

# **The Best of Both Worlds: Implications of the Kunming-Montreal Global Biodiversity Framework on Open-Access Digital Sequence Information and Benefit-Sharing**

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## Introduction

The United Nations Biodiversity Conference (COP15) ended in Montreal, Canada, on December 19, 2022, with a landmark agreement to guide global action on nature through to 2030.<sup>1</sup> The Kunming-Montreal Global Biodiversity Framework (GBF) aims to address biodiversity loss, restore ecosystems, and protect indigenous rights.<sup>2</sup> More specifically, the GBF has four overarching global goals: (A) halting human-induced extinction of threatened species and reducing the rate and risk of extinction of all species tenfold by 2050; (B) using and managing biodiversity sustainably to ensure that nature's contributions to people are valued, maintained and enhanced; (C) sharing of the benefits from the utilization of genetic resources and digital sequence information (DSI) on genetic resources in a fair and equitable way, and protection of traditional knowledge associated with genetic resources; and (D) ensuring that adequate means of implementing the GBF are accessible to all Parties, and in particular the Least Developed Countries and Small Island Developing States.<sup>3</sup> The GBF includes a pledge to conserve 30% of the world's lands, freshwater, and ocean resources by 2030, and also allows for the creation of an open-access platform for sharing gene sequences as well as a new benefit-sharing mechanism.<sup>4</sup> Benefit-sharing is an exchange between those who grant access to

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<sup>1</sup> U.N. Environment Programme, COP 15 Ends with Landmark Biodiversity Agreement (Dec. 20, 2022), <https://www.unep.org/news-and-stories/story/cop15-ends-landmark-biodiversity-agreement> [<https://perma.cc/S2M8-ZL3G>].

<sup>2</sup> Id.

<sup>3</sup> U.N. Environment Programme, CBD/COP/15/L.25, at 30 (Dec. 18, 2022).

<sup>4</sup> Id.

genetic resources and those who provide benefits, rewards or compensations resulting from the use of the genetic resources.<sup>5</sup>

This report will focus on the part of the GBF that addresses sharing benefits from the use of DSI. The first section of the report will discuss why DSI is so important, the relevant international agreements dealing with this subject matter, and the policy positions of various stakeholders leading up to the GBF. The second section of the report will analyze the implications of the new framework on open-access DSI and benefit-sharing, as well as the current recommendations for the newly proposed benefit-sharing mechanism.

### Leading up to the GBF

The part of the GBF addressing DSI and benefit-sharing is the least understood part of the framework and is somewhat controversial.<sup>6</sup> This is largely because the DSI concept is still relatively new, and the technology utilized is still in its early stages.<sup>7</sup> Despite this, a significant majority of recent advances in biology, medicine, and agriculture were achieved by the sharing and mining of freely accessible DSI.<sup>8</sup> The reason why is because DSI, which refers to the digital mapping of DNA or RNA genomes, enables new product development in areas ranging from cosmetics, medicines, conservation, and food security without the physical exchange of biological samples.<sup>9</sup> Hundreds of billions of sequences are stored in public databases which are accessed by researchers in the public and private sector for scientific research.<sup>10</sup> Moreover, conservation efforts, medical research, ecosystem restoration, and sustainable agriculture are all

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<sup>5</sup> Bege Dauda and Kris Dierickx, *Benefit Sharing: An Exploration on the Contextual Discourse of a Changing Concept*, 14 BMC MED. ETHICS 36 (2013).

<sup>6</sup> Stefan Anderson, *Sweeping New Global Biodiversity Deal Sets Out Plan for Sharing Gene Sequences*, HEALTH POLICY WATCH (Dec. 20, 2022), <https://healthpolicy-watch.news/biodiversity-deal-outlines-an-open-access-digital-sequence-information-paradigm/> [https://perma.cc/AG6H-QCZ2].

<sup>7</sup> Id.

<sup>8</sup> Sylvian Aubry, *The Future of Digital Sequence Information for Plant Genetic Resources for Food and Agriculture*, 10 FRONTIERS IN PLANT SCI. 1046 (2019).

<sup>9</sup> Supra, note 6.

<sup>10</sup> Id.

heavily reliant on DSI published on these databases.<sup>11</sup> It is because of the growing use of the technology, resulting in successful research and commercial developments, that concerns were raised about how to ensure fair and equitable compensation for their use in commercial products.<sup>12</sup>

The two international agreements, or more precisely, legal authorities, that historically address access to genetic resources and benefit-sharing, are the UN Convention of Biodiversity (CBD)<sup>13</sup> and the Nagoya Protocol on Access and Benefit-Sharing<sup>14</sup>. The CBD was entered into force in 1993 and its objectives are (1) the conservation of biological diversity (genetic diversity, species diversity and habitat diversity); (2) the sustainable use of biological diversity; and (3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.<sup>15</sup> The Nagoya Protocol, entered into force in 2014 and specifically addressing aim 3 of the CBD, aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way.<sup>16</sup> In both agreements, the phrase “utilization of genetic resources” is defined the same way.<sup>17</sup> At first glance, it appears that DSI falls under the definition of “genetic resources,” however, there are still technical concerns surrounding including DSI in that definition.<sup>18</sup>

Leading up to the drafting of the GBF, there were many proposals and opinions from various stakeholders on how to approach access to DSI and benefit-sharing.<sup>19</sup> Biodiversity rich countries (typically lower-and-middle income (LMIC)) prioritized increased benefit-sharing because they believe their sovereign rights would be undermined if potential monetary gains

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<sup>11</sup> Id.

<sup>12</sup> Supra, note 8.

<sup>13</sup> U.N. Environment Programme, Convention on Biological Diversity, May 6, 1992, 1760 U.N.T.S. 79.

<sup>14</sup> U.N. Environment Programme, 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, Dec. 29, 2010, 2008 U.N.T.S.

<sup>15</sup> Supra, note 13, at art. I.

<sup>16</sup> Supra, note 14.

<sup>17</sup> Supra, note 13 and note 14. (Both define “genetic resources” as “genetic material of actual or potential value,” and “genetic material” as “any material of plant, animal, microbial or other origin containing functional units of heredity.”)

<sup>18</sup> Supra, note 6.

<sup>19</sup> Id.

from DSI through commercialization are not shared back to them, as they otherwise would be with a genetic resource.<sup>20</sup> The scientific community prioritized open access to DSI because it enables efficient and broad scale knowledge generation that efficiently advances developments in a variety of scientific fields.<sup>21</sup> Business organizations prioritized fewer overall benefit-sharing obligations because of the impact more obligations would have on their ability to develop products for commercial use.<sup>22</sup> Specifically, the pharmaceutical industry made it clear that they wanted the agreement to exclude pathogens from benefit-sharing rules because those obligations would hinder their ability to develop vaccines, treatments, and diagnostics.<sup>23</sup> However, pathogens are considered to be part of global biological diversity and, as such, fall under the mandate of the CBD.<sup>24</sup> Ultimately, the GBF established, “a multilateral mechanism for benefit-sharing from the use of [DSI] on genetic resources, including a global fund.”<sup>25</sup>

### Analysis: Implications of Current Proposals

Concerns from private industry about expanding benefit-sharing to DSI utilization stem from the access and benefit (ABS) rules outlined in the Nagoya Protocol.<sup>26</sup> These ABS rules are at the core of the benefit-sharing objectives found in all of the agreements.<sup>27</sup> Biodiverse countries (typically LMIC) grant access to their genetic resources to public and private sector scientists that use the genetic resources in exchange for a share of the benefits or compensations that come from using those genetic resources.<sup>28</sup> Pharmaceutical industry experts at the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) claim that, in practice,

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<sup>20</sup> Amber Hartman Scholz et al., *Multilateral Benefit-Sharing from Digital Sequence Information Will Support Both Science and Biodiversity Conservation*, 13 NATURE COMM'NS 1086 (2022).

<sup>21</sup> Id.

<sup>22</sup> KNOWLEDGE SOLS. DEP'T, INT'L CHAMBER OF COM., DIGIT. SEQUENCE INFO. AND BENEFIT SHARING 1 (2019).

<sup>23</sup> Press Release, Int'l Fed'n of Pharm. Mfrs. and Ass'ns, Multilateral Framework to Nurturing Future Biodiversity Welcomed, Despite No Acknowledgement Yet of the Importance for Glob. Health Sec. to Exempt Pathogens (Dec. 20, 2022).

<sup>24</sup> Supra, note 6.

<sup>25</sup> U.N. Environment Programme, CBD/COP/15/L.30, at 16 (Dec. 18, 2022).

<sup>26</sup> Statement, Int'l Fed'n of Pharm. Mfrs. and Ass'ns, Call for Special Pathogen Sharing Measures to be Included in COP15 Digital Sequence Information Negotiations (Dec. 7, 2022).

<sup>27</sup> Supra, note 20.

<sup>28</sup> Id.

this approach “greatly restricts the speed, certainty, and ease at which pathogens can be shared.”<sup>29</sup> Under the existing framework, ABS rules set obligations for the use of genetic resources through mutually agreed terms between a country and user.<sup>30</sup> IFPMA suggests that to ensure immediate and unhindered pathogen sharing, a crucial piece of global public health security and pandemic preparedness, a public health exemption to ABS rules should be applied.<sup>31</sup> On the other hand, Knowledge Ecology International, a group dedicated to access to knowledge and medicines, wants to ensure that while IFPMA members have access to shared information on pathogens, they also share their knowledge assets to avoid unfairness.<sup>32</sup>

Despite this ongoing and rigorous debate, the GBF has only indicated that there will be a multilateral mechanism for benefit-sharing from DSI use but has not articulated what that mechanism will look like.<sup>33</sup> In an effort to compromise, some groups have indicated that the path forward will be creating new benefit-sharing mechanisms that do not limit open access to DSI.<sup>34</sup> One proposed new mechanism involves the “decoupling” of DSI and benefit-sharing.<sup>35</sup> DSI Scientific Network, describing the proposed mechanism, indicated that “access to DSI from genetic resources is ‘decoupled’ from benefit-sharing from the use of DSI because payment would not be triggered by access to the databases but rather downstream at the point of commercialization or retail.”<sup>36</sup> This mechanism still allows for open access to DSI in real-time without needing to establish mutually agreed terms, but also allows for benefit-sharing at the point of commercialization through a multilateral fund that collects various financial contributions stemming from using DSI.<sup>37</sup>

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<sup>29</sup> Supra, note 26.

<sup>30</sup> Supra, note 22.

<sup>31</sup> Id.

<sup>32</sup> Supra, note 6.

<sup>33</sup> Id.

<sup>34</sup> Supra, note 20.

<sup>35</sup> Id.

<sup>36</sup> Id.

<sup>37</sup> Id.

The vague language of the GBF proposal reflects a larger problem within international agreements that attempt to strike a balance between public and private interests or global north and global south power struggles. It is no surprise that open access to DSI is not controversial, because it results in effective and efficient scientific developments that can be later commercialized. The problem arises when the chickens come home to roost – less developed, biodiverse countries want their piece of the pie, but industry is not willing to pony up. Taxing the profits of commercialized products that come out of using DSI would certainly be an equalizing force. On the other hand, industry might not be able to raise capital from investors because returns would not be as high after making payments to the multilateral fund—ultimately hindering research and development.

Nonetheless, it appears that the establishment of a multilateral fund in this context might be a sign of things to come in international law, more broadly. Key questions still remain regarding how the financial contributions will be made. Will they be voluntary or mandatory? Will they be collected as a tax, royalty, or a dividend? Many of these answers are still being negotiated and there is a long way to go until a concrete mechanism is implemented.

### Conclusion

It is not the first time, nor the last, that there will be rigorous debate and deliberations over a promising and controversial provision in an international agreement. The introduction of DSI has changed the world for the better with the amount of research and development that has come from its growing utilization. International law is merely catching up to these advances. Despite the uncertainty, the GBF has created an opening for a novel and innovative mechanism that guarantees open access to crucial scientific information while also ensuring equitable benefit-sharing.