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Policy Briefing

SUSTAINABLE MICROBIOLOGY OXFORD

Policy Briefing: from access to use—untangling the international legal frameworks that govern microbial resources

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Abstract

The wide geographic distribution of microorganisms, combined with their vast taxonomic and functional diversity, make them indispensable reservoirs of genetic variation that sustain ecosystem resilience and fuel biotechnological innovation. However, to use this diversity, microbiologists must navigate a complex legal and regulatory landscape governed by multiple United Nations treaties and their respective access and benefit-sharing frameworks as well as regulatory frameworks specific to particular ecosystems, biosecurity, pathogens, and intellectual property. This complex regulatory web is also actively growing and changing, which makes it immensely challenging for a "regular" microbiologist to navigate. For policymakers and negotiators, it is also difficult to appreciate the full complexity that practitioners experience. This policy briefing provides a concise regulatory guide for practitioners and policymakers alike, summarized in a graphical overview, to provide more clarity and understanding for those at the edge of decision-making and practice.

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Sustainability statement

Global microbial research, powered by the planet's vast and diverse microbial genetic resources, has the potential to accelerate progress across many United Nations Sustainable Development Goals (SDGs). In this policy briefing, we focus on the need to balance scientific advancement with environmental protection and social justice as exemplified by the SDGs' target 15.6 to "Promote fair and equitable sharing of the benefits arising from the utilization of genetic resources and promote appropriate access to such resources, as internationally agreed." We provide a broad overview of how to ensure international access and benefit-sharing frameworks are respected and where and how other legal frameworks for biodiversity conservation, intellectual property, and biosafety regulations complement each other.

Keywords Nagoya Protocol, Convention on Biological Diversity, BBNJ Agreement, World Intellectual Property Organization, Pathogen Access and Benefit Sharing, Pandemic Influenza Preparedness

Microbial diversity on planet Earth is immense. It is estimated that there are between 10^6 and 10^{12} bacterial and archaea taxonomic units on Earth (Louca et al. 2019, Lennon and Locey 2020), of which only a small fraction has been characterized through molecular methods, and an even smaller subset has been successfully isolated in culture (Lewis et al. 2021). Geographical distribution analysis shows that prokaryotes are rarely endemic to individual countries (Overmann and Scholz 2017, Louca 2022), while alongside microalgae and fungi they play a crucial role in global biodiversity, biogeochemical cycling, ecosystem homeostasis (Loreau et al. 2001, Anantharaman et al. 2016, Voolstra et al. 2024), and offer substantial translational potential from One Health interventions and precision agriculture to biotechnological innovations for climate resilience (D'Hondt et al. 2021, Callens et al. 2022, Ibáñez et al. 2023). Over the past decade, to understand complex environmental communities, many microbiologists have focused on "microbiomes" (Berg et al. 2020) to investigate the intricate cross-talk between microscopic and macroscopic life.

Given all of the above, it is common practice to procure environmental samples that represent snapshots of microbial and host communities from soil, water, air, plants, and animals (including humans). Yet, microbes (Gilbert, 2025) and, indeed, all of biodiversity, are regulated by a variety of international legal frameworks that originated from various United Nations (UN) instruments. This policy briefing provides high-level guidance for scientists who must navigate the resulting regulatory complexities and for policymakers who often focus on a single legal framework and thus might overlook the existing policy complexity. The following sections provide brief summaries of each legal instrument which are compiled together in Fig. 1 and complemented by a list of abbreviations and acronyms in Table 1.

All (non-human) biological samples: UN Convention on Biological Diversity

The UN Convention on Biological Diversity (CBD), which entered into force in 1993, is an international treaty with near-universal participation of 196 Parties (Webpage—Convention on Biological Diversity). The CBD's third objective is the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources" (Webpage—Convention on Biological Diversity). The CBD explicitly confirmed that countries have sovereign rights over biodiversity but excludes human genetic resources (i.e. the 23 chromosomes of *Homo sapiens*). National laws governing access to biodiversity emerged from the CBD.

CBD's Nagoya Protocol

The Nagoya Protocol (NP) is a supplementary legally-binding agreement to the CBD (Fig. 1) (Conference of the Parties to the Convention on Biological Diversity 2011). It is the primary international legal framework governing access to and use of most (non-human) biodiversity. It was adopted in 2010 and entered into force in 2014 and creates concrete legal obligations for contracting Parties. The NP is complex to comply with because each country creates its own national framework. It also can create significant legal repercussions. Thus a separate article focused only on the NP appears in this issue (Faggionato, 2026).

CBD's Digital Sequence Information

The CBD and NP address genetic resources, i.e. physical samples. However, in 2016, given the explosion in genetic data stored in open databases (Webpage—INSDC, Karsch-Mizrachi et al. 2024), the question of how commercial outcomes that used these data could and should be shared became a source of tension in the CBD (Rohden and Scholz 2022), which led to negotiations on Digital Sequence Information (DSI)—a policy term that refers broadly to genetic sequence data and potentially other biomolecular information. In 2024, the 16th CBD Conference of the Parties operationalized a new multilateral benefit-sharing mechanism for the use of publicly available DSI including a new global fund, the "Cali Fund", into which large commercial DSI-using entities are expected to begin contributing (Blom et al. 2025). The agreement ensures that DSI databases can remain open access and that academia has no monetary obligations (Muñoz-García et al. 2025, Orozco and Scholz 2025).

The High Seas' BBNJ Agreement: marine genetic resources

The new agreement on "Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction" (aka BBNJ Agreement) (United Nations 2023) under the UN Convention on the Law of the Sea (UNCLOS) was adopted in June 2023 and came into force on January 17, 2026 (Webpage—SDG Knowledge Hub). The BBNJ Agreement includes benefit-sharing provisions for marine genetic resources (MGR) collected from international waters (200 nautical miles offshore) and their DSI.

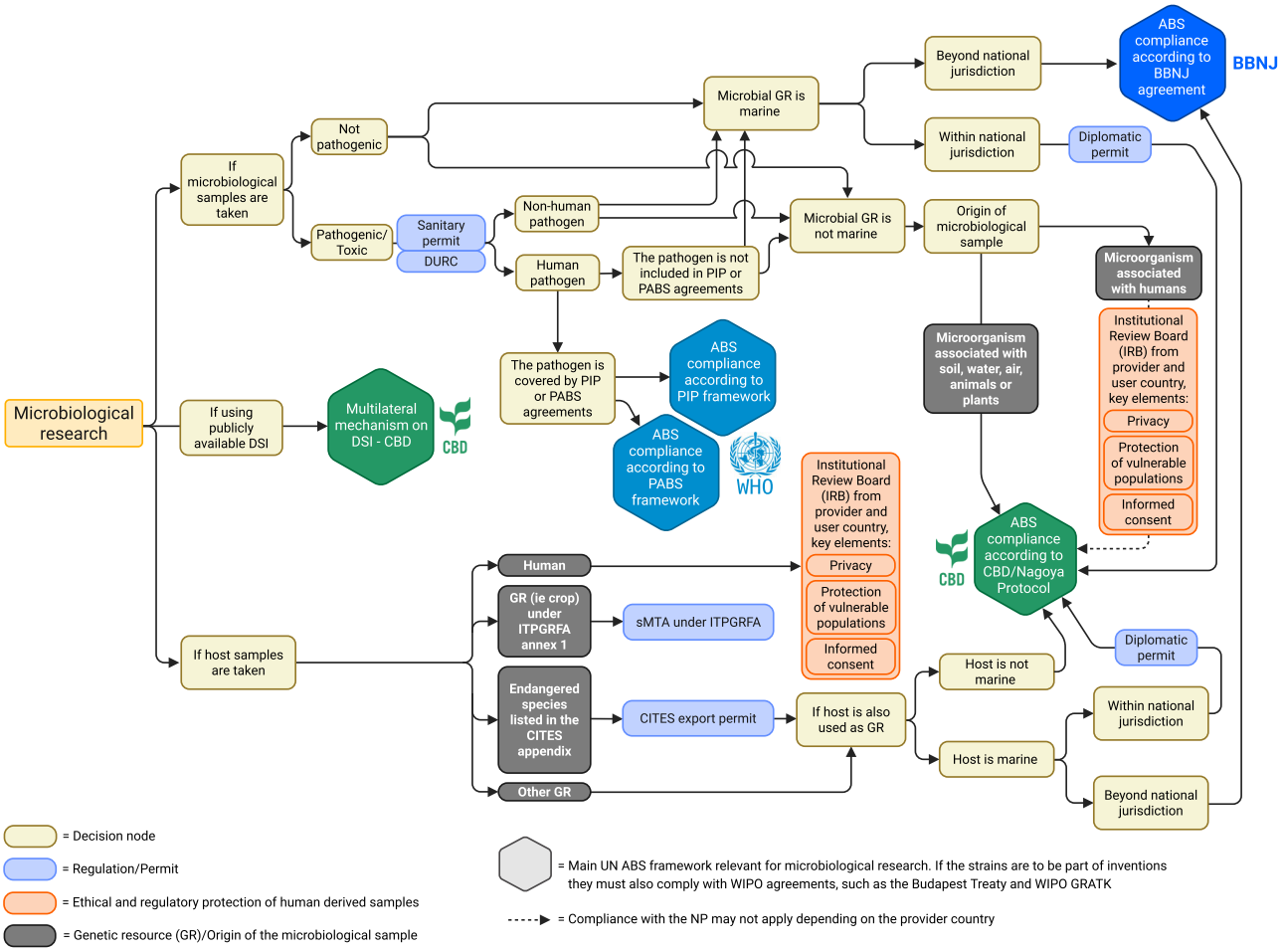

Figure 1 Regulatory landscape governing microbial genetic resources (GR) and their derivatives. Researchers accessing GR must navigate a complex landscape of regulations and permits. Hexagons indicate various access and benefit-sharing (ABS) frameworks. "Microbiological samples" refer to cultures or samples that have not been isolated and may be still associated with their native environment.
Finally, plant or animal-associated samples may fall under further UN multilateral frameworks and require further compliance with the access to or use of their host species. These include the ITPGRFA and CITES (blue ovals). sMTA, Standard Material Transfer Agreement.
Microbial samples may also be subject to additional regulations such as: export controls; diplomatic permits; Dual-use research of concern (DURC) evaluation; or require sanitary certificates (indicated by a blue oval). Some strains may be subject to WIPO treaties. In addition, samples obtained or derived from humans are subject to further ethical and regulatory scrutiny (orange ovals).

Here, microbiologists on a research cruise into the high seas will need to file pre- and post-cruise as well as publication notifications when accessing and utilizing MGR and its DSI. Moreover, researchers need diplomatic permits to enter into the Exclusive Economic Zones (EEZ) of sovereign states and collect biological samples under UNCLOS and NP permits if necessary (Fig. 1).

Microbial "host" samples

Plants

While the CBD covers all of biodiversity, a key exception is the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which establishes a multilateral system for benefit-sharing of 64 of the world's most important crops for food and agriculture (Food and Agriculture Organization of the United Nations 2001). If microbiologists use these plants for their microbial research, they need to follow both the ITPGRFA for the plant (host) by executing a standard Material Transfer Agreement and also potentially the NP for the associated microorganisms (Fig. 1).

Endangered species

For microbial research performed on samples (e.g. blood, tissue, swabs) from endangered or threatened species, the UN Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) applies (Webpage—CITES) (Fig. 1). This is relevant for species listed in any of the CITES appendices even if the focus of the research is on the microbial community and not the host. CITES export permits are required and relatively straightforward to execute (Webpage—CITES Permit system).

Plant pathogens

If working with infectious plant agents, phytosanitary certificates may be required. These are issued by national authorities under the FAO's International Plant Protection Convention (IPPC) to en-

Table 1 Acronyms.

Acronym	Definition
ABS	Access and Benefit-Sharing
aTK	associated Traditional Knowledge
BBNJ Agreement	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
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
DSI	Digital Sequence Information
DURC	Dual-Use Research of Concern
EEZ	Exclusive Economic Zone(s)
EU	European Union
GR	Genetic Resource(s)
INSDC	International Nucleotide Sequence Database Collaboration
IPLCs	Indigenous Peoples and Local Communities
IPPC	International Plant Protection Convention
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IVDR	In Vitro Diagnostics Regulation
MGR	Marine Genetic Resources
NP	Nagoya Protocol
PABS	Pathogens ABS
PIP	Pandemic Influenza Preparedness
SDG	United Nations Sustainable Development Goal
sMTA	Standard Material Transfer Agreement
UN	United Nations
UNCLOS	UN Convention on the Law of the Sea
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WIPO GRATK	WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge

sure plants with potential infectious agents do not cause new outbreaks as they move between borders (Fig. 1) (*Webpage*—IPPC). Beyond plants, other frameworks including the CBD govern invasive species (Shine 2007).

Pandemic flu

The World Health Organization (WHO)'s Pandemic Influenza Preparedness (PIP) Framework is a multilateral ABS instrument which governs pandemic influenza strains (Webpage—WHO PIP Framework) (Fig. 1). Non-commercial researchers can access PIP material through a standard material transfer agreement (SMTA2) from WHO's Global Influenza Surveillance and Response System (GISRS) system (Webpage—WHO GISRS).

Pathogens with pandemic potential

A new WHO treaty, the WHO Pandemic Agreement, was adopted in May 2025 and includes benefit-sharing provisions for pathogens with potential to cause pandemics (Webpage—WHO Pandemic Agreement) (Fig. 1). However, no agreement could be reached on how the pathogen access and benefit-sharing (PABS) system will work (Webpage—Think Global Health). Thus an Intergovernmental Working Group will work until at least May 2026 to agree on topics including which pathogens will be covered, how DSI will be handled, if open access will be maintained, and how databases and collections should handle PABS material and sequences. Once the PABS Annex is agreed, the Pandemic Agreement will be open for ratification.

Dual Use Research of Concern

Pathogens are also in the scope of national and international biosecurity regulations, often referred to as "dual-use research of concern" (DURC). These rules, such as European Regulation No. 2021/821 (European Parliament and Council 2021), aim to ensure that research on/with highly infectious or toxic agents (mainly including pathogens but also proteins and toxins from non-pathogenic cyanobacteria and fungi) will not be used for malignant purposes. Here, microbiologists must consider the pathogenic nature or the presence of toxins in their samples (Fig. 1).

Ethics of human-derived samples

Research involving human-derived microbiome samples must comply with international ethical frameworks such as the Helsinki Declaration and the Oviedo Convention Regulation (Webpage—WMA Declaration of Helsinki, Webpage—Council of Europe), and in the European Union (EU), also with the In Vitro Diagnostics Regulation (IVDR) (EU Reg. 2017/746) and the Data Governance Act (EU Reg. 2022/868) (European Parliament and Council 2017, European Parliament and Council 2022).

World Intellectual Property Organization

Budapest Treaty

In addition to regulations specific to the type and provenance of the samples, if research leads to intellectual property claims, researchers must deposit the corresponding strains in a collection recognized as an International Depositary Authority under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Fig. 1) (Webpage—WIPO Budapest Treaty 1977).

GRATK

Furthermore, a new World Intellectual Property Organization (WIPO) Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (WIPO GRATK) was adopted in May 2024 (Fig. 1). It requires patent applicants to disclose the country of origin of the GR and explicitly acknowledge Indigenous Peoples and Local Communities (IPLCs) who provided associated traditional knowledge (aTK) used to develop the invention (Webpage—WIPO GRATK Treaty). The treaty will enter into force after 15 countries ratify it.

Outlook

The global nature of contemporary microbiological research increasingly requires engagement with a growing array of regulatory frameworks. New frameworks such as the CBD DSI multilateral benefit-sharing mechanism (2024), the BBNJ Agreement (2023), the WHO's PABS framework (2024), and the WIPO GRATK Treaty (2024) represent major new international law that will affect microbiologists. These policy requirements demand early and deliberate institutional planning and may reshape the conditions under which biological samples and data are accessed, shared, and utilized. Research institutions, databases, biobanks, collections, journals, and funders must embed legal and regulatory considerations at the earliest stages of project design, data stewardship, sample management, editorial process, and international collaboration.

At the same time, policymakers must ensure that emerging and existing regulatory frameworks are coherent, practical, and do not inadvertently hinder scientific innovation. A more harmonized and responsive policy ecosystem, developed taking in consideration the experience of the scientific community, will be crucial to ensuring that research can advance responsibly while supporting equitable benefit-sharing and the full realization of the United Nations Sustainable Development Goals (Sett et al. 2025) .

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The figure was generated using biorender.com:

Figure 1: Created in BioRender. Faggionato, D. (2026) https://BioRender.com/t578mte

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Conflicts of interest

No conflict of interest declared.

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Data availability

All relevant data are contained within this article.

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