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Policy in Practice

SUSTAINABLE MICROBIOLOGY OXFORD

Policy in Practice: How to do the Nagoya Protocol: common misconceptions, challenges and best practices for access and benefit-sharing compliance

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Abstract

The Nagoya Protocol establishes an international framework for access and benefit-sharing including for microbial research. Yet many microbiologists have only a vague understanding of what the Nagoya Protocol requires and are unsure how to navigate its complexities, despite the fact that non-compliance can have significant legal consequences and far-reaching reputational and legal impacts. This paper discusses common misconceptions and practical challenges that microbiologists may encounter when complying with the Nagoya Protocol and a step-by-step guide on how to "do" the Nagoya Protocol. We present three case studies to showcase real-life experiences and provide best practice principles for access and benefit-sharing while fostering biodiversity conservation, equitable collaboration, and sustainable innovation.

Sustainability Statement

Compliance with the Nagoya Protocol and applicable national legislation on access and benefit sharing is essential for the responsible use of genetic resources. The elements of the Nagoya Protocol on prior informed consent, mutually agreed terms,

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and fair and equitable benefit sharing were revolutionary and led to the United Nations Sustainable Development Goal 15's Target 15.6: 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. By legally accessing biodiversity and respecting the sovereign rights of provider countries and indigenous peoples and local communities over their genetic resources, the microbiology community will contribute significantly to the advancement of United Nations Sustainable Development Goal 15.

Keywords Nagoya Protocol, Convention on Biological Diversity, access and benefit-sharing, genetic resource, compliance, associated traditional knowledge

Introduction

The days of colonial exploration and a "take what you want" approach to nature and research conduct are long over. Scientific progress cannot be achieved without consideration for the environment, equity, and scientific cooperation at eye-level (Simm 2007, Sirakaya 2022). One key policy instrument to ensure this is the Nagoya Protocol (NP), but many researchers are still unaware of this key legal tool and do not understand what it is nor how it works (Davis et al. 2015, Schneider et al. 2022). Members of this consortium have heard well-regarded scientists confuse the NP with climate change regulation (Kyoto Protocol) or rules governing endangered species. From our experiences at numerous meetings and workshops, we routinely encounter a lack of awareness that biodiversity is governed by this United Nations instrument and every country in the world can have laws in place that govern access to microbial (and other biological) samples.

The consequences of ignoring these legal obligations are concrete and significant. For example, scientific journals and funding agencies increasingly demand proof that genetic resources (GR) (i.e. biological samples) have been accessed and used in compliance with the NP (European Commission, 2021a, German Research Foundation 2021, Marden et al. 2021, Webpage—UiT The Arctic University of Norway 2017). Furthermore, failure to demonstrate compliance can lead to manuscript rejection, grant withdrawal, and damaged professional credibility (Law 2019, 2021, Editor and Publisher of Journal of Natural History 2020, Kim et al. 2020). Beyond the immediate loss of funding or publications, researchers risk long-term reputational harm, loss of collaboration opportunities with countries and communities, and exclusion from future projects. In some cases, violations can carry formal sanctions, fines, and put entire research programs and institutions at risk.

This "policy in practice" paper serves as a blueprint on how to act respectfully and legally in the complex legal environment of Access and Benefit-Sharing (ABS) under the Convention on Biological Diversity (CBD) and its NP (Conference of the Parties to the Convention on Biological Diversity 2011, Webpage—Convention on Biological Diversity, 2025). The CBD and its NP are part of a larger, complex web of international regulation of microbial resources described in a related policy briefing by Faggionato et al. 2026 in this same issue. The principles enshrined in these instruments underlie Sustainable Development Goal (SDG) target 15.6, establishing mechanisms for the fair and equitable sharing of benefits while supporting access to genetic resources (GR) towards the full implementation of the 2030 Agenda for Sustainable Development (Biermann et al. 2017, Weiland et al. 2021). The lens of the authors' consortia is microbiology but the practices are widely applicable to all life scientists. To aid readers in navigating the abbreviations and acronyms used, see Table 1.

History and principles of the Nagoya Protocol

The 1992 CBD's objectives are conservation, sustainable use, and the fair and equitable sharing of benefits arising from the use of biodiversity (Webpage—Convention on Biological Diversity, 2025). The CBD confirms each country's sovereign rights over the biodiversity within their borders, allowing (although not requiring) them to regulate access to GR. However, the details of ABS were not internationally formalized and certainly not standardized. The CBD's NP, which entered into force on October 12, 2014 was intended to solve this problem by providing a binding international legal framework on access to and utilization of GRs, defined as any non-human biological material containing functional units of heredity. The NP also governs *derivatives,* naturally occurring biochemical compounds resulting from the gene expression or metabolism of biological resources, including proteins, lipids and metabolic compounds obtained from GR (Conference of the Parties to the Convention on Biological Diversity 2011).

The NP, while well-intentioned, has garnered a challenging reputation in the research community. This stems from its bilateral nature, meaning agreements are negotiated between a provider (usually a country) and a user of GR (researchers conducting commercial or non-commercial activities). While simple in principle, there is wide variation in how countries have implemented the NP at the national level (Robinson and Von Braun 2019, Chege 2022). This policy-in-practice pieces aims to raise awareness, clarify misconceptions, describe regulatory challenges, and offer practical guidelines for microbiologists.

The main principle of the NP is that users must ask for permission to access GR and/or associated traditional knowledge (aTK) and share benefits with the country from which they were collected and/or with aTK holders (henceforth "providers").

At its core, the NP rests on three pillars:

- **Access:** adherence to national ABS regulations on access to their GR (either *in situ* in country or *ex situ* from a collection) and/or aTK. It may be necessary to obtain Prior Informed Consent (PIC). Countries can decide whether they regulate access to GR or not.
- **Benefit-sharing:** a commitment to share benefits back. It may imply the negotiation of Mutually Agreed Terms (MAT) with the provider(s). Benefits can be monetary (e.g. royalties) or non-monetary (e.g. scientific collaboration) (Conference of the Parties to the Convention on Biological Diversity 2011) which should contribute to the SDG (Normand et al. 2021, Crowther et al. 2024).
- **Compliance**: all parties to the NP must establish measures to ensure that users within their jurisdiction comply with the ABS rules from providers. One example is the EU Regulation No.

Table 1 Acronyms.

Acronym	Definition
ABS	Access and Benefit-Sharing
ABS-CH	ABS Clearing-House
aTK	Associated Traditional Knowledge
CABI	Centre for Agriculture and Bioscience International
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CNA	Competent National Authorities
DEFRA	Department for Environment, Food & Rural Affairs (UK)
EU	European Union
FuEDEI	Fundación para el Estudio de Especies Invasivas
GR	Genetic Resource(s)
ICNP	International Code of Nomenclature of Prokaryotes
IPLCs	Indigenous Peoples and Local Communities
MAT	Mutually Agreed Terms
MAyDS	Ministerio de Ambiente y Desarrollo Sostenible (Ministry of the Environment and Sustainable Development)
MTA	Material Transfer Agreement
NP	Nagoya Protocol
PIC	Prior Informed Consent
SDG	United Nations Sustainable Development Goal
SENASA	Servicio Nacional de Sanidad y Calidad Agroalimentaria (The National Food Safety and Quality Service)
UK	United Kingdom
UN	United Nations
USA	United States of America

511/2014 (European Parliament and Council, 2014 , European Commission 2021b), which establishes obligations for users of GR within the EU and requires national authorities in Member States to implement compliance checks. Despite the requirement, many NP Parties do not have compliance measures but users should still follow national laws in provider countries.

Nagoya Protocol and microbial biobanking

Legal ABS obligations fall on the user who conducts research and development on the GR. However, storage of GR or environmental samples without conducting research is outside the scope of the NP. Nevertheless, biobanks should fulfill international obligations and support the SDGs when distributing such materials. It is good practice to store NP-relevant information, such as the country and date of collection and any associated ABS permits, and to transfer it to the user alongside the biological material. Such practices facilitate future legal utilization because it would be difficult for the final user to obtain relevant NP information from the original depositor without the collection or biobank facilitating it.

Correcting frequent misconceptions about the Nagoya Protocol, the "DOs"

While the principles of ABS and the importance of the NP are straightforward, the requirements are often written in complex legal terms and often only in the local language, making them difficult to understand and follow. Consequently, several misconceptions have emerged within the scientific community over the past decade. In this section, we address common misconceptions and provide clarity on the language of the NP.

Non-commercial academic research is subject to ABS obligations

It is often incorrectly assumed that non-commercial or academic research is exempt from the NP. However, the NP defines the term "utilization" as conducting research and development on the genetic and/or biochemical components of GR (*derivatives*), regardless of the purpose of the research. Although Article 8 of the NP does call for "facilitated access" for conservation, public health, and food security (Conference of the Parties to the Convention on Biological Diversity 2011), many countries do not (yet) have clear provisions that facilitate this type of "public good" research.

Researchers must follow ABS laws of the country where the genetic resource was originally collected—not where it was cultivated or stored

Defining the provider country of a microbial GR is often a source of confusion because of the various ways of accessing microbial GR in practice. The provider country is the one where the material (*in situ* sample) was originally collected. It is *not* the country where the microbial strain was ultimately cultivated or isolated in the laboratory, nor the country of storage (i.e. *ex situ* collection or biobank).

ABS laws often apply to national researchers

Whether ABS regulations apply to domestic researchers varies by country, but often they too must obtain an ABS permit to access and utilize GR within their own country, whether on private prop-

erty or in protected areas. For example, both Brazilians and foreign researchers need to follow Brazilian ABS laws. Some countries offer facilitated procedures for such access and use for national researchers, while others apply the same set of rules that apply to researchers working for foreign research institutions.

Researches from countries that are not a Party to the CBD should still "do Nagoya"

Scientists carrying out research in countries that are non-Parties to the NP, such as the United States of America (USA) (Webpage—NP Parties. Convention on Biological Diversity, 2025), must still comply with the ABS rules established in provider countries and obtain the necessary ABS permits. The key difference is that researchers within the USA will not be checked for compliance by a USA federal authority. But they can damage their reputation and international collaborations if they willfully ignore national laws. Additionally, as the EU is a Party to the NP and its ABS law on compliance applies to all Member States (European Parliament and Council, 2014, European Commission 2021b), all researchers based in the EU have compliance obligations, including those based in non-NP-Parties—such as Italy and Poland.

Utilizing commodities for research purposes changes their intended use and can trigger ABS obligations

Trade and exchange of commodities, whether for direct consumption or as ingredients, e.g. microbial starters in food and drink products, falls outside the scope of NP. However, if research and development are carried out on commodities, the intended use has changed. The user is expected to identify and contact the provider country to determine if ABS permits are needed. However, microorganisms introduced *unintentionally* in the EU (e.g. pathogens or food contaminants) and the isolation and identification of microorganisms from commodities for quality control purposes are out of the scope of the EU Regulation No. 511/2014 on ABS compliance.

Challenges in applying the Nagoya Protocol in non-commercial research

Legal complexity

Obtaining ABS permits often implies understanding multiple legal documents, completing forms (usually in the local language) and, in many cases, long benefit-sharing negotiations with providers. Often, simply being able to confirm whether or not a country regulates access to GR/aTK can be a challenging task, as many Parties have not shared clear guidelines in the ABS Clearing-House (ABS-CH) (Webpage—ABSCH, Convention on Biological Diversity, 2025), an online platform established under the CBD to facilitate the ABS information sharing, and sometimes do not respond timely to enquiries. One particularly ambiguous area is whether the human microbiome is or is not in scope of ABS. There is no simple answer. While human GR and derivatives (such as human chromosomal or organelle DNA, RNA, proteins, and metabolites) are excluded from the CBD and NP's scope, microorganisms, including viruses, residing on or in the human body are not explicitly excluded. Case study 1shares practical experience on how to deal with human microbiome under the NP. Once a determination is made, obtaining the necessary ABS permits can take several months or even years, causing significant delays. Case study 2 highlights the legal complexity arising from a real case on biological control of non-native invasive species.

Diversity of regulatory frameworks and liability fragmentation

The CBD and the NP recognize the sovereign rights of countries over their GR, which enables Parties to define their own ABS rules. Consequently, many aspects differ among ABS legislation, including scope, definitions, requirements, procedures, and even terms used to name ABS permits [such as declaration, notification, registration, MAT, and Material Transfer Agreement (MTA)].

Varying administrative procedures, legal interpretations, and wording may cause misunderstandings, making it difficult for researchers to engage with provider countries, further disrupting project timelines (Heinrich et al. 2020, Ebert et al. 2023, Morgera 2024). In some countries, several Competent National Authorities (CNA) (e.g. ministries, agencies, and local entities) are designated to implement ABS procedures under local legislation, creating challenges in identifying a clear point of contact for users seeking ABS compliance. Temporary rules add to the uncertainty, making it difficult for researchers to navigate regulations efficiently (Ferrari et al. 2024) (Case study 3).

Governance and legal complexities affecting Indigenous Peoples and Local Communities involvement in ABS

The scientific community supports the rights of Indigenous People and Local Communities (IPLCs) as custodians of GR and aTK and their role as providers and beneficiaries of ABS systems. However, lack of official recognition of IPLCs groups by the provider country and unclear governance frameworks, can add further complexity to the process of obtaining ABS permits. Although some national ABS frameworks clearly define the role of IPLCs, in many cases they are not formally recognized as beneficiaries, requiring them to appeal to human rights courts to assert their rights to fair and equitable benefit-sharing and PIC (Zheng 2021). This lack of recognition complicates the identification of authorized representatives, particularly in countries without legal frameworks to uphold collective community rights. This creates practical and methodological challenges that make full compliance difficult.

Retroactive *ex situ* access and utilization rules

Researchers may also face challenges with ABS regulations that cover new utilization of GR collected before the NP entered into force. While international law is generally not retroactive, some countries' legislation is retroactive *de facto* because utilization (not access) triggers ABS, causing confusion and administrative challenges (Bagley and Rai 2014, Rabitz 2015). This particularly affects research on microorganisms from *ex situ* collections and biobanks, where the legal status of these samples varies according to the ABS legislation in the provider country.

Incompatibility of some ABS laws and the International Code of Nomenclature of Prokaryotes

According to the International Code of Nomenclature of Prokaryotes (ICNP), for the valid publication of names of new prokaryotic taxa, scientists must deposit voucher specimens of type strains in publicly accessible *ex situ* culture collections in two different countries that must be made available without restrictions (Rahi

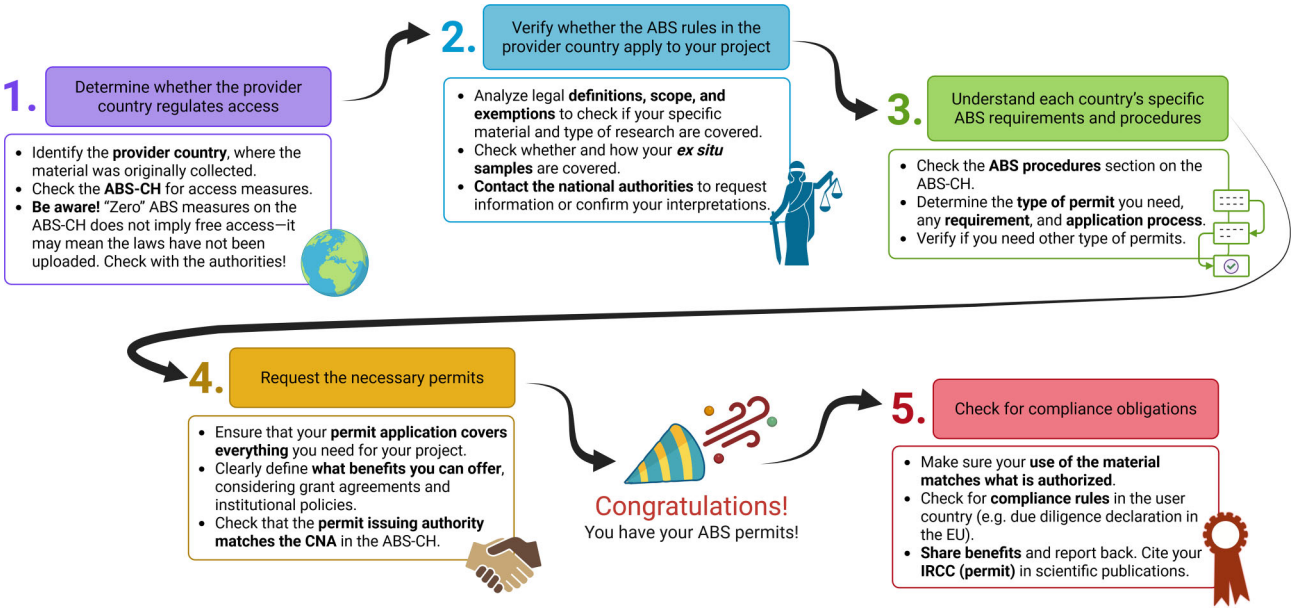

Figure 1 Step by step guide to comply with the Nagoya Protocol. Visual guide outlining the main steps for navigating ABS obligations.

2021). However, if the ABS permit imposes restrictions on sharing them with third parties or requires new ABS permits, the conditions for valid publication under the ICNP cannot be met. As a result, researchers may still describe new taxa, but their names cannot be validated according to the ICNP and therefore will not be internationally recognized. Consequently, some culture collections now refuse deposits of strains originally collected in certain provider countries (Webpage—Strain Deposit, Leibniz Institute DSMZ, 2025).

Insufficient legal and regulatory training in scientific education

Despite over a decade of international NP implementation, training on ABS and other international legal and regulatory frameworks remains largely absent from microbiology education, leaving researchers unprepared (Smith et al. 2017). Researchers often learn informally through experience or colleagues. Integrating legal and regulatory topics into life sciences education is essential to equip future researchers for NP compliance. Similarly, there is a lack of structured ABS-related training and capacity building for biobank managers. Biobanks and collections need to be aware of their obligations and of best practices for NP compliance, in order to manage and transfer NP-relevant information.

How to comply with the Nagoya Protocol: a step-by-step guide

Whether you are collecting new samples in the field or working with previously gathered materials, this section highlights five key stages of the ABS procedure and provides an overview of the main steps (Fig. 1).

The *ABS World interactive infographic* (Webpage—ABS World, German Nagoya Protocol HuB, 2025) can help determine whether ABS laws apply to your project. Not all Parties to the Protocol regulate access (e.g. Germany), while some non-Parties (e.g. Colombia) do (Webpage—NP Parties, Convention on Biological Diversity, 2025). In some cases, ABS laws may only relate to compliance, not access (e.g. EU Regulation 511/2014 on ABS). Therefore, it is critical to review each country's profile on the ABS-CH (Webpage—ABSCH, Convention on Biological Diversity, 2025) and, when needed, follow up directly with national authorities. Partnering with local collaborators can also help navigate procedures and cultural contexts.

When information is insufficient, contact the ABS National Focal Points or CNA listed on the ABS-CH (Webpage—ABSCH, Convention on Biological Diversity, 2025). Provide detailed information about your research, including taxonomic focus, sampling locations, and project objectives. You may also request documentation about forms and procedures and seek confirmation of your understanding of the ABS measures.

Before requesting permits or signing agreements, make sure your planned use—such as transfer to third-party or publishing genetic sequences in open access databases—is covered. Use the *ABS Strategy Checklist* (Webpage—ABS Strategy, German Nagoya Protocol HuB, 2025) to prepare effectively to deal with ABS in provider countries.

Once permits are issued, ensure your use of the material strictly follows the authorized terms. Do not forget to check compliance obligations in your user country. For researchers in the EU, this may include seeking, keeping, and transferring relevant ABS documentation and submitting a *due diligence declaration* via *DECLARE* (Webpage—ENV DECLARE, EU Commission, 2025, European Parliament and Council, 2014). Reading the *EU ABS Guidance Document* is highly recommended—it includes clear explanations and practical examples (European Commission 2021b). For more details, tools, and examples see Supplementary Information.

Outlook

The regulatory frameworks established by the CBD and its NP can appear complex and daunting for microbiologists and other life sciences researchers. However, adherence to these guidelines not

only facilitates equitable research aligned with biodiversity conservation and sustainable use objectives in support of SDG 15, but also opens new opportunities for international collaboration and capacity building. In this context, scientists and institutions working with GR—microbial or otherwise—benefit from collaborating, sharing knowledge, experience, and best practices to address ABS regulatory challenges effectively while advancing the global sustainability agenda (Normand et al. 2021).

Closer engagement between the scientific community, policymakers, and local authorities can facilitate the development of a more effective ABS framework that fulfills both scientific needs and the equitable benefit-sharing objectives outlined in Target 15.6 (Webpage—Fast Track, Leibniz Institute DSMZ, 2025; Webpage—Sustainable Development 15: Life on Land 2015). Such partnerships are particularly important for guiding biological research on biodiversity and environmental sustainability.

The implementation of NP compliance in non-commercial research involving GR from provider countries requires dedication, patience, and a readiness to make compromises (Fig. 1, Case studies 1–3). Nevertheless, these efforts contribute to the development of more ethical research practices that align scientific advancement with respect for the rights and interests of provider communities and nations, ultimately advancing the broader goals of sustainable development and equitable resource sharing enshrined in international agreements and the 2030 Agenda for Sustainable Development (Biermann et al. 2017, Weiland et al. 2021).

Case study 1. Navigating the NP and ABS compliance in human microbiome research—best practices

The globalization of human microbiome research has drawn new attention to the complexities of the NP and associated ABS regulations. While the NP clearly does not apply to human GR, the status

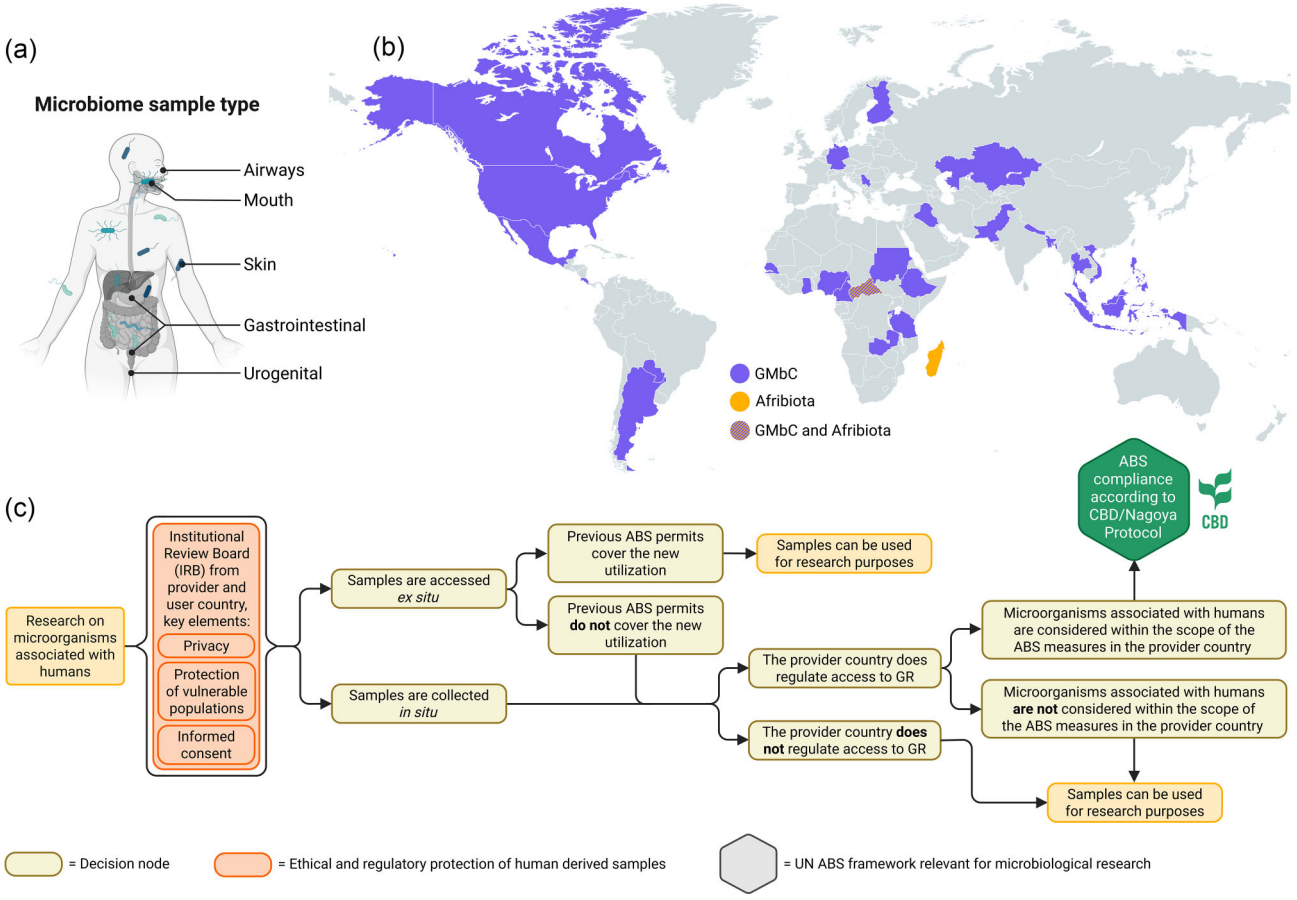

Figure 2 Navigating human-derived microbiome utilization and sample (re)use. The body of every single human being is home to a variety of different microbiomes (a). Geographically distant human communities may have patterns in their associated microbiomes, which can help understand how lifestyle, diet, environment, and other differences alter human microbiomes and may be related to health or disease. International initiatives such as the Global Microbiome Conservancy (GMbC) and Afribiota have developed collaborations in diverse geographical areas to address this type of research questions (b). However, in addition to the imperative to utilize human samples ethically and fairly, the lack of legislative uniformity in regulating ABS for human microbiomes and microorganisms makes it difficult for researchers to navigate the path to legally accessing these microbiological GR (c). Furthermore, (re)use of *ex situ* samples originally collected for other projects, shared by collaborators, or obtained from biobanks may also prove intricate and lead to a complex ABS journey (c). Despite the difficulties in navigating this fragmented regulatory landscape, research consortia like the GMbC and Afribiota demonstrate that human microbiome research can be both NP-compliant and scalable, serving as models for global collaboration (b).

of human–associated microorganisms and/or their genetic material and derivatives remains ambiguous.

Challenge 1: Does human microbiome fall under NP regulations?

National interpretations vary widely: some countries classify human microbiota as within the scope of the NP, others explicitly exclude them, and some offer no official guidance at all. This uncertainty creates an unpredictable landscape for microbiome researchers. Scientists who are not trained in international policy may unknowingly fall into illegality.

In this complex regulatory context, the Global Microbiome Conservancy (GMbC) (Webpage—Global Microbiome Conservancy, 2025) provides a practical example of how an international consortium can advance scientific goals while navigating legal complexity. Aiming to promote diversity in available human–microbiome datasets to better understand the impact of lifestyle on microbiomes and health, GMbC consortium members collect and sequence human microbiome samples worldwide (Fig. 2a, b), which are then stored in a biobank for downstream analysis and distribution of isolated microorganisms.

Since 2016, the GMbC has encountered several NP interpretations, including working with countries that consider human–associated microbiomes within scope and require a formal ABS–permit process (e.g. Pakistan 2021), countries who consider these materials outside the scope of the NP and provided a waiver (e.g. Rwanda 2018), and non-NP Party countries that also provided a waiver (e.g. Paraguay 2024). Despite this variability, the GMbC has adopted a policy of full ABS compliance. Standardized documents are used in all participating countries, including Collaboration and Collection Agreements, and, when applicable, ABS permits or waivers. They include commitments to equitable scientific collaboration, such as co–authorship of publications, capacity–building, and long–term partnerships.

Working closely with national focal points, the GMbC consortium constantly strives to ensure ongoing ABS compliance even if the road to this goal can often be winding (Fig. 2c). Its experience highlights the importance of vigilance: regulations can be modified, countries may become NP Parties, their interpretations of whether human microbiomes fall within scope may change, retroactivity may become an issue, and additional ABS permits or waivers may have to be obtained.

Challenge 2: How to handle subsequent sharing of biomaterial stored in already existing biobanks

As culturing techniques develop, laboratories are building their own microbial repositories. Initially created to address their own research objectives, collected human-derived microorganisms are sometimes requested by others. However, in most cases, original participant consent forms and ABS permits were obtained before such distribution was anticipated. Consequently, this new utilization requires new permits and renegotiated benefit–sharing terms (Fig. 2c).

The Afribiota Consortium (Webpage—Afribiota Project, 2025) has collected human–microbiome samples from children to better understand the physiology of stunted childhood development and its link to gut microbial communities (Fig. 2b). The corresponding ABS approvals or waivers were obtained for these specific research objectives and subsequent sharing of resources was not included in the initial ABS agreement. Therefore, new ABS contracts were needed for that purpose. Retroactive ABS permits or waivers have been crucial to ensure the legally compliant dissemination of biobanked GR. In this case, retroactive permits were granted only because the original consent forms specifically mentioned both long–term biobanking and the possibility of third–party distribution. Had those clauses been absent, the consortium would have had to either re–consent participants or refrain from sharing the material.

The experiences of the GMbC and the Afribiota consortiums highlight that NP-compliant human microbiome research is not only possible but also scalable worldwide. Collaboration with research groups in each provider country should be the norm: it facilitates navigation of local regulations and promotes capacity–building. As microbiome science evolves, the need for clear ABS frameworks for human–microbiomes becomes urgent. International ABS compliance could be strengthened through global guidelines clarifying the scope of the NP with respect to human–associated microbes, and through toolkits to help researchers navigate often complex ABS requirements (Fig. 2c).

Case study 2. Legal labyrinths and biological control: the story of floating pennywort, an aquatic invader

The biological control of non-native invasive weeds illustrates the need for functional ABS systems that safeguard biodiversity by fostering strong international collaboration and engaging committed institutional and academic stakeholders.

Invasive aquatic plants such as floating pennywort (*Hydrocotyle ranunculoides*) are a major environmental and economic challenge: by forming dense, monospecific mats on the surface of lakes and rivers, they threaten local ecosystems and their function, increase flood risk, and damage recreational and commercial activities. Introduced to Europe through the ornamental aquatic plant trade, floating pennywort established itself in English waterways during the 1990s and now cost United Kingdom (UK) stakeholders more than £25 million per year in control and mitigation measures (Webpage—UK Environment Agency and Department for Environment, Food & Rural Affairs, 2026). Faced with this growing impact and the obligations under the EU Water Framework Directive, the UK authorities decided to explore classical biological control, an approach that has been proven for over a century to provide effective and sustainable suppression of invasive exotic weeds through the targeted introduction of host specific natural enemies, from the areas of origin of the plants.

After Argentina became a signatory of the NP in 2011, its ABS framework was fragmented and marked by overlapping national, provincial, and federal laws. As a consequence, the export of the weevil *Listronotus elongatus,* a promising biological control agent from floating pennywort's native South American range, to the Centre for Agriculture and Bioscience International (CABI) was stalled in legal limbo for nearly four years.

It was only with the implementation of Argentina's 2019 Resolution 410, that a simplified regime for the utilization of GR for non-commercial research purposes and minimum standards for provincial competent authorities issuing ABS authorizations were established. Access to GR was streamlined and included MAT and MTA by provincial authorities and national parks, and authorization by the National Food Safety and Quality Service (SENASA)

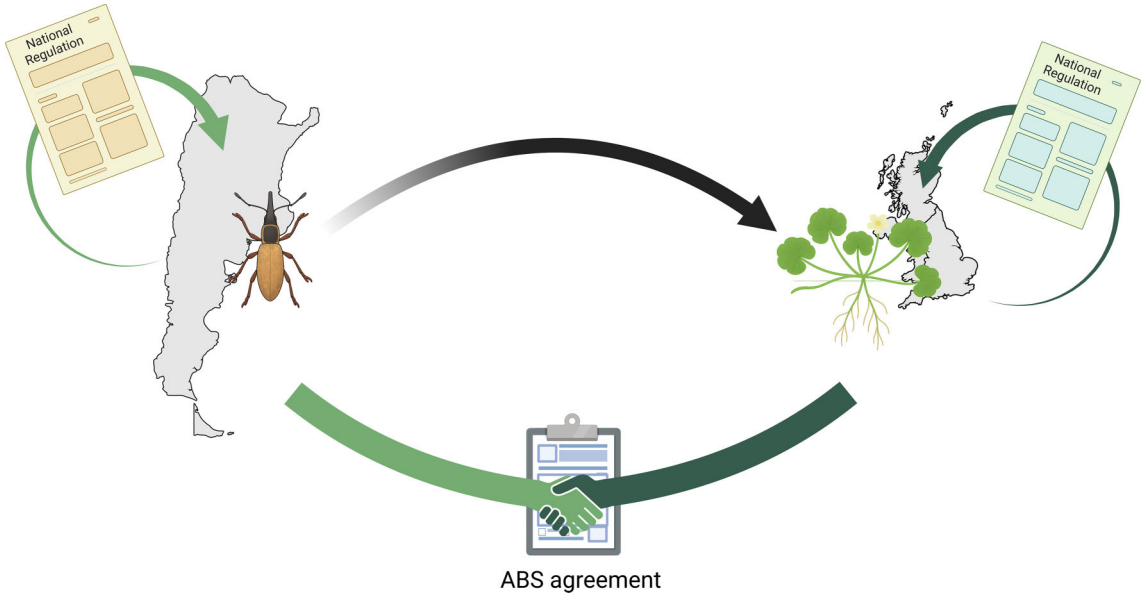

Figure 3 Research on invasive species and its biological control is covered by international and domestic regulation. Before research on GR begins, it requires compliance not only with ABS regulations in the provider country but also with regulations on import and use in the user country. Adherence to different national regulations is challenging and researchers must be perseverant in navigating frameworks for the ethical and equitable governance of biological material use.

and the Ministry of Environment and Sustainable Development (MAyDS) for exporting genetic material to the UK. By late 2019, once access to Argentine GR was clarified, CABI, in collaboration with its in-country partner, the Foundation for the Study of Invasive Species (FuEDEI), was able to restart research on floating pennywort biocontrol funded by the ministerial Department for Environment, Food and Rural Affairs (DEFRA). In early 2020, CABI formally applied to the UK phytosanitary regulators to introduce the weevil *L. elongatus* into England, which would form part of a coordinated national floating pennywort management strategy.

In the UK, CABI complied with national legislation in England and Wales under the Wildlife and Countryside Act 1981, which provides the legal framework for the release of non-native biological control agents. Following a scientific review by independent advisors, consultation with involved governments, and public engagement, ministerial consent was given to CABI in 2021 for the controlled release of *L. elongatus* in England. The weevils were imported into quarantine under a Secretary of State phytosanitary license with CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora) certification confirming they are not subject to trade restrictions (Webpage—CITES, 2025). Their release in the UK is carefully regulated, requiring a license from the Secretary of State. This process includes ongoing environmental monitoring, placement of specimens in official reference collections, and securing additional permits for any trials conducted within protected areas. A dedicated research permit for *H. ranunculoides* allows breeding facilities to transport and cultivate the weevil's regulated host plant for rearing purposes—ensuring full compliance with phytosanitary regulations.

This case highlights the importance of establishing clear minimum standards for local competent authorities in countries with provincial ABS regulations. Such efforts are key to streamlining permitting processes and enabling timely responses to major drivers of biodiversity loss, including the spread of invasive species (Fig. 3).

Case study 3. From complexity to practicality. How can policy evolve, sometimes for the better?

The evolution of France's ABS measures demonstrates how adaptive legal frameworks, precise clarifications, and targeted updates can streamline compliance with the NP underscoring the critical role of open, constructive dialogue between users and regulators in crafting effective ABS legislation.

When the French ABS law came into force in August 2016, it aimed for simplicity: non-commercial users only had to submit a short declaration, while commercial utilization required full authorization. In order to further facilitate access, exceptions were introduced for certain GR that did not require a declaration or authorization. For example, a list of "model species" (Webpage—Légifrance, 2025) and five specific schemes, including one for domesticated and cultivated species, were exempt from the national ABS system. Despite good intentions, navigating the list of "model species" increased regulatory complexity, while the "special scheme for domesticated and cultivated species" remained of little practical use for microbiologists in the absence of clarity if microorganisms were covered. In addition, the documentation associated with ABS obligations was initially only available in French.

Researchers therefore found themselves having to navigate a maze of partly unclear obligations for mainland France, compounded by the fact that French overseas territories, such as New Caledonia and French Polynesia, and for traditional knowledge from French Guiana and Wallis et Futuna, have their own ABS regimes, each requiring separate communication with local focal points.

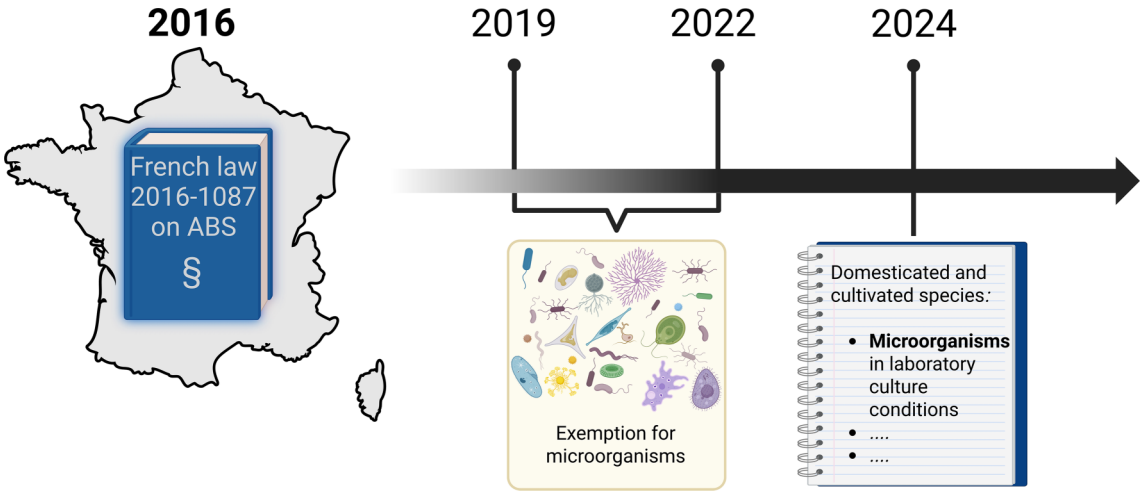

Figure 4 Evolution of French ABS regulation for microorganisms. Three years after coming into force in 2016, the French ABS regulations established a pilot exemption for access to microbial genetic resources from 2019 to 2022. Between 2022 and 2024, microorganisms were re-integrated into ABS regulations, but as of 2024, clarification was provided that, when grown in culture media, they are considered under the "domesticated and cultivated species scheme" and therefore excluded from ABS obligations. Furthermore, "genetic resources collected by the laboratories to prevent and control the serious risks for human health" are also excluded from ABS obligations.

Dialogue between the scientific community and the relevant ministries never ceased, and legislators welcomed the scientific community's comments and managed to broker solutions that gradually addressed some of the operational problems.

A three-year trial period, from 2019 to 2022, temporarily excluded microorganisms from any ABS obligations, allowing unrestricted access, a change that was warmly welcomed by the microbiological community (Ferrari et al. 2024). After 2022, a two-year period of uncertainty followed, as the exemption had expired and it remained unclear whether cultivated microbes were excluded. During this time, scientific communities from several Horizon Europe research projects actively consulted French authorities. By 2024, France clarified in administrative proceedings that microorganisms placed in a culture medium fall into the "domesticated and cultivated species scheme" under which there is no ABS procedure nor obligations to fulfill (Webpage—Ministère de l'Agriculture, de l'Agro-alimentaire et de la Souveraineté alimentaire, 2025) and that the same exception applies to "the genetic resources collected by the laboratories to prevent and control the serious risks for human health .." (Online document—ABSCH, 2025) (Fig. 4). Meanwhile, all guidance documents, declaration forms, and authorization templates have been translated into English over time, breaking down the language barrier that had hindered many non-French-speaking scientists (Online document—ABSCH, 2025; Online document—Ministère de la Transition écologique, de la Biodiversité et des Négociations internationales sur le climat et la nature 2023; Webpage—Formulaire 15786∗02, Service Public Entreprendre, 2025).

Looking ahead, France's experience suggests several guiding principles:

- First, ABS regulatory frameworks must remain adaptable to reflect the evolving needs of stakeholders and changes in the reality of benefit-sharing among nation states.
- Second, unambiguous legislative definitions facilitate regulatory navigation and ensure uniform application.
- Third, multilingual guidelines are essential to promote global collaboration and reduce administrative burdens.

Legislators and users of GR must remain vigilant: legal changes can introduce uncertainty, but they also offer opportunities to improve clarity, accessibility, and ethical rigor in the management of ABS obligation for GR.

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The world map in Fig. 2 and the outlines of Argentina and the United Kingdom in Fig. 3 were created using www.mapchart.net. The icons used in the supplementary information were made by Freepik from www.flaticon.com.

Figures were generated using www.biorender.com:

Fig. 1: Created in BioRender. Faggionato, D. (2026) https://BioRender.com/p9krg7u

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Fig. 4: Created in BioRender. Faggionato, D. (2026) https://BioRender.com/y7ek3pw

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Supplementary material

Supplementary material is available at *Sustainable Microbiology Journal* online.

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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