Bilateral versus multilateral: A comparison of the different Access and Benefit-sharing (ABS) concepts

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Abstract

The bilateral approach of the Convention on Biological Diversity (CBD) and its Nagoya Protocol prescribes negotiations between providers and users of genetic resources, and the sharing of benefits with the specific providers. In the multilateral approach of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Pandemic Influenza Preparedness (PIP) Framework, providers place genetic resources into a common pool, which is accessible under standard contracts, while benefits are shared with all potential providers participating in the system. The aim of this article is to describe these approaches and to assess their implications in practical situations (genebank management and the exchange of influenza pathogens). Compared to the bilateral approach, multilateral ABS instruments have the potential to make access easier, while assuring benefit-sharing. The two multilateral instruments have facilitated access to specific categories of genetic resources, and have provided benefits contributing to food security and public health. Improvements are possible, however, both in the work of the Food and Agriculture Organization (FAO) to implement the ITPGRFA and in the work of the World Health Organization (WHO) to implement the PIP Framework.

Access and Benefit-sharing (ABS) – Convention on Biological Diversity (CBD) – Food security – International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) – Nagoya Protocol – Pandemic Influenza Preparedness (PIP) Framework – Public health – Pandemic potential

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1 Introduction

The term "Access and Benefit-sharing" (ABS) refers to the regulation of access to genetic resources (and traditional knowledge associated with genetic resources) and the sharing of benefits arising from utilisation of these genetic resources with the providers of the genetic resources. The shared benefits can be monetary (e.g. royalties or up-front payments) or non-monetary (e.g. scientific co-operation or technology transfer). The concept of ABS arose in the 1990s, when awareness of the actual or potential value of genetic resources grew, also due to the increasing role of intellectual property rights for market products based on genetic resources (e.g. in medicine, cosmetics and plant breeding), which resulted from advances in biotechnology and genetic engineering. This led to developing countries fearing that they were losing control over their genetic resources (Santilli 2012). As a result, the exchange of genetic resources has been increasingly regulated through various legally binding international agreements.

Basically, two approaches to regulate ABS can be distinguished: bilateral and multilateral. In the bilateral approach, followed in the Convention on Biological Diversity (CBD) and the Nagoya Protocol, access is provided by authorities of the provider country after case-by-case bilateral negotiations between the providers and users of the genetic resource(s) and the conclusion of a contract between the providers and users specifying the modalities of utilisation of the genetic resource(s). Benefits are shared with the providers themselves (critical of the bilateral approach: Kamau 2024 in this issue, pp. 98 – 108). In the multilateral approach, followed in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Pandemic Influenza Preparedness (PIP) Framework, genetic resources are shared by providers in a common pool or laboratory network that handles the specific genetic resources through a standardised agreement. The benefits are thus made available to all potential providers participating in the system, with a view to them being used for activities that promote achievement of the objectives of the instrument. Under the ITPGRFA, seeds of selected crops and forages are shared to enhance food security, and under the PIP Framework, influenza viruses with pandemic potential are shared with the Global Influenza Surveillance and Response System to increase public health security.

An analysis of the merits and drawbacks of bilateral and multilateral approaches is timely and useful, not only with a view to improving the existing ABS systems, but also because discussions are being held on the establishment of new ABS systems, such as for digital sequence information (DSI) under the CBD (Rohden, Scholz 2021; Brink, van Hintum 2022; Scholz et al. 2022; Scholz et al. 2024 in this issue, p. 135 ff.), and an international legally binding instrument on marine biodiversity in areas beyond the national jurisdiction (Biodiversity Beyond National Jurisdiction treaty, BBNJ; Box 1, p. 2) of states in the framework of the United Nations Convention on the Law of the Sea (UNCLOS; Humphries et al. 2020), as well as in the context of the Intergovernmental Negotiating Body that is drafting and negotiating a World Health Organization (WHO) convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+) that is to include a global access and benefit-sharing system for pathogens (Gostin et al. 2021; WHO 2023).

The present article aims to present and compare existing ABS instruments and their different (bilateral and multilateral) approaches, and to analyse the respective advantages and disadvantages of these approaches, with a special focus on genetic resources important for food security and public health.

2 Existing ABS agreements/instruments

2.1 Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (CBD), agreed upon in 1992 and coming into force on 29 December 1993, was the first legally binding international ABS agreement. The CBD established that states have sovereign rights over their biological resources and

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Box 1: BBNJ Treaty – A Nagoya Protocol for the high seas?

1 Introduction

In early 2023, the United Nations (UN) negotiations on an implementing agreement under the 1982 UN Convention on the Law of the Sea (UNCLOS) on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction – the Biodiversity Beyond National Jurisdiction Treaty (BBNJ Treaty) – were concluded. In addition to marine protected areas and environmental impact assessments on the high seas, the agreement also addresses access to marine genetic resources (MGRs) including digital sequence information (DSI) and equitable benefit-sharing arising from activities with respect to MGRs and DSI. Since the start of the negotiations, the MGR regulations were of particular interest and ultimately paved the way for concluding the agreement. The title of the second part "Marine Genetic Resources, including the fair and equitable sharing of benefits" and the subject matter of the MGR chapter are strongly reminiscent of the Nagoya Protocol (NP) on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilisation – but how much Nagoya is actually in the BBNJ Treaty?

2 Special features of the high seas

The negotiations on the BBNJ Treaty are based on two special features. These are of a geographical nature and a matter of international law. Both interrelated factors have significantly narrowed the regulatory corridor of the MGR provisions.

2.1 The high seas

The area of origin of the MGR is decisive for the scope of application of the BBNJ Treaty (the abbreviation MGR is used hereafter exclusively for resources within the scope of application of the BBNJ Treaty). The provisions of the agreement apply exclusively to those MGRs that originate from marine areas beyond national jurisdiction. This umbrella term covers the high seas and the international seabed. In contrast to the NP, genetic resources that do not originate from a specific national territory or functional area, but from an area beyond such allocations, are made subject of regulation here. Due to this special geographical starting position, there is no confrontation between a potential provider country and a user, as it is usual under the NP as a bilateral system.

The international regime of the high seas (Part VII UNCLOS) begins where national jurisdiction – the exclusive economic zone – ends, i. e. beyond 200 nautical miles from the baseline of the respective coastal state. As an international area, the high seas are characterised by the fact that no state may claim sovereign rights to those maritime areas or – at least without further ado – to the resources there. At the same time, the high seas are characterised by the mare liberum principle. According to this approach, the sea as an international space is uncontrollable and states are free to use the sea. When it comes to the MGR debate on the high seas, there has already been talk of the "Mare Geneticum" (Broggiato et al. 2018).

2.2 Legal hierarchy

Another special feature of the negotiations is the hierarchical relationship between UNCLOS and the BBNJ Treaty as an implementing agreement (see UN Resolution 72/249). This means that the provisions of the implementing agreement must be compatible with the provisions of the overarching UNCLOS. Accordingly, there are legal limits to creativity in the setting of norms. For MGR-related activities, this means that the freedom of scientific research applicable to the high seas under Art. 87 para. 1 (f) UNCLOS must be respected. Consequently, the provisions on access to MGRs must be based on the international principle of freedom of marine research. However, this does not provide for the complete absence of regulations on research practice, although overly burdensome requirements would have been difficult to reconcile with the principle of freedom of research.

3 Access to marine genetic resources

The initial situation described above – the lack of a bilateral situation – means that the basic structure of Access and Benefit-sharing (ABS) under the Convention on Biological Diversity (CBD) and the NP is not readily transferable to access to MGRs. Although there is a large number of users, there is no nexus to a provider country on the high seas. In this respect, there are no state sovereign rights over the relevant MGRs. The lack of such jurisdiction over MGRs makes it seem hardly possible to set up an organisation that would first have to grant permission prior to accessing MGRs. In any case, defining access to MGRs as subject to prior permission would hardly be compatible with the freedom of research applicable on the high seas. Instead, a consensus was reached that a notification system would be a more adequate response to the existing tension between freedom of research and traceability (Broggiato et al. 2018). Before and after the collection of MGRs on the high seas, users must transmit information on the collection in situ via the clearing-house mechanism in order to ensure transparency and optimised data exchange. In addition to logistical and geographical information, information on the possibility of participating in research expeditions also need to be submitted. The clearing-house mechanism, which has yet to be set up by the secretariat of the treaty, is to act as the primary information platform. Although these notification provisions create requirements that must be met, they do not constitute a permission regime.

4 Benefit-sharing arising from activities with respect to MGRs/DSI

The described difficulty of the initial situation due to the place of origin of the MGR continues at the later stage of benefit-sharing. In the absence of specific provider countries as potential recipients of benefits, the establishment of a bilateral benefit-sharing regime was rather far-fetched. Instead, for reasons of practicability, the adoption of a multilateral approach was the obvious choice. This includes both non-monetary and monetary benefits. While the former includes access to collections and the transfer of relevant data, it was eventually possible to agree on the establishment of a fund that shall distribute monetary benefits. The fund will be fed by annual contributions from countries of the Global North, irrespective of the extent of the respective research/development activities. The subsequent disbursement of the funds must be used to achieve the objectives of the BBNJ Treaty. Should commercialisation based on the utilisation of MGRs actually occur in the future, it will be up to the Conference of the Parties to decide on new modalities for benefit-sharing. Likewise, modalities for the sharing of benefits in relation to DSI will have to be worked out in the future. In doing so, the anticipated outcome of modalities on DSI under the Convention on Biological Diversity (CBD) will have to be taken into consideration.

5 Conclusion

With regard to the BBNJ Treaty, a certain degree of "Nagoya affinity" cannot be denied. This applies in particular to the basic scientific understanding and individual terms (for instance "utilisation of MGR" and "biotechnology"). However, the special features of the high seas described here disqualify the basic bilateral ABS concept of the NP. Instead, the BBNJ Treaty must pursue its own approaches in order to meet the requirements of the "Mare Geneticum" in a practicable manner. Many aspects still need to be further elaborated in the future. In that matter, the ABS Committee and the Conference of the Parties, which are also yet to be established, will be the key bodies. Hopefully, the relevant specifics will be developed in a practicable manner.

6 References

Broggiato A., Vanagt T. et al. (2018): Mare Geneticum: Balancing governance of marine genetic resources in international waters. The International Journal of Marine and Coastal Law 33: 3 – 33. DOI: 10.1163/15718085-13310030

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that the authority to determine access to genetic resources rests with national governments and is subject to national legislation. According to Article 15 of the CBD, access to genetic resources shall be subject to prior informed consent (PIC) of the contracting party providing such resources, unless otherwise determined by that party, while access, where granted, shall be on mutually agreed terms (MAT). This means that the CBD prescribes a bilateral approach. The CBD applies to all genetic resources, which are defined as "genetic material of actual or potential value", with genetic material being defined as "any material of plant, animal, microbial or other origin containing functional units of heredity".

2.2 Nagoya Protocol

The Nagoya Protocol (full title: "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity"), agreed upon in 2010 and entering into force on 12 October 2014, is not a standalone international ABS agreement but rather a supplement to the CBD. It was developed to improve the implementation of the third objective of the CBD. The Nagoya Protocol follows the bilateral approach of the CBD, with access to genetic resources subject to PIC and MAT (unless otherwise determined by the party providing the resources). As indicated in the full title, the Nagoya Protocol focuses on the access to genetic resources and sharing of the benefits from their utilisation. As for access, parties have to provide rules and procedures for clear and fair access. Every party has to designate a National Focal Point (NFP) responsible for making information available, and a Competent National Authority (CNA) responsible for granting access. To facilitate the sharing of information on ABS, an Access and Benefit-sharing Clearing-House was established, which contains, among other things, the contact details of NFPs and CNAs of countries, administrative and policy measures, and issued permits. The Nagoya Protocol not only applies to genetic resources as defined by the CBD, but also contains provisions regarding traditional knowledge associated with genetic resources. Parties have to monitor the utilisation of genetic resources used in their territories.

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

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is an ABS instrument specifically targeting Plant Genetic Resources for Food and Agriculture (PGRFA). As indicated in Section 2.1, pp. 1 – 3, the CBD applies to all genetic resources, which means that it also applies to PGRFA. However, the importance of PGRFA for food security and sustainable agriculture was recognised, and the Conference for the Adoption of the Agreed Text of the CBD in 1992 decided that a specific system was to be developed for PGRFA. In the following decade, the Food and Agriculture Organization of the United Nations (FAO) drafted the ITPGRFA, which was adopted in 2001 and came into force on 29 June 2004. The objectives of the ITPGRFA, as stated in Article 1, mirror those of the CBD, but are focused on PGRFA. PGRFA are defined as: "any genetic material of plant origin of actual or potential value for food and agriculture".

In contrast to the CBD and the Nagoya Protocol, which prescribe a bilateral approach, the ITPGRFA follows a multilateral approach. The ITPGRFA confirms the sovereign rights of countries over their genetic resources but aims to facilitate the exchange and transfer of PGRFA through the Multilateral System of Access and Benefit-sharing (MLS). For exchanges of PGRFA in the MLS, a standard contract (Standard Material Transfer Agreement, SMTA) is used, and not the PIC and MAT of the CBD. The MLS does not include all PGRFA species, but only 35 food crops (Fig. 1, p. 4) and 29 forages, which are listed in Annex I of the ITPGRFA. Access to PGRFA in the MLS can be obtained by signing the SMTA, but this is only possible when they are used for research, breeding and training for food and agriculture, with other uses (e.g. chemical or pharmaceutical) being explicitly excluded. With respect to benefit-sharing, it is recognised that facilitated access in itself forms an important benefit, but other forms of benefit-sharing, such as the exchange of information, technology transfer, capacity building and the sharing of commercial benefits, are also considered important. Commercial benefits have to be shared if PGRFA obtained under an SMTA are made into commercialised products (e.g. new varieties) that are not freely available for research and breeding by others. These benefits are placed into an international benefit-sharing fund that is used for supporting conservation and sustainable utilisation of PGRFA.

2.4 Pandemic Influenza Preparedness (PIP) Framework

When A(H5N1), an influenza virus with human pandemic potential, re-emerged in 2004, some developing countries were concerned that despite sharing virus samples with the WHO-coordinated Global Influenza Surveillance and Response System (GISRS), a worldwide network of public health laboratories that collect, monitor and share influenza viruses, they were unable to access vaccines developed from the viruses they had shared. It became clear that a new system was needed to not only ensure that viruses were shared for public health risk assessment but also that products resulting from such sharing would also be available to all who needed them on a fair, equitable, timely and affordable basis. After four years of negotiation, the PIP Framework was unanimously adopted on 24 May 2011 by the 194 member states of the WHO. The PIP Framework brings together countries, laboratories, industry and civil society to strengthen pandemic influenza preparedness and response, introducing greater equity and solidarity among nations when the next pandemic strikes. The PIP Framework establishes many responsibilities among member states, the WHO, GISRS laboratories and manufacturers. These include sharing influenza viruses with pandemic potential (IVPPs) and contributing to a global benefit-sharing system.

The PIP Framework has two goals that are pursued on an equal footing:

- the sharing of H5N1 and other IVPPs, and
- access to vaccines and sharing of other benefits.

Influenza viruses are shared by WHO member states through GISRS. In addition to serving as a virus-sharing platform, GISRS also shares genetic sequence data derived from these viruses, develops and shares reagents, and undertakes risk assessments. One of its critical functions is to develop candidate vaccine viruses (CVVs), which are used by influenza vaccine manufacturers to develop vaccines against seasonal and pandemic influenza. In exchange for receiving IVPPs and associated data from the GISRS, manufacturers contribute to pandemic preparedness and response in two ways:

- They pay an annual partnership contribution that the WHO uses in two ways: 70 % of the funds are used to strengthen preparedness capacities in countries where they are weak, and 30 % are reserved for use at the time of the next influenza pandemic for response activities. This partnership contribution is a sustainable financing mechanism provided by influenza product manufacturers.
- Manufacturers that receive PIP biological materials from the GISRS are required to conclude legally binding advance supply contracts (Standard Material Transfer Agreement 2, SMTA2) with the WHO to provide vaccines, antivirals, diagnostics or other products to the WHO, in real time, at the time of the next pandemic.

Fig. 1: Accessions of cultivated barley (*Hordeum vulgare*) in the field. The genus *Hordeum* (barley) is listed in Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). (Source: © Leibniz Institute of Plant Genetics and Crop Plant Research/IPK)

Fig. 2: Sealed glass jars with grains of various accessions of cultivated barley (*Hordeum vulgare*) in a cold store. (Source: © Leibniz Institute of Plant Genetics and Crop Plant Research/IPK)

3 Case studies relevant to food security and public health

3.1 Federal ex situ Gene Bank at the Leibniz Institute of Plant Genetics and Crop Plant Research (IPK)

An impetus for the worldwide, structured collection and use of cultivated plants and their wild relatives in gene banks as well as their genetic classification was already given by the Russian geneticist Vavilov at the beginning of the 20th century. He developed the theory of gene or diversity centres as important centres of biological diversity. Vavilov also recognised the importance of preserving regionally adapted crop varieties as a resource for future breeding (Peres 2016). In many regions of the world, landraces are gradually being replaced by modern plant varieties, so that the crop diversity of the past is in danger of disappearing. The task of gene banks is to preserve these plant genetic resources and prevent the loss of genetic diversity and biodiversity (cf. Fig. 1). There are about 1,750 gene banks worldwide with about 7.4 million accessions (FAO 2010). The one at the IPK hosts more than 150,000 accessions of 2,933 plant species (776 genera). It has been estimated that about 7,000 (Mansfeld 1986; Khoshbakht, Hammer 2008) of the estimated 300,000 vascular plant species worldwide (Christenhusz, Byng 2016) are cultivated plants. Thus, the ex situ Gene Bank at the IPK houses a significant part of this genetic diversity. This diversity is made available to scientists, plant breeders and interested people from all over the world, and over a million samples have been delivered by the ex situ Gene Bank to date.

Most accessions are stored as dried seeds at – 18 °C (Fig. 2). In contrast, accessions that are vegetatively propagated are permanently cultivated in the field or preserved in liquid nitrogen at – 196 °C. On the online portal of the ex situ Gene Bank (https://gbis.ipk-gatersleben.de/), interested parties can view and search the stored accessions and their associated "passport data" and request material on a non-commercial scale. A current focus of the scientific work of the ex situ Gene Bank is on linking the stored biodiversity with its molecular data. Gene banks worldwide are undergoing a transformation process towards bio-digital resource centres (Mascher et al. 2019). The number of well-characterised accessions and the amount of detailed information stored alongside the biological material is increasing rapidly due to easier access to better, faster and cheaper sequencing and other "omics" technologies.

To safeguard the ex situ Gene Bank collections, the IPK works together with the Svalbard Global Seed Vault and regularly transfers collection holdings to this central backup facility. Requests to return part of the collection to areas of origin, so-called repatriation, are also supported by the Gene Bank. For example, the repatriation of Ethiopian material and establishment of local structures as well as establishment of standards and logistics through training and education are a prominent example. A total of 7,498 Ethiopian accessions from 32 different genera were repatriated from the Federal ex situ Gene Bank, including 5,561 barley and 1,340 wheat accessions. These accessions had been acquired through collection expeditions or had been received from other gene banks or research institutes.

The acquisition and inclusion of material in the collection and the distribution of material from the gene bank is done under the SMTA of the ITPGRFA. This facilitates access under standardised conditions and for specific purposes. The same applies to derived PGRFA and material under development for which the SMTA can also be used, which means that rapid subsequent use is possible. Experience has shown that the acquisition of new material that cannot be obtained under these standardised conditions is difficult, since bilateral agreements have to be concluded for direct access by way of collecting trips as well as for indirect acquisition from existing collections or other material donors. Experiences of IPK scientists range from smooth processes, even with states that have not ratified the Nagoya Protocol themselves, to a lack of response from states that have ratified the Nagoya Protocol. In case of indirect access, bilateral negotiations often prove to be a major hurdle, also because of the increased amount of research required on the provider country. The same also applies to PGRFA that are not covered by the ITPGRFA. Thus, it can be said that the multilateral system enables significantly faster access to the material and its appropriate use under already defined conditions of access and intended use. On the other hand, an advantage of bilateral ABS could be that conditions can be negotiated that are more precisely tailored to actual utilisation needs.

3.2 Influenza and non-influenza pathogen-sharing

For influenza viruses with pandemic potential (IVPPs), the PIP Framework established an access and benefit-sharing system where WHO member states have recognised that they have a commitment to share, on an equal footing, IVPPs and the benefits arising from such sharing, considering these as equally important parts of the collective action for global health (PIP Framework, Section 1.3).

As such, WHO member states are expected to share IVPPs in a rapid, systematic and timely manner, with a WHO-collaborating centre of their choice (Section 5.1.1). The sharing of PIP materials into, within and outside of GISRS is governed by the PIP Framework's two Standard Material Transfer Agreements (SMTA1 and

SMTA2). Through SMTA1, the provider (generally a national influenza centre) consents to the onward transfer to and use of the PIP materials by entities outside of the WHO GISRS on the condition that the prospective recipient has concluded an SMTA2 with the WHO. Through the combined provisions of SMTA1 and SMTA2, the PIP Framework has established a system whereby countries that share viruses with the GISRS give their prior informed consent to the onward transfer and use of such materials to entities outside the GISRS (e.g. manufacturers), knowing that they can expect to receive in return (i) funding (through the partnership contribution) to strengthen capacities to respond to an influenza pandemic, and (ii) access to pandemic-response products in the event of a pandemic through the SMTA2 agreements.

The PIP Framework applies only to pandemic influenza viruses, and to date it remains the only multilateral framework for ABS in public health. Table 1, p. 6, presents important viral diseases and sets out current practices and procedures that aim to streamline pathogen sharing. However, in the absence of an international multilateral instrument for pathogens other than influenza viruses with pandemic potential, the exchange of most pathogens falls under the bilateral Nagoya Protocol ABS system, e.g. if the provider country is a party to the Nagoya Protocol, and in that case, additional requirements, such as obtaining PIC and MAT, would arise.

Since the PIP Framework was adopted in 2011, two important developments have created challenges to its implementation. The first was the entry into force of the Nagoya Protocol and the growing number of countries with ABS laws. Implementation of such laws is raising questions about the sharing of seasonal influenza viruses, which are not covered by the PIP Framework, and in particular the use by industry of seasonal CVVs. While the PIP Framework itself is not considered at risk, the global system for pandemic influenza preparedness and response rests fully on the strength of the GISRS seasonal system. If this is disrupted, pandemic influenza prevention and control is, in turn, weakened. The second is the increasing reliance on genetic sequence data in the development and production of pandemic-response products such as vaccines. Questions about how to ensure fair and equitable benefit-sharing from the use of sequence data remains a priority for the WHO and its member states.

4 Discussion

Thirty years after the entry into force of the first international ABS agreement that follows the bilateral approach (the CBD in 1993), doubts have arisen around the efficiency and effectiveness of the bilateral ABS approach. As of March 2023, more than 4.600 so-called Internationally Recognised Certificates of Compliance (IRCC) have been published in the ABS Clearing-House. This gives an indication of the number of successfully concluded negotiations between providers and users, but detailed information, e.g. on the forms and amounts of benefit-sharing, is usually lacking because of confidentiality considerations. Literature reports indicate that national ABS rules and regulations, based on the CBD, have made access more difficult and have hindered research and international collaboration, while the transactions that did take place did not generate substantial benefits for conservation (Prathapan et al. 2018; Aubry et al. 2020; Brink, van Hintum 2020; Laird et al. 2020). The case studies in Section 3 also indicate that there may be problems with the Nagoya Protocol in the activities of gene banks and the sharing of seasonal influenza viruses (which do not fall under the PIP Framework). The case study of the IPK ex situ Gene Bank mentioned that bilateral negotiations often prove to be a major hurdle for accessing PGRFA, and that authorities of provider countries do not always respond to inquiries. On the other hand, it is mentioned that the bilateral approach offers the opportunity to negotiate conditions that are tailored to specific utilisation needs. The case study on influenza sharing mentioned that problems with the sharing of seasonal influenza viruses (which are not covered by the PIP Framework) may have negative effects on the global system for pandemic influenza preparedness and response.

Multilateral ABS agreements have the potential to make access easier, because it is not necessary to have case-by-case negotiations between users and providers. In case standard contracts are used, such as the SMTAs of the ITPGRFA and the PIP Framework, the conditions for use of the material are set and known in advance to both users and providers. The case study of the IPK ex situ Gene Bank concluded that the multilateral system allows significantly faster access to the material and its appropriate use under defined conditions of access and intended use. This confirms the findings of Brink and van Hintum (2020) that the ITPGRFA has been more effective than the CBD in providing access to PGRFA, even though not all PGRFA are incorporated in the MLS, and not all PGRFA in the MLS are easily available, sometimes due to reluctance of provider countries to allow access to their PGR through the MLS. As of June 2022, about 6.4 million PGRFA samples had been transferred under the SMTA of the ITPGRFA, with about 91,000 SMTAs. Of these samples, about 89 % were distributed by international organisations and about 11 % by contracting parties (FAO 2022). The benefit-sharing fund of the ITPGRFA, established in 2009, has distributed 26 million USD to 81 projects in 67 developing countries, with the projects focusing on

- supporting on-farm management and improvement of crop varieties,
- on-farm and in situ conservation of crop varieties,
- farmer-to-farmer exchanges of crop varieties,
- the development of local seed value chains, and
- a better flow of PGRFA from ex situ collections to farmers and back (ITPGRFA 2022).

Through the PIP Framework, pandemic influenza preparedness and response capacities in all six WHO regions and over 100 countries have been strengthened using a portion of the more than 280 million USD collected to date through the PIP partnership contributions. The PIP Framework has supported the improvement of national regulatory systems, helping countries to accelerate the authorisation of pandemic vaccines and other products. SMTA2s are significantly improving the predictability of equitable access to future pandemic influenza vaccines and other products. In the event of a pandemic, 10 of every 100 doses of vaccine produced will be set aside for the WHO, and 8 of those will come to the WHO on a donation basis. To date, 91 SMTA2s have been signed, 16 of which are with manufacturers of pandemic-response products such as vaccines, diagnostics and antivirals. These agreements specify that the products they cover will be delivered to the WHO for use in countries that need them and have little or no other means of access to them. By putting these agreements in place, the WHO, member states and industry aim to ensure that when the next influenza pandemic starts, there is structured, predictable, fair, efficient and equitable access to critical supplies for all countries.

However, there is room for improvement. The case studies in Section 3 show that the multilateral instruments ITPGRFA and the PIP Framework cover only fractions of PGRFA and viruses with pandemic potential, respectively. To improve access to and utilisation of important genetic resources for food security and public health, expansion of these instruments would be desirable. Although the ITPGRFA offers the possibility for countries to voluntarily also use the SMTA for distributing PGRFA which are not among the 35 food crops and 29 forages listed in Annex I of the ITPGRFA, only 0.5 % of the PGRFA transferred with the SMTA belong to crops not listed in Annex I (FAO 2022). In the ITPGRFA, contracting parties have resumed discussions on expansion of the scope of the MLS of the ITPGRFA from the 64 food crops and forages presently mentioned in Annex I of the ITPGRFA to include all PGRFA. In the WHO, a global access and benefit-sharing system

Table 1: Important viral diseases with current practices and procedures aiming to streamline pathogen sharing.

Pathogen	Formal network (designated labs, structures)	Reasons for sample sharing	International instrument	Sample and data sharing agreements	What is shared?	Global pathogen sharing tracking mechanism	Benefits to originating countries (monetary/ non-monetary)
Influenza	GISRS	Seasonal influenza viruses: routine surveillance, vaccine development, antiviral resistance monitoring	Seasonal influenza: no	Seasonal: influenza: yes, network TORs	Clinical biological material, culture, genetic sequence data, inactivated virus for external quality assurance schemes	Seasonal influenza: no	Seasonal influenza: benefits include public health information, risk assessment, funding, capacity building, reagents, reference viruses, external quality assurance program
		IVPPs: new pathogen confirmation, risk assessment, vaccine development, antiviral resistance monitoring	IVPPs: yes, PIP Framework	IVPPs: yes, network TORs, SMTA1		IVPPs: IVTM	IVPPs: benefits include all the above, and in addition funding for capacity building (through the PIP Partnership Contribution), access to pandemic products (through SMTA2s)
Polio	Global Polio Network	Routine surveillance, outbreak confirmation	No	Yes, network TORs	Clinical biological material, genetic sequence data, environmental samples, inactivated virus for external quality assurance schemes	No	Funding, capacity building, reagents
Measles	No	Routine surveillance, outbreak confirmation	No	Yes, network TORs	Clinical material, genetic sequence data, inactivated virus for external quality assurance schemes	No	Funding, capacity building, reagents
Zika	No	Outbreak confirmation, advanced characterisation	No	National and/or international partner MTA	Clinical biological material, culture, genetic sequence data, inactivated virus for external quality assurance schemes	No	Dependent on requests incorporated within MTA; funding, training, technology transfer, scientific collaboration
Ebola	No	Outbreak confirmation, advanced characterisation, product development	No	National and/ or international partner MTA	Clinical biological material, culture, genetic sequence data, inactivated virus for external quality assurance schemes	No	Dependent on requests incorporated within MTA; funding, training, technology transfer, scientific collaboration
COVID19	No (between 2020 – 2023)	Outbreak confirmation, advanced characterisation, product development	No	National and/ or international partner MTA	Clinical biological material, culture, genetic sequence data, inactivated virus for external quality assurance schemes	No	Dependent on requests incorporated within MTA; funding, training, technology transfer, scientific collaboration
Mpox	No	Advanced characterisation, product development	No	National and/ or international partner MTA	Clinical biological material, culture, genetic sequence data, inactivated virus for external quality assurance schemes	No	Dependent on requests incorporated within MTA; funding, training, technology transfer, scientific collaboration

COVID-19 = Coronavirus Disease 2019, GISRS = Global Influenza Surveillance and Response System, IVPPs = Influenza Viruses with Pandemic Potential, IVTM = Influenza Virus Traceability Mechanism, MTA = Material Transfer Agreement, PIP = Pandemic Influenza Preparedness, SMTA = Standard Material Transfer Agreement, TORs = Terms of Reference

is being discussed by the Intergovernmental Negotiating Body that is drafting and negotiating a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+; Gostin et al. 2021; WHO 2023). Where the PIP Framework only covers influenza viruses with pandemic potential, the new global access and benefit-sharing system could cover all pathogens with pandemic potential (WHO 2023) or, alternatively, all pathogens, if member states decide so. The INB will submit its outcome document for consideration by the 77th World Health Assembly in May 2024.

Not only the access aspects, but also the benefit-sharing aspects could be improved. The benefit-sharing fund of the ITPGRFA is mainly filled by voluntary donor country contributions, with only limited amounts of monetary benefits shared by users of PGRFA (Brink, van Hintum 2020; Wynberg et al. 2021). To remedy this, parties to the ITPGRFA are considering the idea of establishing a subscription system for the MLS to assure earlier and more monetary benefit-sharing. The PIP Framework has been hailed by some as a "milestone in global health governance" (Fidler, Gostin 2011), but others have remarked that it is not certain that the SMTA2s will really deliver access to pandemic-response products, for instance because it will be up to the member states where such products are manufactured to allow their export (Rourke 2019).

Both case studies also highlight the increasing importance of molecular information such as genomic sequence and omics data. Discussions on whether and how the utilisation of these data, often referred to with the undefined placeholder term "digital sequence information" (DSI), should be subject to Access and Benefit-sharing (ABS) obligations, like the utilisation of genetic resources already is, are ongoing in the CBD, the WHO, the ITPGRFA and other international fora. In December 2022, the Conference of the Parties to the CBD (COP) decided that benefits from the utilisation of DSI on genetic resources should be shared (Goal C and Target 13 of the agreed Kunming-Montreal Global Biodiversity Framework). In a separate decision on DSI, it was stated that benefit-sharing from DSI would follow a multilateral approach, with a global benefit-sharing fund, and that a follow-up process would be started to discuss further details of this multilateral benefit-sharing system (more details in Scholz et al. 2024 in this issue, pp. 135 – 142). A new access and benefit-sharing system being considered by member states that are negotiating the WHO CA+ could include pathogens as well as their genomic (digital) sequence data (GSD/DSI). As for the ITPGRFA, the meeting of the Governing Body of the ITPGRFA in October 2022 decided that the DSI outcomes of the CBD COP meeting in December 2022 would be taken into account in the re-opened discussions on the enhancement of the MLS, next to other important aspects, including expansion of the MLS and creation of a subscription system for the MLS. The first formal meeting to discuss the enhancement of the MLS took place in July 2023 and focused on a stocktaking of views.

5 Conclusion

It can be concluded that compared to the bilateral system of the Nagoya Protocol, multilateral ABS instruments certainly have the potential to make access easier while assuring more fair and equitable benefit-sharing directed at promoting the objectives of the instruments. The two existing multilateral systems (the ITPGRFA of the FAO and the PIP Framework of the WHO) have been successful in facilitating access to genetic resources important for food security and public health, and in providing support for projects aiming to increase food security in developing countries and activities to strengthen pandemic influenza preparedness capacities in countries where these are weak. However, improvements are always possible, both in the work of the FAO to implement the ITPGRFA and in the work of the WHO to implement the PIP Framework.

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