiative on Sharing Avian Influenza Data (GISAID) provides genetic data for influenza viruses as well as the SARS-CoV-2 coronavirus. The Mutant Variety Database, co-hosted by the UN Food and Agriculture Organization and the International Atomic Energy Agency, provides data on artificially induced plant mutations, a breeding technique that generates significant genetic variation (and thus potentially useful physical characteristics) in plants. Databases such as SoyBase and LegumeIP offer genetic data for specific types of plants, NONCODE provides genetic data for non-coding ribonucleic acid (RNA), and an abundance of databases deals with human genetics in the context of medicine, with at least seven initiatives presently dedicated to SARS-CoV-2 and COVID-19.[22] It is noteworthy, though, that entries in these databases overwhelmingly originate from the International Nucleotide Sequence Database Collaboration, with only a miniscule amount of direct contributions. The International Nucleotide Sequence Database Collaboration, in other words, is the primary public and global database architecture for nucleotide sequences. The format, structure, and even programming language of nucleotide databases has become increasingly harmonized over the years. Various tools for information retrieval allow users to browse their content, for instance via BLAST (Basic Local Alignment Search Tool) searches that can match search queries to nucleotide sequences or amino acid sequences that are recorded in a database. Other tools allow for cross-referencing and integration between different databases, or for linking genetic sequence data to information about the corresponding organisms, including, for instance, any potential genetic diseases which they might be expressing. The sequences that a given database contains may come from a variety of sources. Biomedical scientists have been committed to the free sharing of data for decades and have adopted voluntary codes of conducts such as the 1996 Bermuda Principles, mainly intended to ensure open access to data generated in the Human Genome Project, the 2003 Ford Lauderdale Agreement, and the 2009 Toronto Agreement on prepublication data-sharing. Academic journals in the life sciences enforce this commitment by requiring underpinning genetic sequence data to be available without restriction. Nucleotide sequence data can also become part of open-access databases in the context of patent claims: patents are usually granted under the condition that the claimed invention is sufficiently disclosed to the public. For commercial products and applications in the life sciences, this can well include a legal requirement to disclose nucleotide sequences.

The developments sketched out earlier have profound implications for science, human well-being, and the global economy, but also for environmental sustainability. The rest of this chapter centres on several dimensions within this wider

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

technological panorama which have in recent years emerged as key themes in global environmental governance, particularly within the field of biodiversity. Here, biotechnology implies promises and perils in several dimensions. Bioinformatics greatly facilitates the creation of scientific knowledge about biodiversity and improves the ways in which it can be measured and monitored in situ. It also allows for the digital storage of genetic sequence data, including as a potential safety backup if sudden and large-scale losses of biodiversity were to occur. The associated technological promises thus related both to the information commons as well as to enhanced impact management from supporting efforts at biodiversity conservation. Yet the collection, storage, and utilization of sequence data also creates perils by threatening to create or reinforce injustice. Such injustice, as a matter of ethics as well as of international law, can entail exclusionary effects from intellectual property rights intruding into the domain of unrestricted sequence data-sharing. They can also amount to restrictions on the ability of states and societies to shape the conditions under which their domestic biodiversity is being used for commercial and non-commercial purposes alike, and to participate in the various benefits that might be created as a result. Beyond bioinformatics, certain developments in the field of synthetic biology, including so-called gene drive systems, might offer unprecedented leverage for global biodiversity conservation. These technological approaches could potentially partially compensate for the systemic policy failure that characterizes the global efforts at conserving planetary biodiversity.[23] These ideas for the large-scale engineering of biodiversity are extremely contentious. What makes them perilous are not just their unprecedented risks, some of which cannot even be estimated with standard risk assessment methodologies.[24] Similar to the case of climate engineering (to be discussed in Chapter 5), they might also create a problem of crowding out feasible alternatives if they deter rigorous policy action in the present because stakeholders are holding out for convenient technological options that may or may not become feasible in the future.

The CBD has emerged as the central international forum for these issues. With 195 member states plus the European Union, and the three objectives of biodiversity conservation, sustainable use, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, the convention is among the most comprehensive multilateral institutions in global environmental governance. Considering the inherent affinities between the issue areas of biotechnology and biodiversity, the central role of the convention may not be particularly surprising. However, one of its peculiarities is a notable tendency for mandate creep so that, over time, the activities of the convention have expanded into numerous areas that are at times only indirectly related to its core mission. This is primarily a result of prodding by developing countries, who tend to consider the convention to be more

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

amenable to their specific policy priorities than is the case with many other international institutions. On the side of both developed countries as well as relevant industries, however, this has led to a perception of the convention being an 'anti-technology' forum. From the outset, this creates a bias towards institutional responses centred on precaution and regulatory restrictions, for better or worse. As the subsequent discussion will show, it also consistently and predictably leads to political conflagrations that often, but not always, break down along the North–South axis. Beyond the CBD, in the increasingly fragmented architecture of global biodiversity governance, other institutions play specialized and sectoral roles. Here, this notably includes the Seed Treaty of the UN Food and Agriculture Organization as well as the United Nations Convention on the Law of the Sea. While not immediately relevant for the environmental context, the World Health Organization (WHO) is a crucial forum dealing with the digitalization and sharing of certain sequence information, as well as with some biosafety aspects of gene drive systems.

The following three subsections will delve more deeply into issues of policy and politics pertaining to the promises and perils of biotechnology discussed earlier. Afterwards, I go through the various international instruments and discuss how they have responded (or not responded) to the technological challenge. In the concluding section of this chapter, I evaluate these institutional responses with the conceptual framework introduced in Chapter 3.

4.1 Bioinformatics and Biodiversity Conservation

While aggregate biodiversity loss rates are currently at a level that is unprecedented throughout all of human history, effective policy interventions require a precise informational basis. This requires a firm understanding of what is being lost, where, and how fast. In combination with rapid advances in sequencing technology, computational methods provide increasingly sophisticated analyses of population genetics, including for the migration, evolution, and demographics of a given population.[25] This includes assessments of how anthropogenic pressures shape evolutionary processes, including for understanding potential feedback loops between conservation policies and natural evolution.[26] In principle, evolutionary responses that potentially undermine the effectiveness of policy interventions can happen on rather short timescales, for instance meaning that policies that create strong selection pressure could lead to undesired results. Large-scale genetic analysis also facilitates the creation of robust policy priorities by approximating the relative conservation values of different populations.[27] The digital storage of genetic sequence data, finally, hedges against extinction risk. Even where species might become extinct, the preserved sequence data would be available for future

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

scientific research or could, in principle, even be recreated in the laboratory, possibly as synthetic organisms for simpler species or via interspecies nuclear transfer cloning, where genetic material from one species is inserted into an egg cell of a related species and subsequently grown inside a surrogate.[28]

Albeit still facing limitations both at the technical level and in terms of scientific understanding, such methods hold immense potential for proofing global agricultural biodiversity against anthropogenic pressure. To fully appreciate the gravity of what is at stake here, we first need to take a step back. Cultivation and conservation of agricultural biodiversity stands at the beginning of human civilization. The crops that nowadays form the staple of the global food system emerged from just a few geographic hot spots in the Near and Middle East, China, New Guinea, and the Andes.[29] Starting from the Neolithic age and continuing into the modern era, crop biodiversity diffused into other world regions as a result of trade and migration.[30] Local agricultural systems thus became increasingly linked through global transfers of seeds as well as of associated agricultural knowledge.[31] The availability of suitable and diverse seeds is essential for breeding new plants that have higher yields, better nutritional value, improved taste, higher resistance to environmental stress, or other such properties. The emergence of the contemporary global food system, which performs reasonably well in feeding a world population of roughly 8 billion, would have been impossible without sufficient agricultural biodiversity or without breeders being able to access and utilize this biodiversity. This is not to disregard either the existing injustices in the contemporary global food system or the historical injustices associated with global seed exchanges, particularly during the European colonial era. However, it is beyond doubt that the historical roots of our contemporary civilization rest in agricultural practices for which rich agricultural biodiversity was a precondition.

Yet, starting in the early twentieth century, several long-term processes began kicking in that increasingly undermined the availability and accessibility of agricultural biodiversity. Starting from early innovations in agricultural chemistry and continuing with mechanization and the emergence of industrialized agriculture, the so-called Green Revolution led to unprecedented historical increases in agricultural yields while also leading to serious social and environmental harm, particularly in developing countries.[32] The emergence of genetics in the 1950s and agricultural biotechnology in the 1970s reinforced this process.[33] Legally, the scope and stringency of intellectual property rights for plants and plant components increased substantially, as a result both of different international treaties (such as the 1961 International Convention for the Protection of New Varieties of Plants and the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights) and of landmark judicial decisions in Europe and North America (such as the 1980 US Supreme Court ruling in *Diamond* v. *Chakrabarty* on the patentability of living

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

organisms).[34] This led to various limitations on plant breeders when accessing agricultural biodiversity for breeding purposes, primarily in developing countries. In parallel, the market structure in global agriculture has become increasingly centralized since the middle of the twentieth century, and particularly since the late twentieth century, to the extent that there is a de facto cartel in the global supply of seeds and related agricultural products and services.[35] One major consequence is mono-cropping – that is, the cultivation of crops with limited genetic variety in order to maximize profits through economies of scale. In addition to harmful effects for agricultural biodiversity, this leads to various other adverse social and environmental impacts.[36]

In the context of various existing efforts and initiatives for conserving agricultural biodiversity and for maintaining accessibility from the side of plant breeders, bioinformatics has significant potential for mitigating these harmful structural developments. At the forefront of global conservation efforts, the International Agricultural Research Centers that are loosely organized within the Consultative Group for International Agricultural Research (CGIAR) leverage science and technology for sustainability and food security, often in partnership with other stakeholders. The CGIAR centres also hold some of the largest ex situ collections of plant genetic resources for food and agriculture (PGRFA), stored and conserved in seed banks but also increasingly as digital sequence information within virtual databases. These digital data are being used for identifying species that are at risk of extinction in the wild, thus allowing targeted interventions, including replantation. Big data methods for the analysis of large digital libraries also assist with the identification of plant varieties that possess favourable agronomic traits, such as tolerance to environmental stressors, for subsequent cultivation.[37]

Sequencing and digitalization also provide a potential fallback option in case of an extinction event destroying significant parts of global agricultural biodiversity. While incredibly rare in geological history, there is evidence that anthropogenic pressures are leading, or have already led, to the sixth major extinction event in the roughly 4.5 billion years for which the Earth is said to have existed. Given what is at stake, there must be ways to attempt to (at least partially) reconstruct agricultural biodiversity after a catastrophic loss. In fact, a so-called Global Seed Vault, located underground on the Norwegian island of Svalbard, was created exactly for this purpose: keeping safety copies of seeds to preserve agricultural biodiversity in the face of existential threats.[38] Yet the Svalbard facility also demonstrated the risk of the centralized storage of physical specimens when, in 2017, melting permafrost from rising Arctic temperatures led to water penetrating the building.[39] And, as with conventional gene banks, centralization is a necessary condition for political control and exclusion. Notwithstanding the noble intentions behind the creation of the Global Seed Vault, such considerations are

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

vital considering that nothing less than the agricultural common heritage of humanity might be at stake at some point in the future. A vast genomic library of comparable scope to the Svalbard collection could complement centralized physical storage with decentralized digital storage.

4.2 Gene Drives and Synthetic Biology for Biodiversity Conservation and Restoration

As previously pointed out, the unprecedented anthropogenic decline in terrestrial and marine biodiversity has, so far, not been met with effective policy responses. As the international community braces for the implementation of the CBD's Global Biodiversity Framework, governments may yet be able to drastically change course although, if history is any guide, this is rather unlikely. In the meantime, problems associated with biodiversity loss and biological control have given rise to some rather creative alternatives. Gene drives are among them. As with many other technologies discussed throughout this book, these are to some extent speculative and their precise nature subject to ongoing technological and regulatory developments that feed back on each other. The diversity of applications sometimes subsumed under the label 'gene drives' even makes some biologists working in the field doubt whether the term is useful, or whether it simply lumps together various applications that have little in common with each other.

This latter point is nothing to dismiss out of hand. However, at the most general level, we may understand gene drives as biotechnological interventions that bias inheritance patterns – that is, they skew the probabilities with which certain genetic characteristics are inherited during sexual reproduction. Harking back to the difficulty of agreeing on a common terminology, some authors extend the scope of gene drives to asexually reproducing species as well, although others would disagree. Why would we want to bias patterns of inheritance? There are two broad reasons. The first is to 'replace' an existing population of species: by increasing (or decreasing) the probability with which specific genes are inherited during reproduction, over time, all members of that species in a given geographical region, and possibly beyond, will carry (or lack) these genes. This is genetic engineering at the population level. The second reason is often referred to as population suppression and effectively implies its elimination, or at least a drastic reduction in its size. This might be considered for species that are deemed inherently harmful in a given context. It is crucial to point out here that, in principle, this technology could be applied to any kind of species, including humans. In practice, and the legal and ethical barriers notwithstanding, gene drives are only effective in species that reproduce quickly – that is, in a matter of days or weeks rather than years. The reason is that the share of modified, drive-carrying organisms in a population

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

increases exponentially with each reproductive cycle. Compared to other species, humans (and arguably most other mammals) reproduce too slowly for gene drives to be useful – again, ethical and legal considerations notwithstanding.

A major reason for the development of gene drives is their utility in disease vector control. Many debilitating contemporary infectious diseases, such as malaria, chikungunya, and yellow fever, particularly prevalent in developing countries, are transmitted via mosquitoes. Controlling the vector means controlling the disease: reducing, at the genetic level, the capacity of mosquitoes to transmit diseases would provide a significant boon for global public health, in particular considering how research on many such diseases is underfunded (at least when compared to common medical conditions primarily affecting wealthy citizens of the Global North), and how many developing countries lack the national capacities for effectively dealing with them. The outright elimination of mosquito populations through gene drive interventions would of course have a similar effect. The same goes for invasive species. Presently, thirty such species account for 58 per cent of extinctions of birds, mammals, and reptiles.[40] Invasive species are a major threat to vulnerable ecosystems, where they may enjoy significant competitive advantages.[41] This is also the case in agriculture. Specialized agricultural pests are already causing damage in the order of tens of billions of dollars per year, mostly to farming systems in developing countries. The vulnerability of agriculture to such pests is, of course, also a result of the trend towards mono-cropping: the large-scale plantation of genetically similar (or uniform) crops means that any pest specializing in predating this particular genetic profile has hit the evolutionary lottery. With pesticides being dangerously overused in many regions of the world, and with pests accordingly having evolved resistances, the question of how to proof food systems against such biological threats is not trivial. While there are thus potentially substantial pay-offs to be had, the biosafety risks associated with an eventual release of gene drive organisms are considerable and likely well beyond those commonly associated with conventional GM organisms. Their technical peculiarities also imply that traditional (international and national) regulatory frameworks may well be inadequate. The ways in which governance systems respond is thus crucial for the question of how to capture potential promises of gene drives while mitigating potential perils.

While gene drives have received substantial scrutiny in recent years, another type of self-propagating artificial genetic element with possibly even greater impacts and risks is currently under development yet without receiving nearly as much attention. Whereas gene drives operate vertically, meaning that they bias the rate with which target genes are passed down from generation to generation, this other type disperses target genes horizontally, by having GM insects deliver GM viruses in order to carry out genetic modifications in wild populations. Research on

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

these so-called Horizontal Environmental Genetic Alteration Agents is being done under the auspices of the Defense Advanced Research Projects Agency which operates under the US Department of Defense.[42] Purportedly, the reason is to develop potential rapid responses to natural or engineered threats to the food system. In addition to the dual use problem that results from the military context in which it is being developed, it is presently unclear whether this 'can become a manageable technology for rapid and large-scale interventions for peaceful applications with acceptable risk potential'.[43] Horizontal Environmental Genetic Alteration Agents would, in principle, allow for even more rapid and deep intervention in natural systems than gene drives. Their associated biosafety risks are likely even greater due to the interaction between three components: vectors, viruses, and target organisms; the complexity of such a system 'is beyond any risk assessment ever performed in the field of biotechnology'.[44] Yet, according to the Defense Advanced Research Projects Agency itself, such technology might deliver 'targeted therapies' to pests, droughts, and other disruptors of agricultural systems 'within a single growing season'.[45] As such, Horizontal Environmental Genetic Alteration Agents could provide an unprecedently powerful tool for safeguarding global food security. As with gene drives, the key question is whether the benefits of this technology can be had without confronting grave biosafety risks.

4.3 Genetic Resources and Digital Sequence Information

The digital revolution in biotechnology has complex effects. International law regulates the utilization of genetic resources across different domains. The term 'genetic resources' broadly refers to the genetic materials contained in plants, animals, and microbes.[46] These materials are potentially very valuable: a range of pharmaceutical products, from aspirin to high-end cancer treatments, has been developed on the basis of genetic materials found in nature. The situation in agriculture is even more specific: here, farmers worldwide have been using PGRFA (i.e. seeds) for millennia and, through constant improvement of plant varieties, laid the foundations of the modern global food system. Such genetic resources have always been something of an ambiguous governance object. They are being used in a variety of contexts for their informational content or genotype. They are not raw materials in the sense that, say, timber or coal is. What makes a *natural* resource into a *genetic* resource, in other words, is the relevance of its genetic code for commercial and other applications. Genetic resources are thus usually understood to include 'functional units of heredity'.[47] This term in all likelihood refers to the coding regions of a genome – that is, nucleotide sequences that are translated into proteins with (potentially or actually) useful properties.[48] The term may also include biochemical compounds that result from gene activity,

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

such as enzymes, although the legal status of these so-called derivatives is a matter of dispute.[49] While genetic resources are utilized for their informational content (as well as the proteins, derivatives, and other materials that result from this content), they are generally understood as *physical* materials, not mere disembodied information.

Internationally, various types of genetic resources fall within the scope of instruments for access and benefit-sharing. These instruments aim to ensure that users of genetic resources (such as pharmaceutical companies or agribusiness) share parts of the benefits which they obtain from their use (including commercial profits but also non-monetary benefits such as research results or intellectual property) with the providers of that resource or other entitled entities. Providers might be national governments that exert sovereignty over genetic resources that originate from within their territories. In other cases, local and indigenous communities, societies, or even humanity at large might hold claims to receiving benefits that result from specific uses of specific genetic resources. The idea behind benefit-sharing is not just to redistribute commercial profits and other assets. Rather, benefit-sharing streams are generally intended to feed back into nature conservation, whilst at the same time compensating those individuals or groups which have cultivated or stewarded genetic resources, sometimes over centuries or millennia.

The turn towards digitalization in the life sciences means that some types of research and development can now be carried out *in silico* – that is, based on computer simulations of gene, gene expression, gene networks, and so forth, without requiring physical materials. Where such physical materials are required, they can, in principle, be synthesized in the laboratory based on the digitalized genetic sequence data. This matters not just in the realm of environmental sustainability. For analysing and responding to pandemic threats, notably the recent SARS-CoV-2 virus, genetic sequence data is being used extensively for the synthesis of live viruses, including for vaccine development. With the relevant international instruments generally not considering genetic sequence data to constitute genetic resources, the use of these data is largely unrestricted. Notably, this also includes data from the International Nucleotide Sequence Database Collaboration discussed earlier. No benefit-sharing obligations usually attach to the use of these data. This is an issue because international benefit-sharing instruments were negotiated in order to ameliorate distributive injustices in the structure of the global biotechnology industry: individuals, groups, and societies that had contributed to the creation and stewarding of genetic resources (primarily in the Global South) had become excluded from the benefits which biotechnology companies (primarily in the Global North) generated from these resources and then appropriated for themselves.[50] Digitalization exacerbates this normative problem because genetic sequence data usually does not fall under benefit-sharing obligations and, even if it

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

would, then the implementation of these obligations would be hampered by the substantial challenges associated with monitoring data transfer and use in a transnational context.[51] There is thus the very real risk of technological changes in the life sciences hollowing out international institutions which, over the course of many years, have been carefully designed in an attempt to reconcile the partially incompatible interests of users and providers of genetic resources, as well as of the governments of developing and industrialized countries.

At this stage, it is important to note, though, that sequence data does not possess scientific, commercial, or other value by itself. Such value depends on information about the *source* of the sequence data – for instance, the organism that it has been extracted from and the specific properties which it may be physically expressing as a result of its genetic code. Without such information, sequence data amounts to little more than strings of letters. This also means that, for the utilization of sequence data, the corresponding physical sample may matter a great deal. Dedicated databases such as BioSample address this challenge by providing descriptions of the source material corresponding to (some of the) sequence information hosted in other databases. When compared to physical genetic resources, the technical characteristics of genetic sequence data may also imply a need for new governance approaches. Determining the legal and geographical provenance of physical samples is presently a complex yet indispensable step for identifying the existence of benefit-sharing obligations and other requirements on users. Digital exchanges of genetic sequence data are likely to be less transparent and more difficult to track and trace. The extent to which genetic sequence data create new types of compliance problems is a matter of debate, though. Some studies suggest that the existing data infrastructure would in principle allow efficient monitoring of the utilization of sequence data: in the International Nucleotide Sequence Database Collaboration, sequences have unique accession numbers that can, in principle, be cross-referenced with data on patent applications as well as databases that list the corresponding physical samples. Some sequence data are associated with other metadata, such as regarding geographical origin, that may facilitate establishing a link to the 'provider' of the resource and thus contributing to the effective implementation of benefit-sharing.[52]

All of this is not to say that the concept of benefit-sharing is without problems. International institutions that aim to secure fair and equitable benefit-sharing may ameliorate distributive injustices, yet they simultaneously create a potential chilling effect for research. Users of genetic resources can incur quite substantial legal, administrative, and other costs in order to demonstrate their compliance with the relevant regulatory frameworks – costs which will naturally hit public and basic research harder than private and applied research. In trying to correct distributive injustices, there is thus the risk of harming innovation in areas with potentially

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

important social and environmental pay-offs. While the different international instruments attempt to carve out exemptions and flexibilities for non-commercial research, determining the precise border between commercial and non-commercial purposes is not without challenges. This is why, within the global life sciences research community, substantial scepticism regarding the regulation of digital sequence information has emerged.[53] Also, some evidence suggests that the provision and use of digital sequence information does not follow a classic North–South pattern. Rather, countries such as Canada, China, and the United States, as well as the European Union, have emerged as the most important providers *and* users.[54] This raises the question of to what extent the regulation of digital sequence information, under these circumstances, would correct historical patterns of North–South injustice.

4.4 The Seed Treaty

The International Treaty on Plant Genetic Resources, or 'Seed Treaty', is a multilateral agreement under the auspices of the United Nations Food and Agriculture Organization (FAO), currently comprising 148 contracting parties. The broader story of this treaty is the subject of various insightful historical accounts and will thus not be repeated here in depth.[55] It aims at conservation and sustainable use as well as fair and equitable benefit-sharing in the context of agricultural biodiversity. Yet the treaty is not merely an instrument for the protection of nature; it also attempts to safeguard the utilization of PGRFA in the context of agriculture and plant breeding against two threats that had been emerging throughout the 1980s and 1990s. First, changes in intellectual property law at national, regional, and international levels had started to create legal barriers for access to PGRFA. As noted earlier in this chapter, plant breeding for food and other purposes requires breeders to combine the genetic material of various already existing plants. The expanding scope and depth of intellectual property rights in the field of plant breeding and agricultural biotechnology, however, increasingly limited the open use of PGRFA. This was due to legal changes under US, European, and Japanese patent law, but also due to the effects of novel international agreements, notably the World Trade Organization's (WTO) 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights and the 1991 International Convention for the Protection of New Varieties of Plants. Together with the emergence of ever larger multinational agricultural companies dominating the global markets, this placed in jeopardy the global system of agricultural innovation based on the largely unrestricted exchange of seeds among plant breeders.

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

Second, and in response to this threat, developing countries pushed for greater legal recognition of their historical role in stewarding and cultivating an overwhelming share of global plant biodiversity. Considering the variety of ways in which the nascent biotechnology industry had begun utilizing and commercializing plant genetic resources during the 1980s, both in the agricultural field and beyond, developing countries pressed for an international mechanism that would allow them to capture a fair share of the commercial profits and other benefits that would otherwise be exclusively appropriated by the countries of the Global North. The 1992 CBD accordingly created a system whereby countries exert sovereignty over genetic resources originating from their respective territories, with prospective users accordingly having to negotiate the terms of access, utilization, and benefit-sharing with the national agencies of a given provider country. This model ended up being spectacularly unsuccessful in bringing about the financial windfalls that some developing countries expected. Even worse, it raised additional challenges for the agricultural sector, where the negotiation of potentially dozens of separate agreements between plant breeders and a host of provider countries was simply unrealistic. Thus, a way had to be found for breeders to be able to access crucial PGRFA without interference either from intellectual property rights or from the CBD.

The FAO Seed Treaty, concluded in 2001 and entering into force in 2004, is a curious beast. It acknowledges the principle of state sovereignty over PGRFA and allows for the full commercial appropriation of such resources through intellectual property rights, while simultaneously attempting to salvage what can be salvaged from the FAO's International Undertaking which, during the 1980s, had considered plant genetic resources the common heritage of humanity (that is, as resources that can neither be privatized nor subjected to sovereignty claims). In practice, the Seed Treaty creates a global network of seed banks from which plant breeders (or, in fact, any other natural or legal person) can obtain seed materials that are listed in the Treaty's Annex I,[56] materials included in the collections under the Consultative Group on International Agricultural Research, as well as materials which governments and private entities have included on a voluntary basis. The transfer and utilization of these plant genetic resources is governed by a Standard Material Transfer Agreement – a non-negotiable contract which stipulates the rights and obligations of providers and users. In principle, these also include payment obligations for certain (very specific) situations in which PGRFA drawn from the system are commercialized. In such situations, users (such as commercial breeders) would need to feed parts of their profits back into the system, from where they would be distributed (primarily) towards farmers in developing countries. While this system is arguably successful in facilitating access to plant genetic resources, it has failed in mobilizing financial resources to compensate farmers in developing countries for their historical and ongoing contributions in creating and stewarding global

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

agricultural biodiversity.[57] This is not necessarily a problem: unlike for the CBD, the fair and equitable sharing of monetary benefits arising out of the utilization of plant genetic resources matters less for the purposes of the Seed Treaty than securing some form of unrestricted, or 'facilitated', access to these resources. Still, fair and equitable benefit-sharing remains one of the three objectives of the Seed Treaty – one that the genomics revolution indeed threatens to hamper or undermine.

As in other areas, the utilization of genetic resources in agricultural biotechnology is increasingly dematerializing – that is, centred on genetic sequence data rather than physical specimens.[58] The Seed Treaty formally applies to 'any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity' that is 'of actual or potential value for food and agriculture'.[59] This definition is open to a variety of interpretations. On the face of it, the expression 'material . . . containing functional units of heredity' suggests an exclusive focus on physical materials, with sequence information associated with these materials being excluded and accordingly being outside the scope of the Seed Treaty's Multilateral System. However, other interpretations have been proposed that consider genetic sequence data to be an integral and inseparable aspect of genetic resources, accordingly making them fall within the scope of the Multilateral System in the same way that physical specimens do. Even assuming that genetic sequence data fully fall within its scope, additional challenges arise on the implementation side, as users operating with large genomic databases may be unaware of their legal obligations with regard to specific sequences, and as the digitalization dramatically complicates monitoring user compliance with these obligations.[60]

Between 2013 and 2019, the problem of genetic sequence data formed part of a broader package that the contracting parties of the Seed Treaty attempted to resolve. The two key, interlinked issues in the reform discussions were, first, that no monetary benefits were being shared (i.e. as a share of commercial sales of plant varieties incorporating materials drawn from the Multilateral System) and, second, that the limited coverage of the system reduced its attractiveness to potential users. This led to a chicken-or-egg problem. Some parties argued that the inclusion of additional PGRFA, particularly from seed banks in developing countries, would improve the commercial attractiveness of the Multilateral System and thus deliver monetary benefit-sharing. Other parties were apprehensive about making additional resources available as long as the system did not deliver on monetary benefit-sharing, and as long as the PGRFA currently outside of its scope could potentially be monetized more profitably through bilateral arrangements under the CBD and its Nagoya Protocol (see Section 4.5).[61] Genetic sequence information figured into this core problem because it was being perceived as increasingly undermining the benefit-sharing component of the Seed Treaty.

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

Intergovernmental negotiations largely succeeded in tying up a comprehensive reform package with two key elements. First, a subscription model would complement the Standard Material Transfer Agreement for governing access to the resources within the Multilateral System: in exchange for an annual fee, subscribers would get full access to *all* genetic resources within its scope. The rationale was that this would have lowered the costs of regulatory compliance (thus improving the attractiveness of the system to prospective users) while also delivering benefit-sharing streams (from subscription fees). Second, the reformed treaty would cover *all* PGRFA held in the public collections of contracting parties, not merely those listed in Annex I. While some parties have, in the past, chosen to voluntarily make available their non-Annex I resources through the system, many have refrained from doing so. The reform package thus promised an immense increase in mandatory coverage which likely would have been a gamechanger in the global politics of agricultural biodiversity.[62]

Yet by November 2019, negotiations had collapsed. Not all of the details are entirely clear. What *is* clear, though, is that the role of digital sequence information within the reform package turned out to be a deal breaker.[63] The fracture lines followed long-standing divisions in the international politics of genetic resources: (industrialized) countries with strong domestic biotechnology sectors considered digital sequence information to not constitute genetic resources for the purposes of the Seed Treaty while also downplaying their commercial value, whereas (developing) countries, as the primary countries of origin for genetic resources, stressed that digital sequence information either constitutes genetic resources, constitutes ways of utilizing genetic resources, or allows for the synthesis of genetic resources, thus (partially or in full) falling within the scope of the treaty and its provisions on fair and equitable benefit-sharing.[64]

At the time of writing, it is unclear to what extent (parts of) this reform process might be salvageable and to what extent the Seed Treaty has suffered irredeemable political damage. However, the failure to find a response to the challenges and opportunities of bioinformatics means that, for the time being, the scope for access and benefit-sharing will be determined by technological factors rather than institutional ones. Absent international regulation, the continuing use of digital sequence information in public and private research and development has specific distributional implications: users of digital sequence information benefit from open access and do not suffer either benefit-sharing obligations or associated compliance costs, and providers of the genetic resources which form the substrate of digital sequence information will remain excluded from the direct monetary and other benefits associated with the utilization of this information, although they might receive indirect benefits through innovation spin-off effects. The question then becomes: do the indirect benefits that result from innovation under an open access regime

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

exceed the total benefits which a regulated regime yields, both through indirect innovation effects and through direct benefit-sharing? In some sense, this question goes to the core of what the debate on access and benefit-sharing is about: governments of high-innovation countries tend to see research and development on genetic resources as a public good which, temporary limitations through patents and other intellectual property rights notwithstanding, overall benefits societies everywhere, not just those in the Global North. Conversely, governments of biodiversity-rich (developing) countries tend not to agree with the existence of such an alleged automatism, but rather stress the crucial role of regulation for ensuring their fair and equitable participation in the benefits that result from biotechnological innovation.

Due to this ambiguity, the consequences of the failed treaty reform (or the likely consequences of hypothetical success) are difficult to establish. What is clear, though, is that the trend towards digital sequence information increasingly leads to new types of distributional injustice that will remain unmitigated for the time being. Legally, the distinction between physical samples and digital sequence information revolves around the differences between 'soft copies' and 'hard copies'.[65] While various grounds exist for questioning the benefit-sharing principle or the operational details of its implementation, there is simply no good reason for requiring benefit-sharing from physical samples but not from their digital representations. Possibly, the operational challenges in designing an effective transaction-based regime for digital sequence information simply indicate the need for an alternative approach. Access to resource pools rather than single resources, as proposed in the FAO context, could be one such approach. A possibly simpler, more effective and yet politically utterly unrealistic alternative would be national levies on seed sales, at rates which are harmonized at the international level, and placed in an international fund with a mandate to finance sustainability and innovation in agriculture. But then, for any international institution dealing with distributional issues, dysfunctionality has its stakeholders.

More successful attempts at leveraging the bioinformatics revolution have been made in regards to the Global Information System which, pursuant to Article 17 of the Seed Treaty, will 'facilitate the exchange of information, based on existing information systems, on scientific, technical and environmental matters related to plant genetic resources for food and agriculture'.[66] This system is partially to facilitate access and benefit-sharing, but also to contribute to conservation efforts, including by providing early-warning capacities for potential threats to the 'efficient maintenance of PGRFA, with a view to safeguarding the material'.[67] In 2015, the Treaty's Governing Body adopted a six-year programme for developing a 'global entry point to information and knowledge for strengthening the capacity for PGRFA conservation, management and utilization'. Among others, the Global

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

Information System aims to 'provide a comprehensive overview and facilitate access to sources of PGRFA and associated information', to 'promote and facilitate interoperability among existing systems', and to 'create and enhance opportunities for communication and international and multidisciplinary collaboration to increase knowledge about and add value to PGRFA'.[68] This programme is accompanied by a dedicated scientific advisory committee. In recent years, the Global Information System has entered into partnerships and initiatives with other information systems such as the World Information and Early Warning System (which assesses conservation and sustainable use of PGRFA at country level) or Genesys (a public database on global crop biodiversity collections). Other types of collaboration are underway, with DataCite and CrossRef for associating PGRFA with scientific publications that analyse or otherwise reference them.[69] This could enable the scientometric profiling of PGRFA, for instance to identify those resources that are of greatest scientific interest.

The Global Information System has also developed a mechanism for digital object identifiers that allow different PGRFAs to be permanently linked to a unique handle, thus facilitating information exchange, tracking, and data-mining.[70] These identifiers aim to provide a universal system to remedy the lack of standardization that has previously hampered PGRFA data exchanges. They allow for permanent linkages between PGRFA and any associated information. As digital object identifiers can be resolved online and automatically, this system also facilitates the application of big data techniques in PGRFA conservation, management, and use. The system also includes PGRFA within the scope of the Seed Treaty's Annex 1 and can accordingly assist users in complying with the terms of the Standard Material Transfer Agreement (including reporting requirements) governing the use of materials which they draw from the Treaty's Multilateral System. Finally, digital object identifiers can contribute to user compliance, for PGRFA both within the scope of Annex I and beyond. This is because the identifiers facilitate the tracing of transfers of genetic resources across multiple intermediaries and end users; and it also enables users to easily identify the specific legal and regulatory obligations that attach to a given genetic resource. The implementation of this novel approach is making rapid progress, with CGIAR centres and other seed banks around the world incorporating digital object identifiers for their PGRFA accessions.[71]

The Global Information System thus goes beyond narrow questions of access and (monetary) benefit-sharing to also address issues of conservation and sustainable use, while keeping in line with the Seed Treaty's general orientation towards public goods and common resource pools. The system thus also highlights the ambiguity of technology: while perceived by many actors as a detrimental factor for the sharing of commercial benefits arising from the utilization of PGRFA, digitalization and big data in contemporary biotechnology can simultaneously provide

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

information and knowledge that facilitate the conservation and management of agricultural biodiversity.

4.5 The Nagoya Protocol

Unlike the Seed Treaty, the CBD and its Nagoya Protocol aim at bilateral benefit-sharing between a user of a genetic resource and a provider, such as a national government. And while the Seed Treaty covers certain PGRFA, the convention and its protocol covers *all other* genetic resources, with some exceptions such as human genetic resources and resources from areas beyond national jurisdiction. Its economic scope is accordingly much larger. The CBD itself was the first international instrument to codify the objective of fair and equitable benefit-sharing, stipulating that access to genetic resources is subject to the prior informed consent of the provider country, and that the rights and obligations of providers and users are negotiated bilaterally. As access to genetic resources takes place before benefits result, including benefits of a commercial nature, and as users generally do not have incentives to voluntarily share parts of their assets with providers, this governance construct faces a massive compliance challenge – one that is significantly larger than is the case for the Seed Treaty, where the obligation to share commercial profits is designed to trigger only in rather hypothetical scenarios, and where sharing is limited to a fraction of a per cent of seed sales. The Nagoya Protocol is thus primarily intended to address the compliance issue as the missing link between access, on the one hand, and benefit-sharing, on the other.

As with the Seed Treaty, the definition of 'genetic resources' under both the convention and the protocol does not include digital sequence information. While the protocol accordingly deals neither with access to digital sequence information nor with the sharing of benefits resulting from such access, both it and the convention itself aim at fair and equitable benefit-sharing arising from the *utilization* of genetic resources, which the protocol defines as 'research and development on the genetic and/or biochemical composition of genetic resources'.[72] The use of digital sequence information does, in fact, constitute a way of carrying out such research and development. Now, the tricky aspect is that commercial and other benefits that are generated on the basis of digital sequence information shall be shared fairly and equitably, but the operational provisions of the protocol only apply with regard to the physical specimens from which a digital copy originates. That is, the requirement for the prior informed consent of the provider country, the obligation to negotiate mutually agreed terms between users and providers, and the compliance components which are intended to ensure the existence of prior informed consent and mutually agreed terms do not apply for users that are only accessing the digital sequence information rather than the physical sample too. As far as the material

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

specimens are concerned, though, it is possible for users and providers to agree on specific provisions regarding the associated digital sequence information in the context of mutually agreed terms. That is, in negotiating the contractual details of access and benefit-sharing, users and providers could, in principle, agree on distinct benefit-sharing arrangements for the digital copy. Notably, they might also agree that users would be prohibited from making the associated digital sequence information publicly available, for instance through open-access online databases. The Conference of the Parties, the highest decision-making body of the CBD, recently confirmed this by noting that 'when genetic resources are accessed for their utilization, mutually agreed terms can cover benefits arising from the commercial and/or non-commercial use of digital sequence information on these genetic resources'.[73]

As noted in Section 4.4, we may discuss whether the categorial differentiation between physical samples and their digital counterparts is reasonable, or whether the consequences of treating both of them identically would even be desirable. As is the case with the Seed Treaty, the issue is politically explosive. In the context of the Nagoya Protocol, the discussion follows the familiar North–South pattern, yet with the notable exception that a growing number of scientists are warning about the potentially dire consequences of regulating digital sequence information as genetic resources.[74] The Nagoya Protocol anticipated some of these concerns, with article 8.a obliging parties to create simplified access procedures for certain types of non-commercial research. In practice, however, the border between commercial and non-commercial research may be difficult to draw, including for jurisdictions (such as the United States) where researchers are able to commercialize under patent protection inventions that result from non-commercial (public) research. In addition, the article 8.a exemption only applies to research which 'contributes to the conservation and sustainable use of biological diversity', meaning that large parts of the life sciences would not be eligible for such simplified access procedures in the first place.

The parties to the Nagoya Protocol and the convention have so far been dealing with the challenges and questions which digital sequence information raises by bouncing the issue back and forth between the level of political negotiations and the technical level of expert advice in subsidiary bodies. In 2016, the Conference of the Parties to the CBD created a technical expert group which subsequently failed to find consensus on all of the major issues. When political agreement at the 2018 session of the Conference of the Parties proved elusive, parties again shifted the issue to the technical level. Digital sequence information continues to be a major sticking point under the CBD's Global Biodiversity Framework that parties adopted in December 2022 and where they, nevertheless, reached agreement on some elements of a potential future solution, notably by committing to

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

a multilateral benefit-sharing mechanism that will operate without a need to track and trace individual transfers.[75] The political challenge, however, lies in the operational details. The collapse of the negotiations on the reform of the Seed Treaty is a stark reminder of how politically contentious the issue is. At the same time, the trend towards digitalization in the life sciences increasingly undermines benefit-sharing under the Nagoya Protocol – for better or worse.

4.6 The Cartagena Protocol

The Cartagena Biosafety Protocol is a major international instrument dealing with the safe handling, transfer, and use of GM organisms or, in its own parlance, 'living modified organisms'. The Cartagena Protocol was negotiated against the background of transgenic food being widely commercialized since the 1990s and the ensuing controversies regarding their potential risks for human health and the environment. Two axes of conflict defined the political process leading up to its adoption in the year 2000. On the one hand, the preference of developing countries to have the instrument cover a broad range of biotechnological issue areas collided with the preference of key actors from the Global North to limit its ambit to the agricultural sphere. On the other hand, large exporters of transgenic food preferred a regulatory model under which import restrictions would only be admissible in instances where there is incontrovertible evidence of harm to humans or the environment. Others, notably the European Union and its member states, preferred a precautionary solution under which import restrictions would be admissible also for transgenic food that cannot conclusively be proven as harmless.[76] The latter model ultimately prevailed, making the Cartagena Protocol the first major international instrument to adopt and operationalize the precautionary principle after its initial emergence at the 1992 Rio Earth Summit, and simultaneously putting it into a tense relationship with the law of the WTO, which generally limits the import restrictions that its member states may adopt for instances of provable harm.[77]

Far beyond what its drafters could have envisaged during the late 1990s, today the Cartagena Protocol is the by far most important international instrument addressing gene drive organisms. To a large extent, these would likely constitute 'living modified organisms' for the purposes of the protocol. Under its article 3, a living modified organism is 'any biological entity capable of transferring or replicating genetic material' which 'possesses a novel combination of genetic material' as a result of biotechnological methods that 'overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection'. This unwieldy definition would, to a large extent, apply to gene drive organisms. The definition is not watertight, though, since some drives might be conceived of as genetic modifications that do not

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

'overcome' recombination barriers but merely modify the probability with which specific genes are inherited in the course of an otherwise regular evolutionary process.[78] This is not just legal hairsplitting, as the question of when and which gene drive organisms satisfy the Article 3 criteria directly affects whether or not the rules of the protocol apply to these organisms. In other words, potential regulatory gaps might exist in the protocol simply as a result of its definition of living modified organisms, which has remained unchanged for more than twenty years.

As an instrument primarily designed for the regulation of the international trade in GM agricultural products, it is perhaps unsurprising that the Cartagena Protocol faces some challenges in providing a regulatory framework for something as distinct as gene drive organisms. The biggest problem is this: depending on their type and the location of release, gene drive organisms are extremely likely to cross international borders. For the purposes of the protocol, this transboundary movement can either be understood as unintentional (i.e. an unintended by-product of a release intended for exclusively domestic purposes) or intentional (i.e. a domestic release of gene drive organisms that will predictably migrate across international borders). If understood as unintentional, the protocol would, for practical purposes, likely prohibit the release of *any* gene drive organisms, seeing that its Article 16.3 obliges parties to 'take appropriate measures to prevent unintentional transboundary movements of living modified organisms'. With unintentional transboundary movements being largely unavoidable, it would follow that the only appropriate measure consistent with that article would be to refrain from, or to not permit, any release at all!

If we understand the transboundary movement of gene drive organisms to be intentional, however, things get much more complicated. For one, the protocol generally requires that the intentional transboundary movement of a living modified organism is subject to the prior approval, or Advance Informed Agreement, of the importing country. This would accordingly apply to gene drive organisms as well. However, for any given release of gene drive organisms, there might be multiple countries that would potentially be affected by transboundary movements, and they might well differ in terms of the likelihood with which such movements might occur. A release in, say, Burkina Faso would be highly likely to also affect the territories of the Ivory Coast, Ghana, Togo, and Benin. It might be less likely to spread from Benin to Nigeria and then to Cameroon, and there might be a residual chance of spreading to other continents as a result of international trade or travel. In this hypothetical situation, the question becomes which countries would be required to provide their Advance Informed Agreement before gene drive organisms could lawfully be released in Burkina Faso. The answer is we do not know because the procedure on Advance Informed Agreement has been designed for international trade with clearly definable countries of export, import, and transit,

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

rather than for situations in which various countries have different probabilities of gene drive organisms diffusing onto their territories.[79]

The problem of Advance Informed Agreement is compounded by the problem of risk assessment. Countries of import generally have the right to require a prior risk assessment, conducted in accordance with criteria set out under the protocol. Yet gene drive organisms are so different from other types of living modified organisms that existing risk assessment methodologies cannot be applied.[80] There are different reasons for this. First, unlike for conventional cases, we cannot define the receiving environment for a potential release of gene drive organisms in advance, because of their geographical diffusion. Second, while risk assessments typically compare living modified organisms to similar and unmodified organisms, this comparative approach is not feasible here due to gene drive organisms targeting wild types with great degrees of genetic variation in between them. Third, whereas a crucial component of conventional risk assessment is the stepwise testing of a living modified organism under conditions of decreasing containment possibly up to open field trials, this is not feasible here since any release of gene drive organisms would likely lead to their comprehensive environmental diffusion. In other words, there would possibly not be much of a difference between semi-contained testing and a full-blown release. For all of these reasons, conventional criteria for risk assessment of living modified organisms cannot simply be applied to gene drive organisms. Thus, even if we might somehow clarify the question of which countries would need to grant their Advance Informed Agreement to an envisaged release, the consequences of any of those countries requiring a prior risk assessment are unclear.

In spite of these potential issues, limited political appetite exists for any sort of formal amendment or similar steps under international treaty law, at least as of the time of writing. Possibly the largest reason for that is the immense difficulty of negotiating a legally binding international solution within a political context as polarized as the CBD. Rather, the issue of gene drive organisms has so far been addressed at the level of governing body decisions as well as at the level of expert consultations. The Conference of the Parties to the CBD has urged precautionary decision-making on gene drive organisms while also installing a novel horizon-scanning mechanism for evaluating relevant technological developments, both in gene drives and other relevant fields of biotechnology.[81] Expert groups on synthetic biology as well as risk assessment are meanwhile looking into different aspects related to gene drive organisms, emphasizing the existing technical and scientific uncertainties but also pointing out the problem of risk assessment as a sticky issue in need of further consideration.[82] Finally, in December 2022, the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol launched a process for the development of dedicated, voluntary guidance for risk assessment of gene drive organisms.[83]

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

4.7 The World Health Organization

The WHO does not deal with environmental issues *stricto sensu*. Its broad focus on human health implies, however, that it indirectly interfaces with international environmental institutions in a variety of ways. Two such ways matter for the purposes of this chapter: the linkages between genetic resources and viruses, and the environmental implications of genetic vector control, including but not limited to gene drives.

To start with the first point, significant contemporary threats to global public health involve pathogens of animal origin. Depending on legal interpretation, such pathogens may or may not constitute 'genetic resources' in the context of the earlier discussion on access and benefit-sharing. A peculiar mechanism sits at the intersection between genetic resources and pandemic influenza viruses: the 2011 Pandemic Influenza Preparedness Framework, which grew out of the 2006/2007 H5N1 'avian flu' crisis As with other potentially or actually pandemic influenza viruses, H5N1 is a zoonotic virus which originated from animal reservoirs and mutated to become a human pathogen. Generally, the rapid pace with which such viruses evolve, as well as their ability to genetically fuse themselves with other viruses in order to generate potentially dramatic antigenic shifts, means that they can easily bypass the human immune system. Whilst vaccination is the only effective pharmaceutical response to viral pandemic threats, the rapidly shifting genetic profiles of viruses mean that vaccine development must be targeted at specific profiles. In other words, vaccines cannot be mass produced and stockpiled well in advance of a potential pandemic. Rather, development, production, and distribution only occur in response to a given outbreak. This has long been understood to be a problem: with limited global production capacities, wealthy countries have the ability to secure the entire market supply of vaccines for themselves, with developing countries having to wait in line until the population of the Global North has been sufficiently protected. It is not surprising that this is exactly the pattern which has been playing out with the COVID-19 pandemic. Yet, the earlier H5N1 crisis showed something else: that governments might leverage access to viral specimens and digital sequence information to extract concessions regarding the global distribution of vaccines, as well as other products which are crucial for effective pandemic response (such as testing kits and protective equipment).

In order to facilitate rapid vaccine development, it has been standard practice for member states of the WHO to rapidly and unconditionally share viral materials with each other since the 1950s. The WHO's International Health Regulations of 2005 contain additional requirements on mutual notification and information exchange in the case of a so-called public health emergency of international

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

concern, which some interpret to also cover the exchange of viral specimens or digital sequence information. At the end of 2006, however, the government of Indonesia, one of the epicentres of the H5N1 outbreak, suspended the multilateral sharing of samples on the grounds that the vaccines that would end up being produced from them would not be available to the Indonesian population: the patents with which multinational pharmaceutical companies would protect their intellectual property would lead to inflated market prices which, in turn, would restrict access to countries with sufficient purchasing power. This decision was controversial: on the one hand, it wilfully endangered global public health for the purpose of gaining political leverage. On the other hand, the essence of international cooperation being diffuse reciprocity, it is not entirely clear why Indonesia (or any other government, for that matter) should facilitate pharmaceutical innovation abroad which exclusionary market mechanisms would then channel towards *other* countries.

The stir which the Indonesian decision created led to broader negotiation processes under the WHO, at the end of which the Pandemic Influenza Preparedness Framework was adopted by the WHO's World Health Assembly in 2011. The idea behind the framework is that governments would commit to the unconditional and rapid sharing of samples from influenza viruses constituting a pandemic threat; in return, pharmaceutical manufacturers receiving such samples would commit to sharing parts of their vaccine production, or other pharmaceutical products, with developing countries in case of an influenza pandemic. Notably, this latter requirement applies to physical specimens only, whereas the use of digitized viral sequences does not trigger the mandatory sharing of vaccines and other benefits. As with the other benefit-sharing instruments discussed earlier, although significantly more acute in this case, one major concern related to potential access restrictions: with medical researchers routinely sharing sequence data through specialized databases such as FluNet, any requirement to enter into negotiated terms that might make data-sharing conditional would possibly delay vaccine development in the case of a pandemic emergency. The question of monitoring and regulating the utilization of digital information in a transboundary context similarly raised challenges.

Just as with pandemic influenza viruses, the WHO's activities with regard to vector control have only indirect environmental implications. Vector control targets species that are responsible for the transmission of pathogens to humans. Mosquitoes are the most common and most important vector, with some species transmitting the parasite that causes malaria and others carrying the chikungunya or Zika viruses. So far, no effective vaccination has been developed for many such vector-borne diseases.[84] This means that, historically, vector control was the primary means for preventing infections, including with mosquito nets but also with insecticidal

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

chemicals such as the notoriously toxic Dichlorodiphenyltrichloroethane (DDT). One potential alternative is sterile insect techniques or incompatible insect techniques. These were originally developed for pest control during the 1930s and considered as a tool against mosquito-borne diseases during the 1970s and 1980s. In the past decade, various technical advances have reinvigorated interest in their use for vector control.[85] These techniques revolve around the release of large numbers of modified male mosquitoes that, when mating with unmodified females in the wild, do not produce viable offspring. One method for achieving this is to sterilize male mosquitoes via radiation. This method has notably been developed under the Programme on Nuclear Techniques in Food and Agriculture, which the FAO and the International Atomic Energy Agency have been jointly running since 1964. Another technique is to release male mosquitoes infected with the *Wolbachia* bacterium, preventing viable offspring except with females carrying the same strain of *Wolbachia*.[86] The incorporation of genetic engineering has given these methods new significance.[87] The biotechnology company Oxitec pioneered the use of genetic modifications in sterile insect techniques,[88] with recent environmental releases in Brazil, the United States, and Dutch overseas territories. It is important to stress that these releases do not entail gene drive systems – that is, they do not uncontrollably propagate novel genetic elements through a target species and perhaps beyond. Nevertheless, and their compliance with domestic regulatory requirements notwithstanding, they are the subject of intense public scrutiny and controversy.[89]

Against this background, the WHO adopted a Guidance Framework for Testing Genetically Modified Mosquitoes in 2014 and an updated version in 2021. This framework provides recommendations for the evaluation of efficacy and safety, as well as regulatory and ethical aspects, in relevant research programmes. The framework distinguishes between mosquitoes carrying gene drive systems and mosquitoes subject to other types of genetic modification. Notably, the framework affirms the applicability of the Cartagena Biosafety Protocol to the transboundary movement of either type of mosquito, without, however, clarifying the complex legal issues surrounding Advance Informed Agreement as well as intentionality, as discussed previously. In addition, the WHO's Vector Control Advisory Group provides advice and expert assessments for novel vector interventions, including sterile insect techniques, incompatible insect techniques, and gene drive systems. The purpose of the advisory group is to assist the WHO in providing high-quality policy recommendations to its member states. This means working with product developers to ensure that they provide sufficient data for the advisory group to assess potential new vector interventions, and, on the basis of these assessments, to give advice which the WHO may take into consideration when developing policy recommendations.[90] The group previously issued a 'strong' recommendation to continue pursuing field trials with incompatible/sterile insect techniques in *Aedes*

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

aegypti and *Aedes albopictus* mosquitoes, while encouraging further research into gene drive systems for vector control.[91] In this regard, it is perhaps noteworthy that the Vector Control Advisory Group was established and operates with the financial support of the Bill and Melinda Gates Foundation, with two grants in 2012 and 2020 together amounting to US$ 5 million in funding.[92] The Gates Foundation has also financially supported several previous members of the advisory group in their individual capacities as scientific experts. The role of the Gates Foundation in the development of genetic vector control techniques is controversial and subject to various speculations of both the well-founded and the conspiratorial type.[93]

Finally, the WHO issued a broader policy declaration in late 2020 to clarify its position on genetically modified mosquitoes for disease vector control. Subject to regulatory and ethical caveats, the organization 'takes the position that all potentially beneficial new technologies, including GMMs [genetically modified mosquitoes], should be investigated to determine whether they could be useful in the continued fight against diseases of public health concern'. Notably, the evaluation of genetically modified mosquitoes 'should account for the potential benefits to health in terms of disease control and not be limited to potential environmental risk'.[94] This last element is crucial here: it implies that adverse environmental impacts are acceptable to the extent that they are outweighed by considerations related to public health. Regulatory decision-making, in other words, is to be based on the expected net effects instead of the avoidance of adverse impacts as such. The assessment criterion of net effects is not atypical in international law. What gives this element a specific edge, however, is its assumption that potential conflicts might arise at the interface between environment and public health, and that such conflicts might be resolved by subsuming environmental protection objectives to considerations of public health, or vice versa. In other words, the WHO seems to be aware that genetic vector control may well imply inconsistencies or even contradictions between different domains of global governance.

4.8 Conclusions

The promises and perils of novel biotechnologies are diverse. Modern gene technologies offer various ways for managing anthropogenic impacts on the environment or environmental impacts on human societies, and the emergence of bioinformatics brings with it a new information commons with the potential to revolutionize global exchanges of data and knowledge. At the same time, caveats about potential environmental harm from genetic modifications continue to apply; asymmetric global patterns of ownership and control raise questions of justice, principally between North and South; and the increasing consideration of biotechnological methods for

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

biological control, for increasing the resilience of agricultural systems or vulnerable ecosystems, but also for disease vector control pose a threat of crowding out feasible alternatives if policies continue to rely on technologies that might turn out to be infeasible or even harmful in the future. These problems are compounded by a high degree of technological ambiguity, with diverse uncertainties of scientific, technical, or economic types gravely complicating the assessment of technological costs, benefits, and risks, as well as their distribution.

The ways in which the relevant international institutions have responded to the challenge of contemporary biotechnology are surprisingly similar. For the most part, they involve measures limited both in scope and depth, with a major focus on scientific and technical assessment. At the same time, we can also observe important institutional non-responses in the face of a rapidly changing technological environment, acutely threatening to undermine the political relevance which these institutions enjoy. Under the Seed Treaty, disagreement over digital sequence information led to the collapse of a process for comprehensive treaty reform, while the Global Information System attempts to leverage bioinformatics for conservation purposes as well as for information exchange more broadly. Under the Nagoya Protocol, efforts to cope with the challenge of digital sequence information have, as yet, been unsuccessful. Major developments in the field of synthetic biology, notably the possibility of de-extinction for bringing back species that have been lost due to anthropogenic pressure, have so far not met any institutional response at the international level. The same applies for Horizontal Environmental Genetic Alteration Agents that would likely surpass gene drives in terms of both impacts and biosafety risks. For gene drives themselves, the response under the Cartagena Protocol has likewise been muted, albeit with a pathway towards the development of specialized and comprehensive risk assessment techniques. While the CBD's 15th Conference of the Parties adopted the new Kunming-Montreal Global Biodiversity Framework in December 2022 in what was widely perceived as a 'make or break' moment in global biodiversity policy, the meeting yielded only non-substantial progress on digital sequence information, synthetic biology, and gene drives. The WHO, finally, provides a narrow and shallow mechanism for the governance of pandemic influenza viruses yet without an adequate solution for the associated problem of digital sequence information. Aside from that, the WHO also assumes an encouraging and possibly legitimizing stance towards new types of disease vector control, apparently being cognizant of the potential for some interventions to result in environmental harm. In light of all this, the contribution that international institutions make to either realizing the promises of biotechnology or to the avoidance of its perils is extremely limited. While scientific, economic, and technological developments in bioinformatics, synthetic biology, and gene drives are surging ahead, international institutions largely limit themselves to

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

consultations and deliberations at a technical level rather than the level of political negotiations. Beyond any doubt, technology outpaces international regulation.

What light do the three theoretical perspectives developed in Chapter 3 shed on all of this? To start with, the *international constellation of interests* in the field tends, for the most part, towards distributive bargaining. This is most notable with regard to digital sequence information, a hot button issue from the CBD to the FAO to the WHO. The question of whether and how digital sequence information should be regulated from a perspective of access and benefit-sharing has obvious and direct distributional implications. Treating digital sequence information in the same, or a similar, way as is the case with physical genetic resources implies a significant transfer of assets away from high-innovation economies and towards developing countries. This implicates not only commercial users of digital sequence information but also, importantly, public and non-commercial research. It is perhaps important to bear in mind that the near-universal availability of open-access sequence information constituted a major factor for the unprecedented level of global scientific cooperation that emerged in response to the COVID-19 pandemic – just as the lack of an effective international benefit-sharing mechanism is a core reason for global injustice in access to vaccination. Against this background, institutional responses that aim to redress the injustice which modern biotechnology brings about may well be inconsistent with institutional responses that seek to leverage the promise of information commons. This is precisely how the international interest constellation breaks down: on one side, governments that emphasize the indirect global benefits from unfettered innovation based on an information commons; on the other side, governments that prioritize direct and intrusive benefit-sharing mechanisms as a way of redressing injustice. This disparity in interests goes a long way towards explaining the lack of any meaningful progress on digital sequence information across all relevant international institutions so far. The question of interest constellations is more complex in the case of biotechnological methods for biodiversity conservation, biological control, and vector control. The metaphorical North–South divide does not hold here. Whereas some European countries toe the line of precaution and appear willing to consider restrictive responses up to and including moratoria, several developing countries have signalled a more accommodating stance.[95] And for countries such as Australia or New Zealand, where invasive alien species can pose severe threats to environmental integrity, the political acceptability of gene drive research appears to be much larger than for their European counterparts.[96] In some sense, the constellation of interests in gene drive systems, and possibly in related biotechnological interventions such as de-extinction, appears to be driven more by disparities in the status and relevance of precautionary decision-making than by the conventional North–South divide. While more complex, this constellation of interests is at the

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

same time clearly malignant which, in turn, may explain why institutional responses have been limited to shallow governing body decisions, lacking both specificity and legal bindingness, as well as technical deliberations on risk assessment and risk management. Finally, bioinformatics for biodiversity conservation, such as with the FAO's Global Information System, is characterized by a more benign, integrative constellation of interests due to its public goods character. Information exchange under the system, be it for the documentation of PGRFA accessions or for other types of information exchange, including for the early detection of threats to PGRFA conservation, might be more beneficial for some actors than others while, overall, appearing to be clearly pareto superior.

From a perspective of *normative fit*, the issue of digital sequence information would appear to match very closely with the pre-existing international regulatory framework. The two primary justifications for the fair and equitable sharing of benefits in the context of genetic resources easily extend to digital sequence information. On the one hand, providers are to be rewarded for stewarding, conserving, protecting, and providing genetic resources for the benefit of other parties. On the other hand, benefit-sharing has always been understood as a financial mechanism to support conservation and related activities in, primarily, developing countries. Asking whether or not digital sequence information fall within the scope of the definition of 'genetic resources', or whether or not they amount to 'derivatives', thus partially misses the point: the reasons why fair and equitable benefit-sharing is appropriate for the case of genetic resources apply equally to the case of digital sequence information; everything else amounts to legal technicalities. When adopting the CBD and other relevant instruments, governments have accepted fair and equitable benefit-sharing as a normative principle that would provide limited redress for global injustice and mobilize limited financial means for policies with clear public-good characteristics. This is not changed by the fact that these governments could not have predicted how technological developments in later years would increase the economic stakes. At the operational level, however, existing international instruments were designed for verifiable, bilateral transfers of physical specimens between providers, intermediaries, and users, not for the decentralized, unverifiable high-volume and high-speed exchange of digital sequence information. Still, it appears that there is a relatively tight normative fit between the technology and the pre-existing regulatory framework, which is of course inconsistent with the lack of international regulatory action or, in the case of the FAO Seed Treaty, the collapse of international negotiations.

Partially, this is also the case for gene drive systems and related techniques. It is true that the Cartagena Protocol does not provide an operational framework for regulating the release of gene drives in a transboundary context. However,

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

the protocol, but also the CBD and, for that matter, the 1992 Rio Declaration on Environment and Development, take a clear normative stance on risk technologies, especially in the domain of biotechnology. In the discussions under the CBD and the Cartagena Protocol, this essentially comes down to differences in the interpretation of the precautionary principle: does precaution imply the need for an international moratorium until (or unless) gene drives can be proven not to cause adverse environmental impacts? Or does it imply regulatory decision-making on a case-by-case basis, subject to international guidance on risk assessment and risk management, as well as other international rules on, for instance, liability and redress? Much more than with benefit-sharing from digital sequence information, the strong normative fit with international biosafety regulations cannot resolve ambiguities at the operational level. In that sense, strong normative fit has apparently been insufficient for producing a comprehensive regulatory response to gene drive systems under the Cartagena Protocol. In parts, this may be explicable due to the Protocol's design as (primarily) a trade-based instrument: geared towards bilateral transfers of living modified organisms between exporters, importers, and intermediaries, the Protocol is not well equipped to regulate the transboundary diffusion of self-propagating artificial genetic elements in a plurilateral context.[97] The normative fit of technologies such as de-extinction or Horizontal Environmental Genetic Alteration Agents is arguably even lower, possibly explaining inaction at the level of international institutions. Finally, the normative fit for bioinformatics in PGRFA conservation and associated information exchange appears to be substantial. Here, such novel methods simply constitute innovative tools that fold into the existing conservation portfolio without any friction. In fact, the continuous integration of novel and innovative technologies has been a central feature in the global efforts to conserve PGRFA for at least half a century. In this sense, the use of novel computational tools is not particularly surprising, nor does it present a notable departure from past practice.

Governance object constitution, finally, is precarious for both digital sequence information and gene drive systems. To start with the former: international negotiations and technical deliberations on digital sequence information, across all relevant forums, consist, to a substantial degree, of attempts at conceptual clarification. The term 'digital sequence information' itself is broadly considered a placeholder, with other terms (such as 'genetic sequence data') having been proposed as well. This alone indicates a high degree of ambiguity regarding what, exactly, governments are negotiating about. The same ambiguities apply to the relationship between genetic resources and digital sequence information. Is 'information' a constitutive element of genetic resources as such, considering that 'genetic' resources are not 'natural' resources in the same way that, say, coal, cobalt, and timber are? If genetic resources are being utilized not only for their

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

physical properties but also for their informational content *in relation with its phenotypic traits*, does that mean we can simply detach digital sequence information from the associated genetic resource and assume that benefit-sharing obligations and related rules do not apply? Thus, beyond the question of interests and who-would-gain-what from the inclusion of digital sequence information under international benefit-sharing mechanisms, there is a very real sense of insecurity about what, precisely, the object of the political negotiations is. The same applies to gene drive systems. For one, the parties to the CBD and the Cartagena Protocol only recently started to understand gene drive systems as a distinct governance object, having previously considered it as part of the wider package of 'synthetic biology', a term that is itself notoriously fuzzy. There was never a strong justification for doing so, considering that many gene drive systems are merely based on CRISPR/Cas9 technology – that is, a standard approach in the contemporary biotechnological mainstream and rather outside of the focus on the design of synthetic life that very broadly characterizes the field of synthetic biology. Yet this raises additional questions: from the technical side, it is not entirely clear why we should choose the term 'gene drives' to refer to different types of biotechnological interventions that are, in part, drastically different from each other. CRISPR-based drives have a quite different profile from say, MEDEA drives (Maternal Effect Dominant Embryonic Arrest, a toxin–anti-toxin system).[98] The term 'gene drive' is notoriously underspecified and its prominent usage in the political and technical deliberations under the CBD simply masks the substantial differences between the technologies which it subsumes. Aggravating the problem of object constitution is the lack of consensus on what constitutes new, transformative, and disruptive elements in contemporary biotechnology, and what merely amounts to incremental improvements to technologies that are already quite established. This notably extends to CRISPR, which some parties to the CBD regard as an imperfect and error-prone biotechnological method, both in the context of gene drives and beyond, whereas many others arguably consider it a conventional, mainstream method. The absence of a well-defined governance object with well-understood characteristics, in other words, may explain the indecisiveness of the institutional response. For technological approaches such as de-extinction that are largely speculative, object constitution is even more problematic. Bioinformatics, again, appears to be the exception. As a tool for PGRFA conservation and information exchange, it has unambiguous conceptual boundaries and its properties are well understood. The Seed Treaty's Global Information System, from the outset, was explicitly intended to strengthen existing capacities related to databanks and information exchange. In that sense, the limited empirical role for bioinformatics builds upon and enhances pre-existing practices, rather than departing from or being inconsistent with them.

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

At the most general level, the institutional responses described herein are largely piecemeal, haphazard, and insufficient. What better options are there? For one, the multiple trade-offs that exist in this field mean that observers may, to some extent, disagree on the meaning of 'better'. As with the other empirical chapters of this book, I attempt to avoid coming down on either side of these trade-offs. For instance, whether an unregulated open-access regime for digital sequence information has ultimately greater overall benefits than a benefit-sharing regime with intrusive compliance components is perhaps not the most important question. Much more interesting from a governance perspective, but also from a perspective of thinking through politically feasible and consensus-oriented solutions, is the question of how we can manage or partially overcome trade-offs in order to ensure progress on multiple and partially inconsistent goals simultaneously? To start with digital sequence information: is it necessarily the case that regulatory interventions for ensuring fair and equitable benefit-sharing have undue, adverse consequences for non-commercial research or for commercial research with public good characteristics? To a large extent, the answer appears to revolve around the problem of transaction costs: how could a benefit-sharing regime for digital sequence information ensure proper monitoring without creating excessive red tape for users in terms of their costs of regulatory compliance? One solution would be to leverage innovative technical options such as distributed ledgers. Blockchain technology, for instance, could be used for seamlessly and transparently documenting transfers of digital sequence information between providers, intermediaries, and users.[99] A compliance mechanism for benefit-sharing from digital sequence information could also use an evergreen of the international debate: the mandatory disclosure of the origin of a genetic resource (and/or its associated digital sequence information) as a means to check whether users comply with the conditions set out by the original provider. The existing data infrastructure of the International Nucleotide Sequence Database Collaboration could possibly facilitate the implementation of disclosure requirements for digital sequence information. Alternative institutional models could comprise subscription models that would forego the need for covering individual transactions of genetic resources or digital sequence information with separate legal contracts.[100] A more radical solution would be to completely disconnect benefit-sharing from transactions of digital sequence information in the first place, instead levying taxes as a very small percentage of commercial profits in relevant industrial sectors with little or no differentiation between user categories. This would have a miniscule impact on market performance and innovation while mobilizing funds that could be distributed multilaterally, with particular priority given to developed countries, least-developed countries, or specific groups (such as farmers) in these countries. The chief advantage of taxation-based benefit-sharing would be to do away with the bureaucratic red tape that is an inevitable

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

consequence of transaction-based systems. This would also assuage the concerns of the scientific community regarding the possibly excessive compliance costs brought about by international benefit-sharing regimes (particularly the Nagoya Protocol) and its domestic implementation (particularly in the EU). Such a system might comprise international minimum rates for domestic taxation (so as to avoid a fiscal race to the bottom) and an international fund which pools national levies, as well as rules for determining the priority recipients of benefit-sharing flows. Notwithstanding the obvious problem that such a scheme would likely be politically challenging, to say the least, an international mechanism along those lines would be easier to operate than contemporary transaction-based regimes, and by a long shot. By largely eliminating transaction costs on the bureaucratic and administrative side, this system would do away with what is arguably the most controversial aspect of current international benefit-sharing mechanisms. This would provide some redress for the global injustice associated with the asymmetric patterns of provision and use of genetic resources and associated digital sequence information, but it would also have only a minimally negative impact on the supply of various types of public goods resulting directly and indirectly from basic and applied biotechnological research, both commercial and otherwise.

Possible solutions for gene drives are more difficult to devise. Here, the challenge is to avoid environmental harm while possibly drawing on the potential of the technology to reduce pressure on ecosystems and agricultural systems. One obvious first step could be the development of robust methods for risk assessment, which is something that parties to the CBD are already considering. But there is a problem with this: by producing a regulatory framework that is conducive to eventual environmental releases, the peril of crowding out feasible alternatives could emerge, meaning that the expectation of future releases might divert attention and resources away from alternative (and possibly less risky) approaches in the present. By creating or strengthening the belief that, for instance, gene drives would realistically be available for proofing agricultural systems against pests, stakeholders might become less likely to pursue costly and difficult alternatives, such as enhancing agricultural biodiversity in order to hedge against genetically specialized pests. More fundamentally, and in the context of agriculture, if governments were to create encouraging regulatory signals, gene drives might further delay the urgently needed transformation of a global food system where pests are only one proximal pressure point among much more critical factors such as genetic erosion and overuse of pesticides and fertilizer. A more fundamental question is whether risk assessment for gene drives is ultimately feasible. A variety of factors make gene drive organisms so distinct from other types of GM organisms that it is currently not even clear what, in principle, risk assessment methods might even look like. The phased releases that are part of the risk assessment for conventional

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

GM organisms, where environmental behaviour is assessed through multiple stages of decreasing containment, is clearly not feasible for gene drives, as even a limited environmental release will likely lead to its full-scale propagation.[101] While there might be technical safeguards which would allow controlled releases of gene drives for purposes of risk assessment, the specific risk profile of gene drives is perhaps more strongly determined by their ultimate purpose (meaning large-scale and rapid genetic engineering) rather than their specific technical implementation.[102] If there are significant and unmanageable environmental risks, this means that there is simply no way to realize the technology's potential for the mitigation of environmental impacts while, at the same time, avoiding the peril of environmental harm that it might *also* bring about.

Notes

1. Johnson, I. S. (1983). Human Insulin from Recombinant DNA Technology. *Science*, *219*(4585), 632–7.
2. Paine, J. A., Shipton, C. A., Chaggar, S., et al. (2005). Improving the Nutritional Value of Golden Rice through Increased Pro-Vitamin A Content. *Nature Biotechnology*, *23*(4), 482–7.
3. Shiva, V. (1991). *The Violence of the Green Revolution: Third World Agriculture, Ecology and Politics*. London: Zed Books; Arentsen, M. J., Falkner, R., & Kalfagianni, A. (2009). *Corporate Power in Global Agrifood Governance*. New York: MIT Press.
4. Doudna, J. A., & Charpentier, E. (2014). The New Frontier of Genome Engineering with CRISPR-Cas9. *Science*, 346(6213), 1258096.
5. Lusser, M., Parisi, C., Plan, D., & Rodriguez-Cerezo, E. (2012). Deployment of New Biotechnologies in Plant Breeding. *Nature Biotechnology*, *30*(3), 231–9; Greely, H. T. (2019). CRISPR'd Babies: Human Germline Genome Editing in the 'He Jiankui Affair'. *Journal of Law and the Biosciences*, *6*(1), 111–83.
6. CBD Decision XIII/17, Synthetic Biology, 16 December 2016.
7. Smolke, C. D. (2009). Building Outside of the Box: iGEM and the BioBricks Foundation. *Nature Biotechnology*, *27*(12), 1099–102.
8. Hutchison, C. A., Chuang, R. Y., Noskov, V. N., et al. (2016). Design and Synthesis of a Minimal Bacterial Genome. *Science*, *351*(6280).
9. Herdewijn, P., & Marliere, P. (2009). Toward Safe Genetically Modified Organisms through the Chemical Diversification of Nucleic Acids. *Chemistry & Biodiversity*, *6*(6), 791–808.
10. Benner, S. A., & Sismour, A. M. (2005). Synthetic Biology. *Nature Reviews Genetics*, *6*(7), 533–43.
11. Packer, M. S., & Liu, D. R. (2015). Methods for the Directed Evolution of Proteins. *Nature Reviews Genetics*, *16*(7), 379–94.
12. Wang, Y., Xue, P., Cao, M., et al. (2021). Directed Evolution: Methodologies and Applications. *Chemical Reviews*, *121*(20), 12384–444.
13. Church, G. M., & Regis, E. (2014). *Regenesis: How Synthetic Biology Will Reinvent Nature and Ourselves*. New York: Basic Books; Richmond, D. J., Sinding, M. H. S., & Gilbert, M. T. P. (2016). The Potential and Pitfalls of De-extinction. *Zoologica Scripta*, *45*, 22–36.
14. Nakabachi, A., Yamashita, A., Toh, H., et al. (2006). The 160-Kilobase Genome of the Bacterial Endosymbiont Carsonella. *Science*, *314*(5797), 267.
15. Diniz, W., & Canduri, F. (2017). Bioinformatics: An Overview and Its Applications. *Genetics and Molecular Research*, *16*(1), 1–21; Baldi, P., Brunak, S., & Bach, F. (2001). *Bioinformatics: The Machine Learning Approach*. Cambridge, MA: MIT Press.
16. Shendure, J., Balasubramanian, S., Church, G. M., et al. (2017). DNA Sequencing at 40: Past, Present and Future. *Nature*, *550*(7676), 345–53; p. 345.

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

17. Mardis, E. R. (2017). DNA Sequencing Technologies: 2006–2016. *Nature Protocols*, *12*(2), 213–18.
18. Pareek, C. S., Smoczynski, R., & Tretyn, A. (2011). Sequencing Technologies and Genome Sequencing. *Journal of Applied Genetics*, *52*(4), 413–35; Shendure, J., Balasubramanian, S., Church, G. M., et al. (2017). DNA Sequencing at 40: Past, Present and Future. *Nature*, *550* (7676), 345–53.
19. van Dijk, E. L., Jaszczyszyn, Y., Naquin, D., & Thermes, C. (2018). The Third Revolution in Sequencing Technology. *Trends in Genetics*, *34*(9), 666–81.
20. Momand, J., & McCurdy, A. (2017). *Concepts in Bioinformatics and Genomics*. New York: Oxford University Press, chp. 2.
21. Clarke, L., Zheng-Bradley, X., Smith, R., et al. (2012). The 1000 Genomes Project: Data Management and Community Access. *Nature Methods*, *9*(5), 459–62.
22. Rigden, D. J., & Fernández, X. M. (2021). The 2021 Nucleic Acids Research Database Issue and the Online Molecular Biology Database Collection. *Nucleic Acids Research*, *49*(D1), D1–D9.
23. Reynolds, J. L. (2021). Engineering Biological Diversity: The International Governance of Synthetic Biology, Gene Drives and De-Extinction for Conservation. *Current Opinion in Environmental Sustainability*, *49*, 1–6.
24. For example, Dolezel, M., Lüthi, C., & Gaugitsch, H. (2020). Beyond Limits – The Pitfalls of Global Gene Drives for Environmental Risk Assessment in the European Union. *BioRisk*, *15*, 1–29.
25. Pearse, D. E., & Crandall, K. A. (2004). Beyond FST: Analysis of Population Genetic Data for Conservation. *Conservation Genetics*, *5*(5), 585–602.
26. Narum, S. R., Buerkle, C. A., Davey, J. W., Miller, M. R., & Hohenlohe, P. A. (2013). Genotyping-by-sequencing in Ecological and Conservation Genomics. *Molecular Ecology*, *22* (11), 2841.
27. Petit, R. J., El Mousadik, A., & Pons, O. (1998). Identifying Populations for Conservation on the Basis of Genetic Markers. *Conservation Biology*, *12*(4), 844–55.
28. Church, G. M., & Regis, E. (2014). *Regenesis: How Synthetic Biology Will Reinvent Nature and Ourselves*. New York: Basic Books.
29. Murphy, D. J. (2007). *People, Plants & Genes: The Story of Crops and Humanity*. Oxford: Oxford University Press.
30. Mazoyer, M., & Roudart, L. (2006). *A History of World Agriculture: From the Neolithic Age to the Current Crisis*. New York: Monthly Review Press, p. 71.
31. Harlan, J. R. (1992). *Crops and Man*. Madison: American Society of Agronomy, p. 239.
32. Shiva, V. (2016). *The Violence of the Green Revolution: Third World Agriculture, Ecology and Politics*. Lexington: University Press of Kentucky.
33. Murphy, D. (2007). *Plant Breeding and Biotechnology: Societal Context and the Future of Agriculture*. Cambridge: Cambridge University Press.
34. Andersen, R. (2013). *Governing Agrobiodiversity: Plant Genetics and Developing Countries*. Aldershot: Ashgate.
35. Mooney, P., & ETC Group. (2015). CRFA – The Changing Agribusiness Climate: Corporate Concentration, Agricultural Inputs, Innovation and Climate Change. *Canadian Food Studies/La Revue Canadienne des Études sur L'alimentation*, *2*(2), 117–25.
36. Rasmussen, L. V., Coolsaet, B., Martin, A., et al. (2018). Social-Ecological Outcomes of Agricultural Intensification. *Nature Sustainability*, *1*(6), 275–82.
37. Halewood, M., López Noriega, I., Ellis, D., et al. (2018). Using Genomic Sequence Information to Increase Conservation and Sustainable Use of Crop Diversity and Benefit-sharing. *Biopreservation and Biobanking*, *16*(5), 368–76; Halewood, M., López Noriega, I., Ellis, D., et al. (2017). Potential Implications of the Use of Digital Sequence Information on Genetic Resources for the Three Objectives of the Convention on Biological Diversity. A Submission from CGIAR to the Secretary of the Convention on Biological Diversity (CBD). https://hdl .handle.net/10568/92049; Mascher, M., Schreiber, M., Scholz, U., et al. (2019). Genebank Genomics Bridges the Gap between the Conservation of Crop Diversity and Plant Breeding. *Nature Genetics*, *51*(7), 1076–81.
38. Fowler, C. (2008). The Svalbard Seed Vault and Crop Security. *BioScience*, *58*(3), 190–1.

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

39. Carrington, D. (2017). Arctic Stronghold of World's Seeds Flooded after Permafrost Melts. *The Guardian*, 19 May. www.theguardian.com/environment/2017/may/19/arctic-stronghold-of-worlds-seeds-flooded-after-permafrost-melts.
40. Doherty, T. S., Glen, A. S., Nimmo, D. G., et al. (2016). Invasive Predators and Global Biodiversity Loss. *Proceedings of the National Academy of Sciences*, *113*(40), 11261–5.
41. Hartley, S., Taitingfong, R., & Fidelman, P. (2022). The Principles Driving Gene Drives for Conservation. *Environmental Science & Policy*, *135*, 36–45.
42. Reeves, R. G., Voeneky, S., Caetano-Anollés, D., Beck, F., & Boëte, C. (2018). Agricultural Research or a New Bioweapon System? *Science*, *362*(6410), 35–7. Notably, the Defense Advanced Research Projects Agency is a major funder of research on gene drive technology as well.
43. Pfeifer, K., Frieß, J. L., & Giese, B. (2022). Insect Allies – Assessment of a Viral Approach to Plant Genome Editing. Online first at *Integrated Environmental Assessment and Management*, p. 10. http://dx.doi.org/10.1002/ieam.4577.
44. Simon, S., Otto, M., & Engelhard, M. (2018). Scan the Horizon for Unprecedented Risks. *Science*, *362*(6418), 1007–8, p. 1007.
45. See Statement from Dr. Blake Bextine, DARPA Program Manager for Insect Allies, www.darpa.mil/attachments/DARPA%20Response%20to%20Science%20Opinion%20Piece%20-%20Oct%204%202018.pdf, accessed October 5, 2022.
46. Due to the ethical implications, human genetic resources fall under an entirely different and significantly less permissive regulatory framework.
47. For example, CBD Article 2.
48. Tvedt, M.V., & Schei, P. J. (2013). The Term 'Genetic Resources': Flexible and Dynamic while Providing Legal Certainty? In S. Oberthür & G.K. Rosendal (eds.), *Global Governance of Genetic Resources: Access and Benefit-sharing after the Nagoya Protocol*. New York: Routledge, pp. 18–32.
49. Buck, M., & Hamilton, C. (2011). The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity. *Review of European Community & International Environmental Law*, *20*(1), 47–61.
50. Fowler, C., & Mooney, P. (1990). *The Threatened Gene: Food, Politics and the Loss of Genetic Diversity*. Cambridge: Lutterworth Press; Rosendal, G. K. (2000). *The Convention on Biological Diversity and Developing Countries*. Dordrecht: Kluwer.
51. Bond, M. R., & Scott, D. (2020). Digital Biopiracy and the (Dis)Assembling of the Nagoya Protocol. *Geoforum*, *117*, 24–32.
52. Oldham, P. (2020). Digital Sequence Information – Technical Aspects. https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Final_Report_technical_aspects_of_DSI.pdf (available from https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/13e87f0f-efbd-463e-86f7-42eddd8f5480/details?download=true).
53. For example, Ribeiro, C. D. S., Koopmans, M. P., & Haringhuizen, G. B. (2018). Threats to Timely Sharing of Pathogen Sequence Data. *Science*, *362*(6413), 404–6; Sherman, B., & Henry, R. J. (2021). Access to Biodiversity for Food Production: Reconciling Open Access Digital Sequence Information with Access and Benefit-sharing. *Molecular Plant*, *14*(5), 701–4.
54. Scholz, A. H., Lange, M., Habekost, P., et al. (2021). Myth-Busting the Provider-User Relationship for Digital Sequence Information. *Gigascience*, *10*(12), 1–8.
55. For example, Coupe, S., & Lewins, R. (2007). *Negotiating the Seed Treaty*. Rugby: Practical Action Publishing; Halewood, M., Noriega, I. L., & Louafi, S. (eds.). (2012). *Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance*. Abingdon: Routledge; Andersen, R. (2016). *Governing Agrobiodiversity: Plant Genetics and Developing Countries*. Abingdon: Routledge.
56. To the extent that these are 'under the management and control of the Contracting Parties and in the public domain'; Article 11.2 Seed Treaty.
57. Rabitz, F. (2017). Access without Benefit-Sharing: Design, Effectiveness and Reform of the FAO Seed Treaty. *International Journal of the Commons*, *11*(2), 621–40.

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

58. Laird, S., & Wynberg, R. (2018). *A Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and the Nagoya Protocol*. CBD/DSI/AHTEG/2018/1/3. Montreal: Secretariat of the Convention on Biological Diversity; Nawaz, S., Satterfield, T., & Hagerman, S. (2021). From Seed to Sequence: Dematerialization and the Battle to (Re)Define Genetic Resources. *Global Environmental Change*, *68*, 102260.
59. Article 2 Seed Treaty.
60. Welch, E., Bagley, M. A., Kuiken, T., & Louafi, S. (2017). Potential Implications of New Synthetic Biology and Genomic Research Trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture. *Emory Legal Studies Research Paper*.
61. Rabitz, F. (2017). Access without Benefit-Sharing: Design, Effectiveness and Reform of the FAO Seed Treaty. *International Journal of the Commons*, *11*(2), 621–40.
62. Earth Negotiations Bulletin. (2019). Ninth Meeting of the Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture: 17–21 June 2019. *Earth Negotiations Bulletin*, 9(731).
63. Earth Negotiations Bulletin. (2019). Summary of the Eighth Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture: 11–16 November 2019. *Earth Negotiation Bulletin*, 9(733).
64. IT/GB-8/19/16.1/Inf.1.
65. Bond, M. R., & Scott, D. (2020). Digital Biopiracy and the (Dis)Assembling of the Nagoya Protocol. *Geoforum*, *117*, 24–32.
66. See Ker, C. , Louafi, S. , & Sanou, M. (2012). Building a Global Information System in Support of the International Treaty on Plant Genetic Resources for Food and Agriculture. In M. Halewood, I. L. Noriega, & S. Louafi (eds.), *Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance*. Abingdon: Routledge, pp. 294–320.
67. Article 17.2.
68. IT/GB-6/15/Res 3.
69. IT/SAC-GLIS-3/18/3, p. 9.
70. Alercia, A., López, F. M., Sackville Hamilton, N. R., & Marsella, M., 2018. *Digital Object Identifiers for Food Crops – Descriptors and Guidelines of the Global Information System*. Rome: Food and Agriculture Organization.
71. IT/SAC-GLIS-3/18/3.
72. Nagoya Protocol Articles 1 and 2.c.
73. Decision 14/20 of the Conference of the Parties to the Convention on Biological Diversity, 30 November 2018.
74. Karger, E. J., & Scholz, A. H. (2021). DSI, the Nagoya Protocol and Stakeholders' Concerns. *Trends in Biotechnology*, *39*(2), 110–12; Deplazes-Zemp, A., Abiven, S., Schaber, P., et al. (2018). The Nagoya Protocol Could Backfire on the Global South. *Nature Ecology & Evolution*, *2*(6), 917–19.
75. See CBD/COP/15/L.30. While the mechanism was formally adopted in December 2022, its operational details are still unclear at the time of writing, including its linkages with the Nagoya Protocol itself. The parties have given themselves until 2024 to hammer out the specifics. Considering the contested politics and the procedural inertia characteristic of the CBD, this timeline is extraordinarily optimistic.
76. Gupta, A. (2000). Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety. *Environment: Science and Policy for Sustainable Development*, *42*(4), 22–33; Falkner, R. (2007). The Political Economy of 'Normative Power' Europe: EU Environmental Leadership in International Biotechnology Regulation. *Journal of European Public Policy*, *14*(4), 507–26.
77. Oberthür, S., & Gehring, T. (2006). Institutional Interaction in Global Environmental Governance: The Case of the Cartagena Protocol and the World Trade Organization. *Global Environmental Politics*, *6*(2), 1–31.

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

78. Rabitz, F. (2019). Gene Drives and the International Biodiversity Regime. *Review of European, Comparative & International Environmental Law*, *28*(3), 339–48.
79. Rabitz, F. (2021). The International Governance of Gene Drive Organisms. *Environmental Politics*, 1–20.
80. Dolezel, M., Lüthi, C., & Gaugitsch, H. (2020). Beyond Limits – The Pitfalls of Global Gene Drives for Environmental Risk Assessment in the European Union. *BioRisk*, *15*, 1–29; Kuzma, J. (2021). Procedurally Robust Risk Assessment Framework for Novel Genetically Engineered Organisms and Gene Drives. *Regulation & Governance*, *15*(4), 1144–65.
81. COP Decisions XIII/17 and XIV/19.
82. For example, CBD/CP/RA/AHTEG/2020/1/5.
83. MOP Decision CP-9/13.
84. A novel Malaria vaccine, Mosquirix, was recently endorsed by the World Health Organization and others, including ones using the novel mRNA technology first used for COVID-19 vaccination, are in the pipeline.
85. Krafsur, E. S. (1998). Sterile Insect Technique for Suppressing and Eradicating Insect Population: 55 Years and Counting. *Journal of Agricultural Entomology*, *15*(4), 303–17; Lees, R. S., Gilles, J. R., Hendrichs, J., Vreysen, M. J., & Bourtzis, K. (2015). Back to the Future: The Sterile Insect Technique against Mosquito Disease Vectors. *Current Opinion in Insect Science*, *10*, 156–62; Klassen, W., Curtis, C. F., & Hendrichs, J. (2021). History of the Sterile Insect Technique. In V. A. Dyck, J. Hendrichs, & A. S. Robinson (eds.), *Sterile Insect Technique. Principles and Practice in Area-Wide Integrated Pest Management*. London: CRC Press, pp. 1–44.
86. Wang, G. H., Gamez, S., Raban, R. R., et al. (2021). Combating Mosquito-Borne Diseases using Genetic Control Technologies. *Nature Communications*, *12*(1), 1–12.
87. Benedict, M. Q., & Robinson, A. S. (2003). The First Releases of Transgenic Mosquitoes: An Argument for the Sterile Insect Technique. *Trends in Parasitology*, *19*(8), 349–355, p. 350.
88. For example, Ant, T., Koukidou, M., Rempoulakis, P., et al. (2012). Control of the Olive Fruit Fly Using Genetics-Enhanced Sterile Insect Technique. *BMC Biology*, *10*(1), 1–8.
89. De Campos, A. S., Hartley, S., de Koning, C., Lezaun, J., & Velho, L. (2017). Responsible Innovation and Political Accountability: Genetically Modified Mosquitoes in Brazil. *Journal of Responsible Innovation*, *4*(1), 5–23; Schairer, C. E., Najera, J., James, A. A., Akbari, O. S., & Bloss, C. S. (2021). Oxitec and MosquitoMate in the United States: Lessons for the Future of Gene Drive Mosquito Control. *Pathogens and Global Health*, *115*(6), 365–76.
90. World Health Organization. (2020). *Standard Operating Procedures for Vector Control Advisory Group (VCAG) Applicants. WHO/CDS/VCAG/2018.02.rev 3*. Geneva: World Health Organization.
91. World Health Organization. (2016). *Fifth Meeting of the Vector Control Advisory Group*. Geneva: World Health Organization.
92. Bill and Melinda Gates Foundation grants OPP1032376 and INV-002173.
93. ETC Group. (2020). *Driven to Exterminate. Bill Gates and Gene Drive Extinction Technology.* Montreal: Action Group on Erosion, Technology and Concentration.
94. World Health Organization. (2020). *Evaluation of Genetically Modified Mosquitoes for the Control of Vector-borne Diseases. Position Statement*. Geneva: World Health Organization, p. 2.
95. Reynolds, J. L. (2020). Governing New Biotechnologies for Biodiversity Conservation: Gene Drives, International Law and Emerging Politics. *Global Environmental Politics*, *20*(3), 28–48.
96. Dearden, P. K., Gemmell, N. J., Mercier, O. R., et al. (2018). The Potential for the Use of Gene Drives for Pest Control in New Zealand: A Perspective. *Journal of the Royal Society of New Zealand*, *48*(4), 225–44.
97. Rabitz, F. (2021). The International Governance of Gene Drive Organisms. Online first at *Environmental Politics*.
98. Champer, J., Buchman, A., & Akbari, O. S. (2016). Cheating Evolution: Engineering Gene Drives to Manipulate the Fate of Wild Populations. *Nature Reviews Genetics*, *17*(3), 146–59, pp. 152–4.
99. Gils, T., & Frison, C. (2021). Blockchain Technology for Food Security? Resilience Potential and Risk Identification for the Multilateral System of the International Treaty on Plant Genetic

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004

Resources for Food and Agriculture. In F. Sindico, S. Switzer, & Q. Tianbao (eds.), *The Transformation of Environmental Law and Governance. Risk, Innovation and Resilience*. Cheltenham: Edward Elgar, pp. 206–24.
100. Rabitz, F. (2017). Access without Benefit-Sharing: Design, Effectiveness and Reform of the FAO Seed Treaty. *International Journal of the Commons*, *11*(2), 621–40.
101. Dolezel, M., Lüthi, C., & Gaugitsch, H. (2020). Beyond Limits – The Pitfalls of Global Gene Drives for Environmental Risk Assessment in the European Union. *BioRisk*, *15*, 1–29.
102. Rabitz, F. (2021). The International Governance of Gene Drive Organisms. Online first at *Environmental Politics*.

Downloaded from https://www.cambridge.org/core. UNIVERSIDAD AUTONOMA METROPOLITANA, on 15 Nov 2026 at 11:44:06, subject to the Cambridge Core terms of use, available at https://www.cambridge.org/core/terms. https://doi.org/10.1017/9781009352635.004