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ARTICLE

The De-Legalization of Novel Biotechnology Governance under the Convention on Biological Diversity

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Abstract
In the 1990s, the Convention on Biological Diversity (CBD) emerged as the primary international forum for managing the interface between biodiversity and biotechnology. Three legally binding protocols to the Convention were concluded, all aiming to regulate bio-innovation. Despite the rapid pace of biotechnological innovation, however, and its implications for biodiversity and equity, CBD policy outcomes have recently shifted towards lower stringency in substance and weaker institutionalization in process. To confirm this trend, we examine decisions adopted by the CBD Conferences of the Parties in 2022 and 2024. We focus on outcomes on three key agenda items: (i) digital sequence information on genetic resources, (ii) risk assessment of living modified organisms, and (iii) synthetic biology. We analyze shifts towards lower stringency in the light of scholarship on legalization and de-legalization, including the softening of international law. We conclude by assessing the implications for the CBD, and for global biotechnology governance more generally.

Keywords: Biodiversity; Biotechnology; Biosafety; Access and benefit-sharing; International organizations; Kunming-Montreal Global Biodiversity Framework

1. Introduction

During the 1990s, the Convention on Biological Diversity (CBD)[1] emerged as the central international forum for managing the complex interface between biotechnology and biodiversity. Issues such as ownership and control of genetic resources, biosafety, and distribution of the benefits of biotechnology were at the heart of negotiations that led to the agreement.[2] In the two decades that followed adoption, three legally binding protocols to the Convention were concluded: the 2000 Cartagena Protocol on Biosafety,[3] the 2010 Nagoya-Kuala Lumpur Supplementary Protocol on

[1] Rio de Janeiro (Brazil), 5 June 1992, in force 29 Dec. 1993, available at: https://www.cbd.int/convention/text.
[2] D.R. Downes, 'New Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology, and Intellectual Property in the Convention on Biological Diversity' (1993) 4 *Touro Journal of Transnational Law*, pp. 1–46.
[3] Montreal (Canada), 29 Jan. 2000, in force 11 Sept. 2003, available at: https://bch.cbd.int/protocol/text.

Liability and Redress to the Cartagena Protocol on Biosafety,[4] and the 2010 Nagoya Protocol on Access and Benefit-Sharing (ABS).[5] All three protocols regulate bio-based innovation, albeit at different points of the value chain. The Nagoya ABS Protocol addresses matters related to access to genetic resources – the raw material of biotechnological innovation – and the sharing of benefits arising from genetic resource utilization and commercialization of resulting products. The two biosafety-related protocols address the management of the potential environmental risk of such biotechnological innovation, and liability considerations, focusing on living modified organisms (LMOs) such as genetically modified seeds.

Rapid scientific and technological developments in recent years have resulted in an array of novel biotechnological methods and applications. Discussed in detail below (Sections 3, 4 and 5), these developments come with renewed promises and novel risks for the CBD objectives, namely the conservation and sustainable use of biodiversity, and the fair and equitable sharing of the benefits arising from the utilization of genetic resources.[6] However, CBD parties in the past decade have tended to engage less. As we demonstrate below (Sections 3, 4 and 5), in contrast to the period up to 2010, CBD engagement in the field of biotechnology is currently characterized by reduced law-making activity, lower stringency in the substance of international rules, and weaker institutionalization of associated international processes. At the same time, we argue, the CBD Conference of the Parties (COP) has failed to keep up with developments in the field or to provide the required guidance for the implementation of legal obligations under the Convention and its Protocols, because of limitations in agenda-setting and decisions with convoluted and imprecise language.

As a result, the CBD is increasingly less relevant for global biotechnology governance, compared with its role during the 1990s and early 2000s. This is problematic: on the one hand, opportunities might be missed to leverage novel biotechnologies for the CBD's three objectives. On the other, rapidly advancing biotechnologies posing various environmental and socio-economic risks with bearings on these objectives may end up without appropriate international regulation or guidance.[7]

Held in 2022, COP15 was a landmark meeting for global biodiversity governance.[8] The adoption of an ambitious, albeit non-legally binding, package of measures,

[4] Nagoya (Japan), 15 Oct. 2010, in force 5 Mar. 2018, available at: https://bch.cbd.int/protocol/NKL_text.shtml.

[5] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the CBD, Nagoya (Japan), 29 Oct. 2010, in force 12 Oct. 2014 (Nagoya ABS Protocol), available at: https://www.cbd.int/abs/text.

[6] CBD, n. 1 above, Art. 1.

[7] F. Rabitz, J.L. Reynolds & E. Tsioumani, 'Emerging Technologies in Biodiversity Governance: Gaps and Opportunities for Transformative Governance', in I. Visseren-Hamakers & M. Kok (eds), *Transforming Biodiversity Governance* (Cambridge University Press, 2022), pp. 137–54.

[8] See United Nations Environment Programme (UNEP), 'COP15 Ends with Landmark Biodiversity Agreement', 20 Dec. 2022, available at: https://www.unep.org/news-and-stories/story/cop15-ends-landmark-biodiversity-agreement; World Economic Forum, 'COP15: What's Next for Historic Deal to Protect Nature?', 27 Jan. 2023, available at: https://www.weforum.org/stories/2023/01/cop15-historic-deal-protect-nature-earth-2030.

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including the Kunming-Montreal Global Biodiversity Framework[9] and decisions to support implementation through resource mobilization and monitoring, was a powerful political symbol in times of accelerating and catastrophic global biodiversity loss. Yet, parties increasingly distanced themselves from pressing biotechnological questions, with respective outcomes being weak in substance and process. The trend was confirmed at COP16 in 2024, as illustrated, in particular, by deliberations on synthetic biology (Section 5).

Arguing that the observed trend has major implications for global biodiversity and biotechnology governance, we focus on the results of these two COP meetings for three key issues that have been on the CBD agenda for at least a decade: (a) digital sequence information (DSI) on genetic resources (Section 3), (b) risk assessment and risk management for novel types of LMO (Section 4), and (c) horizon-scanning, monitoring and assessment in the field of synthetic biology (Section 5). These items cover the broad scope of CBD involvement in biotechnological innovation, from access to genetic resources to release of LMOs into the environment, posing both risks and opportunities for its objectives. We analyze this trend in the light of scholarship on legalization and de-legalization, including the softening of international law (Section 2). We discuss its potential drivers (Section 6) and conclude by assessing implications for the CBD in particular, and global biotechnology governance in general (Section 7).

2. Legalization and De-legalization

Back in 2000, the world was witnessing 'a move to law' in international relations, according to the introduction to the special issue of *International Organization*, which laid the foundation for the concept of 'legalization'.[10] Some 20 years later, the Interest Group on Social Sciences and International Law of the European Society on International Law (ESIL) issued a call for papers on the 'de-legalization' of international law,[11] drawing attention to the opposite trend. In this section we review relevant literature from political science, international relations, and international law, and apply it to the CBD context. We use this terminology while acknowledging that scholars use different terms to explore the function of international collaboration and the resulting normative activity or lack thereof.[12]

Kenneth Abbott and co-authors conceptualized 'legalization' along three dimensions: (i) obligation, meaning that states and other actors are legally bound

[9] CBD COP, Decision 15/4, 'Kunming-Montreal Global Biodiversity Framework', 19 Dec. 2022, UN Doc. CBD/COP/DEC/15/4.

[10] J. Goldstein et al., 'Introduction: Legalization and World Politics' (2000) 54(3) *International Organization*, pp. 385–99, at 385.

[11] ESIL Interest Group on Social Sciences and International Law, 'Call for Papers: The De-legalization of International Law: Social Science Perspectives', Pre-workshop to the 2023 ESIL Annual Conference in Aix-en-Provence (France), 30 Aug. 2023, available at: https://esil-sedi.eu/wp-content/uploads/2023/01/CfP-ESIL-IG-Social-Sciences-and-International-Law-workshop_ESIL2023.pdf.

[12] As an illustration of the enduring nature of the concept of legalization, as well as terminological challenges, see H. Carey & S.M. Mitchell, *Legalization of International Law and Politics: Multi-Level Governance of Human Rights and Aggression* (Springer, 2023) (in which the authors refer to positive and negative legalization).

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by international rules or commitments; (ii) precision, referring to the unambiguous content of the rules; and (iii) delegation, referring to the authority of third parties to implement, interpret, and apply the rules.[13] 'Each of these dimensions is a matter of degree and gradation, not a rigid dichotomy', they noted; the concept of legalization thus 'encompasses a multidimensional continuum'[14] from hard to soft law, with forms of legalization involving different combinations of attributes.[15] Their analysis has some limitations: it understands law narrowly, as a 'collection of formalized and institutionalized features',[16] and does not take into consideration the underlying processes and effects of legitimacy, including the relation between legitimacy and obligation and the 'continuum of legality from informal to more formal norms'.[17] However, it is still a useful starting point for this discussion.

Legalization is reflected in the emergence of increasingly dense webs of international treaties over the course of the second half of the 20th century, including a proliferation of legally binding multilateral environmental agreements, and in the rise of international courts and tribunals in areas that range from trade and investment to international humanitarian law.[18] Beyond a historical trend towards binding treaty law and an international judiciary, one particularly salient conceptualization refers to the *specificity* with which international rules describe state rights and obligations.[19] Typically, the legalization of global politics is associated with higher degrees of effectiveness in the implementation of international rules, relative to soft law solutions that are usually limited in binding effect, accuracy, and enforceability. While deeply legalized international arrangements are costly to negotiate and may be prone to defection,[20] 'binding rules involve more credible commitments and are often accompanied by more stringent procedures for verification, review and response'.[21]

While the concept of legalization captures important elements of the development of the post-1945 international order, mounting evidence suggests that it is not a unidirectional phenomenon. Already in the 2000 special issue, it was noted that the trend is 'hardly uniform'.[22] Abbott and Snidal integrated soft law in the legalization continuum, optimistically arguing that 'international actors often deliberately choose softer forms of legalization as superior institutional arrangements'.[23] Although soft

[13] K.W. Abbott et al., 'The Concept of Legalization' (2000) 54(3) *International Organization*, pp. 401–19.
[14] Ibid., p. 401.
[15] K.W. Abbott & D. Snidal, 'Hard and Soft Law in International Governance' (2000) 54(3) *International Organization*, pp. 421–56.
[16] M. Finnemore & S.J. Toope, 'Alternatives to "Legalization": Richer Views of Law and Politics' (2001) 55(3) *International Organization*, pp. 743–58, at 744.
[17] Ibid.
[18] K.J. Alter, 'The Evolving International Judiciary' (2011) 7(1) *Annual Review of Law and Social Science*, pp. 387–415.
[19] Abbott et al., n. 13 above.
[20] V.H. Tørstad, 'Participation, Ambition and Compliance: Can the Paris Agreement Solve the Effectiveness Trilemma?' (2020) 29(5) *Environmental Politics*, pp. 761–80.
[21] J.B. Skjærseth, O.S. Stokke & J. Wettestad, 'Soft Law, Hard Law, and Effective Implementation of International Environmental Norms' (2006) 6(3) *Global Environmental Politics*, pp. 104–20, at 105.
[22] Goldstein et al., n. 10 above, p. 386.
[23] Abbott & Snidal, n. 15 above, p. 423.

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law is 'by no means a brand-new phenomenon'[24] and has clear doctrinal characteristics regarding its legal effects and lack of justiciability,[25] legal scholars continue to debate its nature and relation to binding international law, drawing attention to questions of effectiveness, legitimacy, and persuasiveness, and ultimately the distinction between law and non-law.[26]

As novel forms of governance arrangements are on the rise, expansion of international treaty law has been slowing down in recent years and may be approaching its limits.[27] While global challenges deepen, 'multilateralism is in retreat'.[28] Some authors note a tendency towards 'dejudicialization of international politics', that is, 'the complete removal from judicial cognizance of a policy issue that had previously been subject to judicialization'.[29] The deadlock of dispute settlement under the World Trade Organization, once considered an archetype of international judicialization, highlights the possibility of retrenchment in the face of pushback from powerful nation states.[30] Resistance against international tribunals is accompanied by increasing disrespect for their judgments and lack of implementation of even binding commitments in all areas but international trade and finance,[31] raising difficult questions about the reach and impact of international law. This retreat is further illustrated by the increasing employment of soft law and a steep decline in the precision of legal provisions in both treaties and soft law instruments. Addressed here under the concept of de-legalization, these trends can possibly be explained through structural changes in the international system, including economic or geopolitical ones, as a result of unilateralism, rising nationalism, or resistance to the unequal allocation of resources.[32]

Beyond a few scattered cases, empirical evidence for de-legalization and theoretical engagement with its drivers remain limited. We address both gaps by focusing on de-legalization trends at the intersection between global environmental and technology governance: rule development on novel biotechnologies under the CBD. This article thus addresses central questions of international regulation in a

[24] M. Goldmann, 'We Need to Cut Off the Head of the King: Past, Present, and Future Approaches to International Soft Law' (2012) 25(2) *Leiden Journal of International Law*, pp. 335–68, at 336.

[25] Ibid.

[26] Ibid. For a review of relevant theoretical approaches see also K. Kulovesi & E. Recio, 'Fighting a Hard Battle with a Soft Weapon: Is International Climate Change Law Softening?', in M. Eliantonio, E. Korkea-aho & U. Mörth (eds), *Research Handbook on Soft Law* (Edward Elgar, 2023), pp. 320–36.

[27] K.W Abbott, J.F. Green & R.O. Keohane, 'Organizational Ecology and Institutional Change in Global Governance' (2016) 70(2) *International Organization*, pp. 247–77.

[28] B.S. Chimni, 'Crisis and International Law: A Third World Approaches to International Law Perspective', in M.M. Mbengue & J. d'Aspremont (eds), *Crisis Narratives in International Law* (Brill, 2022), pp. 40–53, at 50.

[29] D. Abebe & T. Ginsburg, 'The Dejudicialization of International Politics?' (2019) 63(3) *International Studies Quarterly*, pp. 521–30, at 521.

[30] J. Kucik, L. Peritz & S. Puig, 'Legalization and Compliance: How Judicial Activity Undercuts the Global Trade Regime (2023) 53(1) *British Journal of Political Science*, pp. 221–38.

[31] S.J. Hoffman et al., 'International Treaties Have Mostly Failed to Produce Their Intended Effects' (2022) 119(32) *Proceedings of the National Academy of Sciences of the United States of America*, article e2122854119.

[32] ESIL Interest Group on Social Sciences and International Law, n. 11 above.

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technological field with profound significance for research, development, and innovation across multiple social and economic sectors, including agriculture and health, and major implications for global equity and sustainable development. Historically, the CBD has been at the forefront of international biotechnology regulation, contributing to the institutionalization of international norms on precaution and on the fair and equitable sharing of benefits arising out of the (biotechnological) utilization of genetic resources of plant, microbial, and other origin.

In the CBD context, de-legalization occurs at the level of rule development. International institutions require constant adaptation to changes in their institutional environment lest they gradually drift into irrelevance as the conditions for which they were initially created increasingly cease to hold. This is particularly the case for institutions dealing with fast-moving technological changes.[33] Appropriate rule development thus ensures that an institution remains relevant and can continue to assert its principles and objectives even in the face of changing circumstances. De-legalization threatens such institutional adaptation: while some rules continue to be produced, their soft law nature and increasingly vague normative content limit their potential for implementation at the national level, as well as the potential for inducing behavioural changes in line with institutional objectives. As we discuss below, the de-legalization of rule development for biotechnology under the CBD is driven primarily by shifts in coalition politics, underpinned by the shifting global political economy of biotechnology. We thus highlight the role of international interest constellations in shaping the trajectory of international law, in the direction of either legalization or de-legalization, further drawing attention to underlying socio-economic considerations. Focusing on three CBD agenda items at different points of the biotechnological value chain – DSI, risk assessment and risk management, and synthetic biology – we show why and how the de-legalization trend leads to widening gaps in the international legal framework for novel biotechnologies. We argue that, because of the central role of the CBD in global biodiversity governance, this trend has important implications for environmental multilateralism more broadly.

In the following section we start by exploring policy developments on DSI, a term referring to data derived from genetic resources. A crucial tool in biotechnological innovation, as well as the conservation of genetic resources, the governance of DSI is a highly controversial topic in all ABS-related processes, including the CBD.

3. Digital Sequence Information on Genetic Resources

Scientific and technological advances in genomics and bioinformatics have transformed the process of sourcing raw material for use in bio-based research and development. Improvements in computing power and the development of tools that can generate and analyze large quantities of genotypic, phenotypic, and

[33] F. Rabitz, 'Institutional Drift in International Biotechnology Regulation' (2019) 10(2) *Global Policy*, pp. 227–37.

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environmental data, along with reductions in the cost of sequencing,[34] have led to a dramatic acceleration of the innovation process, and to the generation and potential exchange of a 'tsunami of genomic information',[35] termed DSI in the CBD context. Synthetic biology and other approaches have made possible the use of the information content of genetic resources in the industrial, pharmaceutical, and agriculture sectors, with no need for access to physical samples. In the pharmaceutical sector, for example, the ability to use DSI has resulted in the emergence of new approaches to vaccine development that do not require live influenza viruses.[36] In agricultural research, large-scale sequencing techniques allow the searching of genebank accessions for material containing desired genetic elements for use in plant breeding programmes, with the value lying in the amount of data analyzed, rather than in a single sample.[37]

Such developments not only facilitate biotechnological innovation but also have a crucial role in biodiversity conservation and sustainable use,[38] including through identifying species and monitoring ecosystems. However, they have created challenges for the ABS architecture of the CBD and other ABS-related processes. With physical genetic resources no longer required, there is a risk of bypassing benefit-sharing obligations for access to genetic resources provided for by national laws, and thus undermine the third CBD objective on fair and equitable benefit-sharing.

CBD debates on DSI were initiated in 2015, during technical discussions on synthetic biology. Participating experts identified potential adverse effects of synthetic biology for the third CBD objective, and a 'shift in the understanding of what constitutes a genetic resource'.[39] In the years that followed, the need to ensure benefit-sharing from the use of DSI became a central topic in the CBD negotiations, involving questions which are primarily political, as well as legal and technical. Legal and technical discussions revolved around the term 'genetic resource' – and whether it could be interpreted to include non-material elements such as information, while remaining within the scope of the Convention and the Nagoya ABS Protocol – and implementation-related concerns regarding identification of users and tracking of DSI use. The political challenge relates to the deep-rooted conflict between developed and

[34] S.J. Hiemstra, M. Brink & T. van Hintum, 'Digital Sequence Information (DSI): Options and Impact of Regulating Access and Benefit Sharing – Stakeholder Perspectives', CGN Report 42, Centre for Genetic Resources and Wageningen University and Research, Jan. 2019.

[35] P. Phillips, S. Smyth & J. de Beer, 'Access and Benefit-Sharing in the Age of Digital Biology', in C. Oguamanam (ed.), *Genetic Resources, Justice and Reconciliation* (Cambridge University Press, 2018) pp. 181–95, at 181.

[36] World Health Organization (WHO), 'New Technologies Using Genetic Sequence Data, Factsheet', Sept. 2018.

[37] S. Aubry, 'The Future of Digital Sequence Information for Plant Genetic Resources for Food and Agriculture' (2019) 10(1046) *Frontiers in Plant Science*, pp. 1–10.

[38] M. Halewood et al., 'Using Genomic Sequence Information to Increase Conservation and Sustainable Use of Crop Diversity and Benefit-Sharing' (2018) 16 *Biopreservation and Biobanking*, pp. 368–76.

[39] CBD, Ad Hoc Technical Expert Group on Synthetic Biology, 'Report of the Ad Hoc Technical Expert Group on Synthetic Biology', 7 Oct. 2015, UN Doc. UNEP/CBD/SYNBIO/AHTEG/2015/1/3, p. 9.

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developing countries on who benefits from biotechnological innovation and the need and intention to fulfil benefit-sharing requirements.[40]

The question of benefit-sharing from the use of DSI received major political attention on the road to the Kunming-Montreal Global Biodiversity Framework. Considerable technical work and several rounds of consultations addressed legal and implementation challenges. Positions at COP15 remained polarized, however, with some developed countries maintaining the view that DSI falls outside the scope of the CBD and the definition of genetic resource.[41] The final agreement to establish a global multilateral mechanism for benefit-sharing from DSI use, including a global fund,[42] came as a surprise.[43] Part of a package of six key decisions proposed by the meeting's Presidency, with success in reaching agreement, reflected a key compromise between the negotiating blocs of industrialized and developing countries, which involved items beyond DSI, such as specific targets of the Kunming-Montreal Global Biodiversity Framework.

The DSI decision had major political significance: it marked a move by the international community towards accepting the need for benefit-sharing from DSI use, and thus 'a phase shift in the approach to governance of genetic resources'.[44] Indeed, the political compromise behind the decision arguably opened the way for adoption of the legally binding Agreement under the UN Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ Agreement),[45] which establishes an ABS mechanism with regard to the utilization of marine genetic resources as well as DSI.[46] It is also expected to influence the process under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA),[47] which negotiates the revision of its own multilateral system for ABS regarding plant genetic resources for food and agriculture, with benefit-sharing from DSI use remaining a deeply controversial issue.

At the same time, the COP15 decision on DSI reveals a lack of legal precision, as well as gaps and inconsistencies, which call into question the successful operationalization of the multilateral mechanism. In addition to recognizing in its preamble the divergent views on whether DSI falls within the scope of the CBD, virtually all

[40] C. Frison & E. Tsioumani, 'Access and Benefit Sharing and Digital Sequence Information: Unravelling the Knot', in C. Lawson, M. Rourke & F. Humphries (eds), *Access and Benefit Sharing of Genetic Resources, Information and Traditional Knowledge* (Routledge, 2022), pp. 122–38, at 127–8.

[41] E. Tsioumani et al., 'UN Biodiversity Conference Highlights: Thursday, 8 December 2022' (2022) 9(787) *Earth Negotiations Bulletin*, pp. 1–2.

[42] CBD COP, Decision 15/9, 'Digital Sequence Information on Genetic Resources', 19 Dec. 2022, UN Doc. CBD/COP/DEC/15/9.

[43] E. Tsioumani et al., 'UN Biodiversity Conference Highlights: Sunday, 18 December 2022' (2022) 9(795) *Earth Negotiations Bulletin*, pp. 1–2.

[44] P. Oldham, C. Chiarolla & S. Thambisetty, 'Digital Sequence Information in the UN High Seas Treaty: Insights from the Global Biodiversity Framework-related Decisions', *LSE Law School Policy Briefing 53/2023*, p. 5, available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4343130#.

[45] New York, NY (United States), 19 June 2023, not yet in force, available at: https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXI-10&chapter=21&clang=_en.

[46] Ibid., Arts 9–16.

[47] Rome (Italy), 3 Nov. 2001, in force 29 June 2004, available at: https://www.fao.org/plant-treaty/en.

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operational details of the multilateral mechanism remained unresolved. This includes the questions of how the multilateral mechanism would interact with the Nagoya ABS Protocol, which establishes a system based on bilateral transactions between providers and users of genetic resources, or how it would interact with national ABS measures, as well as the rights of Indigenous peoples over their traditional knowledge and genetic resources. Most importantly, the decision glosses over questions of patents and other intellectual property rights. The interface between ABS and intellectual property has been extraordinarily controversial in both the CBD and intellectual property forums, including the World Trade Organization and the World Intellectual Property Organization (WIPO).[48] The WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge,[49] concluded in May 2024 after almost 25 years of negotiations, is the first international instrument to address this interface. Albeit remarkable as an achievement for establishing a mandatory disclosure requirement of the origin or source of genetic resources and traditional knowledge in patent applications,[50] the WIPO Treaty takes a narrow approach to this requirement and is silent on patents based on DSI, although most patents concerning genetic resources are based on DSI.[51]

The operational modalities of the CBD global multilateral benefit-sharing mechanism were adopted at COP16 in 2024.[52] A surprisingly horizontal approach to benefit-sharing from DSI is put forward: DSI users in sectors that directly or indirectly benefit from its use in their commercial activities should contribute to the newly established 'Cali Fund', depending on their size.[53] These sectors involve pharmaceuticals, cosmetics, and animal and plant breeding, among others.[54] At the same time, the potential effectiveness of this admittedly broad approach is jeopardized by multiple layers of imprecision and legal uncertainty. While implementation in any case rests with national governments and requires national legislation or policies, the decision uses weak legal language that does not correspond to any clear obligation: parties and non-parties are *invited* to take administrative, policy or legislative measures, *consistent with national legislation*, to *incentivize users* in their jurisdiction to contribute to the Fund.[55] The assimilation of parties and non-parties further accentuates the absence of any legal obligation to implement. In addition, the basis of

[48] K. Raustiala & D.G. Victor, 'The Regime Complex for Plant Genetic Resources' (2004) 58(2) *International Organization*, pp. 277–309.

[49] Geneva (Switzerland), 24 May 2024, not yet in force, available at: https://www.wipo.int/edocs/mdocs/tk/en/gratk_dc/gratk_dc_7.pdf.

[50] Ibid., Art. 3.

[51] Third World Network (TWN), 'TWN Info Service on Intellectual Property Issues', 28 May 2024, available at: https://twn.my/title2/intellectual_property/info.service/2024/ip240506.htm.

[52] CBD COP, Decision 16/2, 'Digital Sequence Information on Genetic Resources', 1 Nov. 2024, UN Doc. CBD/COP/DEC/16/2.

[53] Ibid., Annex: Modalities for Operationalizing the Multilateral Mechanism for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources, including a Global Fund, para 3.

[54] Ibid., Enclosure I: Indicative List of Sectors that May Benefit Directly or Indirectly from the Use of Digital Sequence Information on Genetic Resources.

[55] Ibid., Annex, para. 13 (emphasis added).

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benefit-sharing contributions is highly uncertain: both the rates for benefit-sharing contributions by users, as well as the list of sectors that benefit from DSI use, are merely indicative.[56] This imprecise and open-ended legal wording aims to allow a high degree of flexibility for national implementation in an effort to reach intergovernmental consensus on a divisive policy matter. It is questionable, however, whether this lack of precision can promote effectiveness in implementation, and this is implicitly acknowledged in the decision, with a process for review of effectiveness to begin at COP18.[57] Overall, the wording of the decision reveals parties' reluctance to assume any legal obligations with regard to benefit-sharing from DSI use, which stands in contrast with the Nagoya Protocol negotiations 15 years ago.

In the next section, we continue by examining policy developments on LMOs, the outcome of biotechnological innovation that is often commercialized and released into the environment, which have been on the CBD agenda since its inception.

4. Risk Assessment of Living Modified Organisms

LMOs have been used in an increasing variety of contexts since the early 1990s. Agriculture has seen a rapid rise in the cultivation of living modified (LM) crops over the past three decades, particularly in South and North America, and LM fish are produced in commercial aquaculture.[58] LMOs are also used in industrial applications, such as for the production of specific enzymes. Some environmental remediation techniques, including for oil spills, revolve around releases of LM bacteria. Emerging applications include the use of LM crops to produce pharmaceuticals, in what is known as 'biopharming'.[59] In the past few years, mass releases of insects genetically engineered for sterility have taken place in Brazil and the United States (US) for the suppression of natural insect populations that cause harmful environmental and health-related impacts, including as vectors for infectious diseases.[60]

Alongside their potential and actual benefits, the risks that LMOs may pose to biodiversity have been a major area of concern under the CBD since its earliest days. Under Article 8(g) CBD, parties must establish and maintain appropriate regulatory frameworks for associated risks, while Article 19.3 commits parties to consider the modalities of a potential biosafety protocol, culminating in the conclusion of the Cartagena Protocol on Biosafety in 2000. The Protocol aims for safety in the transfer, handling, and use of LMOs with potentially adverse impacts on biodiversity.[61]

[56] Ibid., Annex, para. 3.
[57] Ibid., Annex, para. 29.
[58] A.I. Myhr & R.A. Dalmo, 'Introduction of Genetic Engineering in Aquaculture: Ecological and Ethical Implications for Science and Governance' (2005) 250(3–4) *Aquaculture*, pp. 542–54.
[59] P. Ahmad et al., 'Role of Transgenic Plants in Agriculture and Biopharming' (2012) 30(3) *Biotechnology Advances*, pp. 524–40.
[60] A.S. de Campos et al., 'Responsible Innovation and Political Accountability: Genetically Modified Mosquitoes in Brazil' (2017) 4(1) *Journal of Responsible Innovation*, pp. 5–23.
[61] A. Gupta, 'Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety' (2000) 42(4) *Environment: Science and Policy for Sustainable Development*, pp. 22–33.

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It establishes a mechanism for regulating bilateral trade in agricultural LMOs, while also providing rules and guidelines on risk assessment of LMOs.[62] Risk assessment is central to its operation, especially with regard to controls on transboundary movements.[63] The development of international guidance thus contributes to the diffusion of minimum standards and best practices. In the years since adoption, the COP serving as the Meeting of the Parties to the Protocol (MOP) has explored the need for further developing the risk assessment component through a series of decisions as well as intersessional work under ad hoc technical expert groups. In 2018, MOP9 established a structured process for identifying new priority issues for risk assessment.[64]

The discussion following MOP9 focused on two key areas: engineered gene drives and LM fish. Both areas pose biosafety risks that go beyond the scope of existing risk assessment methodologies. Engineered gene drives are genetic modifications that bias inheritance rates and thus allow, in principle, for the large-scale biological control of species with short reproduction cycles.[65] Gene drives are presently under development as possible instruments for disease vector control as well as to combat invasive alien species.[66] LM fish is an area of growing commercial interest, including in the context of marine sustainability, as industry claims that aquaculture keeps overfishing partially in check.[67] Biosafety risks relate to their mobility, the potential for invasiveness and hybridization with wild populations, and crossing of national borders.[68]

The development of risk assessment guidance for these two areas of biotechnological applications links to the regulation of transboundary movements of LMOs under the Biosafety Protocol. In principle, such transboundary movements are subject to the advance informed agreement (in other contexts known as prior informed consent) of the importing party.[69] Parties have the right to require a risk assessment prior to the authorization of any such transboundary movement.[70] The existence of appropriate risk assessment methodologies is thus a precondition for decision-making regarding

[62] Cartagena Protocol on Biosafety, n. 3 above, Art. 15 and Annex III.

[63] F. Rabitz, 'Gene Drives and the International Biodiversity Regime' (2019) 28(3) *Review of European, Comparative & International Environmental Law*, pp. 339–48.

[64] Cartagena Protocol on Biosafety MOP, Decision 9/13, 'Risk Assessment and Risk Management (Articles 15 and 16)', 30 Nov. 2018, UN Doc. CBD/CP/MOP/DEC/9/13.

[65] Committee on Gene Drive Research in Non-Human Organisms: Recommendations for Responsible Conduct; Board on Life Sciences; Division on Earth and Life Studies; National Academies of Sciences, Engineering, and Medicine, *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty and Aligning Research with Public Values* (National Academies Press, 2016).

[66] J. Godwin et al., 'Rodent Gene Drives for Conservation: Opportunities and Data Needs' (2019) 286(1914) *Proceedings of the Royal Society B*, article 20191606-15.

[67] S.B. Longo et al., 'Aquaculture and the Displacement of Fisheries Captures' (2019) 33 *Conservation Biology*, pp. 832– 41.

[68] A.S. Okoli et al., 'Sustainable Use of CRISPR/Cas in Fish Aquaculture: The Biosafety Perspective' (2021) 31 *Transgenic Research*, pp. 1–21; Cartagena Protocol on Biosafety Ad Hoc Technical Expert Group on Risk Assessment, 'Report of the Ad Hoc Technical Expert Group on Risk Assessment', 15 Apr. 2020, UN Doc. CBD/CP/RA/AHTEG/2020/1/5.

[69] Cartagena Protocol on Biosafety, n. 3 above, Arts 7–10.

[70] Ibid., Art. 15.

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the environmental release of LMOs such as LM fish, or gene drive systems that are plausibly prone to transboundary migration.[71]

In 2022, MOP10 decided to proceed with the development of voluntary risk assessment guidance for gene drive systems with the focus on gene drive mosquitoes, but not for LM fish.[72] MOP11, in 2024, 'welcomed' the voluntary guidance materials developed through an Ad Hoc Technical Expert Group[73] and did not identify further areas in need of specific guidance for risk assessment.[74] While the MOP left in place the process for the identification of new issues established by MOP9, further rule development on risk assessment under the Cartagena Biosafety Protocol has ceased for the time being.

A related discussion emerged on the basis of a recommendation by the Protocol's Compliance Committee concerning the case of genome-edited plants. Today, genome editing is increasingly used as a plant breeding technique, which uses genetic pathways for obtaining outcomes, such as induced mutagenesis, which are at the core of conventional (non-genetic) techniques. As these so-called new genomic techniques do not involve the insertion of foreign DNA, there are ongoing debates in the European Union (EU) and elsewhere on the extent to which the resulting organisms fall under LMO regulation.[75] The issue only appeared on the MOP's agenda in 2024, as the Compliance Committee recommended considering the implications of diverging interpretations of the definition of LMO and the varying legislative approaches among parties resulting from developments including genome editing.[76]

The question of whether organisms produced via novel biotechnological techniques of considerable commercial relevance fall within the scope of the Cartagena Biosafety Protocol, and are thus subject to its risk assessment provisions, is of major legal significance. However, stark divergences among parties, mainly between EU Member States and large exporters of LM crops, resulted only in a limited information-gathering exercise. In a further illustration of current limitations on rule development, the MOP *encouraged* parties to submit information regarding relevant national legislation, regulations and guidelines on new developments in modern biotechnology that are not published in the Protocol's Biosafety Clearing House.[77]

[71] Gupta, n. 61 above.

[72] Cartagena Protocol on Biosafety MOP, Decision 10/10, 'Risk Assessment and Risk Management (Articles 15 and 16)', 19 Dec. 2022, UN Doc. CBD/CP/MOP/DEC/10/10.

[73] Cartagena Protocol on Biosafety Ad Hoc Technical Expert Group on Risk Assessment, 'Additional Voluntary Guidance Materials to Support Case-by-Case Risk Assessments of Living Modified Organisms Containing Engineered Gene Drives', 27 Aug. 2024, UN Doc. CBD/CP/MOP/11/9.

[74] Cartagena Protocol on Biosafety MOP, Decision 11/7, 'Risk Assessment and Risk Management', 30 Oct. 2024, UN Doc. CBD/CP/MOP/DEC/11/7.

[75] German Federal Agency for the Protection of Nature, 'For a Science-Based Regulation of Plants from New Genetic Techniques', Policy Brief No. 2, Feb. 2024, available at: https://www.bfn.de/en/publications/policy-brief/science-based-regulation-plants-new-genetic-techniques.

[76] Cartagena Protocol on Biosafety Compliance Committee, 'Report of the Compliance Committee under the Cartagena Protocol on Biosafety on the Work of its Eighteenth and Nineteenth Meetings', 2 May 2024, UN Doc. CBD/CP/MOP/11/3, Annex, para 1.

[77] Cartagena Protocol on Biosafety MOP, Decision 11/1, 'Compliance', 30 Oct. 2024, UN Doc. CBD/CP/MOP/DEC/11/1, Section C.

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In principle, elaboration of additional guidance on risk assessment would ensure synchronization between the Biosafety Protocol and rapid developments in the life sciences that lead to novel types of LMO that have novel risk profiles and are prone to transboundary migration. It is thus remarkable that the only additional such guidance developed so far is limited to gene drive systems for one specific species, mosquitoes, in a manner that may risk duplication with work undertaken in the context of the World Health Organization (WHO)[78] and does not capture the full range of applications that are currently being explored, notably rodents.[79] In addition, while the Ad Hoc Technical Expert Group on Risk Assessment did not see a need for the development of guidance on LM fish, various studies do point to novel biosafety issues with LM fish, as well as other LMOs in the aquatic environment.[80]

Adjustments to the risk assessment regime of the Cartagena Biosafety Protocol have thus been minimal, while the development of LMOs with novel risk profiles is proceeding apace. The limited output that does exist, on gene drive systems in mosquitoes, is normatively weak by design, as implied by its title 'additional voluntary guidance materials' and the fact that the MOP did not 'adopt' it but 'welcomed' it.[81] For the purposes of Article 15 of the Biosafety Protocol, it amounts to a 'recognized risk assessment technique' to be taken into account by governments in their decision-making process. An alternative legal route to address the numerous biosafety issues associated with the emergence of new types of LMO would be to amend or add to the mandatory criteria contained in the Protocol's Annex III. Yet, the MOP has chosen to create non-binding guidance with the focus on a subset of novel biotechnological applications.

Such limitations in agenda-setting, which have an impact on the capacity of the CBD to provide a governance framework for novel biotechnologies, are coupled with limitations in policy development in the field of synthetic biology, explored in the next section.

5. Horizon-Scanning, Monitoring and Assessment of Synthetic Biology

Synthetic biology is an umbrella term used for a wide range of potentially disruptive biotechnological innovations. Areas typically associated with synthetic biology include computer-designed cells synthesized from inorganic components, genetic sequences that incorporate nucleotides which do not exist in nature, directed evolution, metabolic pathway engineering and protein design.[82] There is no scientific

[78] WHO, *Position Statement: Evaluation of Genetically Modified Mosquitoes for the Control of Vector-Borne Diseases* (WHO, 2020); WHO Special Programme for Research and Training in Tropical Diseases and Foundation for the National Institutes of Health, *Guidance Framework for Testing Genetically Modified Mosquitoes* (WHO, 2021).

[79] Godwin et al., n. 66 above.

[80] A. Pott, M. Otto & R. Schulz, 'Impact of Genetically Modified Organisms on Aquatic Environments: Review of Available Data for the Risk Assessment' (2018) 635 *Science of the Total Environment*, pp. 687–98.

[81] Cartagena Protocol on Biosafety MOP, Decision 11/7, n. 74 above, para 2.

[82] CBD Secretariat, 'Synthetic Biology', *CBD Technical Series*, No. 100, Apr. 2022.

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consensus on which technologies should fall within the term, resulting in the lack of an agreed definition.[83] Current CBD work is guided by an operational definition developed in 2016, according to which synthetic biology is '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'.[84] This encompassing definition, in practice, covers any contemporary biotechnological development, ranging from commercialized applications, such as genome-edited plants, to speculative methods for large-scale *in situ* genetic engineering.

Synthetic biology falls fully within the definition of biotechnology under Article 2 CBD as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'. The CBD thus has a clear mandate to engage with its implications for its three objectives. In addition, there are several other CBD provisions relevant to LMOs produced via synthetic biology, such as those on putting in place domestic regulatory frameworks to address risks associated with LMOs, enhancing participation in biotechnological research, and promoting technology transfer and technical and scientific cooperation.[85] Synthetic biology applications also generally fall within the scope of the Cartagena Biosafety Protocol, and are highly relevant for ABS, as noted in the section on DSI. There is thus ample legal basis for the CBD to engage with synthetic biology. Past practice also indicates that the CBD has typically responded to novel biotechnological developments in a robust manner. This includes not only the Cartagena Biosafety Protocol and its Supplementary Protocol on Liability and Redress, but also COP decisions, such as that on genetic use restriction technologies intended to engineer agricultural crops for sterility to enforce intellectual property rights.[86]

The COP first addressed synthetic biology in 2012, when it noted 'the need to consider the potential positive and negative impacts of components, organisms and products resulting from synthetic biology techniques'.[87] In 2014, the COP urged parties to adopt a precautionary approach towards synthetic biology and established an Ad Hoc Technical Expert Group for further assessment during the intersessional period.[88] By 2018, the COP had agreed on a need for broad and regular

[83] European Commission, Scientific Committee on Health and Environmental Risks, Scientific Committee on Emerging and Newly Identified Health Risks & Scientific Committee on Consumer Safety, *Opinion on Synthetic Biology I: Definition* (EU, 2014).

[84] CBD COP, Decision XIII/17, 'Synthetic Biology', 16 Dec. 2016, UN Doc. CBD/COP/DEC/XIII/17, para. 4.

[85] CBD, n. 1 above, Arts 8(g), 16, 18–19.

[86] CBD COP, Decision V/5, 'Agricultural Biological Diversity: Review of Phase I of the Programme of Work and Adoption of a Multi-Year Work Programme', May 2000, UN Doc. UNEP/CBD/COP/5/23, pp. 85–102, at 88–89, paras 19–29. The COP recommended that products incorporating genetic use restriction technologies should not be approved by parties for field testing or commercial use: ibid., para. 27.

[87] CBD COP, Decision XI/11, 'New and Emerging Issues relating to the Conservation and Sustainable Use of Biodiversity', 5 Dec. 2012, UN Doc. UNEP/CBD/COP/DEC/XI/11, para. 3.

[88] CBD COP, Decision XII/24, 'New and Emerging Issues: Synthetic Biology', 17 Oct. 2014, UN Doc. UNEP/CBD/COP/DEC/XII/24.

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horizon-scanning, monitoring and assessment of the most recent technological developments in the field.[89] COP15 established an operational process for broad and regular horizon-scanning, monitoring and assessment, to be supported for one intersessional period by a multidisciplinary Ad Hoc Technical Expert Group (mAHTEG) seeking to ensure a wide range of expertise, yet under terms of reference largely similar to those of its previous incarnation.[90] The work of this mAHTEG resulted, inter alia, in the identification of five priority items for further consideration by parties, including gene drive systems for rapid and large-scale *in situ* genetic engineering, self-spreading vaccines for use in wildlife, and the convergence between synthetic biology and artificial intelligence.

COP16 subsequently gutted the process for horizon-scanning, monitoring and assessment, and merely 'noted' the intersessional work of the mAHTEG.[91] Work on this agenda item during the following intersessional period will revolve primarily around the development of a thematic action plan on capacity-building in synthetic biology. Whereas the COP had previously sought a balanced approach towards the potential negative and positive impacts of synthetic biology vis-à-vis the objectives of the Convention, the COP16 decision gives priority to potential positive impacts and related capacity-building. The lack of any reference to the priority items identified by the mAHTEG further highlights how COP16 has de-prioritized the consideration of biosafety risks and equity challenges associated with synthetic biology.

Several factors have been complicating CBD deliberations on synthetic biology. Firstly, a major debate until COP15 revolved around the question of whether synthetic biology formally constitutes a 'new and emerging issue', which would make it a permanent fixture on the CBD agenda. Because of political disagreements, COP15 crafted a compromise by deciding *not to decide* on the matter.[92] Beneath what appears to be an arcane procedural question lies fundamental disagreement on whether the CBD should address synthetic biology in the first place. A second complicating factor relates to whether synthetic biology should be addressed under the CBD or the Cartagena Biosafety Protocol. Addressing the item under the Protocol would imply a narrow focus on risks of LMOs produced via synthetic biology, while addressing it under the CBD allows a broader perspective on the technological field beyond organisms, including applications and techniques such as artificial intelligence and generative biology, as well as consideration of potential benefit-sharing considerations, alongside risks. As a further indication of the complexity and politicization of the process, some parties at COP16 curiously argued in favour of *both* moving synthetic biology to the Cartagena Biosafety Protocol *and* prioritizing its potential benefits.

Having provided empirical evidence of de-legalization in the context of three critical agenda items linked to biotechnology governance under the CBD and its Protocols, in the following section we explore possible explanations and drivers of this de-legalization trend in the broader institutional and socio-economic context.

[89] CBD COP, Decision 14/19, 'Synthetic Biology', 30 Nov. 2018, UN Doc. CBD/COP/DEC/14/19.
[90] CBD COP, Decision 15/31, 'Synthetic Biology', 19 Dec. 2022, UN Doc. CBD/COP/DEC/15/31.
[91] CBD COP, Decision 16/21, 'Synthetic Biology', 1 Nov. 2024, UN Doc. CBD/COP/DEC/16/21.
[92] CBD COP, Decision 15/31, n. 90 above.

6. Exploring Drivers of the De-legalization of Novel Biotechnology Governance under the CBD

The CBD has historically been more than a classic nature protection instrument. It has addressed diverse politically contentious technological questions over the years, with the rapid pace of innovation raising new regulatory challenges.[93] However, at a time when the use of biotechnologies is expanding and accelerating,[94] CBD policy outcomes at the last two COP meetings appear to shift towards lower stringency in substance and weaker institutionalization in process, indicating that CBD parties distance themselves from biotechnology governance.

A possible explanation of the observed trend is that large steps in international environmental governance are often preceded by smaller ones.[95] The Nagoya ABS Protocol, for instance, was the result of more than a decade of soft law rule-making on the basis of Article 15 CBD,[96] including in the form of the non-binding 2002 Bonn Guidelines on ABS.[97] There is thus merit in considering the steps the CBD has taken in the past decade on DSI, risk assessment, and synthetic biology as necessary preconditions for reaching more robust legal outcomes further down the road. Rather than pointing to incremental regime formation, however, we argue that the post-2010 period is indicative of a de-legalization trend through a progressive softening of the law and governance framework, vague normative content, and limitations in agenda-setting that stand in contrast to the pace of technological development. We explore this argument below with regard to the ABS and the biosafety side of biotechnology governance, in turn.

Part of the broader ABS agenda, the 2022 and 2024 decisions on DSI are a compromise between developed and developing countries, and part of overall 'package deals'. The COP15 package explicitly included the Kunming-Montreal Global Biodiversity Framework and decisions on resource mobilization and monitoring.[98] This is a familiar trend in CBD decision-making. As most developed countries are reluctant to accept benefit-sharing obligations, which would arguably limit their industries' innovation potential, past breakthroughs on ABS have also required 'package deals': the Nagoya ABS Protocol was itself part of a package, which also included the Strategic Plan for Biodiversity 2010–2020 and a decision on

[93] D. Collingridge, *The Social Control of Technology* (Pinter, 1980); R. Wynberg & S.A. Laird, 'Fast Science and Sluggish Policy: The Herculean Task of Regulating Biodiscovery' (2018) 36(1) *Trends in Biotechnology*, pp. 1–3; A. Taeihagh, M. Ramesh & M. Howlett, 'Assessing the Regulatory Challenges of Emerging Disruptive Technologies' (2021) 15(4) *Regulation & Governance*, pp. 1009–19.

[94] UN Conference on Trade and Development (UNCTAD), *Technology and Innovation Report 2021* (United Nations, 2021).

[95] O.R. Young, *Institutional Dynamics: Emergent Patterns in International Environmental Governance* (The MIT Press, 2010), pp. 86–7; J.I. Allan, 'Dangerous Incrementalism of the Paris Agreement' (2019) 19(1) *Global Environmental Politics*, pp. 4–11.

[96] CBD, n. 1 above, Art. 15 (on 'Access to Genetic Resources').

[97] 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization', adopted through CBD COP, Decision VI/24, 19 Apr. 2002, UN Doc. UNEP/CBD/COP/DEC/VI/24.

[98] E. Tsioumani et al., 'Summary of the UN Biodiversity Conference: 7–19 December 2022' (2022) 9(796) *Earth Negotiations Bulletin*, pp. 1–19.

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implementation of the resource mobilization strategy.[99] Yet, COP10 resulted in a legally binding instrument – the Nagoya ABS Protocol – while COP15 resulted in merely a barebones decision on DSI, which established a process forward but lacked both in legal obligation and in legal precision, as detailed above. While ambitious in reach, the modalities of the global multilateral benefit-sharing mechanism adopted at COP16 follow the same direction of intentionally limited obligation and precision, which will have an impact on implementation and effectiveness.

On the ABS front, there is at least consensus among parties to continue with a process going forward on DSI. By contrast, on the biosafety front, influential member states are making sustained efforts to curtail the CBD's biosafety agenda in unprecedented ways. The proceedings of the meetings of both the COP and the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) provide evidence in that respect.[100] Notably, the Kunming-Montreal Global Biodiversity Framework does not contain a single reference to precaution, and its 'target' on biosafety is not a real target but merely repeats Convention language.[101] Reference to synthetic biology was dropped during the negotiations, following consistent opposition by a number of parties, despite its dominance in contemporary life sciences. No biosafety-related decision was considered prominent enough to make it into a 'package deal'.

One way of examining the drivers of the observed trend is to start by reversing the question and ask why the CBD engaged with it in the first place. For one, the global politics of biotechnology have become considerably messier since the 1990s. Back then, biotechnological research, development and innovation were marginal or non-existent in most developing countries, leading them to oppose at the international level a technological field likely to entail substantial commercial advantages for large exporters of agricultural commodities but risks for importers and more diverse agricultural economies. At the time, the European Union pushed for precautionary international regulation to reflect its own stringent regulatory framework, developed as a result of broad societal concerns, as well as to address its lack of competitiveness vis-à-vis the US, Canada, and a handful of others.[102]

[99] E. Tsioumani et al., 'Summary of the Tenth Conference of the Parties to the Convention on Biological Diversity: 18–29 October 2010' (2010) 9(544) *Earth Negotiations Bulletin*, pp. 1–28; S. Oberthür & F. Rabitz, 'On the EU's Performance and Leadership in Global Environmental Governance: The Case of the Nagoya Protocol' (2014) 21(1) *Journal of European Public Policy*, pp. 39–57.

[100] E. Tsioumani et al., 'Summary of the 2024 UN Biodiversity Conference: 21 October–1 November 2024' (2024) 9(855) *Earth Negotiations Bulletin*, pp. 1–21; A. Tsioumanis et al., 'Summary of the 26th Meeting of the Subsidiary Body on Scientific, Technical and Technological Advice and the 4th Meeting of the Subsidiary Body on Implementation of the Convention on Biological Diversity: 13–29 May 2024' (2024) 9(836) *Earth Negotiations Bulletin*, pp. 1–25.

[101] Kunming-Montreal Global Biodiversity Framework, n. 9 above, Target 17.

[102] E. Tsioumani, 'Genetically Modified Organisms in the EU: Public Attitudes and Regulatory Developments' (2004) 13(3) *Review of European, Comparative & International Environmental Law*, pp. 272–88; R. Falkner, 'The Political Economy of "Normative Power" Europe: EU Environmental Leadership in International Biotechnology Regulation' (2007) 14(4) *Journal of European Public Policy*, pp. 507–26.

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Over the years, the landscape of both the regulation and political economy of biotechnology has changed. In a significant change of course, with conflicts deepening among its Member States, the EU is currently considering deregulating at least some genome-edited crops,[103] thus excluding them from the requirements of its regulatory framework on genetically modified organisms.[104] Monsanto, once the epitome of the aggressive and potentially unsafe exploitation of novel biotechnological methods within the lenient regulatory environment of the US, was bought by German Bayer AG in 2018. Brazil today is a major powerhouse in biotechnology, in agriculture and beyond, and appears to prefer the CBD to pull back from biotechnology regulation.[105] China and India have become major players in agricultural and pharmaceutical biotechnology. The African Union has been addressing novel biotechnologies, including genome editing, with a focus on their development and agricultural productivity potential.[106] Some African countries, as well as Australia and New Zealand, are considering gene drives as potential options for addressing vector diseases or biological invasions. Only a handful of civil society organizations currently push for precautionary biotechnology regulation by the CBD. Instead, the emphasis has shifted towards the sharing of the benefits of technological innovation, including biotechnology, and away from the regulation of risks. The COP16 decision on synthetic biology, focusing mainly on the development of a capacity-building plan, is a testament to that.

These changes also reflect a shift in societal discourse: the attention of environmental movements has largely shifted away from LMOs and towards climate change. The industry has long been advocating the supposed benefits of biotechnology for climate adaptation, further arguing that more than 30 years of experience with agricultural biotechnologies have relieved many of the fears regarding environmental risks. Yet, questions of biosafety have become more significant with recent biotechnological developments, while questions of corporate power, market consolidation, and ownership of intellectual property rights remain central for the fair and effective global governance of biodiversity and biotechnology alike. In the current context of extreme patent expansion and market concentration in the agro-chemical sector,[107] industrialized agriculture is among the main drivers of biodiversity

[103] European Commission, 'Proposal for a Regulation of the European Parliament and of the Council on Plants Obtained by Certain New Genomic Techniques and Their Food and Feed, and amending Regulation (EU) 2017/625', 5 July 2023, COM(2023) 411 final; S. Sanchez Manzanaro, 'EU Split on Deregulating Gene-Edited Food as Council Deadlock Persists', *Euractiv*, 26 June 2024, available at: https://www.euractiv.com/section/agriculture-food/news/italys-first-gene-edited-crop-trial-sabotaged-as-deadlock-on-new-eu-rules-persists.

[104] See H.-G. Dederer & D. Hamburger (eds), *Regulation of Genome Editing in Plant Biotechnology: A Comparative Analysis of Regulatory Frameworks of Selected Countries and the EU* (Springer, 2019).

[105] Based on participant observation of the negotiations. See also TWN, 'Biodiversity Meeting Agrees on Limited Action on Technology and Synthetic Biology', 27 Dec. 2022, available at: https://www.twn.my/title2/biotk/2022/btk221206.htm.

[106] African Union High Level Panel on Emerging Technologies, 'Policy Framework for Applications of Genome Editing in African Agriculture', Sept. 2022, available at: https://www.nepad.org/publication/policy-framework-applications-of-genome-editing-african-agriculture.

[107] International Panel of Experts on Sustainable Food Systems (IPES-Food), 'Too Big to Feed: Exploring the Impacts of Mega-Mergers, Consolidation and Concentration of Power in the Agri-Food Sector', Oct 2017 available at: https://www.ipes-food.org/_img/upload/files/Concentration_FullReport.pdf.

loss, while the ABS approach alone fails to deliver tangible benefit-sharing streams to promote biodiversity conservation and address global inequities.[108] The case of gene drives exemplifies the combination of socio-economic and environmental risk. A controversial novel biotechnology with significant biosafety risks, gene drives are promoted to have a potentially transformative impact on sustainable development challenges relevant to the developing world. However, the first systematic account of its organizational structure has shown that global gene drive research has limited organizational and geographical diversity and is firmly dominated by elite US-based organizations,[109] posing the question of who reaps the benefits and who bears the risks.

The course of the CBD also needs to be considered in the context of regime complexity, as multiple and partially overlapping international institutions address related issues. The ABS landscape has become increasingly complex. ABS has become the 'go-to' solution for international negotiators, having provided space for discussions on equity and justice in bio-based innovation.[110] DSI on genetic resources is thus under consideration in several forums addressing access to genetic resources for research and development purposes beyond the CBD and its Nagoya ABS Protocol, including the ITPGRFA, the WHO Pandemic Influenza Preparedness Framework,[111] and the WHO Pandemic Agreement.[112] The BBNJ agreement contains legally binding and far-reaching ABS rules addressing both marine genetic resources and associated DSI.

Various organizations have also been addressing biosafety issues as part of their mandate. The WHO has developed technical guidance on risk assessment of genetically modified mosquitoes;[113] and the Food and Agriculture Organization of the United Nations (FAO), which has been addressing LM fish in its technical work, was invited by the UN General Assembly to provide guidance on the potential risk and effects of genetically engineered fish species on wild fish stocks and biodiversity.[114] The International Union for the Conservation of Nature (IUCN) has also been addressing conservation aspects of synthetic biology for several years.[115]

[108] Frison & Tsioumani, n. 40 above, pp. 122–38.

[109] F. Rabitz, 'The Organizational Structure of Global Gene Drive Research' (2024) 84 *Global Environmental Change*, article 102802-814.

[110] S. Laird et al., 'Rethink the Expansion of Access and Benefit Sharing' (2020) 367(6483) *Science*, pp. 1200–2.

[111] World Health Assembly (WHA) Resolution WHA64.5 and Annex 2, 'Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits', 24 May 2011.

[112] Geneva (Switzerland), 20 May 2025, available at: https://apps.who.int/gb/ebwha/pdf_files/WHA78/A78_R1-en.pdf.

[113] See WHO, n. 78 above.

[114] UN General Assembly Resolution 78/68, 'Sustainable Fisheries, including through the 1995 Agreement for the Implementation of the Provisions of the UN Convention on the Law of the Sea of 10 December 1982 relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks, and Related Instruments', 5 Dec. 2023, UN Doc. A/RES/78/68, para. 48.

[115] K.H. Redford et al. (eds), *Genetic Frontiers for Conservation: An Assessment of Synthetic Biology and Biodiversity Conservation* (International Union for the Conservation of Nature, 2019).

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This regime complexity raises risks of fragmentation while underscoring needs for coordination and cooperation.[116] The CBD Working Group on benefit-sharing from DSI use acknowledged such needs,[117] with an inter-forum body or process on DSI being proposed as a way to facilitate coordination and ensure mutual supportiveness.[118] At COP16, parties opted for a clause on mutual supportiveness, including an invitation for collaboration with the multilateral mechanism, 'to avoid the stacking of obligations and, where appropriate, to streamline processes'.[119] COP decisions frequently refer to the need to pursue 'coordinated and non-duplicative' approaches,[120] with the expectation that parallel policy processes would transition from initial inconsistencies and tensions between the relevant international institutions to a distinct division of labour, whereby respective institutional jurisdictions are clearly demarcated.[121] At the same time, the failure of the CBD in making substantive progress on DSI, risk assessment, and synthetic biology may jeopardize its central role in the wider governance architecture for bio-based innovation.[122] One implication of de-legalization may thus be a trend towards decentralization, as the CBD increasingly abdicates its coordinating and orchestrating institutional function in these issue areas.[123]

7. Conclusion

In this article we argue that, in the past decade, the engagement of CBD parties with pressing biotechnological developments of potential relevance to CBD objectives follows a de-legalization trend, with limitations in agenda-setting and outcomes being weak in substance and process. To confirm this, we analyze the results of the last two

[116] International Law Commission (ILC), 'Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law', 13 Apr. 2006, UN Doc. A/CN.4/L.682, and ILC, 'Conclusions of the Work of the Study Group on the Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law' (2006) *Yearbook of the International Law Commission*, Vol. II Pt 2, pp. 177–84.

[117] 'Report of the Ad Hoc Open-ended Working Group on Benefit-Sharing from the Use of Digital Sequence Information on Genetic Resources on its First Meeting', 18 Nov. 2023, UN Doc. CBD/WGDSI/1/3, para. 61.

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COP meetings, focusing on three key issues: DSI, risk assessment of LMOs, and synthetic biology. These items cover the broad scope of CBD involvement in the value chain of biotechnological innovation and aim to follow technological advances which pose both risks and opportunities for the three CBD objectives. We explore this trend in the light of scholarship on legalization and de-legalization, including the softening of international law; and discuss potential drivers in the changing socio-economic and regulatory landscape of biotechnology, including in the context of regime complexity.

While a range of international organizations and processes address specific aspects of biotechnological innovation, either at the ABS or at the biosafety side of the value chain, no other international forum has the overarching reach and collective expertise of the CBD in biotechnology-related issues. In addition, given the CBD's history, near-universal application, and inclusive culture, a change of course towards weaker policy outcomes carries the risk that opportunities will remain unrealized for fair and effective biodiversity management, and that the environmental and socio-economic risks of recent technological developments will remain unmitigated. Our analysis thus serves as an argument for increased engagement of CBD parties with biotechnological developments. Such engagement would enhance international capacities for the precautionary regulation of novel biosafety risks and for achieving fairness and equity in the context of digitalization in the life sciences, while embracing potential opportunities for leveraging novel biotechnologies for biodiversity policy and sustainable development more broadly, including through knowledge-sharing or technology transfer.

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