

Multilateral negotiations on access and benefit sharing obligations for access to genetic resources and traditional knowledge



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Knowledge Ecology International (KEI)
February 25, 2026.

- Draft -

Comments via email: ip-tm-project@keionline.org.

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Introduction

This is a discussion of the challenges of multilateral negotiations on Access and Benefit Sharing (ABS) regimes, as they relate to access to and use of genetic resources and related digital sequence information, and traditional knowledge. The discussion provides a historical and legal analysis of the evolution of ABS regimes that spans seven decades of international policy, from early International Labour Organization (ILO) conventions to the present. These negotiations have taken place in multiple fora, sometimes in parallel.

At present, negotiations are taking place in the following fora:

- World Health Organization (WHO) negotiations on the WHO Pandemic Agreement Annex on Pathogen Access and Benefit Sharing system (PABS),
- The implementing rules for the third implementing agreement of the Agreement under the United Nations Convention on the Law of the Sea (UNCLOS), regarding Biodiversity Beyond National Jurisdiction, known as the Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ),
- The implementation of the Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources, established under Decision 16/2 of the Convention on Biological Diversity (CBD), and
- The World Intellectual Property Organization (WIPO) negotiations in the Intergovernmental Committee (IGC) and implementation of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (GRATK).

This discussion also refers to additional relevant negotiations, including:

- Pre-CBD ILO conventions on the rights of Indigenous and Tribal Populations,
- The UN's Food and Agriculture Organization (FAO) International Undertaking (1983),
- The Convention on Biological Diversity (1992),
- The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (2001),
- The Nagoya Protocol (2010),
- The WHO Pandemic Influenza Preparedness Framework (2011), and

- The European Union Health Data Space Regulation (2025).

In recent decades, the role of Digital Sequence Information (DSI) has become a central point of tension, and is integrated into the WHO Pandemic Agreement, the BBNJ Treaty and the creation of the Cali Fund, although the implementation in each of the three is a work in progress.

This document traces the shift in international law on access to genetic resources from the 1983 "common heritage of mankind" approach to the 1992 CBD principle of national sovereignty and subsequent attempts to create multilateral systems.

The international recognition of the role and rights of Indigenous peoples and local communities have also evolved, from early frameworks focused on assimilation (ILO 107) toward autonomy and rights-based approaches (ILO 169 and UNDRIP), and unique and separate roles and rights from states in some ABS regimes.

Also included in this document is a discussion of the 2025 European Union Health Data Space (EHDS) Regulation, and the mandatory sharing of health related data for secondary research purposes through a decentralized system with registration and permits, limits and safeguards on uses of data, and "soft" obligations that products benefiting access are available and affordable.

Annex I argues that pathogens should not be treated as genetic resources under the CBD, suggesting they sit uncomfortably within a framework designed for conservation rather than emergency public health response.

Annex II provides selected passages from the influential 1987 Report of the World Commission on Environment and Development: Our Common Future, known as the Brundtland Report.

Annex III provides commentary on the state of play in the WIPO IGC negotiations in February 2026, including ongoing procedural and substantive deadlocks in those negotiations.

Annex IV is a comment on the use of the term "mutually agreed" in negotiations over technology transfer.

Annex V is a discussion of the open source dividend incentive to share access to knowledge, biologic resources, inventions and technology.

Pre-CBD ILO conventions on Indigenous and Tribal Populations

Before the 1992 Convention on Biological Diversity (CBD), the international community largely viewed indigenous issues through the lens of labor rights or human rights.

The International Labour Organization (ILO) [Indigenous and Tribal Populations Convention, 1957 \(No. 107\)](#) was the first international convention designed to protect Indigenous and Tribal

Populations from oppression and discrimination. The purposes and objectives of the agreement are largely set out in Article 2.

Article 2

1. Governments shall have the primary responsibility for developing co-ordinated and systematic action for the protection of the populations concerned and their progressive integration into the life of their respective countries.
2. Such action shall include measures for--
 - (a) enabling the said populations to benefit on an equal footing from the rights and opportunities which national laws or regulations grant to the other elements of the population;
 - (b) promoting the social, economic and cultural development of these populations and raising their standard of living;
 - (c) creating possibilities of national integration to the exclusion of measures tending towards the artificial assimilation of these populations.
3. The primary objective of all such action shall be the fostering of individual dignity, and the advancement of individual usefulness and initiative.
4. Recourse to force or coercion as a means of promoting the integration of these populations into the national community shall be excluded.

ILO Convention 107 was designed to facilitate the assimilation of Indigenous peoples into the dominant society, and not to preserve distinct knowledge, customs or culture. It was later replaced by the ILO Indigenous and Tribal Peoples Convention, 1989 ([No. 169](#)), an agreement that preceded the CBD by three years.

ILO Convention 169 (1989) fundamentally changed how international law viewed Indigenous peoples, shifting from a goal of assimilation to one of autonomy and participation. While the previous 1957 Convention (ILO 107) assumed Indigenous cultures would eventually "disappear" into the modern state, ILO 169 recognized them as permanent, distinct societies with the right to determine their own development.

The 1983 FAO International Undertaking on Plant Genetic Resources

The Food and Agriculture Organization (FAO) is a specialized agency of the United Nations tasked with the mission of defeating hunger. The 22nd FAO Conference, meeting in Rome in November 1983, adopted an International Undertaking on Plant Genetic Resources. The purpose of the agreement was to ensure that "plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes." The agreement declared that there was a "universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction." The undertaking sought to "facilitate the exchange of genetic material, to promote international cooperation in the preservation, evaluation and documentation of plant genetic resources, and to establish an internationally coordinated network of national, regional and international centres, including a network of base collections of gene banks under the auspices or jurisdiction of FAO." Implementation measures

included the establishment by the FAO Council of a new FAO Commission on Plant Genetic Resources. Seeds were shared without users signing material transfer agreements (MTAs).

By framing plant genetic resources as the "heritage of mankind," and the networking of gene banks using an open sharing mechanism, the FAO sought to establish a global commons for certain agricultural genetic resources.

The 1989 FAO Resolutions on Farmers Rights

While the 1983 FAO Undertaking was designed to create a global commons for certain agricultural genetic resources, there was also a significant and expanding effort globally to grant *sui generis* rights for plant breeders, not to mention patents on seed varieties.

The International Convention for the Protection of New Varieties of Plants (the "UPOV Convention") has been around since 1961, and has been revised three times, including in 1972, 1978, and 1991. The revisions have gradually expanded the level of protection UPOV members grant to plant breeders and narrowed the rights of farmers who use their seeds. The term 'Farmers Rights' is used to describe exceptions in national plant breeder laws that are used by farmers to retain and experiment with otherwise protected seed varieties.

In 1989, the FAO sought to address both the concern of farmers over their freedom to use seeds and the reluctance of some countries to join the 1983 FAO Undertaking on plant genetic resources, given apparent conflicts with the UPOV Convention. The result was the November 1989 adoption, at the 25th Session of the FAO Conference, of two resolutions (4/89 and 5/89), which provided an "agreed interpretation" of the 1983 International Undertaking on Plant Genetic Resources, and an endorsement of the concept of Farmers' Rights.

Resolution 4/89, titled "Agreed Interpretation Of The International Undertaking," stated that:

- *"Some countries have not adhered to the [1983 FAO] Undertaking and others have adhered with reservation because of possible conflict of certain provisions of the Undertaking with their international obligations and existing national regulations;*
- *These reservations and constraints may be overcome through an agreed interpretation of the Undertaking which recognizes Plant Breeders' Rights and Farmers' Rights."*

Resolution 4/89 further provided that:

- *"Plant Breeders' Rights as provided for under UPOV are not incompatible with the International Undertaking;*
- *A state may impose only such minimum restriction on the free exchange of materials covered by Article 2.1 (a) of the International Undertaking as are necessary for it to conform to its national and international obligations;*
- *The term "free access" does not mean free of charge."*

Resolution 5/89, titled “Farmers Rights,” stated that “plant genetic resources are a common heritage of mankind to be preserved, and to be freely available for use, for the benefit of present and future generations,” and noted that:

- *“In the history of mankind, unnumbered generations of farmers have conserved, improved and made available plant genetic resources;*
- *The majority of these plant genetic resources come from developing countries, the contribution of whose farmers has not been sufficiently recognized or rewarded;*
- *The farmers, especially those in developing countries, should benefit fully from the improved and increased use of the natural resources they have preserved.”*

Resolution 4/89 formally

- *“Endorses the concept of Farmers' Rights*
- *Farmers' Rights mean rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the International Community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions [...].”*

Paragraph 105 from the Conference reports described the actions¹ as follows:

“The Conference welcomed in particular the text for two complementary draft resolutions aimed to improve the participation of countries in the International Undertaking. The first one, presented by the Delegation of Spain, was based on the text prepared by the Commission for an agreed interpretation of the International Undertaking. The second one was prepared by the Commission and regarded farmers' rights. The draft resolutions, preserving the principle of unrestricted availability of germplasm, recognized the rights of both donors of technologies and donors of germplasm to be compensated for their contributions through the simultaneous recognition of plant breeders' and farmers' rights. The Conference recognized that both resolutions were intended to lay the basis for an equitable and lasting global system for sharing the costs and benefits of the world's plant genetic resources for present and future generations.”

UPOV 1991 Revisions (March 19, 1991)

The following year, the International Union for the Protection of New Varieties of Plants (UPOV) revised its UPOV Convention. Approved on March 19, 1991, in a diplomatic conference in Geneva, the revisions expanded its *sui generis* protection regime to apply to “all plant genera and species”² and effectively narrowed the scope for national exceptions for farmers.³

¹ <https://www.fao.org/4/x5588E/x5588e06.htm#Resolution5>

² Explanatory Notes On Genera And Species To Be Protected Under The 1991 Act Of The UPOV Convention, adopted by the Council at its forty-third ordinary session on October 22, 2009, UPOV/EXN/GEN/1. https://www.upov.int/documents/d/upov/explanatory-notes-en-upov_exn_gen.pdf

³ Shiney Varghese, “Battling for Farmers' Seed Systems: UPOV 91 and Trade Agreements,” Institute for Agriculture & Trade Policy, August 20, 2025. <https://www.iatp.org/battling-for-farmers-seed-systems>

Breeders' rights in the earlier versions of the UPOV Act (1961, 1972, 1978) were limited to production for purposes of commercial marketing, the offering for sale, and the marketing of the reproductive or vegetative propagating material. This meant that under these acts, farmers could still save and exchange seeds freely. . . . This changed with the adoption of the revised 1991 Act of the UPOV convention (UPOV 91), when breeders' rights were broadened to include all forms of "multiplication" -- production and reproduction of a protected plant variety -- while also introducing an optional and limited "farmers' privilege", which prohibits the sale and exchange of seeds from protected varieties in principle, and limits the use of farm-saved seeds to certain crops, which may be subject to payment to the seed breeder.

The farmers' privilege referred to above is an optional exception to the breeder right, provided for in Article 15(2) of the 1991 revision. This limits the farmer's privilege exception to "reasonable limits and subject to the safeguarding of the legitimate interests of the breeder," and only allows the farmer to use seeds for propagating purposes, "by planting, on their own holdings."

The phrase "safeguarding of the legitimate interests of the breeder" is interpreted in some national laws to mean that farmers (except small-scale ones) must pay a "remuneration" (a discounted royalty) to the breeder even for seeds they saved themselves.

The 1991 revision does include three mandatory exceptions to the breeder's right, relating to research, breeding other varieties, and private non-commercial uses.

Article 15, Exceptions to the Breeder's Right

(1) [Compulsory exceptions] The breeder's right shall not extend to
(i) acts done privately and for non-commercial purposes,
(ii) acts done for experimental purposes and
(iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.

(2) [Optional exception] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii)

The mandatory breeder's exemption ensures that the genetic pool remains open to other professional breeders, even if it is closed to farmers for saving/exchange.

The Dunkel Draft of TRIPS (December 1991)

The General Agreement on Tariffs and Trade (GATT) negotiations that led to the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) officially began with the launch of the Uruguay Round in September 1986 at Punta del Este, Uruguay. The negotiating groups for the TRIPS Agreement were formed

in early 1987, and the final text of the TRIPS Agreement was agreed upon in 1993 but the most significant milestone was the 1991 Dunkel Draft, which presented a near final version of the text.⁴ Article 27.1 of the TRIPS Agreement required WTO members to grant patents on all fields of technology, subject to certain exceptions set out in Articles 27.2 and 27.3. Members of the WTO that did not grant patents on plant varieties were required to have an “effective sui generis system.”

There was no reference in the TRIPS Agreement text referring to traditional knowledge, an omission that has been criticized by some of its members and is the subject to continued discussions in the WTO.⁵

The 1992 Convention on Biological Diversity

The Convention on Biological Diversity (CBD) was the product of years of negotiations on sustainable development. In 1983, the UN General Assembly created an independent World Commission on Environment and Development (WCED), chaired by Gro Harlem Brundtland. This commission published a report titled “Our Common Future,” also known as the Brundtland Report.⁶ The 247-page report defined the concept of sustainable development and linked environmental and social issues with economic development. Referring to Indigenous and Tribal Communities, the report stated:⁷

These communities are the repositories of vast accumulations of traditional knowledge and experience that links humanity with its ancient origins. Their disappearance is a loss for the larger society, which could learn a great deal from their traditional skills in sustainably managing very complex ecological systems.

In 1988, the United Nations Environment Programme (UNEP) established an Ad Hoc Working Group of Experts on Biological Diversity, and in 1989, UNEP’s Governing Council authorized negotiation of a legally binding treaty.

The negotiations on the text of the CBD were concluded on May 22, 1992, with the Nairobi Final Act. Beyond finalizing the treaty text, the Final Act included resolutions that linked the new CBD regime back to earlier FAO work. Specifically, Resolution 3 identified the need to resolve outstanding issues regarding Farmers’ Rights and *ex-situ* collections of genetic resources (those gathered before 1992), and directed the FAO to “harmonize its existing agreements with the

⁴ The only changes from the 1991 Dunkel draft were (1) additional language in Article 27.3.b to require a review of the TRIPS treatment of plant varieties: “The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement,” and (2) the so-called “Intel” amendment to Article 31.c, on non-voluntary authorizations to use patents, stating, “in the case of semi-conductor technology [a non-voluntary authorisation of a patent] shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;”

⁵ See for example, Reviving Discussions On The Relationship Between The Trips Agreement And Convention On Biological Diversity Communication From Brazil, India And Peru, IP/C/W/719, 18 March 2025. Thiru Balasubramaniam, WTO: Brazil, India and Peru call for the inclusion of a mandatory disclosure requirement in the WTO TRIPS Agreement, June 20, 2025. <https://www.keionline.org/40837>

⁶ <https://www.are.admin.ch/en/1987-brundtland-report>

⁷ Selected passages from this report are included in an Annex attached below.

newly established principles of national sovereignty and benefit-sharing." The agreement was formally opened for signature at the Rio Earth Summit in June 1992.

Article 15 of the agreement broke with the earlier FAO undertaking by declaring that national governments had sovereignty over genetic resources and could determine the conditions for access through national legislation. Article 15 also provided that "Each Contracting Party shall take legislative, administrative or policy measures . . . with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources," and that "Such sharing shall be upon mutually agreed terms." Prior informed consent was required for access "unless otherwise determined by that Party."

Like many agreements that would follow, there were less binding provisions aimed at capacity building and technology transfer. The CBD urged ("shall endeavour") Contracting Parties "to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties."

Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and

Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the

commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.
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Articles 16, 17, 18, 19 and 20 have provisions on technology transfer. These provisions are largely procedural and facilitative obligations regarding technology transfer and use terms such as “take measures” or “with the aim of,” and are ambitious in rhetoric but lack specific actionable obligations and no enforcement mechanism.

Article 16 (Access to and Transfer of Technology) provides that Parties “shall provide and/or facilitate” the transfer of technology, then provides that this must be on “mutually agreed terms” and “consistent with the adequate and effective protection of intellectual property rights, making the obligation” subject to the consent of the intellectual property (IP) holders. That said, Article 16 also provides that “patents and other intellectual property rights may have an influence on the implementation of this Convention,” and requires Parties to “cooperate” in national legislation and international law in order to ensure that “such rights are supportive of and do not run counter to [the agreement] objectives.”

Article 17 (Exchange of Information) is two paragraphs, and requires Parties to “facilitate the exchange. . .relevant to the conservation and sustainable use of biological diversity” including results of technical, scientific and socio-economic research, and also, “where feasible, include repatriation of information.” The reference to repatriation of information refers to the history of researchers from developed nations collecting samples and data that were then stored in Northern museums, universities, and botanical gardens, and implies an obligation to return copies of specimen data, field notes, and maps held in foreign herbaria or museums, and documented traditional knowledge to the Indigenous and local communities from which it was gathered.

Article 18 (Technical and Scientific Cooperation) is a soft obligation on “promote”, subject to “mutual agreement” and “encourage and develop” collaborations on research.

Article 19 (Handling of Biotechnology and Distribution of Its Benefits) requires parties to “take legislative, administrative or policy measures. . .to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research. . .on a fair and equitable basis.” The obligations are qualified by terms like “as appropriate,” and again noting that “access shall be on mutually agreed terms.” A harder obligation is stated in Article 19.4, “Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction. . .provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms. . .[where] those organisms are to be introduced.”

Some firms have objected to the obligations to disclose safety information, claiming that they violated protections for trade secrets or Confidential Business Information (CBI). The obligations

to address concerns over safety and the protection of CBI would later be addressed and elaborated in the Cartagena Protocol on Biosafety (2000), as well as in Article 39 of the 1995 TRIPS Agreement.

Article 20 (Financial Resources) states that developing country obligations under the Convention “will depend on effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology.”

Traditional Knowledge in the CBD

The role of Indigenous and local communities and their traditional knowledge were addressed in the Preamble and several articles of the 1992 CBD.

The Preamble recognises “the close and traditional dependence many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components.”

Article 8 (In-situ Conservation) addresses the protection of plant and animal species, particularly those that are endangered, within their natural habitats and environments.

Article 8(j) requires Parties to “respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity,” and to promote “their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.”

Article 10 (Sustainable Use of Components of Biological Diversity) includes a requirement (Article 10.c) for Parties to “Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.”

As mentioned earlier, Article 17 (Exchange of Information) refers to “specialized knowledge, indigenous and traditional knowledge,” and, where feasible, the repatriation of such information, so that traditional knowledge documented by foreign researchers would be (where feasible) returned to the communities of origin.

As noted, Article 18 (Technical and Scientific Cooperation) requires Parties to “encourage and develop methods of cooperation for the development and use of technologies,” specifically including “indigenous and traditional technologies.”

The inclusion of traditional knowledge in the 1992 CBD was a watershed moment in international law. Concepts of indigenous rights and cultural heritage had emerged in other agreements, but the CBD was the first legally binding global treaty to explicitly link traditional knowledge to the conservation of nature and economic benefit-sharing.

US Fails to Ratify the CBD

One hundred and ninety-five states and the European Union have become parties to the CBD. The United States signed the agreement in 1993, but never ratified it, making it the only UN Member State that is not party to the convention

In asking the US Senate to ratify the agreement, President Bill Clinton proposed seven conditions or understandings, largely to accommodate the pharmaceutical and biotechnology companies.⁸ (Convention on Biodiversity, Message from the President of the United States, November, 1993, Treaty Doc 103-20, 103d Congress, 1st Session, Senate).

The Seven U.S. Conditions / Understandings (Text Of Resolution Of Advice And Consent To Ratification As Recommended By The Committee On Foreign Relations)

(1) The Government of the United States of America understands that Article 3 references a principle to be taken into account in the implementation of the Convention.

(2) It is the understanding of the Government of the United States of America with respect to provisions addressing access to and transfer of technology that:

(a) "fair and most favorable terms" in Article 16(2) means terms that are voluntarily agreed to by all parties to the transaction;

(b) with respect to technology subject to patents and other intellectual property rights, Parties must ensure that any access to or transfer of technology that occurs recognizes and is consistent with the adequate and effective protection of intellectual property rights, and that Article 16(5) does not alter this obligation.

(3) It is the understanding of the Government of the United States of America with respect to provisions addressing the conduct and location of research based on genetic resources that:

(a) Article 15(6) applies only to scientific research conducted by a Party, while Article 19(1) addressed measures taken by Parties regarding scientific research conducted by either public or private entities;

(b) Article 19(1) cannot serve as a basis for any Party to unilaterally change to terms of existing agreements involving public or private U.S. entities.

(4) It is the understanding of the Government of the United States of America that, with respect to Article 20(2), the financial resources provided by developed country Parties are to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures that fulfill the obligations of the Convention and to benefit from its provisions and that are agreed between a developing country Party and the institutional structure referred to in Article 21.

(5) It is the understanding of the Government of the United States of America that, with

⁸ Convention on Biodiversity, Message from the President of the United States, November, 1993, Treaty Doc 103-20, 103d Congress, 1st Session, Senate.

respect to Article 21(1), the "authority" of the Conference of the Parties with respect to the financial mechanism relates to determining, for the purposes of this Convention, the policy, strategy, program priorities and eligibility criteria relating to the access to and utilization of such resources.

(6) The Government of the United States of America understands that the decision to be taken by the Conference of the Parties under Article 21, Paragraph 1, concerns "the amount of resources needed" by the financial mechanism, and that nothing in Article 20 or 21 authorizes the Conference of the Parties to take decisions concerning the amount, nature, frequency or size of the contributions of the Parties to the institutional structure.

(7) The Government of the United States of America understands that although the provisions of this Convention do not apply to any warship, naval auxiliary, or other vessels or aircraft owned or operated by a State and used, for the time being, only on government non-commercial service, each State shall ensure, by the adoption of appropriate measures not impairing operations or operational capabilities of such vessels or aircraft owned or operated by it, that such vessels or aircraft act in a manner consistent, so far as is reasonable and practicable, with this Convention.

Despite these conditions or understandings, the US Senate did not ratify the agreement.

WIPO Rejection of Proposed Treaty on the Protection of Databases (1996)

In December 1996, WIPO convened a Diplomatic Conference on Certain Copyright and Neighboring Rights Questions. The negotiations focused on proposals for new intellectual property norms that would address the novel issues presented by the use of digital technologies and the Internet. Three treaty proposals were presented, and two were approved. The two treaty proposals approved were the WIPO Copyright Treaty (WCT) and the WIPO Performances and Phonograms Treaty (WPPT). A third proposal, the "Treaty on Intellectual Property in Respect of Databases," sought to create a new *sui generis* right for non-original databases.

The database proposal sought to give "the maker of a database . . . the right to authorize or prohibit the extraction or utilization of its contents." The industry lobbying for the proposal came from West Publishing, Reed Elsevier (now RLEX) and a handful of other companies selling access to databases that consist of facts or documents that were in the public domain or freely licensed. The proposal followed the adoption in March 1996 of Directive 96/9/EC of the European Parliament and of the Council on the legal protection of databases, which created a similar *sui generis* right for the owners of databases.⁹

Note 1.06 from the WIPO database treaty proposal (CRNR/DC/6) provides this description of its objectives.

1.06. The proposed Treaty seeks to safeguard makers of databases against misappropriation of the fruits of their financial and professional investment in collecting,

⁹ <https://eur-lex.europa.eu/eli/dir/1996/9/oj/eng>

verifying and presenting the contents of databases. It does this by proposing protection that covers the whole or substantial parts of a database against certain acts by a user or by a competitor, for the limited duration of the right. The investment, of course, may comprise financial resources, human resources or both.

Opposition to the Database Treaty came from the library and research community, public interest groups, a coalition of data users and academics working through the Union for the Public Domain, several database companies, including Bloomberg, Dun and Bradstreet, STATS Inc., and various user communities, including those working on genealogical research.¹⁰

The 1996 WIPO Database Treaty proposal failed at the diplomatic conference. In the decades since, the European Commission has evaluated its own Database Directive (96/9/EC) twice (2005, 2018), alongside a 2022 Impact Assessment, repeatedly finding that the *sui generis* right failed to stimulate the EU database market or close the gap with the US. Its scope has been steadily curtailed by the CJEU (2004) and most recently by the EU Data Act (2023), which ensures the right cannot block access to certain types of data, such as those concerning the Internet of Things (IoT).

Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions (1998)

On July 6 1998, the European Union published Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions. The Directive was designed to harmonize the patent laws within the EU regarding biotechnological inventions. Among the controversies were the policies regarding patent eligibility, and the relationship between two different IP regimes: patents on inventions and the *sui generis* rights for plant breeders.

The original proposal was adopted by the European Commission in 1988 but failed to obtain approval and was formally rejected in March 1995, with much of the debate focusing on the patenting of life forms and ethical issues, such as the altering of genes in fetuses in order to eradicate inherited diseases.¹¹

The tension between plant breeders was based on concerns that if genes were patented, the patent holder could "lock up" an entire plant variety, preventing further breeding. The Directive created an accommodation for the plant breeders by creating a mandatory cross license between patent and cross breeder rights, when the use of one right required access to the other right. This was set out in Article 12 of the Directive.

¹⁰ See:

<https://web.archive.org/web/19980118060936/http://www.public-domain.org/wipo/dec96/dec96.html>

¹¹ Parliament rejects proposed Directive on legal protection of biotechnological inventions, <https://cordis.europa.eu/article/id/3808-parliament-rejects-proposed-directive-on-legal-protection-of-biotechnological-inventions>

CHAPTER III
Compulsory cross-licensing
Article 12

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the **holder of the patent will be entitled** to a cross-licence on reasonable terms to use the protected variety.
2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the **holder of the variety right will be entitled** to a cross-licence on reasonable terms to use the protected invention.
3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:
 - (a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;
 - (b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.
4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.

In 2002, James Love and Manon Röss proposed “Access to Genetic Resources & Traditional Knowledge, The Bellagio compulsory cross-licensing proposal for benefit sharing consistent with more competition and openness,”¹² drawing from the approach in Article 12 of the EU Biotechnology Directive.

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (Negotiations began in 2001)

¹² Described in a slide presentation for Roundtable on Intellectual Property, Traditional Knowledge and Folklore: Sponsored by the Science and Human Rights Program of the American Association for the Advancement of Science (AAAS) and Franciscans International. Geneva, December 14, 2002. (Available here: <https://www.keionline.org/41222>)

Since 2001, the World Intellectual Property Organization has conducted negotiations on possible norms for the protection of traditional knowledge (TK), expressions of folklore (now referred to as traditional cultural expressions (TCEs)), and access to genetic resources (GR).

The first session took place at the WIPO headquarters in Geneva from April 30 to May 3, 2001.¹³ The several documents presented at the first meeting by the Secretariat and the member states are useful in understanding the issues that would be raised in the negotiations, which are ongoing and highly divided.

The 1st session documents included:

1. Matters Concerning Intellectual Property And Genetic Resources, Traditional Knowledge And Folklore – An Overview: Document prepared by the Secretariat; WIPO/GRTKF/IC/1/3, March 16, 2001.
https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_1/wipo_grtkf_ic_1_3.pdf
2. Activities Of Other Intergovernmental Organizations And Processes: Document prepared by the Secretariat; WIPO/GRTKF/IC/1/4; March 16, 2001.
https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_1/wipo_grtkf_ic_1_4.pdf
3. Traditional Knowledge And The Need To Give It Adequate Intellectual Property Protection, documents submitted by the Group of Countries of Latin America and the Caribbean (GRULAC); WIPO/GRTKF/IC/1/5; March 16, 2001.
https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_1/wipo_grtkf_ic_1_5.pdf
4. Information Provided by WIPO Member States Concerning Practices Related to the Protection of Biotechnological Inventions; WIPO/GRTKF/IC/1/6; April 6, 2001.
https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=1681
5. Document Of The Holy See On Intellectual Property And Genetic Resources, Traditional Knowledge And Folklore; WIPO/GRTKF/IC/1/7; April 26, 2001.
https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_1/wipo_grtkf_ic_1_7.pdf
6. Documents submitted by the European Union; WIPO/GRTKF/IC/1/8;
 - a. ANNEX I; DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions
 - b. ANNEX II; Explanatory note on recital 27 concerning the indication of the geographical origin of biotechnological inventions (animal and plant aspects)
 - c. ANNEX III; Review Of The Provisions Of Article 27.3(B) Of The Trips Agreement, Communication By The European Communities And Their Member States On The Relationship Between The Convention On Biological Diversity And The Trips Agreement
 - d. ANNEX IV; EU Paper on Intellectual property rights and access to genetic resources and the sharing of benefits arising from their use

¹³ https://www.wipo.int/meetings/en/details.jsp?meeting_id=4295&la=EN

7. Draft Guidelines On Access And Benefit Sharing Regarding The Utilisation Of Genetic Resources: Document submitted by the Government of Switzerland; WIPO/GRTKF/IC/1/9; April 27, 2001.
https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_1/wipo_grtkf_ic_1_9.pdf
8. Proposal Presented By The African Group To The First Meeting Of The Intergovernmental Committee On Intellectual Property And Genetic Resources, Traditional Knowledge And Folklore; WIPO/GRTKF/IC/1/10; May 1, 2001.
https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_1/wipo_grtkf_ic_1_10.pdf
9. Documents submitted by the Member States of the Andean Community; WIPO/GRTKF/IC/1/11; May 1, 2001.
https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_1/wipo_grtkf_ic_1_11.pdf
10. Document submitted by the Delegation of Zambia; WIPO/GRTKF/IC/1/12; May 3, 2001;
https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=1738
11. REPORT adopted by the Committee; WIPO/GRTKF/IC/1/13; May 23, 2001.
https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=1760

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (2001)

As noted previously, the CBD fundamentally broke the earlier FAO norm under which certain plant genetic resources had been treated as the “common heritage of mankind.” By recognizing the sovereign rights of states over genetic resources, the CBD rendered the FAO’s earlier framework legally untenable.

In 1993, the FAO Conference Resolution 7/93¹⁴ called for the negotiation of a revised “International Undertaking” to bring it into harmony with the CBD.

The negotiations took more than seven years. On November 3, 2001, agreement was reached on the text of The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The treaty came into force in 2024.

The ITPGRFA ABS Norms

The ITPGRFA created a Multilateral System (MLS) for access and benefit-sharing covering a set number, initially 64, of food and forage crops. The treaty was seen as an instrument to protect the sharing of certain crop genetic resources in order to support food security and research,

¹⁴ Resolution 7/93, Revision of the international undertaking on plant genetic resources, Adopted 22 November 1993. <https://www.fao.org/4/x5586E/x5586e06.htm#Resolution7>

including plant breeding, but also, following the adoption of the CBD, some benefit sharing obligations.

The agreement provides that recipients of materials from the MLS “shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources . . . or their genetic parts or components, in the form received.” (Article 12.3.d)

The implementation of the MLS involves a Standard Material Transfer Agreement (SMTA), which is a private law contract between parties, setting out conditions that apply when a recipient (a breeder, researcher, company or university) obtains materials from a provider, which is an entity that is part of the MLS. There are currently 18 participating institutions,¹⁵ including national genebanks, a CGIAR center, and some public research institutes.

The benefit sharing obligations are set out in the SMTA and include both mandatory and voluntary measures, and monetary and non-monetary benefits.

Non-monetary Benefits

Section 6.9 of the SMTA **requires** recipients of materials to provide certain information, not considered confidential, that results from research and development, and recipients are **encouraged** to provide additional sharing and capacity building, as well as to place a sample of the product into a collection managed by one of the participating institutions.

*6.9 The Recipient **shall** make available to the Multilateral System, through the information system provided for in Article 17 of the Treaty, all non-confidential information that results from research and development carried out on the Material, and is **encouraged** to share through the Multilateral System non-monetary benefits expressly identified in Article 13.2 of the Treaty that result from such research and development. After the expiry or abandonment of the protection period of an intellectual property right on a Product that incorporates the Material, the Recipient is **encouraged** to place a sample of this Product into a collection that is part of the Multilateral System, for research and breeding.*

Monetary Benefits

Among the mandatory benefits under the ITPGRFA system are monetary payments into a fund established under the treaty, which is officially called the Benefit-Sharing Fund (BSF) of the ITPGRFA. It is administered by FAO under the authority of the Treaty’s Governing Body.

The BSF makes grants, focusing on the support of small-scale farmers, scientists, and breeders to manage crop diversity and adapt to climate change, primarily located in developing countries that are parties to the treaty.

Monetary benefit sharing is required only when a product developed using MLS material is commercialized with restrictions on further research and breeding, due to intellectual property or

¹⁵ Gullotta G, Engels JMM, Halewood M. What Plant Genetic Resources for Food and Agriculture Are Available under the Plant Treaty and Where Is This Information? *Plants* (Basel). 2023 Nov 23;12(23):3944. doi: 10.3390/plants12233944. PMID: 38068581; PMCID: PMC10707996.

contractual protection. Significantly, products that are commercialized without such restrictions are exempt from mandatory monetary benefit sharing.

Under the SMTA, the mandatory monetary payment is set at 1.1 percent of gross sales, less a standard 30 percent deduction for costs, resulting in an effective payment rate of 0.77 percent of gross sales.

Providers of materials are not permitted to impose additional conditions on access beyond those contained in the SMTA, pursuant to Article 12.3(a)–(b) of the Treaty.

Section 6.10 of the SMTA provides that “A Recipient who obtains intellectual property rights on any products developed from the material or its components, obtained from the Multilateral System, and assigns such intellectual property rights to a third party, shall transfer the benefit-sharing obligations of this Agreement to that third party.”

There are no provisions in the ITPGRFA that extend or condition benefit sharing obligations to DSI.

The monetary contributions from users have been modest. According to one FAO web page, “Since the launch of the International Treaty’s Benefit-sharing Fund (BSF) in 2009, it has received contributions of almost USD 30 million” from a combination of voluntary contributions and user-based income.¹⁶ More recent estimates place the contributions to the fund closer to \$38 million. However, the contributions to the BSF from users have apparently been a small fraction of the total. According to one report, only 6 of 25,000 users had made monetary contributions, collectively totaling less than \$1 million.

Over the past two decades, approximately 6.6 million varieties of seeds & planting materials have been shared with nearly 25,000 users. However, only six recipients have contributed to the Benefit-Sharing Fund, totalling \$824,680, which is approximately 2.2% of the Fund’s total.¹⁷

One of the reasons cited for the small number of instances in which mandatory royalty payments are triggered under the ITPGRFA is that many countries provide for some form of exceptions for research and breeding under national patent or plant breeder laws (see Article 15.1 of UPOV 1991), preventing the monetary benefit-sharing trigger from being activated.

Others see the lack of monetary contributions by users as a problem related to a lack of resources and staff devoted to monitoring compliance with the benefit sharing obligation. The Compliance Committee and the Secretariat have often noted that tracking a seed from a

¹⁶ <https://www.fao.org/plant-treaty/areas-of-work/benefit-sharing-fund/financial-resources/en/> Voluntary contributors to the Benefit-sharing Fund include Australia, Austria, Germany, the European Commission, India, Indonesia, Ireland, Italy, the Netherlands, Norway, Spain, Sweden and Switzerland. Further contributions have been made by the European Seed Association, the International Seed Federation, IFAD, SEMAE (formerly, Groupement National Interprofessionnel des Semences), ProSpecieRara Hauptsitz and a Norwegian initiative to contribute a percentage of the value of their annual national seed sales to the BSF.

¹⁷ Kundan Pandey, Global rift over plant treaty as key issues remain unresolved, 18 Jul 2025, Mongabay. <https://india.mongabay.com/2025/07/global-rift-surfaces-over-plant-treaty-as-key-issues-remain-unresolved/>

genebank through 10–15 years of R&D to a final commercial product is a massive administrative task. Without an effective automated tracking system, the Treaty relies largely on self-reporting by companies, which many critics argue is insufficient.

There have been efforts to expand the number of crops covered by the treaty, but this has met resistance, in part because of criticism over the small amount of money contributed from the commercial sales of products and controversy over extending benefits sharing to DSI.

Comments on the ITPGRFA MLS

The ITPGRFA was designed to preserve open and predictable access to plant genetic resources for research and breeding in a post-CBD environment that emphasized benefit sharing and sovereign control. The MLS has been effective in facilitating research and exchange of covered crops, through predictable access, standardized conditions and by eliminating requirements for case-by-case negotiations. The benefit-sharing mechanisms, on the other hand, have delivered far less than originally anticipated, primarily because the mandatory monetary benefit sharing is rarely triggered and lacks enforcement measures.

The UN Declaration on the Rights of Indigenous Peoples (2007)

On September 13, 2007, the United Nations General Assembly adopted the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP).¹⁸ The Declaration is not legally binding on UN Members, but its norms set standards for the individual and collective rights of Indigenous peoples. Among other matters, Article 31 of UNDRIP states that Indigenous peoples have the right to maintain, control, protect and develop rights in intellectual property over cultural heritage, traditional knowledge, and traditional cultural expressions.

Article 31

Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.

The initial vote to adopt the resolution was 143 states in favor, with four votes in opposition (Australia, Canada, New Zealand, and the United States) and 11 abstentions. In 2009 and 2010, officials for all four states that voted against the Declaration made public statements endorsing the Declaration.

¹⁸ Resolution 61/295, United Nations Declaration on the Rights of Indigenous Peoples. 12 September 2007. <https://docs.un.org/en/A/res/61/295>

The UNDRIP, while not legally binding, is widely seen as authoritative. The Declaration strengthened claims that Indigenous peoples are rights-holders for traditional knowledge, and not only stakeholders.

The Nagoya Protocol (2010)

The Nagoya Protocol was adopted on 29 October 2010 at the 10th Conference of the Parties (COP-10) to the Convention on Biological Diversity in Nagoya, Japan. It entered into force on 12 October 2014, after reaching 50 ratifications.

The formal launch of the negotiations began in 2004, at the CBD COP-7 in Kuala Lumpur. The negotiations largely overlapped with parallel negotiations at the WHO on the PIP Framework, which was developed in response to a crisis over the sharing of H5N1 influenza viruses. This framework created a specific system for benefit-sharing related to pandemic influenza preparedness, highlighting the concrete nature of access and benefit-sharing (ABS) disputes.

The Nagoya Protocol was motivated by concerns that the CBD's general ABS provisions lacked legal certainty and effective compliance mechanisms in user countries. The Protocol sought to operationalize Article 15 of the CBD by introducing clearer procedures for prior informed consent and mutually agreed terms. It also requires user countries to adopt measures to support compliance with the provider country's laws, along with establishing monitoring mechanisms. The protocol was influenced in part by experiences under the FAO's 2001 ITPGRFA, and the ongoing negotiations at the WHO on the PIP Framework.

The Protocol created, in Article 4, space for "other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol," and in Article 10, the possibility of a global multilateral benefit-sharing mechanism for "transboundary situations or for which it is not possible to grant or obtain prior informed consent."

Article 1. Objective

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

Article 4. Relationship with International Agreements and Instruments

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.
2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of

the Convention and this Protocol.

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

Article 5. Fair and Equitable Benefit-sharing

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.

5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Article 7. Access to Traditional Knowledge Associated with Genetic Resources

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

Article 10. Global Multilateral Benefit-sharing Mechanism

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

The Pandemic Influenza Preparedness (PIP) Framework (2011)

The WHO PIP Framework is a mechanism whereby Member States share "influenza viruses with potential to cause human pandemic" through a Global Influenza Surveillance and Response System (GISRS). Access to the system by influenza vaccine, diagnostic, and pharmaceutical manufacturers and health researchers is conditioned on contracts signed between companies or institutions and the WHO. The contracts include benefit-sharing obligations.

The benefit-sharing obligations include financial payments to WHO and, for commercial manufacturers, *ex ante* contractual commitments to supply free and affordable-priced vaccines, antivirals, or diagnostics for WHO allocation. Non-commercial users typically provide benefits through capacity-building, training, surveillance support, and research cooperation. While technology transfer and licensing to enable generic manufacturing are included among the listed benefit-sharing options, such commitments have generally not been realized in practice.

The PIP Framework was formally created by the World Health Assembly (WHA) in 2011, following four years of negotiations. The initiative was initially motivated by Indonesia's refusal in 2006–2007 to share H5N1 avian influenza virus samples with the WHO's GISRS without an agreement that would address access and benefit sharing.

A Report by the WHO Secretariat to the WHO Executive Board in 2006¹⁹ included these comments:

8. The Secretariat has recently formulated a set of best practices for the sharing of influenza viruses, which were endorsed during the first meeting of the Influenza Pandemic Task Force (25 September 2006), convened pursuant to resolution WHA59.2. These recommended practices make a clear distinction between procedures specific to the sharing of H5N1 viruses and other long-standing procedures for the sharing of seasonal influenza viruses. Routine sharing of seasonal influenza viruses, coordinated internationally by WHO since 1947, functions smoothly to guide the composition of annual vaccines for seasonal influenza and maintain vigilance for the emergence of novel virus strains, including those with pandemic potential.

9. The sharing of H5N1 viruses raises a unique set of issues not seen during the routine sharing of seasonal influenza viruses. These issues stem from three characteristics of H5N1 viruses: (a) their high pathogenicity for animals and humans, which restricts research to a limited number of specially equipped laboratories; (b) the need to use a patented technology, called reverse genetics, when rendering these viruses safe for use in the development of candidate pandemic vaccines; and (c) the great significance of H5N1 viruses as an agricultural threat and a pandemic threat to international public

¹⁹ Avian and pandemic influenza: developments, response and follow-up, and application of the International Health Regulations (2005), Report by the Secretariat, IB120/15, 14 December 2006.

health, which increases the need for collaborative research on these viruses and the global need for access to medical interventions that may be a product of this research.

In February 2007, David Fidler described the Indonesian decision as follows:²⁰

Indonesia's decision to stop sharing samples with WHO flows from its concern that it and other developing countries are not treated equitably after they share samples with WHO. Vaccine development based on the samples occurs mainly by pharmaceutical companies in developed countries, which patent their vaccines, making them more expensive for developing countries to obtain. In addition, given that influenza vaccine manufacturing capabilities are mainly found in developed countries, developing countries fear that they will have little to no access to vaccine if a pandemic strain emerges. Thus, developing-country participation in sharing viral samples to support global surveillance produces a process that renders access to vaccine interventions inequitable.

In a context permeated by concerns about pandemic influenza, such inequitable access reduces incentives for developing countries to participate fully in sample sharing for surveillance purposes. Instead, Indonesia's negotiations for a commercial arrangement with Baxter International reveal a desire to exploit the potential of the samples more directly for the benefit of Indonesia and perhaps other developing countries.

A March 27, 2007 WHO press release²¹ described the negotiations with Indonesia on sharing influenza virus samples as follows:

H5N1 avian influenza virus samples following a WHO meeting in Jakarta

27 March 2007 News release Jakarta

WHO welcomes the news from the Minister of Health of Indonesia, who announced at a joint news conference today that the country would resume sharing of H5N1 avian influenza virus samples "immediately". This commitment by the Government of Indonesia follows a two-day meeting organized by WHO in Jakarta on 26-27 March 2007.

Indonesia's Minister of Health, Siti Fadilah Supari, has focused global attention on the fact that developing countries have supplied H5N1 virus to WHO Collaborating Centres for analysis and preparation for vaccine production, but that the resulting vaccines produced by commercial companies are likely to be unavailable to developing countries such as Indonesia. She called this system "unfair."

At the same time, withholding viruses from WHO Collaborating Centres poses a threat to global public health security and the ongoing risk assessment for influenza, conducted by WHO Collaborating Centres.

²⁰ David P Fidler, Indonesia's Decision to Withhold Influenza Virus Samples from the World Health Organization: Implications for International Law, [ASIL Insights](#), Volume 11, Issue 4, February 28, 2007.

²¹ Indonesia to resume sharing H5N1 avian influenza virus samples following a WHO meeting in Jakarta 27 March 2007 News release, Jakarta.
<https://www.who.int/news/item/27-03-2007-indonesia-to-resume-sharing-h5n1-avian-influenza-virus-samples-following-a-who-meeting-in-jakarta>

WHO Collaborating Centres perform a number of key influenza-related public health activities, including:

- determining if the virus has acquired human genes or made other significant changes;
- identification of potential vaccine strains;
- testing to determine if the virus remains vulnerable to the recommended class of antivirals;
- tracking the evolution of the virus and its geographic spread; and
- updating diagnostics tests which may be necessary because the H5N1 virus, like all influenza viruses, constantly mutates.

WHO has welcomed the attention that the Minister has focused on this issue and her concern for developing country needs. In order to address these concerns and to maintain sample sharing for risk assessment, WHO organized the Jakarta 26-27 March meeting entitled "High Level Technical Meeting on Responsible Practices for Sharing Avian Influenza Viruses and Resulting Benefits".

Experts at the meeting included representatives from approximately 20 countries which have had H5N1 animal or human outbreaks; senior scientists, including directors of WHO Collaborating Centres; and potential funders, including representatives from the Asian Development Bank and the Gates Foundation.

"We have struck a balance between the need to continue the sharing of influenza viruses for risk assessment and for vaccine development, and the need to help ensure that developing countries benefit from sharing without compromising global public health security," said Dr David Heymann, WHO's Assistant Director-General for Communicable Diseases.

When the meeting ended today, the Minister of Health of Indonesia reviewed the recommendations and concluded that Indonesian viruses could once again be shared with WHO. The specific conclusions of the technical meeting include the following:

WHO Collaborating Centres will continue risk assessment on H5N1 virus samples. The centres will continue to transform virus into seed virus suitable for vaccine production. This process will be documented in a revised Terms of Reference for the WHO laboratories. Other agreed uses of the virus will also be outlined in the terms of reference - including the standard procedures for providing these seed viruses to vaccine manufacturers (which has been the practice for the last 50 years) - in a manner to be determined.

The meeting endorsed WHO's activities to increase safe and effective pandemic vaccine access, including efforts to mobilize the financial support required to develop a vaccine stockpile and to develop guidelines for the equitable and appropriate distribution of stockpiled vaccines to countries if an influenza pandemic occurs.

At the meeting, WHO's activities to strengthen national laboratory capacity, and to designate regional WHO H5 influenza reference laboratories in order to strengthen WHO's global influenza surveillance activities, were strongly endorsed.

Finally, the meeting endorsed WHO's efforts to link vaccine manufacturers in developed and developing countries to speed the transfer of influenza vaccine manufacturing technology.

Transcript of today's news conference

The following is a partial, edited transcript of the comments made by Dr Heymann at the news

conference held today in Jakarta at which Indonesia's Minister of Health announced the resumption of virus sharing.

Dr Heymann: The details will be worked out in the terms of reference which will describe exactly what a Collaborating Centre can do with the viruses provided through surveillance. This will be a standard document developed by WHO and it will be developed with input from WHO's member countries, of course. That document will, we believe, permit WHO to receive shared viruses for risk assessment, to develop non-commercial diagnostic tests and to characterize the viruses in addition to preparing seed strains for vaccine. Those seed strains will then be shared with pharmaceutical companies to develop vaccine, and that mechanism will be outlined in the terms of reference of the WHO Collaborating Centres.

How will vaccine be made available to countries from vaccine manufacturers?

Dr Heymann: That will be necessary for the countries to negotiate. WHO is not involved in financial negotiations, either in selling viruses or buying vaccines. Countries will negotiate bilaterally with vaccine manufacturers. We will certainly facilitate if countries are asking for support but it won't be standard.

...

I think that Indonesia has raised an issue that is very important. An issue which will broaden the dialogue and access to vaccines, and we are very grateful to the Minister for having shown us the way forward with the other 18 developing countries that are here in Jakarta – most of them are virus sharing countries. And our relationship with the Minister of Health has been positive throughout the four months we have been discussing virus sharing - since the very beginning of our discussion in November.

Now we will finalize the WHO best practices for virus sharing that will go to the World Health Assembly where all countries will debate it.

...

Stephanie Nebehay, writing for Reuters, described the negotiations as follows in this August 29, 2007 report:

Poor countries demand fair share of bird flu vaccines

Stephanie Nebehay, for [Reuters](#)

August 9, 2007

Developing countries led by Indonesia demanded a fair deal on Tuesday for providing samples of the deadly H5N1 bird flu virus that drug companies use to make vaccines.

A resolution, presented by 17 countries at the annual World Health Assembly, came as Indonesia said it had resumed sharing virus samples with the World Health Organisation (WHO) after a five-month hiatus.

The United Nations agency, under growing pressure from countries hard-hit by the disease, is trying to come up with a new formula for sharing of samples and the resulting benefits.

Indonesian Health Minister Siti Fadillah Supari said the WHO's 50-year-old sharing system was unfair to poor countries.

"There is an unfair mechanism in which avian flu virus samples are provided free by developing countries but drug companies patented this vaccine and are selling them at unaffordable cost for the developing countries," Supari told the assembly.

Genetic sequencing had been used in published research, commercialisation and patent requests without consent, she said. "Such practice violates the spirit in which virus is given."

David Heymann, the top WHO bird flu official, said that sharing was essential to track the virus's evolution worldwide.

He also acknowledged that some WHO collaborating centres had sought patents on "parts of the virus" they had obtained through the network, but gave no specifics.

...

Indonesia in February signed a memorandum of understanding with a unit of U.S. company Baxter International Inc to develop a bird flu vaccine.

Supari said Indonesia would require drug companies wishing to develop a vaccine from its samples to seek its permission. Jakarta would seek guarantees on preferential pricing, "fair distribution" of vaccines worldwide and transfer of technology.

The WHO PIP Framework ABS Norms

The WHO PIP Framework was created as a response to the 2006 decision by Indonesia to withhold samples of the avian flu virus from GISRS, due to the shared concerns by several developing countries that the recipients of the samples were seeking patents on the virus, not making vaccines or other countermeasures available at reasonable prices, and resisting the transfer of manufacturing technology.

GISRS is a 70-year-old international network of laboratories coordinated by the WHO that serves as an early warning system for influenza, monitoring how viruses are changing and deciding which strains should be part of annual flu vaccines. GISRS is a network of 140 National Influenza Centres (NICs) in more than 115 countries, with different mandates and capacities. GISRS facilitates the collection of samples, high-level genetic and antigenic analysis, and the development of "reagents" and candidate vaccine viruses that companies need to start mass production.

The PIP Framework was formally adopted by the World Health Assembly in 2011, in resolution [WHA64.5](#). The negotiations, which took years, created a system modeled partly after the ITPGRFA but with important differences.

Like the ITPGRFA, contracts are used, but not all contracts are standard. Specifically, contracts with recipients of samples "outside" GISRS are negotiated, working from a template that includes options and elections. Among the benefit sharing options for manufacturers are conditions regarding pricing and access.

Section 6.14 of the PIP Framework establishes a sustainable financing mechanism under which influenza vaccine, diagnostic, and pharmaceutical manufacturers using GISRS are required to make annual partnership contributions to WHO equivalent to 50 percent of the running costs of

GISRS. WHO determines the annual running costs and allocates the total contribution among manufacturers based on objective criteria reflecting their size, nature, and level of engagement.

The SMTA1

The Standard Material Transfer Agreement 1, or SMTA1, is a non-negotiable, standardized agreement designed to ensure the timely sharing of materials within the WHO GISRS.

- SMTA1 has non-monetary benefit sharing obligations, which include: Scientific Collaboration (Article 5.2) and Credit and Acknowledgement (Article 5.3).
- All transfers of samples must be recorded in the Influenza Virus Traceability Mechanism (IVTM).
- Article 6.1 of SMTA1 provides that “Neither the Provider nor the Recipient should seek to obtain any intellectual property rights (IPRs) on the Materials.”
- There are no conditions on pricing, access or monetary payments in the SMTA1.

The SMTA2

The SMTA2 (Standard Material Transfer Agreement 2) is a contract between the WHO and commercial and non-commercial researchers who receive biological materials. These contracts are subject to negotiation. The recipients of biological materials are divided into three categories.

Category A: Manufacturers of vaccines and antivirals (e.g., GSK, Sanofi, Serum Institute of India).

Category B: Manufacturers of products other than vaccines or antivirals, such as diagnostic kits or syringes (Becton Dickinson, Quidel).

Category C: Universities, academic institutions, and biotechnology firms doing research (e.g., Harvard, Oxford, small biotech startups).

Category A Company Benefit Sharing

The Category A manufacturers of vaccines or antivirals are given six options, of which a manufacturer has to commit to at least two. For vaccine manufacturers, options A1, A2, A5 and A6 are relevant. In practice, vaccine manufacturers have elected a negotiated and modified version of A1 and A2.

- A1. Donate at least 10 percent of real time pandemic vaccine production to WHO.
- A2. Reserve at least 10 percent of real time pandemic vaccine production at affordable prices to WHO.
- A3. Donate at least X treatment courses of needed antiviral medicine for the pandemic to WHO.
- A4. Reserve at least X treatment courses of needed antiviral medicine for the pandemic at affordable prices.
- A5. Grant to manufacturers in developing countries licenses on mutually agreed terms that should be fair and reasonable including in respect to affordable royalties, taking into account development levels in the country of end use of the

products, on technology know-how, products and process for which it holds IPR for the reproduction of (i) influenza vaccines, (ii) adjuvants, (iii) antiviral and/or (iv) diagnostics.

- A6. Grant royalty-free licenses to manufacturers in developing countries or grant to WHO royalty-free, non-exclusive licenses on IPR, which can be sublicensed, for the production of pandemic influenza vaccines, adjuvants, antiviral products and diagnostics needed in a pandemic. WHO may sublicense these licenses to manufacturers in developing countries on appropriate terms and conditions and in accordance with sound public health principles.

The WHO provides web pages with copies of signed SMTA2 contracts. All of the 16 Category A companies were vaccine manufacturers, and none of them elected to provide options A5 or A6, which involve licenses for the transfers of know-how or intellectual property rights. Only one of the contracts had agreed to the minimum 10 percent donation of real time production, and none agreed to 10 percent of production at affordable prices.

All of the Category A contracts had at least 10 percent of production committed to some combination of donations and affordable prices. Thirteen of the 16 SMTA2 contracts have exactly 10 percent of production covered by a combination of donations and affordable prices, including 10 SMTA2 contracts that committed 8 percent of production for donations to the WHO and 2 percent reserved for affordable pricing. All of the contracts signed after March 14, 2017, involved a combination of donations and affordable pricing that totaled 10 percent, or half the recommended minimums set out in the SMTA2 template.

Table 2: PIP Framework: Category A Vaccine Company Negotiated Benefit Sharing Terms

Company	Country	Date signed*	Donation	Affordable price
Serum Institute of India	India	Oct 1, 2013	8	2
Sanofi Pasteur	France	Feb 4, 2014	7.5	7.5
Takeda Pharmaceutical Company	Japan	Mar 16, 2016	8	2
China National Biotec Group Company Limited	China	May 13, 2016	8	8
MedImmune LLC	USA	Oct 12, 2016	9	1
Kitasato Daiichi Sankyo Vaccine Co. Ltd.	Japan	Jan 26, 2017	8	2
Sinovac Biotech Co. Ltd.	China	Mar 13, 2017	8	2
Seqirus UK Limited	UK	Mar 14, 2017	10	2.5
Research Foundation for Microbial Diseases of Osaka University (BIKEN)	Japan	Mar 24, 2017	8	2
Green Cross Corporation	Korea	Apr 14, 2017	7	3
Denka Seiken	Japan	May 20, 2017	8	2
KM Biologics Co. Ltd.	Japan	Apr 18, 2019	8	2
Government Pharmaceutical Organization	Thailand	Jun 24, 2020	5	5
Glaxo Group Limited	England	May 26, 2022	8	2

Adimmune Corporation	Taiwan	May 13, 2024	8	2
Zydus Lifesciences Limited	India	Nov 4, 2025	8	2
* Date signed by the company, when available.				

Category B Company Benefit Sharing

Category B companies are required to pick one of six options, including either Options A5 and A6 regarding technology transfer, or two options specific to diagnostic products, one for capacity building and one involving support for technology transfer.

- B1. Donate to WHO at least X diagnostic kits needed for pandemics.
- B2. Reserve for WHO at least X diagnostic kits needed for pandemics, at affordable prices.
- B3. Support, in coordination with WHO, the strengthening of influenza specific laboratory and surveillance capacity in developing countries.
- B4. Support, in coordination with WHO, transfer of technology, know-how and/or processes for pandemic influenza preparedness and response in developing countries.

Only two Category B companies have signed contracts, Becton Dickinson and Quidel Corporation, both USA-based. Becton Dickinson agreed to donate 25 million syringes needed for influenza pandemics, and Quidel agreed to reserve for the WHO at least 250,000 diagnostic kits needed for pandemic response at affordable prices.

Category C Entity Benefit Sharing

Category C recipients are generally non-commercial or small-scale commercial entities that are not primarily focused on the mass production of influenza vaccines or antivirals. This includes academic and research Institutions, laboratories outside the WHO GISRS, firms that may be developing early-stage technologies or diagnostics but do not yet have large-scale manufacturing capacity, and Contract Research Organizations (CROs) performing specific research or testing on behalf of others.

The WHO has published 82 contracts with Category C entities. For 81 of the 82 contracts, the benefit sharing obligation is a standard clause (5.2) that provides a list of 9 measures that the signatory establishment “shall consider” but is not required to undertake. The contracts provide that a Category C recipient may only transfer PIP biological materials to entities that have concluded an SMTA with the WHO.

The 2019 WHA72.12 Decision

In 2019, the World Health Assembly adopted decision WHA72.12, which amended a footnote in Annex 2 of the PIP Framework. The amended footnote provided that manufacturers that have contracts or agreements with recipients of PIP Biological Materials are also required to enter into an SMTA2 contract.

Any manufacturer that enters into any contracts or formal agreements with recipients or GISRS laboratories for the purpose of using PIP Biological Materials on the manufacturer's behalf for commercialization, public use or regulatory approval of that manufacturer's vaccines, diagnostics, or pharmaceuticals shall also enter into an SMTA2 and select from among the commitments identified in Article 4.1.1 (a) to (c) based on their nature and capacities.

This change was designed to address cases where a manufacturer had obtained a virus from an entity that only had the very weak Category C benefit sharing obligations.

The WHO has been trying to extend the requirements to pay dues and undertake the benefit sharing obligations to entities that use digital sequence information, but this remains a legally ambiguous area and has met industry resistance. The WHO has been relatively successful in asserting that manufacturers who never receive physical viruses from the WHO can still be obligated to pay the Partnership Contribution dues. However, industry groups, led by the IFPMA, claim the SMTA2 obligations on sharing donations and tiered priced products are not binding.

The 2023 BBNJ Treaty, Provisions on Access and Benefit Sharing

In 2023, negotiations concluded on the Agreement Under The United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction, known as the BBNJ Agreement. The treaty required 60 ratifications and came into force on January 17, 2026. Key policies on the benefit sharing will depend upon future decisions.

The negotiations began in 2004, with the establishment of an Ad Hoc Open-ended Informal Working Group. In its resolution 59/24 of 17 November 2004, the General Assembly decided to establish an Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction. After nine sessions, the Group made recommendations to the General Assembly (A/69/780) on the scope, parameters and feasibility of an international instrument under the United Nations Convention on the Law of the Sea.²²

The agreement included access and benefit sharing provisions that were significantly different from the CBD, the Nagoya Protocol, the FAO ITPGRFA, or the PIP Framework.

Marine genetic resources (MGRs) are defined to include “any material of marine plant, animal, microbial or other origin containing functional units of heredity of actual or potential value.” The agreement refers to DSI 30 times.

²² General Assembly. A/69/780. Outcome of the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction and Co-Chairs' summary of discussions. 13 February 2013.
<https://docs.un.org/en/A/69/780>

There is no claim for state sovereignty over MGRs, and they are not considered common heritage. The agreement regulates both physical genetic resources and DSI.

There is monetary benefit sharing, which is mandatory, but deferred and only applied to product sales. The terms will be defined later in the Conference of Parties (COP) decisions.

The access and benefit-sharing regime established under the BBNJ Agreement represents a deliberate departure from traditional, transaction-based ABS models. Rather than conditioning access to MGRs on prior consent or negotiated contracts, the BBNJ Agreement preserves open access to resources in areas beyond national jurisdiction and addresses equity through a multilateral benefit-sharing mechanism triggered by use and commercialization.

Non-monetary benefits—such as data sharing, capacity building, and technology transfer—are expected to flow early and broadly, while monetary benefits are to be contributed to a collective mechanism and allocated through COP decisions, without reference to origin or individual access events.

Some of the differences with earlier ABS mechanisms are fundamental to notions of sovereignty. The BBNJ Agreement concerns “areas beyond national jurisdiction,” so national sovereignty over genetic resources does not make sense. On the other hand, the BBNJ Agreement does provide that “traditional knowledge held by Indigenous Peoples and local communities shall only be accessed with the free, prior and informed consent or approval and involvement of these Indigenous Peoples and local communities.” (Article 13).

The BBNJ Agreement integrated DSI into its core text from the start, making it legally central to the treaty's benefit-sharing architecture. The implementation anticipates the use of a Standardized Batch Identifier (SBI), which will be developed in connection with the Agreement's Clearing House Mechanism (CHM). While the concepts have a legal basis in the text, the actual implementation has yet to be worked out.

Aside from whatever arrangements involving Indigenous peoples and local communities regarding traditional knowledge require, there are monetary and non-monetary benefits shared when genetic resources (including DSI) are accessed and used. Significantly, the benefit sharing obligations for the use of genetic resources do not depend on contracts, and are enforced by the treaty parties.

BBNJ Monetary Benefit Sharing

Article 15 of the Agreement creates a 15 member Access and Benefit-Sharing Committee (ABSC), elected by the COP. The COP will ultimately set, assess and periodically review the rules. The monetary benefits from the utilization of MGR and DSI are described in Article 14.7 as follows:

- (a) Milestone payments;
- (b) Payments or contributions related to the commercialization of products, including payment of a percentage of the revenue from sales of products;

- (c) A tiered fee, paid on a periodic basis, based on a diversified set of indicators measuring the aggregate level of activities by a Party;
- (d) Other forms as decided by the Conference of the Parties, taking into account recommendations of the access and benefit-sharing committee.

The milestone payments are expected to be based upon factors such as the filing or approval of patent applications, the completion of a clinical trial or obtaining marketing approval for a product, when the patent or the product is based in part upon relevant MGR/DSI. The milestone payments will be prior to and independent of a product generating sales.

In option (b), payments based upon a percentage of sales, are similar to a royalty or an excise or sales tax on a product.

In option (c), the tiered fee based on a “diversified set of indicators measuring the aggregate level of activities by a Party,” will be higher for countries that have a larger biotech section, or patent filings, and high DSI usage.

Option (d) is open ended, and provides flexibility to innovate on the obligations, going forward.

Legally, all of the monetary benefits are obligations on State Parties, and leave it up to national governments to ensure that money finds its way into the global fund. Governments can require entities that trigger the monetary benefit obligations to contribute directly to the fund, or the government can collect the money from a company, on behalf of the fund.

One parallel would be the UNITAID funding system, which originally assessed fees on its government members based upon the number of economy and premium airline tickets. Some UNITAID members collected fees from airlines, while others paid the UNITAID contributions from general tax revenues.

The upcoming BBNJ PrepCom3 (March 23 – April 2, 2026)²³ in New York is a forum where the “diversified set of indicators” for tiered fees will be discussed. Among the proposals are the number of BBNJ-related patents held by a country's entities and the volume of DSI downloads from high-seas datasets, national R&D budgets, and or gross biotech revenue as proxies for the “aggregate level of activity.”

BBNJ Non-monetary Benefit Sharing

Article 14.2 of the Agreement provides a non-exclusive list of eight types of non-monetary benefit sharing. The list includes measures relating to access to samples and digital sequence information, and “open access to findable, accessible, interoperable and reusable (FAIR) scientific data,” as well as references to the transfer of marine technology, capacity building, scientific cooperation and an open ended “other forms of benefits.”

Of these benefits, the only ones that appear to have a mandatory character, found in other parts of the treaty text, are those relating to access to samples and DSI.

²³ <https://www.un.org/bbnjagreement/en/third-session-23-march-2-april-2026>. The session is mandated by UN General Assembly Resolution 78/272 to finalize recommendations for the first Conference of the Parties (COP1), focusing on the operationalization of the financial mechanism and benefit-sharing rules.

Article 14 - Fair and equitable sharing of benefits

2. Non-monetary benefits shall be shared in accordance with this Agreement in the form of, *inter alia*:

- (a) Access to samples and sample collections in accordance with current international practice;
- (b) Access to digital sequence information in accordance with current international practice;
- (c) Open access to findable, accessible, interoperable and reusable (FAIR) scientific data in accordance with current international practice and open and responsible data governance;
- (d) Information contained in the notifications, along with “BBNJ” standardized batch identifiers, provided in accordance with article 12, in publicly searchable and accessible forms;
- (e) Transfer of marine technology in line with relevant modalities provided under Part V of this Agreement;
- (f) Capacity-building, including by financing research programmes, and partnership opportunities, particularly directly relevant and substantial ones, for scientists and researchers in research projects, as well as dedicated initiatives, in particular for developing States, taking into account the special circumstances of small island developing States and of least developed countries;
- (g) Increased technical and scientific cooperation, in particular with scientists from and scientific institutions in developing States;
- (h) Other forms of benefits as determined by the Conference of the Parties, taking into account recommendations of the access and benefit-sharing committee established under article 15.

3. Parties shall take the necessary legislative, administrative or policy measures to ensure that marine genetic resources and digital sequence information on marine genetic resources of areas beyond national jurisdiction, together with their “BBNJ” standardized batch identifiers, subject to utilization by natural or juridical persons under their jurisdiction are deposited in publicly accessible repositories and databases, maintained either nationally or internationally, no later than three years from the start of such utilization, or as soon as they become available, taking into account current international practice.

While the BBNJ Agreement does present a broad menu of non-monetary benefits, there is a clear legal hierarchy. Article 14.3 stands as the primary mandatory obligation, requiring States to ensure that MGRs and DSI are placed in public databases. In contrast, provisions for technology transfer and capacity building are largely facilitative or 'soft' obligations, qualified by “capabilities” reduced to an obligation to “cooperate to achieve” an objective, or the requirement that technology transfer occurs on “mutually agreed terms,” making them collectively more aspirational in practice.

This hierarchy creates a “Data-First” regime. The treaty ensures that the information (the sequences) is shared globally as a mandatory public good, while the tools to use that information (the technology) remain largely protected by intellectual property norms and voluntary cooperation.

WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (2024)

On May 24, 2024, an agreement was reached on the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge. The Treaty requires patent applicants to disclose the country of origin of the genetic resources and/or the Indigenous peoples or local community providing the associated traditional knowledge, if the claimed inventions are based on genetic resources and/or associated traditional knowledge. The treaty did not establish any substantive rights associated with either genetic resources or traditional knowledge, topics that continue to be discussed at the IGC.

The Cali Fund (2024)

The Cali Fund was established in 2024 during the COP-16 UN Biodiversity Conference in Cali, Colombia, to create a mechanism for benefit sharing tied to the use of DSI on genetic resources.

Negotiations on the Cali fund began in 2018, at COP-14 of the CBD in Sharm el-Sheikh, where parties adopted Decision 14/20 on DSI.²⁴ Decision 14/20 acknowledged the negotiations regarding digital sequence information in other global fora.

Noting the relevant discussions on digital sequence information on genetic resources and related issues in other United Nations bodies and instruments, such as the Food and Agriculture Organization of the United Nations, the International Treaty on Plant Genetic Resources for Food and Agriculture, the World Health Organization, the World Intellectual Property Organization and the United Nations General Assembly.

At CBD COP-15, in Montreal, the Parties adopted Decision 15/9.²⁵ This five-page decision set out the framework for the creation of the Cali Fund.

Decision Adopted By The Conference Of The Parties To The Convention On Biological Diversity 15/9. Digital sequence information on genetic resources. DBC/COP/DEC/15/9, 19 December 2022.

...
Recognizing the different understandings of the concept and scope of digital sequence information on genetic resources, and the range of views regarding the need to define such concept and scope,

²⁴ Decision Adopted By The Conference Of The Parties To The Convention On Biological Diversity 14/20. Digital sequence information on genetic resources. CBD/COP/DEC/14/20. 30 November 2018.

<https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-20-en.pdf>

²⁵ Decision Adopted By The Conference Of The Parties To The Convention On Biological Diversity 15/9. Digital sequence information on genetic resources. DBC/COP/DEC/15/9, 19 December 2022.

<https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf>

1. Agrees on the continuing use of the term “digital sequence information” for further discussions;
2. Also agrees that the benefits from the use of digital sequence information on genetic resources should be shared fairly and equitably;
3. Considers that the distribution of digital sequence information on genetic resources and distinctive practices in its use require a distinctive solution for benefit-sharing;
4. Encourages the depositing of more digital sequence information on genetic resources, with appropriate information on geographical origin and other relevant metadata, in public databases;
5. Recognizes that tracking and tracing of all digital sequence information on genetic resources is not practical;
6. Also recognizes that a multilateral approach on the sharing of the benefits arising from the use of digital sequence information on genetic resources has the potential to meet the criteria identified in paragraph 9 of the present decision;
7. Further recognizes that in the course of further analysis, exceptions to paragraph 6 above may be identified;
8. Agrees to develop a solution for the sharing of benefits arising from the use of digital sequence information on genetic resources;
9. Also agrees that a solution for fair and equitable benefit-sharing on digital sequence information on genetic resources should, inter alia:
 - (a) Be efficient, feasible and practical;
 - (b) Generate more benefits, including both monetary and non-monetary, than costs;
 - (c) Be effective;
 - (d) Provide certainty and legal clarity for providers and users of digital sequence information on genetic resources;
 - (e) Not hinder research and innovation;
 - (f) Be consistent with open access to data;
 - (g) Not be incompatible with international legal obligations;
 - (h) Be mutually supportive of other access and benefit-sharing instruments;
 - (i) Take into account the rights of indigenous peoples and local communities, including with respect to the traditional knowledge associated with genetic resources that they hold;
10. Recognizes that the monetary and non-monetary benefits arising from the use of digital sequence information on genetic resources should, in particular, be used to support

conservation and sustainable use of biological diversity and, inter alia, benefit indigenous peoples and local communities;

11. Agrees that the approach to fair and equitable benefit-sharing from the use of digital sequence information on genetic resources set out in the present decision does not affect existing rights and obligations under the Convention and the Nagoya Protocol, including, as applicable, those related to traditional knowledge and the rights of indigenous peoples and local communities, and is without prejudice to national access and benefit-sharing measures;

An Annex to the decision set out 16 issues for further consideration:

ISSUES FOR FURTHER CONSIDERATION

- (a) Governance of the fund;
- (b) Triggering points for benefit-sharing;
- (c) Contributions to the fund;
- (d) Potential to voluntarily extend the multilateral mechanism to genetic resources or biological diversity;
- (e) Disbursement of monetary benefits, including information on geographical origin as one of the criteria;
- (f) Non-monetary benefit-sharing, including information on geographical origin as one of the criteria;
- (g) Other policy options for the sharing of benefits from the use of digital sequence information on genetic resources, including as identified through further analysis, as referred to in paragraphs 6 and 7 of the present decision;
- (h) Capacity development and technology transfer;
- (i) Monitoring and evaluation and review of effectiveness;
- (j) Adaptability of the mechanism to other resource mobilization instruments or funds;
- (k) Interface between national systems and the multilateral mechanism on benefit-sharing;
- (l) Relationship with the Nagoya Protocol;
- (m) Role, rights and interests of indigenous peoples and local communities, including associated traditional knowledge;
- (n) Role and interests of industry and academia;
- (o) Linkages between research and technology and the multilateral mechanism on benefit-sharing;
- (p) Principles of data governance.

A decision adopted at CBD COP-16 on November 1, 2024,²⁶ set out the modalities for operationalizing the fund. Seven industrial sectors were identified that may benefit directly or indirectly from the use of DSI on genetic resources:

- (a) Pharmaceuticals;
- (b) Nutraceuticals (food and health supplements);
- (c) Cosmetics;
- (d) Animal and plant breeding;
- (e) Biotechnology;

²⁶ Decision by the Conference of the Parties to the Convention on Biological Diversity on 1 November 2024, (CBD/COP/DEC/16/2) <https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf>

- (f) Laboratory equipment associated with the sequencing and use of digital sequence information on genetic resources, including reagents and supplies;
- (g) Information, scientific and technical services related to digital sequence information on genetic resources, including artificial intelligence.

A Steering Committee was established, with an initial composition of 24 members and 6 observers.

- Fifteen members from Parties (three from each region), including the Chair to be designated from among them,
- Seven members from Indigenous peoples and local communities (one from each sociocultural region),
- Two members from United Nations entities, and
- Six observers from civil society, scientific institutions and the private sector (two from each category).

The Cali Fund was officially launched on 25 February 2025 during the resumed session of COP-16 in Rome. It is hosted by the Multi-Partner Trust Fund Office (MPTFO) in partnership with UNDP, UNEP, and the CBD Secretariat.

When the Fund was launched, the UN issued a press release²⁷, which offered additional details, among them:

“Recognizing their role and contributions as custodians of biodiversity, 50 per cent of the resources of the Cali Fund will be allocated to the self-identified needs of indigenous peoples and local communities, including women and youth.”

The press release was reaffirming a policy agreed in the November 1, 2024, Decision 16/2.²⁸

Decision 16/2

Digital sequence information on genetic resources

"21. Where appropriate, and subject to national circumstances and national legislation, at least half of the funding of the global fund should support the self-identified needs of indigenous peoples and local communities, including women and youth within those communities, through government authorities or by direct payments through institutions identified by indigenous peoples and local communities."

There is presently no mechanism to mandate payments to the Cali Fund, and most of the details on its implementation are considered a work in progress. The aspiration is for governments to adopt measures that require contributions from companies, similar to the approach in the BBNJ Treaty, but without a BBNJ-style binding legal obligation for states to do so.

²⁷ PRESS RELEASE. The Cali Fund launches in the margins of the resumed session of COP16. David Ainsworth, For more information: Information Officer david.ainsworth@un.org.

<https://www.un.org/sustainabledevelopment/blog/2025/02/press-release-cop16/>

²⁸ <https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf>

The WHO Pandemic Agreement and the Pathogen Access and Benefit Sharing System (PABS)

On May 20, 2025, the World Health Assembly approved the WHO Pandemic Agreement.²⁹ However, Article 31.2 provides that the agreement will be open for signature only after “adoption of the Annex described in Article 12.2 of this Agreement by the Health Assembly.” Article 12 of the agreement concerns the creation of a Pathogen Access and Benefit-Sharing System (PABS), which will be “a multilateral system for safe, transparent, and accountable access and benefit-sharing for PABS Materials and Sequence Information. . .to be developed pursuant to paragraph 2 of this Article.”

Paragraph 2 of Article 12 reads in full as follows:

2. The provisions governing the PABS System, including definitions of pathogens with pandemic potential and PABS Materials and Sequence Information, modalities, legal nature, terms and conditions, and operational dimensions, shall be developed and agreed in an instrument in accordance with Chapter III (hereinafter the “PABS Instrument”) as an annex. The PABS Instrument shall also define the terms for the administration and coordination of the PABS System by the World Health Organization. For the purposes of the coordination and operation of the PABS System, the World Health Organization shall collaborate with relevant international organizations¹⁴ and relevant stakeholders. All elements of the PABS System shall come into operation simultaneously in accordance with the terms of the PABS Instrument.

/14/ In the context of collaboration with the World Health Organization, “relevant international organizations” is understood in accordance with the Constitution of the World Health Organization.

As its name implies, the PABS has dual objectives. On the one hand the PABS is supposed to provide for the “rapid and timely sharing of “materials and sequence information on pathogens with pandemic potential” (hereinafter “PABS Materials and Sequence Information”). On the other hand, the PABS is supposed to provide “on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes” [Article 12.1]

The benefit sharing obligations for the PABS are set out in Articles 12.6, 12.7 and 12.8, and include:

Article 12.6(a). In the event of a pandemic emergency, as determined in accordance with Article 12 of the International Health Regulations (2005: . . . rapid access targeting 20% of their real time production of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10% of their real time production is made available to the World Health Organization as a donation, and the remaining percentage, with flexibility based

²⁹ https://apps.who.int/gb/ebwha/pdf_files/WHA78/A78_R1-en.pdf

on the nature and capacity of each participating manufacturer, is reserved at affordable prices to the World Health Organization.

Article 12.7. Benefit sharing provisions, in the event of a public health emergency of international concern as determined in accordance with Article 12 of the International Health Regulations (2005).

Article 12.8. Additional benefit sharing provisions to be set out in legally binding contracts signed with the World Health Organization, including options for:

- (a) Capacity-building and technical assistance;
- (b) research and development cooperation;
- (c) facilitating rapid access to available vaccines, therapeutics and diagnostics with a view to responding to public health risks and events in the context of Article 13.3 of the International Health Regulations (2005);
- (d) the granting of non-exclusive licences to manufacturers in developing countries, for the effective production and delivery of vaccines, therapeutics and diagnostics; and (e) other forms of transfer of technology as mutually agreed,¹⁶ including transfer of relevant knowledge, skills and technical expertise.

Negotiations on the PABS Annex have been surprisingly difficult. A number of developed countries have objected to even requiring registration for users of the PABS, raising questions about the enforceability of the benefit sharing obligations. The issue of contractual obligations for benefit sharing is particularly divisive when it comes to DSI, as several developed countries have taken the position that DSI should be free to be commingled with other data and other databases, and that contractual consent is not feasible for important uses of the information. These positions may reflect tactical considerations and do seem contrary to the registration required in the 2025 European Union Health Data Space Regulation (EHDS).³⁰

The negotiations on non-monetary benefit sharing have also proved to be challenging and are important to many delegations.

WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (GRATK) (2024)

The WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (GRATK) was approved in 2024. The Treaty creates a mandatory disclosure requirement in patent applications. When an invention is based on GRs, applicants must disclose the country of origin, if known; or if unknown, the source of the GR. When the invention

³⁰ Arianna Schouten, Registration for Secondary Use Data Access under the European Health Data Space Regulation, KEI Briefing Note 2026:1. February 11, 2026.

is based on associated traditional knowledge (ATK), applicants must disclose the Indigenous peoples or local community that provided the ATK, if known, or the source of the ATK. This applies at the national patent office level in countries that ratify.

Forty-four countries signed the agreement, but to date, only 2, Malawi and Uganda, have ratified.

Among the challenges for ratification are provisions in the treaty that would require changes in national laws. Significantly, one provision that presents ratification challenges is Article 5.2, which provides that “no Contracting Party shall revoke, invalidate, or render unenforceable the conferred patent rights solely on the basis of an applicant's failure to disclose the information specified in Article 3 of this Treaty.”³¹

As noted above, the treaty did not establish any substantive rights associated with either genetic resources or traditional knowledge, topics that continue to be discussed at the WIPO IGC.

Significantly, the treaty does not define digital sequence information, nor does it specify whether inventions based solely on sequence data fall within the disclosure requirement. As a result, the relationship between DSI and the disclosure obligation is left unresolved.

The European Union Health Data Space (EHDS) Regulation (2025)

On March 5, 2025, the European Union published Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847. The European Health Data Space (EHDS) is one of several “Common European Data Spaces” being developed across 14 sectors/domains.

The EHDS regulation is ambitious, setting out obligations for broadly defined data holders and requiring all member states to collaborate on the implementation of standards and systems for expanding access to a wide range of health related information.

The regulation (1) creates an obligation for entities that hold broadly defined health data to store certain records in standardized electronic formats, and (2) gives patients certain rights to control access to those records. The regulation creates (3) technical standards to facilitate the sharing access to data, and (4) nuanced obligations to share access to data. The regulation (5) defines the permitted and prohibited uses of data, (6) requires EU members to designate entities to implement the regulation, and sets out other mechanisms for the governance and enforcement.

The general approach is to give researchers, businesses, and EU governments the ability to use vast amounts of data for both primary (treatment of patients) and secondary uses (research,

³¹ James Love and Claire Cassedy, “Sanctions for Non Disclosure, as Set Out in Article 6 of the WIPO Basic Proposal on Intellectual Property, Genetic Resources and Traditional Knowledge, Should Include Possible Revocation of a Patent” May 15, 2024. Joint PIJIP/TLS Research Paper Series. 127. <https://digitalcommons.wcl.american.edu/research/127>

innovation, policy-making, and regulatory activities), while respecting a number of social objectives. The data spaces approach allows for the data to be held and managed in a decentralized way, featuring trusted entities that can anonymize records and/or facilitate queries for users, when necessary to address concerns over privacy or confidentiality.

The social objectives include protections of the privacy of patients, improvements in the delivery of health care, and avoiding monopolization. There is also a statement that secondary use of data “for research and development purposes should contribute to benefiting society in the form of new medicines, medical devices, and healthcare products and services **at affordable and fair prices for Union citizens, as well as to enhancing access to and the availability of such products and services in all Member States.**”³²

The EHDS Regulation introduces the concept of “health data holder,” which can include any legal person operating in the healthcare sector, developing health products or services, or conducting health-related research, as well as public authorities, agencies, and bodies, including reimbursement services.

Key obligations include the obligation to share health data: When access to health data is granted by the health data access body (HDAB, a national body responsible for assessing health data access requests and applications), health data holders must share the requested health data, unless the patients concerned have opted out of sharing.

The EHDS Regulation specifies the categories of health data that health data holders must share, and which may be requested for access, including:

- Genetic, epigenomic, genomic, proteomic, transcriptomic, metabolomic, lipidomic, and other omic data;
- Data from clinical trials, clinical studies, clinical investigations, and performance studies (note that clinical trial and clinical investigation data may be shared once the trial has ended);
- Personal health data automatically generated through medical devices and “other” health data from medical devices (note that it is not specified what “other” means);
- Health data from biobanks and associated databases;
- Healthcare-related administrative data, including on dispensations, reimbursement claims, and reimbursements;
- Data from registries for medicinal products and medical devices;
- Data from medical and mortality registries;
- Data from population-based health data registries (i.e., public health registries);
- Data from health research cohorts, questionnaires, and surveys after the first publication of the results;
- Data on professional status, and on the specialization and institution of health professionals involved in the treatment of a natural person; and
- Data from wellness applications.

These are the minimum categories of health data concerned by the EHDS Regulation, though EU Member States may add additional categories of health data at the national level.

³² Recital 61.

The EHDS Regulation allows health data to be used for a limited set of “secondary purposes,” including:

- Public interest in the areas of public or occupational health
- Policy-making
- Statistics
- Education
- Scientific research
- Health treatment optimization

Article 54 sets out prohibited secondary uses of data, including:

- (a) taking decisions detrimental to a natural person or a group of natural persons based on their electronic health data; in order to qualify as ‘decisions’ for the purposes of this point, they have to produce legal, social or economic effects or similarly significantly affect those natural persons;
- (b) taking decisions in relation to a natural person or a group of natural persons in relation to job offers, offering less favourable terms in the provision of goods or services, including exclusion of such persons or groups from the benefit of an insurance or credit contract, the modification of their contributions and insurance premiums or conditions of loans, or taking any other decisions in relation to a natural person or a group of natural persons which result in discriminating against them on the basis of the health data obtained;
- (c) carrying out advertising or marketing activities;
- (d) developing products or services that may harm individuals, public health or society at large, such as illicit drugs, alcoholic beverages, tobacco and nicotine products, weaponry or products or services which are designed or modified in such a way that they create addiction, contravene public order or cause a risk for human health;
- (e) carrying out activities in conflict with ethical provisions laid down in national law.

The EHDS regulation includes extensive provisions on enforcement. The sanctions can address such matters as breaches of patient privacy, failures to share data, and using data for a prohibited use. The maximum fine for infringements of the same duties of the health data holder or health data user is 10 million euros or 2 percent of annual worldwide turnover. Higher fines, of 20 million euros or 4 percent of annual worldwide turnover, are possible for the most serious violations of the regulation, such as using data for a prohibited purpose, re-identifying persons data, or extracting personal data from a secure processing environment.

WIPO IGC Negotiations on *Sui Generis* Regimes for GR, TK and TCE (Ongoing)

Negotiators are divided on many issues, and with the exception of disclosure in patent applications, positions have not changed that much over the past 25 years. See: ANNEX III: IGC State of Play.

On February 10, 2026, the United States of America proposed that the WIPO Secretariat compose and disseminate a questionnaire surveying WIPO Member States on the utilization of their domestically available *sui generis* protections for traditional knowledge (TK) and traditional cultural expressions (TCEs), and prepare a summary report of responses to the questionnaire and to present the results of the questionnaire at an IGC meeting, providing a compilation of how *sui generis* systems operate in practice. ([WIPO/GRTKE/IC/52/6](#)).

Table 1: Timeline of relevant ABS negotiations

Year	Instrument / Forum	Key Development
1961	UPOV Council / WIPO	International Convention for the Protection of New Varieties of Plants (UPOV) Created the first international framework for Plant Breeders' Rights (PBR) to protect new plant varieties
1983	FAO	Adoption of the International Undertaking on Plant Genetic Resources - Plant genetic resources treated as the "common heritage of mankind"; - No state sovereignty or benefit-sharing obligations
1989	ILO	Indigenous and Tribal Peoples Convention (no. 169) - Replaced ILO Convention No. 107 - Changed how international law viewed indigenous people from assimilation to a goal of autonomy
1989	FAO	Resolutions 4/89 & 5/89 (Agreed Interpretation) - Reconciled UPOV with the FAO International Undertaking - Endorsement of 'Farmer's Rights' - Free access is not free of charge

1991	UPOV Council / WIPO	UPOV 1991 Act • Significantly expanded breeder rights to include all "multiplication" • Narrowed farmers' rights to an "optional exception" (Article 15.2) for use only on their own holdings
1991	WTO	Dunkel Draft of TRIPS • Proposed mandatory IP protection for plant varieties (Article 27.3b) • Pushing countries towards UPOV style laws
1992	CBD (Rio Earth Summit)	Adoption of the Convention on Biological Diversity • Establishes state sovereignty over genetic resources; • Introduces Prior Informed Consent (PIC) (Article 15.5) and • Mutually Agreed Terms (MAT) (Art. 15.4)
1993	CBD	CBD enters into force • FAO "common heritage" framework becomes legally untenable
1994 - 2001	FAO	Renegotiation of plant genetic resource rules to make them CBD-compatible • Recognition that bilateral ABS is incompatible with crop breeding and food security
1996	WIPO	WIPO rejection of proposed treaty on the protection of databases • Two proposal at the Diplomatic Conference on Certain Copyright and Neighbouring Rights Questions were approved, namely, the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty
1998	UPOV Council / WIPO	UPOV 1991 enters into force • New members are now required to join this more restrictive 1991 version rather than the 1978 version
1998	EU	Directive on the legal protection of biotechnological inventions • Harmonization of patent laws within EU on biotechnological inventions
2001	FAO	Adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) • Introduces a Multilateral System (MLS),

		• collective benefit-sharing, and • Standard Material Transfer Agreement (SMTA)
2001 - Present	WIPO	Intergovernmental Committee on Intellectual property and Genetic Resources, Traditional Knowledge and Folklore
2002	CBD COP-6 (The Hague)	• Agricultural biodiversity recognized as “special” • Takes note of FAO Treaty • Emphasis on harmony and mutual supportiveness with the FAO Treaty
2004	FAO	ITPGRFA enters into force • First operational multilateral ABS system
2004	CBD COP-7	ABS negotiations formally launched • FAO Treaty recognized as relevant precedent
2004 - 2010	CBD COP-7 (Kuala Lumpur)	Negotiations on an international ABS regime under CBD (the Nagoya Protocol) • Driven by weak benefit-sharing, attributed to the asymmetric nature of the obligations, on “provider” rather than “user” countries. • High profile cases involving Neem, Turmeric, Hoodia, Ayahuasca and Basmati fueled narratives that genetic resources are being extracted, patented, and commercialized with zero benefit-sharing. • Challenges presented by dozens of incompatible ABS laws, legal limbo, lengthy permitting delays, and blocking of public sector researchers, • Lobbying by Indigenous and local communities (ILCs) to greater recognition and benefit-sharing independent of state control.
2006	WHO / Indonesia	Indonesia refuses to share H5N1 avian influenza virus samples with the WHO’s Global Influenza Surveillance Network • Highlights inequities and concerns over the unfair nature of the sharing and high prices for products sold by commercial companies that use the samples for R&D.
2006	WHO	EB120/15, Avian and pandemic influenza: developments, response and follow-up, and application of the International Health Regulations (2005), Report by the Secretariat, 14 December 2006.

2007	WHO	WHO meeting in Jakarta on 26-27 March 2007
2007	WHO	Resolution WHA60.29 on Pandemic Influenza Preparedness adopted at the May meeting of the WHA • Mandates the negotiation of a new WHO framework on pandemic influenza preparedness
2007	UN General Assembly	United Nations Declaration on the Rights of Indigenous Peoples (Resolution: A/RES/61/295) adopted on September 13, 2007 • 144 in favor, 4 against (Australia, Canada, New Zealand, United States at the time), 11 abstentions
2010	CBD	Adoption of the Nagoya Protocol (October 29) • Introduces user-country compliance measures; Art. 4.4 creates legal space for specialized ABS instruments
2011	WHO	Adoption of the Pandemic Influenza Preparedness (PIP) Framework by the WHO • Establishes pathogen sharing via GISRS and contractual benefit-sharing through SMTAs
2014	CBD	Nagoya Protocol enters into force • Article 4.4 becomes legally operative
2012 - present	CBD COPs	Ongoing references to the PIP Framework • PIP treated politically as a specialized ABS instrument; • FAO treaty and PIP Framework often cited as precedents in WHO pandemic agreement negotiations • Status of Digital Sequence Information (DSI) as related to ABS becomes a focus of negotiations in several fora
2019	WHO	Amendment in Annex 2 of PIP Framework (WHA 72.12) • Expanded the scope of SMTA2 obligations • Manufacturers contracting with recipients of PIP materials must now also enter into an SMTA2, ensuring benefit-sharing compliance further down the chain
2023	UN Convention on the Law of the Sea	Agreement on Marine Biological Diversity of Areas Beyond National Jurisdiction adopted on June 19, 2023 • No state sovereignty over genetic resources in areas beyond national jurisdiction (ABNJ) • Marine Genetic Resources (MGR) are not declared “common heritage of mankind”

		• Mandatory benefit-sharing obligations, delinked from ownership • Includes digital sequence information (DSI)
2024	CBD	Decision 16/2 creates the Cali Fund • Benefit sharing tied to the use of DSI and GR
2024	WIPO	Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge • Patent applications must disclose country of origin of genetic resources and/or Indigenous peoples or local communities providing associated TK
2025	WHO	Adoption of WHO Pandemic Agreement • Agreement only open to signatures after the adoption of the Annex concerning Pathogen Access and Benefit Sharing (PABS)
2025	EU	European Union Health Data Spaces Regulation • Establishes a "Common European Data Space" for health data • Mandates standardized electronic formats and creates legal obligations for data holders to facilitate access • Defines "permitted uses" for secondary data (R&D/policy) and "prohibited uses" (e.g., insurance discrimination)

Global Policies on IP and Artificial Intelligence

While negotiations focus on the treatment of digital sequence information (DSI) in various ABS regimes, governments and courts worldwide are grappling with whether the act of using data for training artificial intelligence (AI) is a permitted use (transformative or otherwise), or a mass misappropriation that involves infringement or calls for new remuneration or other benefit sharing obligations.

There are similarities in the approaches and challenges between the more general efforts to impose compensation requirements or remuneration regimes on the use of data to train AI and the more focused discussions involving digital sequence data on genetic resources or traditional knowledge.

Size of Datasets Used Train AI Services

Datasets used to train AI services can be so large that they are almost impossible to comprehend. For Large Language Models (LLMs), the datasets used to train flagship services

like Gemini, GPT-5, and Llama have reached scales that make the clearance of rights a practical impossibility.

One measure of the size of databases used to train LLMs is the Token Count (The “Vocabulary” Size). Tokens are the basic units of text (roughly 0.75 words per token). The growth in training data has been exponential:

- GPT-3 (2020): Trained on ~300 billion tokens.
- Llama 3 (2024): Trained on ~15 trillion tokens.
- Gemini 2.5 / GPT-5 (2025-2026 estimates): Modern “Frontier” models are now hitting 15 to 85 trillion tokens.

Moreover models have become multimodal leading to ever larger datasets, trained on billions of images and video and countless hours of speech and music.

The large size of datasets used to train and update AI services increases the difficulty to assign values to specific inputs.

Diverse and Evolving National Legal Regimes

AI services are typically designed to service global markets, but national laws on the legality of using copyrighted works to train AI are diverse and evolving, and policies concerning the AI generated outputs are unsettled.

Users and Purposes of Uses

Discussions about genetic resources and traditional knowledge include the possibility of differential treatment for different users and purposes of use. In the area of mainstream copyright statutory regimes, rights, limitations and exceptions to rights are highly nuanced, and the same is true for patents and other intellectual property regimes. For example, in the 1971 Berne Convention Appendix on Special Provisions Regarding Developing Countries, certain exceptions to exclusive rights have a distinction between cultural works (“works of fiction, poetry, drama and music, and for art books”), and “works of the natural and physical sciences, including mathematics, and of technology.” Patent laws often have special provisions for medical inventions (for example, Article 27.3(a) of the TRIPS Agreement).

Impact of Generative AI on Notions of Patentability, Confidential or Secret Knowledge, and Cultural Works

There is considerable speculation that generative AI will weaken patentability of inventions by changing views on obviousness and finding ways to work around patent claims.³³ Similar

³³ Ryan Abbott, Everything Is Obvious, 66 U.C.L.A. Law Review rev. 2, (2019). <https://www.uclalawreview.org/wp-content/uploads/securepdfs/2019/01/66.1.1-Abbott.pdf>; Billionaire investor Mark Cuban says AI will make companies stop filing patents: ‘because the second you file your patent, even LLM is ...’, Times of India. February 10, 2026.

concerns are being raised about the impact on works now protected by copyright, creating AI generated outputs that are substitutes for works created by humans. Confidential information including trade secrets are also impacted.

Traditional knowledge has historically been protected by its fragmentation and oral nature. Generative AI can now "synthesize" and "reconstruct" these fragments. By ingesting massive datasets of ethnobotanical research, historical records, and digitized archives, AI can infer patterns and "re-discover" secret traditional uses that were previously hidden within disparate or obscure documents.

Concluding Commentary

Laws and norms regarding access and benefit sharing (ABS) for genetic resources and traditional knowledge are motivated primarily by concerns over equity, often expressed as opposition to the unfair extraction of knowledge and control, particularly for culturally sensitive information.

The more established intellectual property systems, including those mandated by the WTO TRIPS Agreement, are known for having a plethora of challenges and controversies in their implementation. Similarly, the newer *sui generis* regimes designed specifically for genetic resources and traditional knowledge face their own significant hurdles.

As noted, the increased attention to DSI and the new and urgent interest in creating or modifying norms for the use of data to train artificial intelligence services present profound conflicts over what can and should be owned, and present new challenges to all intellectual property regimes, including access and benefit sharing approaches.

Challenges to Benefit Sharing

Challenges facing ABS regimes, as implemented and proposed, include the following:

Bilateral ABS is transaction-heavy

Under the Convention on Biological Diversity and its Nagoya Protocol, ABS can require:

- Prior informed consent (PIC),
- Mutually agreed terms (MAT), and
- Monitoring compliance.

This requires:

- Identifying the origin of resources and the holders of rights, if any, in traditional knowledge,
- Negotiating contracts,

<http://timesofindia.indiatimes.com/articleshow/128150327.cms>; Ten Thousand AI Systems Typing on Keyboards: Generative AI in Patent Applications and Preemptive Prior Art, 24 Vanderbilt Journal of Entertainment and Technology Law 375 (2022)
<https://scholarship.law.vanderbilt.edu/jetlaw/vol24/iss3/6>

- Tracking use across borders, and
- Enforcing compliance in user countries.

It can be challenging and sometimes not practical or possible to identify the origins of resources and/or holders of rights in traditional knowledge

There are cases where genetic resources are transnational, and traditional knowledge cannot be assigned to a single community. That is why the CBD Nagoya Protocol included in Article 10 an obligation to consider the need for global multilateral benefit-sharing mechanisms for cases where the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent.

The Problem of Asymmetric Capacity and Information

Implementation is not just about laws; it is about the capacity to use them. Developing countries often struggle with weak regulatory infrastructure, limited scientific capacity to monitor utilization, and a lack of bargaining power in negotiations with multinational companies. They may also lack the resources to track what happens to genetic resources once they leave the country. The same is true for Indigenous and local communities that bargain over rights to use traditional knowledge.

User countries often have strong scientific and industrial sectors but weak or negative incentives to monitor compliance, as the benefits of access flow to their companies and researchers.

Digital Sequence Information (DSI) has fundamentally disrupted the ABS system in a way that negotiators in 2010 did not anticipate

The DSI debate has exposed the fragility of a system built around physical materials in an era of digital biology. It's one thing to have a Material Transfer Agreement (MTA) between parties, and another to have enforceable contracts for DSI over the Internet.

Expectations about the market value of information relating to genetic resources and traditional knowledge can be unrealistic

Both academic and commercial research activities involve increasingly large, even massive amounts of data, most of it having no or no significant stand-alone commercial value. A mismatch between expectations and market realities, combined with high transaction costs for some ABS systems, can result in the under-utilization of information resources.

The value of data is often cumulative and collaborative

Research benefits from more data, the ability to combine data sets, collaboration among researchers, and transparency. ABS regimes that rely upon tracking information become challenging to implement when:

- Data is replicated and redistributed at scale. Once sequences, datasets, or analytical outputs are copied across databases, preprint servers, and repositories, tracing lineage becomes technically and administratively burdensome.
- Information is iteratively transformed. Downstream research frequently involves aggregation, annotation, error-correction, modeling, and integration with other datasets. At some point, the link between the original material and the final output becomes attenuated or ambiguous.
- Modern research may not depend on a single genetic resource or dataset. Products and discoveries often rely on hundreds or thousands of inputs, making attribution and proportional benefit allocation complex and contestable.
- Public repositories and collaborative platforms are designed to reduce friction in access and reuse. Introducing case-by-case permissions, tracking obligations, or downstream conditions can undermine interoperability, raise costs and delay or block research.

Legal Fragmentation

Negotiators on the WHO PABS system were told there were 53 different national ABS regimes. The approaches to the CBD/Nagoya Protocol, the ITPGRFA, the PIP Framework, the BBNJ treaty, the Cali Fund, and the ongoing WIPO IGC negotiations are different enough from each other to create confusion and legal risks for researchers and parties trying to enforce obligations.

The challenges presented by legal fragmentation are not unique to ABS regimes, but nonetheless are important.

Choosing beneficiaries

If monetary benefits are collected, it can be challenging, administratively costly and involve controversy to determine who receives benefits, topics currently being discussed in the implementation of the Cali Fund.

Measures and Rights

There has been an evolution and continuing tension in access and benefit-sharing (ABS) negotiations between rights-based approaches and measure-based approaches to benefit sharing. This tension reflects differing legal and policy norms applied to genetic resources, knowledge about genetic resources, traditional knowledge, and innovations derived from their use.

Rights

Rights are legal entitlements held by a subject, such as a state, Indigenous Peoples and Local Communities (IPLCs), individuals, or legal persons. Rights typically involve:

- recognition of a legal claim,
- agency by the rights holder,
- standing to object, authorize, or refuse uses,

- access to remedies or dispute resolution mechanisms, and
- corresponding duties imposed on others.

In ABS contexts, rights may include, for example:

- sovereign rights of states over genetic resources,
- rights of IPLCs relating to traditional knowledge,
- rights to grant or withhold prior informed consent (PIC), or
- rights to share in benefits arising from utilization.

Where benefit sharing is framed as a right, failure to share benefits may constitute a legal violation capable of challenge or enforcement.

Measures

In ABS negotiations, the term **measures** generally refers to legislative, administrative, regulatory, contractual, or policy actions adopted by states or international organizations to promote, facilitate, or implement benefit sharing.

Measures typically include:

- disclosure requirements in patent or regulatory systems,
- checkpoints or triggers linked to research, commercialization, or intellectual property processes,
- creation and management of databases or information systems,
- contractual provisions, including model agreements and mutually agreed terms,
- monitoring and tracking systems,
- due-diligence obligations imposed on users,
- sanctions or compliance mechanisms,
- obligations for monetary contributions by states or private entities,
- obligations relating to access, availability, or affordability of products,
- commitments to transfer knowledge, know-how, or technology,
- multilateral financing or pooled benefit-sharing mechanisms.

Measures regulate behavior or establish implementation systems, but they do not necessarily create enforceable entitlements for specific beneficiaries.

Relationship Between Rights and Measures

Measures may operationalize, support, or give practical effect to rights. However, ABS negotiations increasingly distinguish between the two because agreement on implementation measures is often easier to achieve than agreement on the recognition of new legal rights.

As a result, many contemporary ABS instruments rely on obligations for Parties to adopt measures intended to promote benefit sharing, rather than establishing directly enforceable rights to benefits.

This distinction has important consequences in practice:

- Rights define who is entitled to benefits.

- Measures define what governments or users must do.

In some cases, measures function as mechanisms to implement recognized rights. In others, measures substitute for unresolved agreement on rights.

Diffusion of biological materials and knowledge

Access and benefit-sharing (ABS) frameworks increasingly distinguish between localized and widely diffused knowledge and biological resources, and also between physical biological materials and the knowledge or information derived from those materials.

Biological materials, such as plants, microorganisms, pathogens, or genetic samples, are tangible objects whose access can, at least initially, be regulated through territorial control or custodianship, where such materials are:

- unique to a particular ecosystem or location,
- collected within national jurisdiction, or
- maintained by identifiable communities or institutions,

Traditional knowledge, including knowledge relating to the properties, uses, preparation, or therapeutic application of biological resources, is intangible and transmitted through social, cultural, and intergenerational practices rather than physical possession. Governance of access and benefit sharing is shaped by the degree to which knowledge remains linked to identifiable custodians.

Some, but not all, traditional knowledge may be:

- maintained or transmitted within identifiable Indigenous Peoples or Local Communities,
- governed by customary laws or community protocols,
- not widely published or incorporated into public scientific literature, and
- closely associated with specific cultural or healing practices.

Information about biological resources, including genetic sequence information, biochemical characteristics, research data, ecological observations, or documented knowledge concerning the properties or uses of organisms, differs from both physical biological materials and traditional knowledge in important respects.

While such information may initially arise from access to specific biological samples or associated knowledge, it can be recorded, digitized, reproduced, and transmitted independently of continued access to the original material or custodians.

Once generated or disclosed, information about biological resources may become:

- incorporated into scientific publications or databases,
- shared through research collaborations and global data infrastructures,
- combined with other datasets and analytical tools,
- replicated without depletion of the underlying resource, or
- used in innovation without further collection of physical samples.

As information diffuses, the connection between utilization and a particular geographic origin, biological specimen, or knowledge holder may become increasingly attenuated.

Where rights-based approaches work best

Rights-based approaches to access and benefit sharing can be most effective when the subject matter, the rights holder, and the act requiring authorization can be clearly identified, and where access can realistically be conditioned or refused. These typically include:

- collection of biological materials *in situ*³⁴,
- access to *ex situ*³⁵ collections,
- access to closely held community knowledge,
- participation in controlled research networks or repositories.

And, as noted, where:

- territorial jurisdiction is clear,
- custodians or authorities can be identified,
- access can realistically be authorized or refused.

Rights-based ABS approaches become progressively more challenging as utilization moves from *in situ* access to biological materials and traditional knowledge, to *ex situ* collections and documented knowledge, and ultimately to *in silico*³⁶ use of digital biological information, where access is no longer dependent on control over physical materials or identifiable custodians.

Role of Measures-based approaches

Measure-based ABS approaches become increasingly central as utilization moves from *in situ* access to biological materials and traditional knowledge, to *ex situ* collections, and ultimately to *in silico* use of digital biological information, where benefit sharing can no longer depend primarily on control over access. Under these conditions, governance increasingly relies on regulatory measures, due-diligence obligations, disclosure requirements, financing mechanisms, and other utilization-based tools designed to promote or secure benefit sharing.

Across recent negotiations, including the Nagoya Protocol, the WHO Pandemic Influenza Preparedness (PIP) Framework, the WIPO GRATK Treaty, the Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ), discussions concerning the

³⁴ Defined in the CBD Article 2: "In-situ conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

³⁵ Genetic resources and traditional knowledge are considered *ex situ* when they are maintained, conserved, or circulated outside the ecological or cultural contexts in which they originated, and access is mediated primarily through institutions, collections, or documented sources rather than original custodians.

³⁶ Genetic resources and traditional knowledge are considered *in silico* when their utilization relies on digital or computational representations of biological or knowledge inputs rather than access to physical materials or engagement with original custodians or contexts.

CBD Cali Fund, and ongoing WHO negotiations on pathogen and data sharing, there has been a gradual shift in emphasis from access control grounded in rights toward governance of utilization through measures.

This shift has been most evident where biological resources are transboundary, widely distributed, or beyond national jurisdiction, and where knowledge and data circulate globally, making exclusive control over access increasingly difficult to maintain.

Decentralization of management and control: Federated ABS Governance

One of the principal challenges for multilateral access and benefit-sharing (ABS) systems is maintaining trust in the fairness, legitimacy, and effectiveness of governance arrangements, particularly where traditional knowledge is not widely diffused and remains linked to identifiable custodians or communities.

Centralized management of access decisions or benefit distribution may raise concerns regarding loss of local control, insufficient recognition of custodial authority, or inequitable allocation of benefits. It is important to explore models of decentralized or federated governance, combining global coordination with locally retained stewardship.

A useful reference point is the data space approach reflected in initiatives such as the European Health Data Space Regulation (EHDS). Data space systems allow data resources to remain under the control of local holders while enabling regulated access across a wider research ecosystem.

Under the EHDS framework, researchers must obtain authorization specifying:

- the research purpose,
- the nature and scope of the requested data,
- conditions governing data use, and
- safeguards protecting the rights and interests of data holders.

Rather than concentrating datasets within a single authority, access is coordinated through interoperable governance rules while stewardship remains decentralized.

Applied to ABS systems involving traditional knowledge or related datasets, a similar approach could permit databases and knowledge repositories to remain under the management of trusted local, national, or community-based entities while participating in a broader multilateral framework governing access conditions and benefit sharing.

This type of arrangement may be understood as federated ABS governance, in which authority is distributed across multiple levels while operating under commonly agreed rules.

Competitive intermediaries for benefit distribution

Decentralization may also be applied to the management of monetary benefit-sharing mechanisms.

Where financial contributions are collected through multilateral ABS arrangements, participating states could be allowed to direct contributions among multiple accredited intermediary organizations responsible for distributing benefits to qualified recipients, including:

- Indigenous Peoples and Local Communities,
- capacity-building programs,
- research partnerships,
- technology transfer initiatives, or
- regional manufacturing and innovation projects.

Competition among intermediaries can strengthen legitimacy, transparency, and performance. States effectively express confidence in governance approaches by allocating contributions to intermediaries whose practices they consider effective and equitable. Over time, such competition may promote innovation in benefit distribution while reducing political concerns associated with centralized financial control.

Federated governance models may help reconcile competing objectives that have complicated ABS negotiations:

- local control and recognition of custodians,
- global access for research and public health,
- scalable multilateral benefit sharing, and
- trust in implementation.

By separating stewardship of resources from coordination of benefits, federated systems offer a potential pathway for ABS regimes operating in increasingly digital and globally interconnected research environments.

Incentives to share

To the extent that policymakers seek to maintain voluntary participation in systems governing the sharing of biological resources, traditional knowledge, data, or technology, the design of effective incentives to share is important, if often underdeveloped.

Many access and benefit-sharing (ABS) frameworks implicitly rely on the expectation that participation in sharing systems will generate benefits over time. These incentives may include both non-monetary benefits, such as technology transfer, research collaboration, capacity building, or improved access to resulting products, as well as monetary benefits derived from commercialization or multilateral financing mechanisms.

However, voluntary sharing systems will be more effective when contributors have a reasonable expectation that their contributions will be recognized and may be rewarded in a transparent and predictable manner.

One approach to strengthening such incentives is the open source dividend model (Annex V). This model seeks to identify beneficiaries of benefit sharing among persons, entities, or communities that openly share knowledge, biological resources, inventions, data, or technology that are later determined to have contributed to the development of a product or innovation.

Although the open source dividend concept was developed outside traditional ABS negotiations, it aligns naturally with evolving multilateral benefit-sharing discussions. The model could operate either:

- as a standalone mechanism rewarding the open sharing of genetic resources or traditional knowledge, or
- as a broader innovation dividend, recognizing contributions from any actor whose openly shared inputs materially supported downstream innovation.

An advantage of a more inclusive approach is that it helps bridge the perceived divide between holders of rights in genetic resources or traditional knowledge and the wider scientific and research communities. By rewarding openness rather than restricting participation, incentive-based mechanisms may encourage earlier and broader sharing while reinforcing trust in multilateral benefit-sharing systems.

Properly designed, such incentives can complement rights-based protections while supporting collaborative innovation environments in which contributions from diverse sources, including communities, researchers, public institutions, and private actors, are recognized as part of a shared innovation ecosystem.

ABS systems increasingly need to incentivize sharing *ex ante* rather than compensate for extraction *ex post*.

Annex I: As a matter of policy, pathogens should not be treated as a genetic resource to be protected under the CBD

The Convention on Biological Diversity was not intended to confer sovereign rights or access-and-benefit-sharing entitlements in pathogens. Article 1 sets out the objectives of the Convention as “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.” The object and purpose of the Convention is thus directed toward the conservation and sustainable use of biodiversity that contributes positively to ecosystems and human well-being.

The States that negotiated the CBD were not seeking to conserve or promote the persistence of pathogenic organisms such as avian influenza, Ebola virus, Zika virus, monkeypox virus, or SARS-CoV-2. To the contrary, such organisms are universally understood as threats to human health, and their eradication or control is a public health objective.

Article 2 of the CBD defines “biological resources” broadly to include genetic resources, organisms, or other biotic components with actual or potential use or value for humanity. While pathogen samples and pathogen-related information may have instrumental value insofar as they enable the development of diagnostics, vaccines, and therapeutics, that downstream utility does not imply that the pathogen itself is an object of conservation or sustainable use within the meaning of the Convention.

This reading is reinforced by Article 3 of the CBD, which affirms that States have “the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.” Rather than framing pathogens as protected genetic resources, the CBD’s structure emphasizes prevention of harm and responsible management of risks.

The Cartagena Protocol on Biosafety further illustrates this distinction. Cartagena establishes obligations concerning the transboundary movement of living modified organisms that may pose risks to biological diversity and human health, focusing on risk assessment, risk management, and notification in cases of potential harm. Although Cartagena does not directly govern pathogen samples or data, its logic is precautionary and harm-preventive, not distributive or entitlement-based.

Taken together, these provisions underscore that the CBD framework distinguishes between biodiversity that the Convention seeks to conserve and utilize sustainably, and biological agents whose primary legal relevance lies in the prevention and mitigation of harm. Pathogens, therefore, sit uncomfortably within an ABS framework designed for conservation and sustainable use, rather than emergency public health response.

Annex II: Selected passages from the Report of the World Commission on Environment and Development: Our Common Future. 1987

Full report available via: <https://www.are.admin.ch/en/1987-brundtland-report>

Among the passages of this report are:

46. Tribal and indigenous peoples will need special attention as the forces of economic development disrupt their traditional life-styles - life-styles that can offer modern societies many lessons in the management of resources in complex forest, mountain, and dryland ecosystems. Some are threatened with virtual extinction by insensitive development over which they have no control. Their traditional rights should be recognized and they should be given a decisive voice in formulating policies about resource development in their areas. (See Chapter 4 for a wider discussion of these issues and recommendations.)

82. Traditional forms of national sovereignty raise particular problems in managing the 'global commons' and their shared ecosystems - the oceans, outer space, and Antarctica. Some progress has been made in all three areas; much remains to be done.

Chapter 4: Population and Human Resources

70. The processes of development generally lead to the gradual integration of local communities into a larger social and economic framework. But some communities - so-called indigenous or tribal peoples - remain isolated because of such factors as physical barriers to communication or marked differences in social and cultural practices. Such groups are found in North America, in Australia, in the Amazon Basin, in Central America, in the forests and hills of Asia, in the deserts of North Africa, and elsewhere.

72. With the gradual advance of organized development into remote regions, these groups are becoming less isolated. Many live in areas rich in valuable natural resources that planners and 'developers' want to exploit, and this exploitation disrupts the local environment so as to endanger traditional ways of life. The legal and institutional changes that accompany organized development add to such pressures.

73. Growing interaction with the larger world is increasing the vulnerability of these groups, since they are often left out of the processes of economic development. Social discrimination, cultural barriers, and the exclusion of these people from national political processes makes these groups vulnerable and subject to exploitation. Many groups become dispossessed and marginalized, and their traditional practices disappear. They become the victims of what could be described as cultural extinction.

74. These communities are the repositories of vast accumulations of traditional knowledge and experience that links humanity with its ancient origins. Their disappearance is a loss for the larger society, which could learn a great deal from their traditional skills in sustainably managing very complex ecological systems. It is a terrible irony that as formal development reaches more deeply into rain forests, deserts, and other isolated environments, it tends to destroy the only cultures that have proved able to thrive in these environments.

75. The starting point for a just and humane policy for such groups is the recognition and protection of their traditional rights to land and the other resources that sustain their way of life - rights they may define in terms that do not fit into standard legal systems. These groups' own institutions to regulate rights and obligations are crucial for maintaining harmony with nature and the environmental awareness characteristic of the traditional way of life. Hence the recognition of traditional rights must go hand in hand with measures to protect the local institutions that enforce responsibility in resource use. And this recognition must also give local communities a decisive voice in the decisions about resource use in their area.

76. Protection of traditional rights should be accompanied by positive measures to enhance the well-being of the community in ways appropriate to the group's life-style. For example, earnings from traditional activities can be increased through the introduction of marketing arrangements that ensure a fair price for produce, but also through steps to conserve and enhance the resource base and increase resource productivity.

77. Those promoting policies that have an impact on the lives of an isolated, traditional people must tread a fine line between keeping them in artificial, perhaps unwanted isolation and wantonly destroying their life-styles. Hence broader measures of human resource development are essential. Health facilities must be provided to supplement and improve traditional practices; nutritional deficiencies have to be corrected, and educational institutions established. These steps should precede new projects that open up an area to economic development. Special efforts should also be made to ensure that the local community can derive the full benefit of such projects, particularly through jobs.

78. In terms of sheer numbers, these isolated, vulnerable groups are small. But their marginalization is a symptom of a style of development that tends to neglect both human and environmental considerations. Hence a more careful and sensitive consideration of their interests is a touchstone of a sustainable development policy.

Annex III: WIPO IGC State of Play

In July 2025, WIPO's General Assembly approved the renewal of the mandate of the Intergovernmental Working Committee on Genetic Resources, Traditional Knowledge, and Folklore for the 2026/2027 biennium.

The General Assembly agreed to a program of work of three sessions of the IGC scheduled for March 2026, September/October 2026, and March/April 2027. Each session will consist of a duration of eight days. In terms of the mandate on traditional knowledge and traditional cultural expressions, the General Assembly decided that the Committee would continue its work “with the objective of finalizing an agreement on an international legal instrument(s), without prejudging the nature of outcome(s), relating to intellectual property, which will ensure the balanced and effective protection of TK and TCEs.”

(https://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_58/wo_ga_58_8.pdf)

With respect to genetic resources, the General Assembly decided that “the Committee will, during the budgetary biennium 2026/2027, continue to discuss intellectual property issues concerning GRs and their interlinkage with TK and TCEs, without normative work on GRs.” (Ibid)

The two documents that will form the basis of discussions on TK and TCEs include: 1) WIPO/GRTKF/IC/51/4 (The Protection of Traditional Knowledge: Draft Articles - Facilitators' Rev) and 2) WIPO/GRTKF/IC/51/5 (The Protection of Traditional Cultural Expressions: Draft Articles - Facilitators' Rev).

The early discussions of IGC 49 (2 December 2024 to 6 December 2024) focused on definitions. There was a lack of consensus on terms, including misappropriation, public domain, local communities, and beneficiaries.

At the conclusion of IGC 49, there was a lack of consensus on transmitting the facilitators' texts on traditional knowledge and traditional cultural expressions to IGC 50; consequently, no text was transmitted to IGC 50. The facilitators for IGC 49 were Mr. Paul Kuruk (African Union) and

Ms. Aurelia Schultz (United States of America). Many developing countries expressed that the holistic non-paper prepared by the former chair, Lily-Claire Bellamy, Chair's Text of a Draft International Legal Instrument relating to IP and TK/TCE (Second Draft), be used as the basis of negotiations for IGC 50.

(https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_47/wipo_grtkf_ic_47_chairs_text.pdf)

IGC 49 decided the following:

“The Committee worked on the basis of documents WIPO/GRTKF/IC/49/4 and WIPO/GRTKF/IC/49/5. However, Member States were unable to reach consensus on the facilitator's proposed texts and decided not to transmit those texts to the 50th Session of the IGC. Instead, the Committee decided to continue working on the basis of documents WIPO/GRTKF/IC/49/4 and WIPO/GRTKF/IC/49/5.

Furthermore, some Member States proposed that the 50th Session of the IGC should use the Chair's text WIPO/GRTKF/IC/47/Chairs Text as a basis for negotiation, while some Member States opposed.”

(https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_49/wipo_grtkf_ic_49_decisions.pdf)

Nigeria voiced its displeasure on the trajectory of the IGC 49 talks and facilitators' texts:

Nigeria strongly aligns with the position expressed by Kenya and Niger to say that the way forward for us, having repeated the position that the facilitators' drafts have not closed any gaps, rather they have escalated them, is to have a fallback position to a document of these proceedings that actually gave us the first major significant and strategic glimpse of how gaps can be narrowed. It is shocking to us that even though it is titled nonpaper, it is a paper that should be taking due notice of the extent of progress we have made. So over this past five days we have taken two steps forward and five steps backwards for such a resource to not have been mentioned or used in any way whatsoever.

(https://webcast.wipo.int/video/WIPO_GRTKF_IC_49_2024-12-06_PM_124129)

The Netherlands on behalf of Group B expressed its disapproval for the Chair's text (WIPO/GRTKF/IC/47/CHAIRS TEXT) to be used as the basis of negotiations for IGC 50.

Thank you very much, Madam Chair. Since we have heard a few interventions making specific reference to the nonpaper containing this Chair's text on TK and TCEs, I would like to put forward that it is Group B's firm view that this Chair's text on TK and TCEs that is laid down in document WIPO/GRATK/IC/47 Chair's text is not a basis for further discussions in this Committee for this group as this document does not reflect the views of the broad membership. (Ibid)

Ghana voiced its support for the Chair's “unified” text covering two subject areas, traditional cultural expressions and traditional knowledge.

Thank you, Madam Chair. The Delegation of Ghana aligns itself with the statement delivered by Kenya on behalf of the African Group. My Delegation believes that formalizing the former Chair's text on traditional knowledge and traditional cultural expressions from IGC 47 currently referred to as document WIPO/GRTKF/IC/47 Chair's text for use at the next session is essential for several reasons. First, the Chair's text reflects the combination of extensive negotiations and deliberations. It serves as a distilled and balanced representation of various inputs offering a structured framework to advance discussions and formalizing it would ensure continuity and build on the progress achieved at IGC/47.

Secondly, having a unified text would reduce fragmentation in discussions by providing a common reference point. This would ensure that Delegates concentrate on refining key provisions rather than revisiting foundational issues thereby promoting negotiation efficiency. Thirdly, endorsing the former Chair's text would signal a commitment to a consensus driven process. It would acknowledge the former Chair's efforts to capture diverse perspectives and uphold the credibility of the IGC as a forum for equitable dialogue on TK and TCEs. Furthermore, a formalized text would provide clarity and predictability enabling Indigenous Peoples, local communities and Member States to prepare meaningful contributions. This inclusivity is vital for ensuring that the outcomes of our meetings are representative and effective in protecting TK and TCEs. Also, it would demonstrate the IGC's readiness to move closer to a legally binding instrument. (Ibid)

Nigeria delivered a riposte to the European Union's assertion that the Chair's text did not enjoy broad support among WIPO's membership.

Our intervention from this desk is one that seeks some clarification from the Honorable Coordinator for Group B. We seek to understand what she means by broad membership. To the best of our knowledge, there is no weighted membership in WIPO. This document to which we made reference, that is to say the Chair's nonpaper dated May 26, 2023 was supported by GRULAC, Africa Group, LMCs and a significant membership of APG. So we seek to get the clarification of what is meant by broad membership support for this document.

To the best of our knowledge, for emphasis, there is no weighted membership in WIPO. Thank you. (Ibid)

IGC 50 followed a different methodological approach from IGC 49. During IGC 50, the chair (Erika Watanabe Patriota) requested Ann Edillon (the Philippines) to serve as Friend of the Chair and tasked her with developing a consolidated document on traditional knowledge and traditional cultural expressions. The consolidated text was presented to Member States on 7 March 2025. However, this text did not meet consensus.

IGC 50 decided:

The Committee developed, on the basis of documents WIPO/GRTKF/IC/49/4 and WIPO/GRTKF/IC/49/5, a consolidated text, "The Protection of Traditional Knowledge and Traditional Cultural Expressions: Draft Articles". However, Member States were unable to

reach consensus on the consolidated text and decided not to transmit this text to the Fifty-First Session of the IGC. Instead, the Committee decided to continue working on the basis of documents WIPO/GRTKF/IC/49/4 and WIPO/GRTKF/IC/49/5.
(https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_50/wipo_grtkf_ic_50_decisions.pdf)

In his analysis of IGC 50, Professor Professor Chidi Oguamanam (University of Ottawa) highlighted the tension between blocs of countries (such as Group B) who supported measure-based approaches to safeguarding TK and TCEs to those demandeurs who favored a rights-based approach.

There was a palpable ideological schism among delegates on the perennial high level conceptual question over the nature of the instrument in relation to intellectual property rights. On one side are demandeur delegations who favour negotiating the TK/TCEs instruments as sui generis, or what one delegate characterizes as “IP+.” On the other side are those who prefer that the instruments be in sync with conventional IP rights – with term limits, elaborate exceptions and limitations, and accommodation of the so-called “vibrant public domain.”

More prominently and equally worrisome at the 50th WIPO-IGC session was a palpable division among delegates along “rights-based” and “measures-based” approaches to the protection of TK and TCEs. In simple terms, the rights-based approach is premised on the recognition of inalienable and existing rights of Indigenous Peoples and Local Communities (IPLCs) to their TK and TCEs as a fundamental anchor for the protection of those rights and the premise upon which any consequential measures are based. On the other hand, proponents of the measures-based approach, who are mainly non-demandeurs led by the United States and its allies in Group B (Japan, Canada, South Korea, Switzerland, UK), the EU, the Central European and Baltic States (CEBS), etc., are inclined toward a measures-based approach. The latter group of proponents of the measures-based approach proactively emphasizes and promotes a list of policy, regulatory, persuasive, and non-binding measures to encourage the “safeguarding” of TK and TCEs. In the opinion of these proponents, a soft-law (i.e., non-binding) approach is the preferred nature of such measures. The argument is that, in accordance with its mandate, the Committee should not prejudge the nature of the instrument that will result from its work. For most non-demandeurs, a measures-based approach is a suitable pathway to a non-binding treaty.

For the demandeurs, that is, IPLCs as well as mostly developing countries of the global south who coalesce around the mainly fluid category of like-minded countries (LMCs), the African Group, the Group of Latin American and Caribbean Countries (GRULAC), India, China, and some members of the Asia Pacific Group (APG), a rights-based approach is preferred. The demandeurs support a stronger and binding instrument in the nature of the already-concluded treaty from the work of the Committee – the 2024 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge. For this group, the fact that the Committee is required not to prejudge the outcome of its deliberations does not preclude designing a binding instrument. For demandeurs, the narrow focus of non-demandeurs on a non-binding instrument misses the other consideration regarding the outcome of the Committee’s work, which relates to

whether it would result in a single or multiple instruments. At the beginning, the Committee set out on a pathway to three instruments, namely, TK, TCEs and Genetic Resources (GRs). It has agreed on only one instrument so far, which is the binding instrument on GRs.

<https://www.oguamanam.com/publications/discord-over-rights-and-measures-based-approaches-to-the-protection-of-tk-and-tces-scuttles-wipo-igc-50>

On the final day of IGC 50, the United Kingdom expressed its opposition to collective rights.

Thank you, Chair. The text includes a number of references to the United Nations Declaration on the Rights of Indigenous Peoples, UNDRIP and Indigenous Peoples and Local Communities. The UK acknowledges and strongly supports the human rights of individuals but does not acknowledge collective rights. As a result, the UK is unable to accept language on collective rights in a document that could become legally binding. Because of that, we would ask that the text is put into square brackets to recognize that it remains under discussion and that Member States will need to further consider the wording and the revised text.

Chair, we would also like to request to see a tracked changed version of the documents in order to fully understand the changes made. We have noted a couple of discrepancies between the previous text and the revised consolidated text that we would need to consider carefully and a tracked changed version would aid transparency and visibility. Thank you, Chair. Thank you, UK, for the suggestion.

https://webcast.wipo.int/video/WIPO_GRTKF_IC_50_2025-03-07_PM_124634

With respect to the combined draft text on TK and TCEs, Namibia on behalf of the African Group stressed that revision, additions, deletions, or modifications of the facilitators' text would need to obtain consensus.

We have also had a small discussion on the proposed text and the African Group would agree to the revisions to the combined draft text on traditional knowledge and traditional cultural expressions based on the understanding that any proposed additions, deletions or modifications of the provisions of the facilitators' alternative text in the combined draft text on TK and TCE must obtain consensus before the changes are affected. Consensus in this context means all Member States present agree to the proposed changes. I thank you. Thank you, African Group.

After the Chair reconvened the session after a break, the United Kingdom used its opposition to collective rights to block transmission of the consolidated text to IGC 51.

As set out in our opening statement, the UK has had concerns with the process of continuing text-based discussions whilst key underlying principles remain undiscussed and unresolved such as whether an instrument will be legally binding, definitions of key terms and understanding of beneficiaries and how any instrument, particularly any

proposed rights-based approach would work alongside Member States existing international copyright and related rights obligations.

We follow discussions in informals and plenary and have considered the text that has been produced in the time available. Regrettably, the UK is unable to accept the transmission of the revised text. We remain concerned at putting forward a revised document with textual edits before holding discussions that could bring members closer on understanding around some of the fundamental questions underpinning this instrument. We note the additions to the text including a number of references to the United Nations Declaration on the Rights of Indigenous People. The UK's position on UNDRIP and collective rights is well-known as set out in our statement made on the 13th of September, 2007 in New York and restated in 2024.

With this in mind, the UK will be taking time to consider the revised text and additions in detail and in particular those references to UNDRIP ahead of IGC 51. We remain ready to engage in the discussions in a constructive manner under an inclusive, transparent, evidence-based and Member State driven process. Thank you, Chair. Thank you, United Kingdom. (Ibid)

China expressed its flexibility to transmit the consolidated text to IGC 51.

Thank you, Madam Chairperson. The Chinese Delegation first of all wishes to thank Madam Chairperson and your friend for your relentless efforts made for this meeting. During this session you have constructed the work which allowed us some stressed progress. For example, we have removed some alternatives. We have unified indigenous people and also we have consulted the texts for our Delegation.

Those are strides and those are progress made and they can be the basis for upcoming meetings or sessions. Now some Delegations mentioned about the modification for consolidated text to reflect their suggestions and modifications proposed on Monday and Tuesday but during the plenary on Monday and Tuesday Delegations including mine also put forward some concerns and suggestions, modifications. For example, regarding the beneficiaries we wanted to add other beneficiaries and consolidated text did not reflect all of our proposals or modification but we know that today is the last day of the session and our purpose is not to reflect all of those proposals, modifications in this consolidated text because it is not realistic and it requires more substantive discussion. Therefore, our Delegation wishes to showcase our flexibility and leave those issues to the next session of the ICG for further discussion. We also call on parties to show their flexibility on this consolidated text and this consolidated text is based on this 49/4 and 49/5 and we do not want any new modifications or additions and we believe that the substantive issues should be left to the next session of ICG in order not to repeat what happened in the 49th session. (Ibid)

At the eleventh hour, Nigeria opposed transmitting the consolidated text to IGC 51.

Nigeria has considered all your efforts and efforts of colleagues throughout this proceedings. Nigeria working in collaboration with the African Group has tried to meet at

the middle, specifically suggesting that some new procedurally or wrongly inserted texts be moved to where we thought it would not compromise rights-based approach and be able to synthesize measures-based approach in a more cohesive order. Nigeria has also wishes to make it clear that what is called consolidated document is actually a merged text and Nigeria opposes strongly the transmission of this document to the next IGC. (Ibid)

Professor Oguamanam provided insight into Nigeria's position:

Afterwards, Nigeria rose in a terse submission and expressed its delegation's instructions to block any decisions based on transmission of the artificially merged text to the next IGC. Nigeria's complaint appeared to be centred around two things. First, Nigeria questioned the value of a merged text, presented in the nomenclature of consolidated text. Second, and perhaps most important, was the marginalization of the rights-based approach and unfettered (even asymmetrical) uptake of the measures-based approach that now compromised the integrity of the rights-based approach.

Following Nigeria's attempt to block the transmission of the merged text to the 51st session of the IGC, the Chair's last-ditch effort again focused on finding a middle ground between Nigeria and those invested along with the US in a measures-based approach. At the end of the day, it was clear that both interests came to the end of their diplomatic flexibilities. At about 23:00 on the last day, delegates resolved to not transmit any text from the 50 sessions of the IGC to the 51st session, thus repeating the experience of the 49th IGC. The difference with the 49th IGC was that at the 50th IGC, there was sufficient diplomatic effort and no lack of trying. It was just that a methodological and procedural vagueness rendered the process vulnerable to magnifying the evident imbalance and polarization of rights and measures-based approaches.

<https://www.oguamanam.com/publications/discord-over-rights-and-measures-based-approaches-to-the-protection-of-tk-and-tces-scuttles-wipo-igc-50>

The 51st session of the IGC (30 May 2025 to 6 June 2025) that preceded the General Assembly paved the groundwork for the renewal of the IGC mandate for the 2026-2027 biennium. IGC 51 "confirmed that the texts contained in the annexes to documents WIPO/GRTKF/IC/51/4 and WIPO/GRTKF/IC/51/5 be transmitted to the 2025 WIPO General Assembly, in accordance with the Committee's mandate for 2024-2025 and the work program for 2025."

https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_51/wipo_grtkf_ic_51_decisions.pdf

Professor Oguamanam reiterated that in terms of content, the key dispute lay between those countries (many developing country demandeurs) who advocated for a rights-based approach and Group B countries who favored a measures-based approach.

In his analysis of the IGC negotiations, Professor Oguamanam noted,

As a compromise, those textual drafts on safeguarding and measures-based were taken on board by the three facilitators of the 51st sessions (Ghana, US and Colombia) in an

ambiguous procedural circumstance and kept in square brackets under “Alternative X”. This was to preserve the sanctity of the Facilitators’ Alternatives carried over from the IGC 49 texts (WIPO/GRTKF/IC/49/4; WIPO/GRTKF/IC/49/5 which was the default working document and same as from IGC 47) around which there remains a broad coalescing of understanding. Thus, the two texts (TK and TCEs) from the 51st session did little to close gaps

In sum, the delegations agreed on modest progress on the two texts of the TK and TCEs from the 51st sessions. The progress included modest striking out of a few texts that did not have the backing of any interested bloc as well as the bracketing of the US and allies-backed Alternative X. The remaining two days were devoted to mandate negotiations. (WIPO-IGC 51st Sessions Breaks Jinx, Recommends Mandate Renewal, 9 June 2025, <https://www.oguamanam.com/publications/wipo-igc-51st-sessions-breaks-jinx>)

At the WIPO General Assembly in 2025, Algeria and Colombia articulated their support of a rights-based approach in protecting TK and TCEs.

Algeria:

The Delegation recognized the strategic importance of negotiations to preserve, protect and value TK and TCEs, and reiterated its commitment to participating actively in the future work of the IGC. In that spirit, the Delegation reiterated its support for the mandate of the IGC, and the importance of continuing negotiations on those issues with a consolidated text and through a rights-based approach to guarantee fairness and balance. (WO/GA/58/14, https://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_58/wo_ga_58_14.pdf)

Colombia:

In 2023, Colombia formally incorporated the FAO International Treaty on Plant Genetic Resources for Food and Agriculture into the legal system, reaffirming its commitment to food sovereignty, agricultural diversity and the rights of traditional farmers. The UNESCO Convention for the Safeguarding of Intangible Cultural Heritage was approaching 20 years since its entry into force and was considered a fundamental pillar for the protection of communities’ living heritage. Those instruments, together with progress at WIPO, created a coherent international regulatory framework that enabled the protection of TK and TCEs from a participatory, rights-based and intercultural perspective. The Delegation would continue to participate actively in those collective efforts with a view to strengthening agricultural justice and ensuring the preservation of ancestral knowledge. (Ibid)

Estonia (on behalf of the Central European and Baltic States bloc) and the European Union reiterated their support of measured-based approaches to safeguard TK and TCEs.

Estonia:

Based on the new mandate of the IGC, the CEBS Group recognized the need for, and value of, further commitment based on a member-driven process that should allow Member States to determine the possible outcomes of ongoing work. It was necessary to establish an efficient and inclusive working methodology that facilitated the exchange of ideas among IGC participants. At the same time, the CEBS Group recalled that one or more future international instruments on TK and TCEs should be non-binding and employ a measures-based approach. (Ibid)

European Union:

The Delegation reiterated that any international instrument on TK and TCEs should be non-binding and should support a balanced, flexible and measures-based approach. (Ibid)

At the General Assembly, Thailand advocated for a careful balance between the right-based and measures-based approaches.

Thailand:

The Delegation supported efforts to streamline the texts by reducing alternatives and clarifying all principles. In the longer term, there was value in consolidating the two texts into a single legal instrument, possibly by carefully balancing rights-based and measures-based approaches. Doing so would pave the way for a future diplomatic conference, not only as a technical objective but as a normative responsibility of all Member States. (Ibid)

IGC 49 (2 December 2024 to 6 December 2024)

The following is a compilation of excerpts from group, country, and IPLC statements at IGC 49. Source: https://www.wipo.int/meetings/en/details.jsp?meeting_id=80927

African Group

This is indeed a historic session as we look back at the milestones achieved over the past 25 years of negotiations. The African Group greatly appreciates the conclusion and adoption of the latest WIPO Treaties: The May 2024 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge and the November 2024 Riyadh Design Law Treaty.

We thank the entire WIPO membership for their diligence and hardwork which led to these commendable outcomes.

We are confident that Member States find the same zeal as we continue our negotiations on Traditional Knowledge and Traditional Cultural Expressions. This would greatly help in narrowing down the gaps toward achieving a legally binding Peoples and Local

Communities remains undiminished . It is our intention to continue constructively engaging the IPLCs to arrive at mutually agreed outcomes.

The African Group is of the view that the Chair's text should form the basis of our negotiations with the understanding that TK and TCEs will be discussed together.

In closing, Chair, let me once again reiterate the African Group's openness to dialogue that is transparent ,accommodative and embraces the gains made over the years.

Brazil

Brazil has been a staunch advocate of solutions to issues related to the misuse and misappropriation of genetic resources and the cultural heritage of indigenous peoples and traditional communities. It is our view that our work at the IGC need to be guided towards the promotion of an intellectual property regime in line with the sustainable development goals taking into account the rights of indigenous peoples and traditional communities.

The recently adopted WIPO Treaty on IP, Genetic Resources and Associated Traditional Knowledge reminds us that, despite divergent positions, it is possible to bridged gaps between biodiversity-rich and technology-rich nations, and to promote inclusiveness by ensuring that the benefits of genetic resources and associated traditional knowledge are equitably shared, and that the knowledge holders are active participants in the global innovation ecosystem. Brazil remains committed to the strengthening the multilateral intellectual property system, while promoting a more equitable, fair, inclusive IP system that recognizes the centuries-long contribution of Indigenous Peoples and local communities.

On a final note, from Brazil's perspective the Chair's text at the 47th session of IGC provides a good basis for our present and future work, as it consolidates in one single document issues that are intertwined and for their indissociable relation should be treated under a holistic approach.

Indigenous Caucus

These negotiations must be aimed at the creation of a sui generis system that recognizes positive protections for our traditional knowledge and cultural expressions. A purely measures based approach in which our rights and cosmovision are forced into the existing intellectual property framework will not protect our expressions or knowledge systems. For us, TK and TCEs are not separate issues, they are inextricably linked. They are integral and essential to the continuation of our spirituality, cultures and lifeways.

The current text acknowledges that we can receive our knowledges and expressions from spiritual sources. They do not have a temporal limitation as they fit within our traditional systems that are governed by our own customary laws. Requiring knowledge or expressions to be in existence for a period of time before protections are extended, or

having protections expire after a certain amount of time, would contribute to misappropriation.

This would divest us of our rights. Furthermore, any exceptions and limitations must be narrowly constructed and only developed with the full and effective participation and free, prior and informed consent of Indigenous Peoples. There can be no balancing of Indigenous Peoples' inherent rights against the interests of third parties.

IGC 50 (3 March 2025 to 7 March 2025)

The following is a compilation of excerpts from group, country, and IPLC statements at IGC 50.

Source: https://www.wipo.int/meetings/en/details.jsp?meeting_id=85308

South Africa

Thank you, Madam Chair, for giving us the floor. South Africa aligns itself with the statement delivered by Namibia on behalf of the African Group. Our principal interest entails balancing a complex set of apprehensions, such as protecting biodiversity; responding to concerns by indigenous communities, exploitation and misappropriation; and ensuring that the benefits derived from such resources are shared more equitably.

It is with great concern and disenchantment that after almost two decades of deliberations in the IGC, there is still no agreement in sight for the TK and TCE's and this reflects poorly WIPO's normative initiatives and the Member States' commitment to a fair and equitable global IP system. Our continent is still in the process of continuous development and South Africa's prospects for improved competitiveness and economic growth hinges, to a great degree, on science, innovation, technology and traditional knowledge, where creativity and innovation is properly rewarded, and the fruits thereof fairly shared by all the peoples of the world. South Africa can no longer have the luxury of other decades of negotiation.

<SNIP>

Hence, we iterate that a legally binding instrument will constitute the sole alternative for an effective and comprehensive solution to the misappropriation of traditional knowledge within the intellectual property context. To this purpose we reiterate our support for other regional positions that reflect that the first objective of protection should be to prevent the misappropriation of Traditional Knowledge and traditional cultural expressions.

South Africa has been persistently enthusiastic about achieving the mandates of the IGC, similarly, as we were when the IGC was born in 2001. It is within this context we need to make sure that our methodology is transparent, progressive and represents the needs of the member states but most importantly delivers the desired outcomes and preserves the integrity of the work achieved over many years.

Finally, South Africa reiterates that a legally binding instrument/s constitute the sole alternative for an effective and comprehensive solution to the rampant misappropriation

of indigenous knowledge and traditional cultural expressions within the intellectual property rights context.

United Kingdom

The United Kingdom would like to thank the Chair and the vice chairs for their continuing efforts. We would also like to thank the WIPO secretariat for the preparatory work for IGC 50.

As raised during the meeting to discuss IGC 50 methodology, on 21 February, the United Kingdom has concerns about continued text-based discussions whilst key underlying principles remain undiscussed and unresolved.

These include fundamental questions such as,

- a. Who and what constitutes indigenous people and local communities for the purposes of this instrument(s).
- b. What constitutes traditional knowledge and traditional cultural expressions for the purposes of this instrument(s).
- c. How any potential instrument(s) or process would work for secret or unidentifiable traditional knowledge and traditional cultural expressions
- d. Who and to what extent indigenous peoples' and local communities', traditional knowledge and traditional cultural expression can or should be recognised or protected as intellectual property or similar rights.
- e. Whether any proposed instrument(s) will be legally binding or not.
- f. Critically, how any instrument(s), particularly any proposed right based approach, would work alongside member states' existing international copyright and related rights obligations?
- g. How this will impact on existing copyright and related right works, performances and broadcasts, as well as right holders, where it is claimed that those are based on or use of traditional knowledge or traditional cultural expressions?

We welcome the discussions in this forum and remain committed to engage on this important topic. It is regrettable that no time has been allocated to discuss these underpinning principles, without which consensus will be hampered. Unfortunately, it leaves us in a position where we can neither engage with nor agree any current text.

Thank you chair.

IGC 51 (30 May 2025 to 5 June 2025)

Source: https://www.wipo.int/meetings/en/details.jsp?meeting_id=85309

United States of America

The United States continues to insist that the TK and TCE texts remain as separate texts. TK and TCEs are distinct topics that implicate different IP equities and must be handled as such. There is no consensus at this time on consolidation or merging of the TK and TCE texts. We expressed our concerns on this issue during the last session of the IGC, and this session we are even more steadfast that we cannot support a proposal to combine these discrete texts.

Turning to the substance of the TK and TCE texts, it is critical that each reflect a flexible, nonbinding, measures-based approach that promotes safeguards for TK or TCEs while ensuring compatibility with the IP system and providing policy space for a variety of perspectives on implementation. Doing otherwise runs afoul of WIPO's clear mandate under the WIPO Convention.

Additionally, as we engage on the texts, we cannot support work that blocks or avoids the inclusion of textual proposals made by a Member State. It is critical that alternatives in each of the respective TK and TCE texts reflect the full range of views expressed by Member States and that the texts are not biased towards any particular outcome. The texts must be inclusive of the views shared by Member States in the discussion or else the phrase "Member State driven process" is meaningless.

It is also essential that committee sessions include real-world examples demonstrating how textual provisions operate in practice.

Annex IV: MAT, VMAT, and Mandates on Technology Transfer

The 1992 Convention on Biological Diversity (CBD) introduced several references (Articles 15.4, 15.7, 16.2, 16.3, 19.2) conditioning agreements on mutually agreed terms (MAT), and effectively institutionalizes MAT as a recurring treaty concept in UN agreements dealing with resources, knowledge, or shared benefits.

In recent negotiations, industry lobbyists have sought to include references to MAT to avoid government mandates on technology transfers and have also sought to add modifiers, leading to formulations such as voluntary and mutually agreed terms (VMAT).

While MAT is an important concept in many areas, it is not an appropriate standard in others. Governments generally reserve rights to regulate industry, including laws or regulations to require transparency, the sharing of know-how, materials and inventions.³⁷

³⁷ See, for example: 2024:3 KEI Briefing Note: What measures do US competition authorities refer to in technology transfer mandates; and 2024:2 KEI Briefing Note: Examples of US competition cases that mandate transfer of technology and know-how.

In terms of international agreements on intellectual property, the environment, food security, or trade, and more generally as a component of benefit sharing, technology transfer is often raised as an aspirational or soft obligation

For example, Articles 7 and 8 of the WTO TRIPS provide an expectation that policies and practices on intellectual property rights **contribute** to the transfer and dissemination of technology “in a manner conducive to social and economic welfare” and that WTO members may adopt “**appropriate** measures . . . to prevent abuses that **unreasonably** restrain trade or adversely affect the international transfer of technology.”

Article 7 - Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8, Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

The 2024 BBNJ treaty and the 2025 WHO Pandemic Agreement are examples of the use of “mutually agreed” language to undermine the use of state power to mandate technology transfer.

The WHO agreement makes several references to the “transfer of technology as mutually agreed.” In each, there is a reference to footnote 8, which reads:

8. For the purposes of the WHO Pandemic Agreement, “as mutually agreed” means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements.

The issue addressed in footnote 8 of the WHO Pandemic Agreement was the last substantive issue resolved before the approval of the agreement by the World Health Assembly in 2025.

Recent examples of mandated sharing of technology and data include a February 24, 2016, report in the Washington Post regarding AI technology held by Anthropic³⁸ and provisions in the 2025 European Health Data Spaces Regulation, discussed above.

Annex V: The Open Source Dividend

The World Health Organization (WHO) and at least one national government have held consultations on the possibility of delinking the incentives to invest in R&D on the grant of exclusive rights to make and market products, for drugs, vaccines and other medical technologies. One proposal is to replace the exclusive patent and regulatory rights to make and sell products with very robust financial rewards, sometimes described as innovation inducement prizes or market entry rewards. Patents on inventions would be used to make claims on the market entry rewards (MERs), but they would not be necessary.

One criticism of innovation inducement prizes is that by eliminating the need to obtain patents on inventions, product developers may rely more on trade secrets to maintain a competitive edge. To address this concern, but more generally to encourage the open sharing of research, an open source dividend was proposed as an incentive.

Specific versions of the Open Source Dividend (OSD) have been included in U.S. legislative proposals and proposals to WHO expert groups.

In H.R. 495, the Medical Innovation Prize Act (115th Congress), Section 11 provided a set-aside for a share of the market entry reward for an “Open Source Dividend” to “the persons or communities that openly shared knowledge, data, materials, and technology on a royalty-free and nondiscriminatory basis.”

In 2009, the governments of Bangladesh, Barbados, Bolivia and Suriname proposed similar incentives (with somewhat different names) in four proposals to a WHO Expert Working Group on R&D Financing (EWG) for delinking R&D incentives from monopolies.³⁹

- PROPOSAL by Bangladesh, Barbados, Bolivia, and Suriname: Chagas Disease Prize Fund for the Development of New Treatments, Diagnostics and Vaccines. 09.04.15 https://web.archive.org/web/20160804123907/http://www.who.int/phi/Bangladesh_Barbados_Bolivia_Suriname_ChagasPrize.pdf
- PROPOSAL by Bangladesh, Barbados, Bolivia, and Suriname: A Prize Fund to Support Innovation and Access for Donor Supported Markets: Linking Rewards for Innovation to the Competitive Supply of Products for HIV-AIDS, TB, Malaria and Other Diseases for Humanitarian Uses.

³⁸ Tara Copp and Ian Duncan, "Hegseth threatens to force AI firm to share tech, escalating Anthropic standoff." *Washington Post*, February 24, 2026. A senior defense official said in a statement to The Washington Post that if the company does not comply by 5:01 p.m. Friday, Hegseth "will ensure the Defense Production Act is invoked on Anthropic, compelling them to be used by the Pentagon regardless of if they want to or not." <https://www.washingtonpost.com/technology/2026/02/24/pentagon-demands-ai-access/>

³⁹ <https://www.keionline.org/25072>

https://web.archive.org/web/20180516220945/http://www.who.int/phi/Bangladesh_Barbados_Bolivia_Suriname_DonorPrize.pdf

- PROPOSAL by Bangladesh, Barbados, Bolivia, and Suriname: Prize Fund for Development of Low-Cost Rapid Diagnostic Test for Tuberculosis. 09.04.15
https://web.archive.org/web/20180516220946/http://www.who.int/phi/Bangladesh_Barbados_Bolivia_Suriname_TBPrize.pdf
- PROPOSAL by Bolivia, Suriname and Bangladesh: Prizes as a Reward Mechanism for New Cancer Treatments and Vaccines in Developing Countries Date: 09.04.15
https://web.archive.org/web/20160502122851/http://www.who.int/phi/Bangladesh_Bolivia_Suriname_CancerPrize.pdf

One suggestion for allocating the OSD money is to rely upon the decision of a jury. Once a product enters the market and qualifies for prize money, administrators of the prize fund would empanel a jury, drawn randomly from a pool of qualified experts, who would review applications for a share of the OSD, from persons, communities or entities that provided evidence to support their claims.