

Multilateral Regulatory Regimes and Plant Breeding

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September 2020

1.0 Introduction

Seeds and other forms of germplasm are the foundation of terrestrial food systems. Germplasm is a generic term for planted genetic resources that are used to produce a crop, including seeds, roots, tubers, bulbs, cuttings, and rhizomes (Louwaars et al., 2010). Good quality, reliable germplasm is vital to crop productivity and resilience. In turn, agricultural productivity and resilience are positively linked to economic growth, employment, trade, food security, and poverty. Germplasm is particularly important for developing countries, the majority of which are more dependent on agriculture than are industrialized economies (Food and Agriculture Organization of the United Nations [FAO], 2018b). In sub-Saharan Africa, farming accounts for an average of one third of the gross domestic product and three quarters of employment (World Bank, 2017). Small-scale producers² provide up to 80% of the food supply in Asia and sub-Saharan Africa and around one third of food supplies globally (Ricciardi et al., 2018). They depend on having access to affordable, good-quality plant-breeding systems.

This brief is addressed to governments developing or reviewing national laws that govern germplasm and plant breeding. Those laws must comply with international laws and obligations. Yet there are competing and incoherent international legal frameworks for the use and reproduction of germplasm. The frameworks come from several areas of international law, including trade agreements, biosecurity measures, biological diversity conservation, the rights of Indigenous Peoples, and intellectual property (IP) rights law (Organisation for Economic Co-operation and Development, 2012).

¹ The authors would like to recognize Mohamed Coulibaly for initiating the brief, and to thank Charles Lawson, Alexandra Lyon, Sara Nawaz, and Daniel Robinson for their helpful reviews.

² There is no universally accepted definition of a small-scale producer. This report follows the approach of Robertshaw et al. (2016) and uses the term for producers whose farm is less than 2 hectares.



The competing priorities and stakeholders include:

1. The rights of patent holders and commercial seed breeders and traders.
2. Farmers' traditional right to store, reuse, share, and sell seeds.
3. Indigenous Peoples' rights to the germplasm associated with their ancestral territories and the knowledge and culture associated with their cultivation.
4. The public interest in protecting and conserving genetic resources.
5. The potential for economic profit and the question of who should share in the profits and other benefits when new genetic traits are introduced and sold commercially.

The international agreements that address germplasm and plant breeding provide national governments with some guidance and boundaries for domestic laws. Some agreements also create legal obligations for national governments. Yet the contradictions make it impossible to conform easily with all the laws. Unsurprisingly, the implementation of international agreements varies substantially among countries (Mulesa & Westengen, 2020). There is no simple guide governments can reference to ensure their plant breeding laws are in compliance with international norms. Nor is there any simple way to protect all the interests involved. Equity and benefit-sharing considerations are particularly difficult to protect.

Despite the legal confusion at the multilateral level, developing country governments have come under increasing pressure to provide patent protection for germplasm in their national laws (Correa et al., 2015). Bilateral and regional free trade agreements often include a requirement that governments create IP rights protections for plant breeders. The proposals tend to privilege the interests of commercial seed firms at the expense of traditional breeders, including Indigenous Peoples, and at the expense of the public interest in protecting biological diversity. The IP protections in bilateral and regional agreements tend to go beyond the minimum required under multilateral agreements (Narasimhan et al., 2008). International IP law allows governments to create national *sui generis* (unique)³ systems for plant variety protection. A *sui generis* system can be designed to accommodate both large commercial firms and the less formal exchange of germplasm that is typically used by small-scale producers. But devising an effective *sui generis* system is not easy. Governments must determine their national interests and then make a judgement among competing international norms (Narasimhan et al., 2008).⁴ This brief is intended to help them make that determination and judgement.

³ “*Sui generis*” refers to “a legal situation whose singular nature prevents it from being classified into an already known category” (Guillien & Vincent, 2010).

⁴ Formal seed systems refer to the organized mechanisms through which farmers obtain seeds of guaranteed quality. Informal seed systems are those used by farmers, primarily in developing countries, to produce and exchange their own seed, which can be referred to as “farm seed” (Louwaars et al., 2010).



2.0 An Overview of the International Agreements

International law on IP and germplasm has evolved in response to several drivers, including technological breakthroughs (in particular in genetics); the growth of global trade and related questions on technology transfer; the urgency of research for plant varieties that are adapted to climate change; the growth in commercial seed research and development (R&D) and commercial production and sales; and growing acceptance from governments of the need to protect biodiversity, Traditional Knowledge, and the rights of communities to benefit from biological resources.⁵

The diversity of these drivers helps to explain the number and variety of international agreements that address some aspect of germplasm and plant breeding. These agreements have different sets of signatories, legal implications, tools for assessing compliance, and enforcement mechanisms (some of the agreements have none). Many of these agreements have been negotiated under United Nations (UN) auspices, including the FAO, the Convention on Biological Diversity (CBD), and the World Intellectual Property Organisation (WIPO). In addition, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organization (WTO) is important, as are the treaties negotiated by an intergovernmental organization called the International Union for the Protection of New Varieties of Plants (UPOV).⁶ Table 1 provides a summary of the central provisions in the principal agreements.

Table 1. Key international agreements and provisions relevant to germplasm

Year takes effect	Agreement	Key provisions	Number of members or signatories ⁷
1961	WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore	<ul style="list-style-type: none"> • Common rules for recognizing and protecting breeders' rights to profit from the new plant varieties that they develop. • Updated most recently in 1991 ("UPOV 1991"). 	76 members

⁵ Commercialization refers to a shift in seed R&D from primarily public to primarily private investment and ownership (Louwaars et al., 2010) and an increasingly consolidated global seed industry (ETC Group, 2018). See Louwaars et al. (2010) for a broader discussion on trends relating to seed IP.

⁶ The acronym UPOV is based on the French name *L'Union internationale pour la protection des obtentions végétales*.

⁷ Membership refers to the number of countries that have signed the treaty or declaration, with the exception of the WTO, where the EU is a member in its own right, in addition to the EU's member states.



Year takes effect	Agreement	Key provisions	Number of members or signatories ⁷
1993	FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	<ul style="list-style-type: none"> • Recognizes state sovereignty over biological resources. • Consent required to collect genetic resources. • Established the principle of mandatory benefit sharing. 	196 parties
1995	UN Declaration on the Rights of Indigenous Peoples	<ul style="list-style-type: none"> • Comprehensive multilateral agreement on IP administered under the WTO. • Article 27.3 (b) obliges members to protect IP of plant varieties. • Least-developed countries exempt from applying most of TRIPS, including Article 27.3(b), with this transition period in place until at least July 2021. • Enforceable by the WTO's dispute settlement mechanism. 	164 members
2001	WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore	<ul style="list-style-type: none"> • A committee on the WIPO; its mandate was renewed in 2019 for the 2020–2021 biennium. • Forum to discuss and negotiate access to genetic resources, benefit-sharing, and protection of Traditional Knowledge and cultural expressions. • Site for negotiations on possible instrument(s) that could address these issues since 2009. 	193
2004	FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	<ul style="list-style-type: none"> • Specialized treaty developed to complement the work of the CBD. • Provides a system for facilitated access to plant genetic resources for 64 crops. • Sets out principles for benefit sharing. • Recognizes farmers' rights to their seeds. 	194



Year takes effect	Agreement	Key provisions	Number of members or signatories ⁷
2007	UN Declaration on the Rights of Indigenous Peoples	<ul style="list-style-type: none"> Article 31.1 includes seeds as one of the manifestations of technology and science that Indigenous Peoples have the right to control, protect, and develop, including through the use of IP rights. 	144 voted in favour; 4 against (all later reversed their vote to support)
2014	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol)	<ul style="list-style-type: none"> Protocol to the CBD (see above). Provides a legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources. 	124
2015	UN Sustainable Development Goals (SDGs)	<ul style="list-style-type: none"> Several SDGs are relevant to seeds and IP, but particularly SDG 2: zero hunger. SDG 2.5 is a commitment to protect the genetic diversity of seeds, cultivated plants, and related wild species. 	193
2018	UN Declaration on the Rights of Peasants and Others Working in Rural Areas	<ul style="list-style-type: none"> Recognizes the rights of peasants to save, use, exchange, and sell farm seeds. Members must support farmers and peasant seed systems, including in IP laws. 	121 voted in favour; 8 against; 54 abstained

Sources: CBD, 2012; Claeys & Edelman, 2020; FAO, n.d.; United Nations, 2015; United Nations Declaration on the Rights of Indigenous Peoples, 2007; WIPO, 2015, 2019b; WTO, 1994.



3.0 Plant Breeding Laws: Five issues

This section sets out five issues that developing country governments need to consider in negotiating new legislation on IP protection for plant breeders. In each case, the issue's importance is presented first, followed by the relevant international agreements.

3.1 Rights of Patent Holders and Commercial Seed Breeders and Traders

3.1.1 WHY ARE THEY IMPORTANT?

IP rights are designed to protect inventors and innovators. Their proponents argue that they create an incentive for investors to support R&D and that R&D has been a powerful engine for improving agricultural strains and increasing crop yields. WTO members are obliged to provide some kind of IP protection for germplasm under the provisions of Article 27.3.b of TRIPs (see Table 1). There is an exception for least-developed countries, as they are exempt from most TRIPs provisions until July 2021, with the likelihood that exemption will continue to be extended.⁸

Advocates for using IP rights to create ownership for plant breeders say such rights are necessary to attract international commercial seed firms into the market. Countries that either have no IP legislation in place or only lax enforcement of IP rules may find international commercial seed firms are reluctant to operate in their markets. Four firms control two thirds of the global seed market (ETC Group, 2018). This level of concentration makes it easier for the industry to maintain a united front on the issue of IP protection. Farmers may also prefer a regulated commercial seed market to less formal seed breeding programs because commercial seed tends to be more reliable. Reliability in this context means that the purchased germplasm can be counted on to exhibit the desired traits and to respond well to specific conditions or stimuli, such as withstanding drought or pests or thriving with the application of a particular fertilizer.

3.1.2 WHICH INTERNATIONAL AGREEMENTS ARE RELEVANT?

The foremost international agreement that protects breeders' rights is UPOV (see Table 1). The treaty was first signed in 1961 and has been updated periodically since, most recently in 1991. It establishes a binding international system with common rules for recognizing and protecting breeders' rights to benefit from the plant varieties they develop. Under the terms of UPOV 1991, a variety will qualify for IP protection if it is:

- New – the variety must not have been previously sold or traded.
- Distinct – it must have characteristics that are unique and distinguishable from other varieties.
- Homogenous – the majority of seedlings in a sowing should be identical.
- Stable – the new and distinct characteristics remain unchanged after repeated propagation.

⁸ See the WTO Analytical Index: https://www.wto.org/english/res_e/publications_e/ai17_e/ai17_e.htm



If these four criteria are met, UPOV provides the breeder with a certificate of plant variety rights that provides exclusive rights to the variety for 20 years. No other breeder can sell the protected seed variety in that period. The breeder's rights extend to all varieties that are derived from the patented variety. Signatories to UPOV are required to create a protection in national law that breeders can use to sue if they consider their rights to have been breached.

UPOV does put some limits on breeders' rights. For example, the "farmers' privilege" was introduced in the 1991 treaty. It allows farmers to preserve and sow seeds from a protected variety if the farmer uses the seed on their own land and grows the crops solely for their own consumption.⁹ However, farmers may neither trade nor sell the seeds, nor the resulting crops. Critics claim this provision in UPOV 1991 curtails traditional breeding and seed exchange (GRAIN, 2019; Louwaars, Le Coent, & Osborn, 2010). Commercial seed is expensive, especially for small-scale producers.

TRIPS is another important component of the international IP rules that protect commercial breeders' rights. TRIPS has 164 signatories (all WTO members have signed), in contrast to UPOV 1991, with only 76 members. Article 27.3(b) of TRIPS specifically obliges WTO members to provide legal protection for breeders of new plant varieties, either through a system of commercial patents or an alternative, but effective, *sui generis* system (WTO, 1994). TRIPS Article 27.3(b) also requires WTO members to grant patents on microorganisms and "non-biological or microbiological processes" that can be used in plant or animal production. The language creates a distinction between the plants themselves and plant varieties: while plant varieties must have some type of IP protection, the TRIPS rules do not require members to provide IP protection for the original plant. In implementing Article 27.3(b), many WTO members have chosen to be guided by UPOV 1991, although TRIPS does not refer to any specific patent agreement (Narasimhan et al., 2008). The UPOV system predates TRIPS. Those WTO members that did not have a pre-existing national IP framework for seeds and plant breeding were strongly encouraged to adopt UPOV by the many developed WTO members that had already signed it (Correa et al., 2015).

According to its provisions, TRIPS Article 27.3(b) is overdue for a review by WTO members. The review, however, was turned by some government negotiators into a proposal to review the relationship between TRIPS and the CBD, as contradictions between the two frameworks became evident. So long as this attempted reconciliation of the two agreements remains deadlocked, the TRIPS review is likely to remain stalled.

⁹ Article 15 of the 1991 Act of the Convention for the Protection of New Varieties of Plants.



3.2 The Rights of Farmers and Indigenous Peoples to Store, Use, Share, and Sell Seeds

3.2.1 WHY IS IT IMPORTANT?

Farmers traditionally save, store, and share germplasm for planting their next crop, a tradition that historically kept the commercial market relatively small. Until very recently, in much of the world except industrialized nations, the vast majority of germplasm exchanges were informal (Correa et al., 2015; Louwaars et al., 2010; Narasimhan et al., 2008). These traditional systems contain a wealth of knowledge about local plants and growing conditions, and by being farmer-owned and controlled, they reduce input costs for producers. However, while informal systems for the exchange or sale of germplasm are inexpensive, they also offer less consistently reliable quality. Certified germplasm offers traceability and fewer contaminants and will more reliably reproduce desired characteristics, including good germination rates. These advantages have encouraged governments to regulate their markets for plant breeding materials, in some cases, in response to farmers' demands. Some governments have gone so far as to outlaw the sale of uncertified germplasm (FAO, 2009). Nearly three quarters of FAO member states now have legislation that stipulates that the commercial production and sale of germplasm is only authorized for varieties that have been formally registered in the country (FAO, 2018a). Very few of these governments have created explicit exemptions for farmers' breeding systems. This means the sale of uncertified germplasm is now formally illegal in much of the world, although these systems persist and, in many places, are still predominant (FAO, 2009). The resulting ambiguity is part of the recent impetus to regularize and update national laws governing plant breeding in developing countries. Similar issues confront Indigenous Peoples, many of whom are farmers. Sometimes Indigenous Peoples have distinct legal recourse, either under national treaties or through multilateral agreements, such as the UN Declaration on the Rights of Indigenous Peoples. But too often, the legal standing of Indigenous Peoples is complicated by unsettled jurisdictional claims.

In an article on the patenting of a nitrogen-fixing maize variety from Mexico, Pskowski (2019) raises a long list of the unresolved concerns that can arise even when a contract is signed between the developers and the original plant breeders. The article describes the agreement between researchers (including United States-based university professors and the food company Mars) and the Indigenous Mixe community in Totontopec, Oaxaca, to develop a Nagoya Protocol-compliant certificate to do research on the maize variety. Among the questions that have been raised by this relationship are the extent to which the variety is exclusive to Totontopec and whether other communities should also be included in the benefits. The Nagoya Protocol does not require transparency, which means that other communities that might feel they have a claim to the plants in question will not necessarily know about a benefit-sharing agreement that has been signed. The role of national governments in providing legal protection and support in negotiations with foreign researchers and companies is not clear and yet may be central to protecting local interests. The government is also responsible for protecting the public interest in protecting biological diversity.



3.2.2 WHICH INTERNATIONAL AGREEMENTS ARE RELEVANT?

The FAO's 2004 ITPGRFA was the first international agreement to recognize that farmers have rights as seed breeders and plant propagators (Halewood & Nnadozie, 2008). The ITPGRFA recognizes farmers' contributions to the development, conservation and improvement of plant genetic resources; the need to ensure that farmers benefit from these resources; and the need for a counterweight to the expansion of plant breeders' rights being established through international patent law (Halewood & Nnadozie, 2008). The treaty states, "Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law." The reference to national law indicates that ITPGRFA assumes signatories will adopt national legislation that protects farmers' rights, including the rights set out in the treaty.

The UN Declaration on the Rights of Peasants and Other Persons Working in Rural Areas was adopted by the UN Human Rights Council in 2018. The declaration gives "peasants and rural persons" the right to preserve, use, exchange, and sell the seeds they produce." This goes further than the UPOV 1991 provision for "farmers' privilege," mentioned above, as it is not restricted to use on a farmer's own land and for self-consumption (UPOV, 1991).

The language in Article 31 of the UN Declaration on the Rights of Indigenous Peoples is explicit that seeds are part of the heritage and knowledge that Indigenous Peoples are entitled to maintain, control, and develop, including through the use of IP rights. Moreover, Article 31 of the declaration (which was supported initially by 144 countries and has today been endorsed by 148 countries) states that:

1. "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, literature, 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.
2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights." (*emphasis added*)

3.3 Conserve and Protect National Genetic Resources

3.3.1 WHY IS IT IMPORTANT?

Agricultural biological diversity is critical to human survival. Biodiversity is a repository for the knowledge and adaptive capacity of all living things. It provides humanity with its food and is at the heart of healthy ecosystems, including watersheds and soils (Diaz et al., 2019). Traditional seeds contain unique properties that result from generations of selection and sharing within agricultural communities (Thomas et al., 2012). The resulting genetic diversity and knowledge of



how to cultivate and propagate plants is a valuable commodity in its own right. Ethiopia, which enjoys a high level of agricultural genetic diversity, formally recognizes the value of its diversity, and its government has implemented restrictive regulations on gene sharing to protect its resources from misappropriation (Mulesa & Westengen, 2020).

The conservation of genetic resources is complicated by the possibilities for financial gain that are created through the work of commercial breeders. The appropriation of genetic resources by commercial seed companies for their R&D programs is seen as theft of Traditional Knowledge by the communities that cultivate the source material and the civil society organizations that work with them. Yet it is not always obvious who the original seed breeders should include and how a benefit-sharing payment should be allocated.

3.3.2 WHICH AGREEMENTS ARE RELEVANT?

The 1962 UN resolution on the Permanent Sovereignty over Natural Resources established the principle that nation-states have “sovereign rights” over the biodiversity within their jurisdiction¹⁰ (Mulesa & Westengen, 2020). This principle was reinforced and elaborated on in the CBD, which established that commercial firms and others must have prior informed consent from the community where the plants are gathered or cultivated before they access genetic resources. The CBD also established the principle of benefit sharing.

The ITPGRFA is a specialized treaty focused on the conservation and protection of plant genetic resources for food and agriculture, including agricultural diversity and wild crop varieties, in order to promote sustainable agriculture. The agreement notes that conservation can be *in situ* (where the genetic resources were found) and *ex situ* (in national or international seedbanks or tissue culture samples). The treaty calls on its signatory governments to support farmers, Indigenous Peoples, and other communities in their efforts to manage and conserve plant genetic resources, including cultivated crops, fodder, and their wild crop relatives (FAO, 2009). The treaty also calls on parties to work together to develop a system for ex situ conservation and to monitor ex situ collections (FAO, 2009).

One of the sub-goals of the UN 2030 Agenda for Sustainable Development, SDG 2.5, specifies a target of 2020 for the maintenance of genetic diversity of seeds through seed banks and the promotion of fair and equitable sharing of any benefits arising from the development of genetic resources and associated Traditional Knowledge (United Nations, 2015). Progress toward the sub-goal is measured by the number of genetic resources secured in conservation facilities and the proportion of local breeds at risk of extinction. Governments are requested to monitor and conserve the genetic diversity of the agricultural seeds used in their jurisdictions.

¹⁰ Resolution 1803 (XVII)



3.4 Access to Germplasm for Research and Development

3.4.1 WHY IS IT IMPORTANT?

One of the tensions highlighted by the conflicting legal frameworks is the different processes and methodologies used by the formal process of commercial research and development compared to a traditional approach. The former is rooted in laboratories, test sites, cross-testing, and experimentation that draws on the knowledge of many scientific disciplines and a range of distinct growing conditions. The latter, in contrast, is based in fields and farmers' experience and in deep knowledge of geographically precise growing conditions and long-standing contextual knowledge. An ideal IP rights system would seek to encourage both approaches, as each makes an important contribution to human knowledge and well-being. To respond to changing environmental conditions and evolving pests and diseases, farmers and scientists alike need to continually look for adaptations and improvements. Access to genetic resources from local communities and further afield, including other countries, is important, as is protecting the possibility of exchange among practitioners who follow different approaches to breeding. As a global average, over two thirds of national food supplies and crops are not indigenous to the country where they are grown. This statistic reflects the important role played by foreign genetic strains in the food supply chains around the world and points to the strong interdependence of genetic resources globally (Khoury et al., 2016).

3.4.2 WHICH AGREEMENTS ARE RELEVANT?

The ITPGRFA includes provisions for signatories to share gene banks for research and breeding purposes. The gene banks are for the 64 food and fodder crops that together account for 80% of all human food consumption (FAO, 2019a). The treaty is a complement to the CBD, and, like the CBD, the ITPGRFA is committed to the protection of benefit-sharing and farmers' rights. Signatories agree to make their country's food and agriculture genetic diversity, and related information about the crops stored in their gene banks, available to all through the Multilateral System (or MLS). According to the FAO (2019a), the MLS, "sets up opportunities for developed countries with technical know-how to use their laboratories to build on what the farmers in developing countries have accomplished in their fields."

Under the treaty, genetic material is exchanged under a Standard Material Transfer Agreement (SMTA) (FAO, 2008). This is instead of the system prescribed by the CBD of prior informed consent and mutually agreed terms (Brink & van Hintum, 2020). The SMTA starts with a template contract between the provider of the genetic material and its recipient. Under the terms of the treaty, the use of the template is mandatory. This ensures that the provisions agreed under the treaty are adhered to by the contracting parties. The SMTA sets out access conditions as well as parties' rights and obligations. It requires details on the destination and use of the material received and a framework for benefit sharing (FAO, 2008).



3.5 Benefit Sharing

3.5.1 WHY IS IT IMPORTANT?

Benefit sharing is arranged between the developer of the new seed and the country or community from which the genetic material was sourced. The CBD affirmed the principle that benefits derived from the use of genetic resources should be shared but did not detail how this should happen. Benefit sharing is premised on an acknowledgement of the source of genetic material and the associated Traditional Knowledge. Yet the principal legal frameworks for protecting plant varieties through IP provisions—namely, TRIPS and UPOV—do not require mandatory disclosure of the source of genetic material or Traditional Knowledge. This leaves the door open for misappropriation (Mulesa & Westengen, 2020). Neither UPOV nor TRIPS provides a satisfactory answer to the commitment in CBD and ITPGRFA to protect benefit sharing. As it stands, international law provides little legal certainty for non-commercial providers and users of germplasm, especially when the germplasm is taken out of the country of origin.

More recently, the emergence and expansion of “digital sequence information” has created a significant new challenge to benefit sharing (Marden, 2018). In brief, the rise of genomic data has further complicated the already difficult negotiations over how to balance effective benefit-sharing protections with a commercial plant-breeding sector. It is unclear whether it is the physical material of the germplasm alone that is covered by the international treaties or the underlying genetic/genomic sequences as well. These developments were not foreseen when the treaties were adopted. There is no obvious solution to this newest source of contention in the negotiations.

3.5.2 WHICH AGREEMENTS ARE RELEVANT?

The Nagoya Protocol provides a legal framework for one of the three objectives of the CBD—namely, the “fair and equitable sharing of benefits arising out of the utilization of genetic resources.” Adopted in 2010 in Nagoya, Japan, the protocol entered into force on October 12, 2014. Under the terms of accession to the protocol, signatories are required to adopt domestic legislation to deal with a number of benefit-sharing issues that are not addressed in UPOV or TRIPS. The terms of accession also make the following demands on signatories:

- “Create legal certainty, clarity, and transparency
- Provide fair and non-arbitrary rules and procedures
- Establish clear rules and procedures for prior informed consent and mutually agreed terms
- Provide for issuance of a permit or equivalent when access is granted
- Create conditions to promote and encourage research contributing to biodiversity conservation and sustainable use
- Pay due regard to cases of present or imminent emergencies that threaten human, animal or plant health
- Consider the importance of genetic resources for food and agriculture for food security” (CBD, 2020).



Before accessing a genetic resource, the terms of the Nagoya Protocol require prior approval from a national authority, which is to be nominated by the government and notified under the protocol.¹¹ Benefit sharing is required in the use of Traditional Knowledge as well as in the use of genetic resources (CBD, 2019). The parties to the protocol have been working to establish the domestic legal and institutional frameworks for its implementation, but the process remains unfinished. A few countries have created a national mechanism that requires any user requesting access to a genetic resource or the associated Traditional Knowledge to demonstrate how they will follow the protocol's rules. Meanwhile, parties to the protocol are still deciding whether to put in place a global multilateral benefit-sharing mechanism, as mentioned in Article 10 of the protocol. The mechanism would be used where the germplasm has no simple place of origin (for example, it is found in more than one country) or in situations in which prior informed consent is not possible to obtain or grant (Pirard & Lapeyre, 2016; United Nations, 2010).¹²

The ITPGRFA provides for benefit sharing (FAO, 2009) using the MLS mentioned above. The MLS creates a pool of plant genetic resources that are shared among the ITPGRFA members for research purposes at no cost or for a minimal administrative fee. A decision-making tool is available to help countries implement the MLS, including the management of the relationships with other access and benefit-sharing agreements, such as the Nagoya Protocol (Joint Capacity Building Programme, 2018). Parties that access genetic material through the multilateral system agree to share any new developments with others free of charge for research purposes. If they wish to obtain commercial benefits, they have to pay a percentage of the benefits to a common fund that was set up in 2008 to support agriculture in developing countries (FAO, 2019b).¹³ Governments are currently revising multilateral provisions and SMTA to enhance the effectiveness of the benefit-sharing arrangements, including in response to recent developments in technology (Wagner, 2019).

Governments are not in agreement over whether the protection of Traditional Knowledge should be dealt with by the TRIPS Council, which is the WTO body that is responsible for the TRIPS Agreement, or under the auspices of WIPO (United Nations Conference on Trade and Development & International Centre for Trade and Sustainable Development, 2005). As mentioned above, the built-in review required in the TRIPS Agreement for Article 27.3(b) was amended to include the relationship between TRIPS and the CBD in the 2001 Doha Declaration. That negotiating process has been stalled for years.¹⁴ Meanwhile, in October 2019, the mandate of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was renewed. That mandate is to negotiate an international

¹¹ Under the Nagoya Protocol, governments must nominate a national focal point for access and benefit sharing. The focal point is responsible for granting access or issuing written evidence that access requirements have been met. It is also responsible for advising on procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms (i.e., benefit sharing) (CBD, 2019).

¹² See also Greiber et al. (2012) for an explanatory guide to the Nagoya Protocol.

¹³ As described in Article 13.2.d

¹⁴ For more background, see https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm.



legal instrument on IP and genetic resources, Traditional Knowledge, and traditional cultural expressions (WIPO, 2019b). A core issue in the negotiations is the mandatory disclosure of the relationship between genetic resources, the associated Traditional Knowledge, and the invention at hand for any patent application involving genetic resources or Traditional Knowledge (WIPO, 2019a). These talks have been underway for over a decade and have stalled more than once for extended periods of time.

4.0 Conclusion

Governments that are renewing or creating new national legislation on germplasm face a number of challenges. One of the biggest challenges is the lack of a single comprehensive, internationally agreed framework to guide national legislation. Since TRIPS was signed in 1994, the system of multilateral organizations has taken important steps toward recognizing, protecting, and extending benefit-sharing provisions, and including Traditional Knowledge and Indigenous culture and innovation in that protection. Yet much remains unresolved. No single treaty or convention addresses all the issues relevant to developing countries and their small-scale food and agriculture producers and plant breeders.

Despite the lack of clarity under international law, developed country negotiators, multinational commercial seed firms, and even some philanthropists have chosen to push developing country governments toward signing UPOV to meet their TRIPS commitment on plant protection (Correa et al., 2015; Narasimhan et al., 2008). Developing countries have their own reasons to adopt this framework, including the commercial advantages inherent in adhering to a standard that is widely accepted in private markets. At the same time, UPOV fails to provide adequate protection for the rights of farmers, local plant breeders, and Traditional Knowledge holders, including Indigenous Peoples. Any system that seeks to protect the creators of a new variety has to balance that protection with the more diffuse idea of protecting the collective right of a population over the generic material they have historically relied upon. Informal seed systems have proven important for the protection of agricultural genetic diversity. This diversity has diminished significantly in food systems that are dominated by commercial seed firms whose interest is in specific genetic traits (Pilling et al., 2020).

The continuing and evolving controversies in multilateral negotiations on these issues should caution developing country governments as they create national laws. The existing international agreements allow policy space that can be used for experimentation. Lawmakers have the flexibility under the TRIPS Agreement, for example, to implement plant protection through a *sui generis* system. India's plant variety protection law is an example of a *sui generis* system whose provisions allow for farmers to save, share, and use protected varieties as long as they do not use a trademarked brand name (GRAIN, 2019). The law also makes provisions for farmers to trade in unregistered traditional varieties. India has not joined UPOV. Other countries, such as Malaysia and the Philippines, have laws that contain provisions favourable to the rights of small-scale producers. The provisions would not be compatible with UPOV 1991 rules (Shashikant, 2016; UPOV, 2007).



Despite the conflicts, multilateral agreements can help governments develop effective and equitable domestic legislation. First, more analysis is needed to understand the challenges of commercial plant breeding in developing countries and LDCs. One concern is that the protection of traditional varieties and breeding technologies, for example, as a form of Indigenous culture, may generate a new cost barrier for small-scale producers, just as the push for IP rights has done. One possible solution is for domestic legislation to offer different levels of IP protection for different sectors, taking into consideration different interests (Louwaars et al., 2011). For example:

- Strong breeders' rights for commercial crops to protect investment and innovation.
- Strong regulation of seed systems for consumer protection, to protect against the introduction of potential allergens, for example, or against the use of genetic technologies that have not passed regulatory review.
- Strong farmers' rights for non-commercial food crops to protect seed sharing and access to traditional varieties.
- Protection of Indigenous Peoples' rights to seeds and germplasm and the associated knowledge and culture.
- More appropriate regulation of varieties and quality controls for informal seed systems to protect the interests of small-scale producers in community-based breeding systems.

It will not be simple to put into effect. Small, medium, and large farms co-exist in the same territories. Their crops and food systems are not easily compartmentalized and instead may overlap. Many small-scale producers produce a mix of commercial and non-commercial crops, and some crops have many markets. Highland farmers in Bolivia, for example, have a local market, a national market, and a formally branded export market for their quinoa (Ofstehage, 2012).

Better guidance from international law could help. Three reforms to international rules that would make them more supportive of inclusive national seed laws are:

1. Reform of UPOV to broaden its scope to better address the needs of small-scale producers, including the imposition of mandatory disclosure requirements when germplasm is collected for commercial research and development. This would be a first step in ensuring that benefit sharing is respected.
2. Consideration in the WTO's TRIPS Council of possible *sui generis* systems that respect TRIPS without defaulting to the UPOV framework. WTO members could also revisit the discussion launched in 2001 on how the TRIPS Agreement relates to the CBD.
3. Introducing a tiered system in international trade that provides a shared platform of core principles that apply to all but adapt specific regulations to better respond to local and regional circumstances. For example, regional exchanges of genetic material might be subject to fewer restrictions than transcontinental trade.



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