Chapter 2
Legal and Ethnoecological Components of Bioprospecting

Morten Walløe Tvedt

Abstract Innovation in the use of biological material has surged ahead over the past decades, closely followed by additions and amendments to the regulatory environment. The aim of this chapter is to explore the most important legal tools relating to the use of genetic resources and to identify the significant changes and additions. This article looks at the critical aspects for a successful implementation of the Nagoya Protocol. Three topics are especially covered: the need for (a) developing sound access and benefit sharing (ABS) contracts; (b) establishing provider and user legislation or regulation in all countries; and (c) avoiding fragmentation at the international legal level concerning ABS. The regulatory environment is increasingly focused on strengthening intellectual property rights (patents and plant breeders' rights) and access to and sharing of benefits arising from the use of genetic resources in terms of ABS. Whereas the regulation of use depends on the laws enacted in each country where bioprospecting occurs, the international arena has become increasingly important for law-making in the last 30 years.

Morten Walløe Tvedt is senior research fellow at the Fridtjof Nansen Institute and assistant professor 2 in law, P.O.Box 326, 1326 Lysaker, Norway. Tvedt has published extensively in the area of biological resources law and intellectual property in recent years (see www.fni.no for a complete list of publications). The research on which this article is based was partly funded by the Norwegian Research Council under the ELSA Program and forms part of the three-year project "Exploring Legal Conditions and Framework for Marine-based Bioprospecting and Innovation – International Law, Open Innovative Systems and Proposals for SMTA for Marbank", project number 208543/O10.

M.W. Tvedt (✉)
Fridtjof Nansen Institute, 326, 1326 Lysaker, Norway
e-mail: mwt@fni.no

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2.1 Setting the Scene – Sovereign Rights and Privatisation Through Patents

Innovation in the use of biological material has surged ahead over the past decades, closely followed by additions and amendments to the regulatory environment. The aim of this chapter is to explore the most important legal tools relating to the use of genetic resources and identify the most importance changes and additions. The regulatory environment is increasingly focused on strengthening intellectual property rights (patents and plant breeders' rights) and access to, and sharing of, benefits arising from the use of genetic resources (ABS). Whereas the regulation of use depends on the laws enacted in each country where bioprospecting occurs, the international arena has become increasingly important for law-making in the last 30 years.

The 1992 Convention on Biological Diversity (CBD) established standards of conservation and sustainable use of biological diversity while enabling the fair and equitable sharing of benefits arising from the use of genetic resources. Under international law states enjoy a sovereign right to their natural resources (Schrijver 2008). This was confirmed by the 1992 Convention on Biological Diversity (CBD), which recognizes in Art. 3 a principle of international law:

> ***States have, in accordance with the Charter of the United Nations and the principles of international law, the*** **sovereign right to exploit their own resources** ***pursuant to their own environmental policies, and 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***. (Emphasis added)

The CBD confirms a principle of international law that endows states with a sovereign right to regulate the genetic resources under their control. The CBD did not introduce a new world order in 1992, of course; *permanent sovereignty* over natural resources was already a well-established principle within the UN (ibid.). The references to the UN Charter and principles of international law inform the general law governing questions concerning *genetic resources*.

During the 1980s, developed countries sought to establish within the UN Food and Agriculture Organization (FAO) a conception of plant genetic resources as the 'common heritage of mankind'.[1] The open access system suggested for plant genetic resources by the 1983 International Undertaking, was, however, abandoned in

[1] *International Undertaking on Plant Genetic Resources* [International Undertaking 8/83], Rome, FAO, Conference Resolution 8/83, entered into force 23 November 1983, adapted at the Twenty-second Session of the FAO Conference. The term 'common heritage of mankind' had already been introduced in the UN Law of the Sea regulating the legal status of exploitation of minerals in the deep sea bed, in the sense that "No State shall claim or exercise sovereignty or sovereign rights over any part of the Area or its resources, nor shall any State or natural or juridical person appropriate any part thereof." Art. 136–137 of *United Nations Convention on the Law of the Sea* [UNCLOS], United Nations, 10 December 1982, 1833 UNTS 3, entered into force 16 November 1994. FAO's understanding of the term was less developed than UNCLOS's, which provided for the creation of a governing authority to oversee the Common Heritage regime.

favour of a new resolution in 1991.[2] The CBD did not alter any general legal principles; the FAO's rather narrow (non-binding) International Undertaking had already been abandoned by the FAO members themselves. The CBD is the first legally binding treaty to specify rules concerning the enforcement of states' sovereign rights to genetic resources. However, a treaty needs national implementation to become a functional tool changing the behaviour of relevant actors.

Parallel to the discussions on sovereign rights to genetic resources, the US, Japan and Europe were changing their practices with regard to granting patents for inventions based on biological material. Increasingly, patents were awarded for biotechnological inventions. While the practice began in a few states, it became a global obligation in 1994 with the enactment of the Agreement on Trade-Related Intellectual Property Rights (TRIPS) which required all members of the World Trade Organization (WTO) to allow patent protection of all types of invention, save certain very specific categories, one being 'plant varieties'. Intellectual property right protection of plant varieties was harmonised by member states and became the International Convention for the Protection of New Varieties of Plants (UPOV).[3] Regulation of access and benefit sharing should be seen as an attempt to counter this trend of privatization of innovation in the biodiversity area with the aim of creating a system for sharing parts of the benefits patents create to their owners back to conservation purposes.

2.2 Principles on Access to Genetic Resources in the Convention on Biological Diversity

Sovereign rights, according to the CBD, include mechanisms set forth in Art. 15 para. 1–6, which can be applied by states for (a) regulating access (to) and (b) Art. 15.7, according to which all states must implement rules to ensure fair and equitable benefit sharing (arising from) the utilization of 'genetic resources'. In treaty law, the CBD contains the first definition of 'genetic resource' as an subject matter of regulation. '*Genetic resources* means genetic material of actual or potential value.' And '*Genetic material* means any material of plant, animal, microbial or other origin containing functional units of heredity.' Thus, a definition of a new subject matter of legal regulation became legally binding.[4]

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[2] International Undertaking 8/83, *Agreed Interpretation of the International Undertaking*, Rome, FAO, Conference Resolution 4/89, entered into force 29 November 1989, adapted at the Twenty-fifth Session of the FAO Conference, and finally *Agreed Interpretation of the International Undertaking*, Rome, FAO, Conference Resolution 3/91, entered into force 25 November 1991, adopted at the Twenty-sixth Session of the FAO Conference.

[3] *International Convention for the Protection of New Varieties of Plants 1991* [UPOV-1991], UPOV, 2 December 1961, UPOV/INF/6/1, as amended on 10 November 1972, 23 October 1978 and 19 March 1991. For a discussion of the UPOV and farmers' rights see Christinck and Tvedt (2015).

[4] For a discussion of the term 'genetic resources', see Tvedt and Schei. "The Term 'Genetic Resources': Flexible and Dynamic while Providing Legal Certainty?" in Global Governance of Genetic Resources Access and Benefit Sharing after the Nagoya Protocol. Edited by Oberthür and

With regard to the plant sector, the principle of regulated access has been judged to be unsatisfactory by some. Open access, as a means of exercising their sovereign rights, was adopted by 145 members of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) for certain specific accessions of plant genetic resources for defined food and agriculture purposes. Elements within the plant sector called for specific solutions when the parties were at the point of agreeing to the CBD. When agreeing to the CBD, the final Resolution from recognised that the global collections of plant genetic resources that existed prior to the CBD instigated a special regulation for them in international law with the agreement of CBD:[5]

> ***Further recognizes the need to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular: (a) Access to ex-situ collections not acquired in accordance with this Convention; and (b) The question of farmers' rights.***

This call for a special regulatory system for collections was considered by the Commission on Genetic Resources on Food and Agriculture of the FAO. For a specific list of plant genetic resources, the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) Art. 11–14 established a Multilateral System for Access and Benefit Sharing (MLS).[6] Accession of plant genetic resources included in the MLS is collectively managed by ITPGRFA member states, and can be called a global common for certain plant genetic resources and certain uses. The argument is often made that it is not possible to identify which country each of the special properties of a plant is developed in, and consequently not possible to allocate sovereign rights to any particular state.[7] Whether this system can be used for other sectors of genetic resources than plants is an open question (Drankier et al. 2012; Greiber 2011; Elferink 2007; Arico 2010).

Slow implementation along with lack of a functional benefit sharing system prompted the parties to the CBD to negotiate a protocol to the convention containing specific rules on access and benefit sharing. In 2010, the parties to the CBD adopted the Nagoya Protocol (NP). The NP specified rules of access and benefit sharing more closely. From the perspective of international law, the obligations according to the CBD are still valid side by side the new regulations in the Nagoya

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Rosendal. New York, Routledge, 2014 and Schei and Tvedt. "Genetic Resources" in the CBD: The Wording, the Past, the Present and the Future. Lysaker, Fridtjof Nansens Institutt, 2010. (FNI Report, no. 4/2010)

[5] *Resolution 3 - The Interrelationship between the Convention on Biological Diversity and the Promotion of Sustainable Agriculture* [Nairobi Resolution 3], entered into force 22 May 1992, the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity.

[6] *International Treaty on Plant Genetic Resources for Food and Agriculture* [ITPGRFA], Food and Agriculture Organization, 3 November 2001, 2400 UNTS 303, entered into force 29 June 2004.

[7] Nevertheless, plant variety protection and plant patents are assuming that it is possible to identify the individual and unique contribution of individuals to new traits in the plant varieties. See UPOV-1991 and *Agreement on Trade-Related Aspects of Intellectual Property (Annex 1C of the Agreement establishing the World Trade Organization)* [TRIPS Agreement], WTO, 15 April 1994, especially Art. 27.

Protocol, as there is no indication of intent to change them in the new text. While negotiating and adopting the Nagoya Protocol a politically difficult question concerning the rights to genetic resources that are held in collections outside the countries of origin and their new uses remained unresolved. The compromise solution was NP Art. 10:

> ***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.***

This Art. 10 provision mandates NP members to consider whether there is a need for a new global multilateral benefit-sharing mechanism. This mechanism shall be considered in respect of two situations in particular: (1) genetic resources in transboundary situations; and (2) when it is not possible to grant or obtain prior informed consent for their use.

In 2011, shortly after agreement was reached on the draft text of the Nagoya Protocol, other forums discussing ABS in relation to specific groups of genetic resources also made rapid progress. The World Health Organisation (WHO) agreed in 2011 to adopt two standard material transfer agreements concerning exchange and use of viral genetic resources with pandemic potential for humans. In these two standard contracts, globally negotiated terms and conditions for rapid access and benefit sharing are pre-set. For the exchange of viral, human pandemic material, speed and unhindered access are crucial to successfully combating outbreaks. One interesting observation is that they also include benefit-sharing clauses that previously were difficult to agree on in the WHO.

For almost a decade, the question of access and benefit sharing arising from the use of genetic resources in areas beyond national jurisdiction (ABNJ) has been on the agenda of the UN Convention on the Law of the Sea (UNLCOS). Negotiations are currently underway on a mandate for future talks relating to a special regime for this category of marine genetic resources. It could include, for example, genetic resources taken from the seabed and/or the high seas. Discussions under the auspices of the Antarctic Treaty are also probing how to regulate genetic resource material from one of the world's most remote, yet biologically unique areas.

In addition, there are large collections of foreign genetic material in genebanks. These collections are seen by some scholars and lawyers as outside the scope of the CBD since they were collected prior to its entry into force. Whether these collections will be subject to rules on benefit sharing and with whom the benefits shall be shared is currently an unresolved question.

Also in 2011, the Commission on Genetic Resources for Food and Agriculture (CGRFA) under the Food and Agriculture Organization of the UN (FAO) agreed to intensify work on access and benefit sharing for genetic resources for food and agriculture (GRFA). These negotiations are particularly interesting in a publication

like this with contributions dealing with the different sectors of users of genetic resources. Section 2.5 below explains the current work of the CGRFA in more detail.

2.3 Patent Law and Plant Breeders' Rights

To round out the discussion of ABS and regulation of genetic resources we need to include intellectual property right systems, such as patents and plant breeders' rights. The increase in the patenting of inventions based on genetic material created a global imbalance where powerful companies could establish time-limited exclusive rights to technologies based on genetic material, while the countries conserving biological diversity were left without the legal tools to participate in this value creation. A patent creates a time-limited exclusive right to an "invention". It is the individual claiming to have made the invention who describes what he claims to have invented in the patent claims. In many countries, practice regarding the granting of patents was increasingly aimed at permitting patent protection of microorganisms, genes and methods in combination with biological material. If an invention meets the criteria of novelty, sufficient inventive step and industrial application, then the applicant is awarded a patent. This is why the objectives of the CBD about sustainable use of biological diversity and those of the FAO about food security are interrelated in the granting of patents to bio-inventions.

The CBD almost never discusses patents and plant breeders' rights, but there are some discussions at the COP about the relationship between ABS and patents. Under the CGRFA, intellectual property rights are never discussed, while IPRs are only discussed by ITPGRFA's Governing Body as a trigger for the benefit-sharing obligation. The positive or negative effect from patent on food production is never on the agenda. Thus, there is a lack of seeing these legal systems in conjunction.

The use of patents and plant breeders' rights features to varying degrees in the different areas of innovation based on biological material. For example, the use of intellectual property rights is particularly intensive in the pharmaceutical and enzyme industry, and in the plant sector. In the animal sector, aquaculture sector and forest tree breeding sector, intellectual property rights play a smaller role.

2.4 The Challenges and Potential of the Nagoya Protocol

Access and benefit sharing (ABS) as instruments of law and policy entered into a new phase with the October 2014 entry into force of the NP, and the first Meeting of the Parties (MOP) at the COP to the CBD. The October meeting was a watershed moment in the decades of work to make ABS a functional mechanism for raising funds for the conservation and sustainable use of biological diversity. A lot of effort was put into the negotiations that led to the NP and now the challenge is to make the mechanisms work by functional implementation (Tvedt 2014; Oberthür and

Rosendal 2014). The idea behind ABS is that the world's most biodiverse regions, usually located in developing countries and dubbed "providers", shall partake in the benefits created by "users", located more traditionally in richer economies. The obligations under CBD Art. 15 have not been sufficiently clear, however; as of writing, provider countries of biodiversity under ABS arrangements have only received a limited amount of the monetary benefits. Following the *modus operandi* of the Nagoya Protocol, users of genetic resources should be ploughing some of their profits and other non-monetary benefits drawn from the commercialisation of genetic resources into conservation and sustainable use of biodiversity.

Three issues remain to be resolved to make the ABS regime more functional: (1) contractual mechanisms for access and for benefit-sharing need to be created; (2) domestic legislative, policy and administrative measures in both user and provider countries need to be put in place; and 3) the possibility of unregulated genetic resources in certain arenas needs clarifying at the international level.

2.4.1 Making Genetic Resources Contracts Work

Article 15 of the Convention on Biological Diversity (CBD) prescribes two contractual mechanisms. A contract can be made either at the time of access to the genetic material or at the point of time of utilisation to ensure sharing of benefits arising from its use. According to both CBD Article 15 and the Nagoya Protocol, the principal method of enforcing a country's sovereign rights is by invoking private law contracts – mutually agreed terms – between the provider country and/or country of origin and user. The user is often thought of as a private company from another country. ABS therefore relies on private contracts as the relevant means of regulating exchange and sharing returns (Young 2013). Nevertheless, little research has been done systematically to explore the contractual mechanisms with a view to making the contractual system functional. Companies need clearer incentives to enter into ABS contracts and fulfil their obligation to share benefits accruing from their research and development fairly and equitably. Neither does the Nagoya Protocol resolve the challenges thrown up by these contractual mechanisms.

ABS contracts will be negotiated and enforced as commercial contracts. This raises a number of challenges. ABS contracts must be drafted in such a manner as to make them legally viable in the jurisdiction and under the legal system of the user. Since the Nagoya Protocol does not prescribe a uniform or standardised system of user country legislation, the contracts need to resolve complex legal questions, which will typically vary among countries. Since ABS contract law is a relatively new and unexplored area, background jurisprudence is limited. This raises a number of technical and difficult challenges in contract law. Existing global legal contract tools do not overcome these challenges and international private law has only a limited potential in this area as well.

Another contract-related challenge is how to regulate the subject matter that is being transferred. An ABS contact regulates what is sometimes a highly dynamic

situation with a high degree of scientific and commercial potential. “Genetic resources”, as they are defined in the CBD and Nagoya Protocol, rarely constitute a commercial product as such and their connection with a product on the market will therefore be more or less remote (Schei and Tvedt2010). For a contract to embody the creation of value arising from the use of genetic resources, it needs to some extent to foresee future developments of the material. The degree of change and uncertainty, however, will vary among the genetic material’s users and uses. Often this is presented as a matter of tracing, though it is perhaps more complex, as it is also about understanding the relative contribution of the genetic resource, research, development and other investments. The careful drafting of the subject matter of the contract and the actions allowed by the contract will become crucial to the functionality of this type of right. It would be advisable to avoid as far as possible the term genetic resources to define the subject of the contract (Tvedt 2013). Instead, parties should spell out in detail what actions the contractual partner has an explicit right to perform with the biological material. In addition a number of legal issues of commercial contracts must be observed and resolved in these contracts. For a further analysis of these questions, Tomme, Young and Tvedt are publishing a monography on this topic in 2017.

2.4.2 Domestic ABS Legislation as a Core Tool

Well-drafted ABS contracts will work better if supported by ABS laws in the different countries. Both the CBD and the Nagoya Protocol are based on a perception that it is the providing countries that have the primary responsibility for regulating ABS at the point of access. During the negotiations that eventually led to the new instrument, an understanding of “utilisation of genetic resources” gradually gained momentum (Tvedt and Young 2007; see also Hendrickx et al. 1993). The Nagoya Protocol builds on CBD Art. 15.7 in defining what exactly utilisation constitutes under Arts 2(c) and (d). During the process of pinning down the Nagoya Protocol a number of countries likely halted their processes of regulating access to their genetic resources in expectation of the new international framework. Several issues remain to be considered now as states continue to implement ABS access-side legislation. For example, should they set up a national ABS system to avoid the use of biological diversity without a full ABS contract, or should governments encourage users to enter into a contract in a more deliberative way? Related to this, some governments are attempting to strengthen the incentives for users to enter into such contracts.

Australian ABS legislation is viewed as pioneering in this respect, with its simplified mandatory permits for all types of bioprospecting, including for non-commercial use (Prip et al. 2014). The law also includes a built-in clause to cover “change of intent”: if activities change from purely scientific or non-commercial to commercial, the user must return to the authorities and have the necessary changes made to the contract. Even more important, this requirement is based on an existing legal instrument known as the statutory declaration, which binds the user to

Australian criminal law, although admittedly it has limited force if genetic material is transferred to third parties. Furthermore, even though the Australian system has been in place for a while, almost none of the initial bioprospecting agreements has resulted in the user coming back to enter into a benefit sharing contract. This demonstrates the scale of the challenge facing countries when it comes to surveying and tracing the use and commercialisation of products based on their genetic resources.

To facilitate the tracing of uses and genetic resources through to final products on the market, steps must be taken by all CBD countries, not only those currently party to the Nagoya Protocol. All CBD countries are already obliged to make ABS functional, as demonstrated by Art. 15.7. The latter places a clear obligation on all parties to take measures to implement ABS both on the user and provider side. Provider countries would be advised in this sense to require all user countries to submit reports to the next CBD COP on all relevant ABS measures put in place.

2.4.3 Avoiding Fragmentation in the International Arena

Among the more polarising questions in the NP negotiations was the relationship between the ABS in the CBD and other international legal regimes touching on genetic resources. The debate circled around rules already in place and possible new regimes. These concerns led to the inclusion of Article 4 recognizing that the Nagoya 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." The scope of the other regimes will therefore be crucial to define which genetic resources are covered by the Nagoya Protocol.

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) has been in force since 2004. It is still however not clear which plant resources that are within its mandatory scope (Tvedt 2015a). There are substantial differences in the views expressed by Correa (2013), Halewood et al. (2013: 70–96), and Medaglia et al. (2013) on the interpretation of mandatory scope. These differences have also surfaced in the so-called "tandem meetings" between the CBD and ITPGRFA, focal points organised in the past year by the ABS Capacity Building Initiative (2014), and also at a September 2014 Nordic meeting on access and benefit sharing (FNI 2014). In effect, concern for food security under the ITPGRFA trumps the greater emphasis on equity found in the ethos of the CBD ABS. Beyond these unresolved grey zone questions, work is ongoing under the Plant Treaty to explore the conditions for expanding the scope of the list of crops that are covered by the MLS (Tvedt 2015a, b). Expanding the scope of the multilateral system under the Plant Treaty will necessarily lead to a narrowing of the scope of the Nagoya Protocol. A working group under the Governing Body of the ITPGRFA is looking at both the scope for access and how to make the benefit-sharing mechanism more functional. If the functionality of the benefit-sharing mechanism is not improved, the lack of payment by agro-businesses for using plant genetic resources might undermine the open access regime.

2.5 The Challenges for ABS from the Commission on Genetic Resources for Food and Agriculture

The ABS is in danger of fragmenting further. The work by the Commission on Genetic Resources for Food and Agriculture (CGRFA) under the UN Food and Agriculture Organisation (FAO) may fragment ABS in the future. The CGRFA is discussing questions related to access and benefit sharing for six groups of genetic resources, namely, animals; aquatic; invertebrates; plants; forest; and microbial. During the tenth regular session of the CGRFA in 2005, a recommendation was made that the FAO and CGRFA to do more work on ABS issues to improve its support of agriculture considering that all components of biological diversity are essential for improving food and agricultural systems.

In July 2011, the CGRFA ABS discussions began to explore ABS issues related to specific sectors of agriculture. According to Chiarolla et al., there was a debate within the CGRFA on whether to develop 'specialized instruments' for GRFA (Chiarolla et al. 2013). In a background paper prepared for FAO, Schloen et al. (2011) enumerate direct and indirect impacts ABS measures can have on GRFA. While legal certainty and clarity on measures that govern exchange and use of GRFA and transaction costs, time and capacities needed to implement the ABS provisions form the direct impacts; the incentives for exchange and use form the indirect impacts. They also recommend reducing administrative bottlenecks, aggregating and standardizing ABS processes and decoupling benefit sharing from individual providers and individual genetic resources. While these options are worth discussing in a critical light, this cannot be done in a vacuum given the critical role of the nature of the resource, the holding and ownership of the resource, type of use, potential for commercial utilization, risk of resource privatization through IPR and accrual of benefits to the country and communities. As Schloen et al. (2011) argue, if GRFA is left within the scope of the general ABS regulations, several problems will need to be faced. Since the ABS systems under the NP and CBD are not fully developed, nothing more needs to be said on these prospective challenges.

In January 2015, the Commission urged FAO to adapt the "Elements to facilitate domestic implementation of access and benefit-sharing for different subsectors of genetic resources for food and agriculture", included in Annex B to the Report.

The Commission recalls the 2000 CGRFA in calling attention to the GRFA's "special features":

> ***5. The special nature of GRFA, which are included in agricultural biodiversity, its distinctive features and problems needing distinctive solutions, is widely acknowledged. The Conference of the Parties to the CBD, at its fifth meeting in 2000, considered the distinctive features of agricultural biodiversity to include the following:***
>
> ***(a) Agricultural biodiversity is essential to satisfy basic human needs for food and livelihood security;***
>
> ***(b) Agricultural biodiversity is managed by farmers; many components of agricultural biodiversity depend on this human influence; indigenous knowledge and culture are integral parts of the management of agricultural biodiversity;***
>
> ***(c) There is a great interdependence between countries for the genetic resources for food and agriculture;***

(d) For crops and domestic animals, diversity within species is at least as important as diversity between species and has been greatly expanded through agriculture;

(e) Because of the degree of human management of agricultural biodiversity, its conservation in production systems is inherently linked to sustainable use;

(f) Nonetheless, much biological diversity is now conserved ex situ in gene banks or breeders' materials;

(g) The interaction between the environment, genetic resources and management practices that occurs in situ within agro-ecosystems often contributes to maintaining a dynamic portfolio of agricultural biodiversity. (FAO 2015)

In 2000, CGRFA was mainly concerned with plant genetic resources, so these features mainly concern the situation for plants. It is an open but complex question whether these features apply to an equal degree to the other groupings of genetic resources. These distinctive features are used as arguments for CGRFA to regulate genetic resources for food and agriculture in a different manner than prescribed in the CBD and NP. There seems to be a tacit assumption here that implementing the NP will reduce access and in turn hinder efforts to ensure food security. The is little systematic or empirical evidence that a careful implementation of the Nagoya Protocol will have this effect, but to prevent it hindering the achievement of these objectives, there is a need to discuss and better understand the gene flow and potential in access to genetic resources for food and agriculture outside the plant sector. *When perusing discussions of the sectors in the other chapters in this volume, this author would encourage the reader to reflect on the whether these characteristics are accurate for other sectors than plants.*

The extent to which these assumptions apply to all six sectors (animals, aquaculture, forest, plants beyond the ITPGRFA, micro-organisms and invertebrates) needs to be further explored before using them as reasons for differentiating legal regulations. Thus a country needs to assess whether any of these GRFA groupings have these features or not. An assessment is therefore necessary to establish whether these sectors have specific needs with respect to ABS regulation, and what they are. Certain general features of these branches using GRFA can be identified even without having to explore the special situation of the sectors in each country.

The Nagoya Protocol itself foresees two important mechanisms for handling ABS in relation to special branches of genetic resources. Article 19 urges the development and updating of information on model contracts. The essence here is that sectoral and cross-sectoral model contracts can be negotiated under the auspices of the Nagoya Protocol to serve special purposes. This is one potential tool in preventing ABS from becoming fragmented by international organisations negotiating separate systems for access and benefit sharing.

2.6 Conclusions and Challenges for Sector Approaches

Access and benefit sharing of the dividends from genetic resources have now entered a critical phase following the entry into force of the Nagoya Protocol. One would expect to see examples of functioning benefit sharing contracts within relatively

short time if the Nagoya system is not to lose momentum and the CBD is not to lose credibility. New genetic variations could possibly help plants adapt to a warmer climate. Collecting activities and collections could therefore prove very useful by making material available that can ease efforts to adapt to a changing climate.

Business representatives often claim that genetic resources are of limited value. At the same time, however, the business community is vocal in calling for secure access to genetic resources. This creates something of a paradox for access and benefit sharing. If genetic resources have limited value – actual or potential – why should access to genetic resources be important to business? Furthermore, the fact that patents are taken out on bio-innovation outcomes, the value for business created from the utilisation of genetic resources would appear to be not wholly insignificant.

If the current system of access and benefit sharing in relation to genetic resources does not provide funds for conservation and sustainable use of biological diversity, one of the raisons d'être of the CBD is in jeopardy. It is therefore increasingly urgent for the CBD to get the ABS to work as intended. The entry into force of the Nagoya Protocol represents a step in this direction. The new instrument, however, cannot solve these issues alone and much will therefore rely on functional implementation moving forward.

In light of the following chapters in this volume, it is interesting to reflect on whether the general regulation of the CBD and NP will apply in a fruitful manner to each sector or whether there will be a need for an open access regime where access is combined with complete freedom to privatise the inventions based on the genetic material while benefit sharing objective is not prioritised. In this scenario, those with the expertise of and in the different sectors need to inform law makers and legislative processes at the international level.

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