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AN INTRODUCTION TO THE INTERNATIONAL ABS REGIME AND
A COMMENT ON ITS TRANSPOSITION BY THE EU

Evanson Chege Kamau and Gerd Winter

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1

SETTING THE STAGE: OWNERSHIP OF GENETIC RESOURCES

Human beings have utilised terrestrial and marine biological resources such as plants, animals and micro-organisms since time immemorial. Some of the most common traditional uses of biological resources include use for food, fuel and construction. By law, command over biological resources for consumption or 'bulk uses', as referred to at times, is vested in states, private owners or collectives depending on relevant international and domestic law. While such command has widely been clarified by existing law – states have sovereignty over the plants and animals in their territory, individuals or collectives have property rights according to domestic legislation – new dispositions must be taken since the genetic programme of biological resources has been discovered as a resource 'beneath' the consumable plant or animal 'expressed' by the genome. Research and development of the genetic programme has sprung up as a promising new branch of scientific and industrial activities, aiming at new knowledge and products such as pharmaceuticals, chemicals, cosmetics, dietary products, etc. It has to be determined to whom such genetic potential belongs, both on the level of international law which allocates sovereign rights and on the level of domestic law which allocates private property. Often, the genetic properties of a specific organism, for example, a pea, a cow, a bacterium, are largely the same in any of these organisms. If the specimens of a species spread over many properties or even over several countries, who shall be the proprietor or holder of sovereign rights? Moreover, should the holder of ownership or sovereignty over a specimen also be the owner of its genetic potential and thus have command over its access and utilisation?

An analysis of the sovereignty and property (or 'ownership' which shall be used as the generic term in this article) over the genetic potential of a biological resource must take into consideration two possible objects of ownership over the genetic potential: the genome being the material substratum and the information about the genome being the 'intellectual' complement. The legal ownership of

these two components can be determined by national and international law.

1.1 Ownership of the Genome

The genome is a chemical compound which triggers chemical reactions such as the production of proteins. The international discourse on the ownership of genes has always tended to represent two opinions divided along the line of resource rich and resource poor countries, the former being mainly developing countries and the latter developed countries. One opinion argued that the material genome is a product of nature not of humans and therefore should be defined as a common property of mankind. This argument is nonetheless made weak by the fact that there are other nature-created resources over which private ownership is recognised, for example minerals and oil. The other opinion insisted on having the sovereignty of states not only over their biological resources but also over the genetic traits of such resources recognised.

Finally an agreement was reached that led to the conclusion of the Convention on Biological Diversity (CBD or the Convention). The CBD clearly recognises the sovereign rights of states over their natural resources and the authority of national governments to determine access to genetic resources subject to national legislation and subject to prior informed consent (PIC) of the state providing the genetic resources (Article 15 (1), 15 (5) CBD). This is reaffirmed in the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity (NP or Protocol) in Article 6.¹ The user is encouraged to utilise the genetic resources for sustainable purposes

1 The 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, Nagoya, 29 October 2010 [hereafter Nagoya Protocol] is the instrument implementing the third objective of the Convention on Biological Diversity (CBD), i.e., the fair and equitable sharing of benefits arising out of the utilisation of genetic resources. It will enter into force after the 50th instrument of ratification, acceptance, approval or accession has been deposited by states or regional economic integration organisations that are Parties to the CBD (Article 33 (1)).

(Article 1 CBD) but is in turn required to share the accruing benefits with the provider in a fair and equitable manner (Article 15 (7) CBD, Article 5 NP). It is expected that benefit sharing, in addition to appropriate funding, shall contribute to the conservation of biological diversity and (further) sustainable uses (Article 1 NP).²

On the level of international law, the sovereign rights of states extend to the genomes of their biological resources. For the domestic realm this implies that the state can decide to internally make them state property or allocate property or other kinds of rights to individuals or communities.

1.2 Ownership of Information About the Genome

In principle both national and international law consider information on nature as been in the public domain. That means, such information can be freely distributed, accessed and used. However, this rule does not include information that entails a specific individual effort and that consists of a service to the community. Such information can be privately owned and protected, for example, by patents and copyrights. The criteria necessary to satisfy this requirement are laid out by intellectual property law. For patents, the information/invention must be new, involve an inventive step and be industrially applicable.

Although the privatisation of information was initially meant for 'bulk uses', the privatisation of genetic potential through intellectual property protection began as early as in the 1920s. Breeders' rights for crops (but not for animals) subject to novelty, distinction, uniformity and stability of the plant gave breeders the non-exclusive right to use the seed for reproduction (for their own purposes) and further breeding (if only against the payment of a compensation to the right holder). Concurrently, patent law was reinterpreted to also cover information about life forms, including organismic genetic traits and their functions, microorganisms, and

2 While Article 1 CBD can be read to understand sustainable uses as a source of sharable benefits, Article 1 NP sees such uses as a result of benefits. A harmonising interpretation should allow for both ways or rather see a circle of uses, benefits and again uses.

genetically modified individual plants and animals (but not related species). This was done in disregard of the fact that life cannot be a human invention.³ The CBD left this intellectual property system untouched but introduced a requirement that the traditional knowledge (TK) associated with genetic resources and held by local and indigenous communities should belong to such communities (Article 8 (j) CBD). However, no intellectual property law regime for traditional knowledge has been established as of yet.⁴

Another issue as important as traditional knowledge that the CBD did not resolve is the question of crops and animals bred by farmers, in other words, landraces. The issue cross-cuts with traditional knowledge if farmers are part of local or indigenous communities. Traditional knowledge has made a significant contribution in the development of new crop types and conservation of crop biodiversity. It is also particularly important in the development of farming systems adapted to local conditions and farming practices.⁵ Breeding by farmers however cannot be simply classified as traditional knowledge as it involves more inventive labour by the farmer that makes it distinct from traditional knowledge, for example, on herbal medicine which, although also developing, is often rather ancestral knowledge passed down through generations. By its nature, breeding is also closer to the concepts of breeders'/farmers' rights while medicinal knowledge is more akin to patent rights. Although there were considerations to create a form of intellectual property for farmers' rights, the approach changed when the matter was handed over to the World Intellectual Property Organisation (WIPO) with the focus being shifted from developing a 'positive' concept of community rights towards a 'negative' approach that aims at protecting self-bred seeds from privatisation through modern intellectual property rights (IPRs).

3 Gerd Winter, 'Patent Law Policy in Biotechnology' 4/2 *Journal of Environmental Law* 167 (1992).

4 Eliamani Laltaika, 'Western Intellectual Property Rights Regimes and Traditional Knowledge Protection Systems in Africa', in Oliver Ruppel and Katarina Ruppel-Schlichting eds, *Environmental Law and Policy in Namibia* 201 (Windhoek: Hanns Seidel Stiftung, 2011).

5 Queen Mary Intellectual Property Research Institute, *The Relationship between Intellectual Property Rights (TRIPS) and Food Security* (June 2004), available at http://trade.ec.europa.eu/doclib/docs/2005/february/tradoc_121618.pdf.

Of course, in the absence of international harmonisation, resource-rich states could decide and are entitled under international law to introduce their own elaborate version of IPRs both for traditional knowledge and crops.⁶ This would be binding only on activities within the given states, though. But, it has been argued that the violation of such rights by actors within user states, including illicit transfer to another country, could trigger tort liability under user state laws.⁷

All in all, the fact that states have sovereign rights over genetic resources means that genetic resources have been privatised in relation to other states. Each state however has the prerogative to either use these rights or waive them making genetic resources a global common good. In regard to traditional knowledge associated with genetic resources however, the CBD requires states to put a system in place in order to protect it and to ensure the sharing of benefits arising from its utilisation with its holders (Article 8(j) CBD).

The CBD and the NP specify the content and limits of the sovereign rights of states over genetic resources. In the following section, the most important provisions will be presented with a discussion on how they could be integrated into national law.

2 THE CONTENT OF SOVEREIGN RIGHTS OVER GENETIC RESOURCES

According to the CBD and the NP, the sovereign rights of states over genetic resources consist of

mainly the right to provide genetic resources, the right to determine the conditions of access and the right to a fair and equitable share in benefits that accrue from the utilisation of genetic resources. These rights are based on Article 15 CBD and have been taken up in Articles 5 and 6 NP.

2.1 The Right to Provide Genetic Resources

By 'providing' we refer to permitting access to (or 'the taking of') and the use of a genetic resource. The right to (legally) provide genetic resources is determined by Article 15 (3) CBD. It states: 'For the purpose of this Convention, the genetic resources being provided by a Contracting Party, [...] are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention'. Article 6 (1) NP which is the relevant provision reaffirms this requirement. These provisions delineate two groups of right holders.

The first group can be referred to as first-level holders of genetic resources. The CBD refers to them as countries of origin, that is, countries that possess the genetic resources provided in in-situ conditions (Article 2). Genetic resources in in-situ conditions are those existing within their ecosystems or natural habitats. Domesticated and cultivated species, that is, those existing in the surroundings where they have developed traits distinct from those they possessed in their initial ecosystems and habitats are also considered as existing in in-situ conditions.⁸ In addition, species which have existed for some time (and in any case before the entry into force of Article 15 CBD) away from their original in-situ conditions and have become part of new natural and cultured

6 See as an example the introduction of farmers' rights by the Indian 'The Protection of Plant Varieties and Farmers' Rights Act, 2001' which provides for, inter alia, the right of farmers and communities to a share in benefits drawn from breeders' rights on varieties based on local crops. See Article 26 of the Act. The Act is available online at <http://agricoop.nic.in/PPV&FR%20Act,%202001.pdf>.

7 Christine Godt, 'Enforcement of Benefit-sharing Duties in User Countries', in Evanson Chege Kamau and Gerd Winter eds, *Genetic Resources, Traditional Knowledge and the Law. Solutions for Access & Benefit Sharing* 419 (London: Earthscan, 2009).

8 Domestication and cultivation is a result of human intervention through the selection and breeding of plants, animals or microbes over centuries in order to meet human needs. This process gives new or very different traits to these organisms that vary from those they possessed in in-situ conditions. See also Lyle Glowka et al., *A Guide to the Convention on Biological Diversity* 18 (Gland and Cambridge: IUCN, 1994) and Thomas Greiber et al., *An Explanatory Guide to the Nagoya Protocol on Access and Benefit Sharing* 98 (Gland: IUCN, 2012).

ecosystems are also regarded as existing in in-situ conditions. A country possessing any of these genetic resources is hence a country of origin.⁹

The second group can be referred to as second-level holders of genetic resources. These are states that are not countries of in-situ origin of the genetic resources being provided but that legitimately possess such genetic resources in ex-situ conditions. Such acquisition is legitimate under either of two possible conditions: 1) It took place before the CBD entered into force;¹⁰ 2) It took place after entry into force of and in compliance with the CBD.¹¹ The latter entitles provider states to either require PIC and the conclusion of mutually agreed terms (MAT), or not to establish such a requirement.¹²

2.2 The Right to Determine the Conditions of Access

The parties on the provider side that must be involved in giving consent and agreeing on mutual terms include the provider state itself (Article 6 NP) and – according to domestic legislation – indigenous and local communities that hold genetic resources (Article 6 (2) NP) and/or associated traditional knowledge (Article 7 NP). The NP does not mention private landowners but does not hinder states from recognising them as owners of genetic resources and therefore as having the right to be involved in PIC procedures. The Kenyan access and benefit sharing legislation,¹³ under Section 9 (2), for example, requires that an application for an access permit must

be accompanied by PIC of inter alia ‘interested persons’. It goes on to specify whose PIC should be sought under its First Schedule (2.0 (g)) where it explicitly mentions private land owners.

The right of a provider state to determine the conditions of access emanates from the sovereign rights of states over their natural resources. The core of this right is the PIC of the provider state as stipulated in Article 6 NP. A provider state that opts for PIC may decide either to subject all genetic resources to this requirement, only certain types of genetic resources, or choose to waive or subject them according to the purpose of access.¹⁴ However, whichever approach is taken, a provider state that subjects access to PIC is required to facilitate access (Article 15 (2) CBD; Article 6 (3) NP).

Greiber et al. distinguish five possible primary stages of an access determination process that need to be regulated by a provider state:¹⁵

- Application to a competent authority: the specific information that needs to be provided by an applicant has to be decided.
- Review of the access application: the access and benefit sharing (ABS) measures need to provide for a transparent and non-arbitrary review process.
- Reaching MAT: it needs to be clear with whom the applicant must negotiate MAT, when MAT should be negotiated, and what minimum criteria need to be fulfilled by the agreement.
- Access determination: the ABS measures need to specify by which criteria the application is judged, and they need to determine that a written permit (indicating possible conditions) or a written denial (indicating the reason(s) leading to the negative decision) is given within a specified and reasonable period of time.

⁹ See Glowka et al., *id.*; Greiber et al., *id.*

¹⁰ The CBD entered into force on 29 December 1993 and is thus not applicable to resources acquired before that date.

¹¹ Nagoya Protocol, note 1 above, Article 6 (1), para 1.

¹² Cf. Article 15 (3) and (4), CBD.

¹³ The legislation that regulates access and benefit sharing in Kenya is known as The Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006 and can be accessed online at http://www.nema.go.ke/index.php?option=com_phocadownload&view=category&id=23:biodiversity-benefit-sharing-regulations&Itemid=567 or http://www.abs-initiative.info/fileadmin/user_upload/Documents_ICIPE/Legal_Texts/Legal_Kenya_ABS_REGS_text.pdf.

¹⁴ Greiber et al., note 8 above, at 96, 282f.

¹⁵ *Id.*, at 283.

- Appeal: it also has to be decided whether appeals are handled through existing administrative procedures, and on which procedural and/or substantive grounds appeals can be based.

As already mentioned, the right of PIC should be weighed against the obligation to provide procedural facilitation of access. The Protocol is very specific and elaborate on this. Each Party that opts for PIC is required to provide for 'legal certainty, clarity, and transparency' of their domestic ABS legislation, 'fair and non-arbitrary rules and procedures' on access to genetic resources, 'information on how to apply for prior informed consent', clear, cost-effective and timely decision-making, and recognition of a permit or its equivalent as evidence of PIC.¹⁶

Responsible for advising on PIC and MAT are national focal points and competent national authorities (CNA) (Article 13 (1) and 13 (2)). The latter are also responsible for granting access (Article 13 (2)). One single entity may be designated to fulfil the functions of both focal point and CNA (Article 13 (3)).

The NP introduces a new scenario in regard to entities with the right to determine access to genetic resources. Unlike the CBD which limited the right of the indigenous and local communities (ILCs) to determine access to traditional knowledge associated with genetic resources, the NP acknowledges their right to determine access to genetic resources *per se* where they have the established rights over genetic resources (Article 6 (2)) as recognised by international or domestic law.¹⁷ Such a right may relate to wild genetic resources or domesticated landraces. If access

is taking place in territories of such communities, or involves their genetic resources, their PIC or approval and involvement¹⁸ become mandatory. The requirement for PIC or approval and involvement of the ILCs for access to their traditional knowledge associated with genetic resources and the establishment of MAT is dealt with under Article 7.

The NP seems to suggest a slight difference in PIC requirements under Article 6 (1) and Articles 6 (2) and (7). Whereas the former limits PIC to access for utilisation purposes, the latter seem to suggest that PIC is the norm for access to genetic resources of ILCs and traditional knowledge associated with genetic resources, even if there is no declaration of the intention to utilise them. Concerning facilitation of access, Articles 6 (2) and (7) do not refer back to the measures set in Article 6 (3). It is doubtful, however, that this implies that facilitation should not be provided. Indeed Article 13 (b) and (c) indicate that the provider state is obliged to have clear procedures for PIC and MAT as well as information as to who the relevant ILCs are. In addition, though Article 6 (3) refers directly to Article 6 (1) ('Pursuant to paragraph 1 ...'), it requires Parties under its subparagraph (f) to set out criteria and/or processes, where applicable and subject to domestic legislation, for obtaining PIC or approval and involvement of ILCs for access to genetic resources. What the NP seems to be totally mute about is the establishment of MAT in cases of access to genetic resources of the ILCs. However, whereas the NP does not deprive the ILCs of their right to organise ABS related to their genetic resources and traditional knowledge independently should they have the capacity to do so, it seems to have placed the task of organising such ABS on the Parties.¹⁹ That would include ensuring that MATs are established. This conclusion can also be reached from an interpretation of Articles 5 (2) and (5).

The participation of Parties in organising ABS related to ILCs comes with several other obligations, including the obligations: to establish mechanisms to inform users of traditional knowledge associated

¹⁶ According to Article 6 (3) (g) (i)-(iv), MAT include, among others, dispute settlement clauses and terms on benefit sharing, including intellectual property rights; subsequent third-party use; changes of intent; and sharing information on implementation of MAT.

¹⁷ The CBD only required Parties to promote, as far as possible and as appropriate, the wider application of traditional knowledge associated with genetic resources with the approval and involvement of the holders of such knowledge and encourage the equitable sharing of benefits arising from its utilisation (Article 8 (j)). For an in-depth discussion *see* Greiber et al., note 8 above, at 99ff.

¹⁸ For the use of the terms 'prior informed consent', 'approval' and 'involvement' *see* Greiber et al., note 8 above, at 110f.

¹⁹ *See* Greiber et al., note 8 above, at 100f.

with genetic resources about their obligations with effective participation of communities (Article 12 (2)); to support the development by ILCs of community protocols in relation to ABS of genetic resources and traditional knowledge associated with genetic resources, minimum requirements for MAT and model contractual clauses for benefit sharing from utilisation of traditional knowledge associated with genetic resources (Articles 12 (3) (a)-(c)); to ensure that the customary use and exchange of genetic resources and associated traditional knowledge within and among ILCs are not restricted, in accordance with the objectives of the Convention (Article 12 (4)); to organise meetings of communities, establish a help desk for communities, and involve communities in the implementation of the Protocol in order to increase awareness of genetic resources and traditional knowledge associated with genetic resources held by communities (Articles 21(b)-(c) and (h)); and to improve capacities of communities and especially of women in order to enable effective participation of communities in the implementation of the Protocol (Articles 22 (3) and 22 (5) (j)) – owing to their vital role in ABS processes, policy making, and implementation of biodiversity conservation (Preamble, para. 11). While implementing their obligations, Parties are obliged to consider ILCs' customary laws, community protocols and procedures with respect to traditional knowledge associated with genetic resources (Article 12 (1)).

2.3 Utilisation of Genetic Resources and Traditional Knowledge and the Right of Benefit Sharing

According to Article 6 (1), access to genetic resources is only subject to PIC for utilisation purposes and the right to benefit sharing is triggered by utilisation of such resources (Article 5 (1)). It implies that if a declaration is made at the moment of physical access that the genetic resources are meant for utilisation purposes, the PIC and benefit-sharing obligations would arise from that moment. These obligations can arise at a later stage depending on when the intention to utilise arises or when utilisation takes place. That makes the term 'utilisation' as well as its definition crucial.

'Utilisation of genetic resources' as defined under Article 2 (c) NP means 'to conduct research and

development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention'. The Protocol does not have a list of activities that can be considered as R&D. There were activities listed as such in the deliberations leading to the adoption of the Protocol which can still be used as indicators. The document resulting from Working Group 7 contained a non-exhaustive list consisting of the following activities:²⁰

- Genetic modification
- Biosynthesis (use of genetic material as a 'factory' to produce organic compounds)
- Breeding and selection
- Propagation and cultivation of the genetic resource in the form received
- Conservation
- Characterisation and evaluation
- Sequencing genes or genomes
- Production of compounds naturally occurring in genetic material (extraction of metabolites, synthesis of DNA segments and production of copies).

Although the definition of 'utilisation of genetic resources' in Article 2 (c) of the Protocol does not directly include R&D on 'derivatives', it does so indirectly by defining 'utilisation' to include R&D through the application of biotechnology. 'Biotechnology' is defined in Article 2 (d) as '... any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'. This means that R&D on derivatives, that is, the naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources (Article 2 (e)), are

²⁰ See WG-ABS official document 7/2, Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UN Doc. UNEP/CBD/WG-ABS/7/2 (2008).

also covered by ABS requirements.²¹ The inclusion of derivatives is highly consequential because the extraction of chemicals from biological resources for medicinal, cosmetic or other purposes is subjected to access conditions and benefit-sharing obligations.²² Arguably this blurs the line between bulk uses and the use of the genetic potential of biological resources. It is up to provider state legislation to find a reasonable criterion of distinction that avoids excessive reach of PIC requirements. We suggest that harvesting within the provider state of derivatives should be PIC-free provided this is done in respect of all other laws concerning, inter alia, land ownership, environmental protection, customs, etc.

Like access to genetic resources under Article 6 (1), the trigger for the benefit-sharing obligation for genetic resources and traditional knowledge of ILCs is utilisation (Articles 5 (2) and 5 (5)). What seems to be lost in regard to access under Articles 6 (2) and 7 however is the link created between PIC and benefit sharing under Article 6 (1) (that is, if access is subject to PIC then the purpose of access is utilisation and the consequence is benefit sharing). This seems to indicate that despite a seemingly obligatory PIC requirement under Articles 6 (2) and 7, it might be difficult to determine the benefit-sharing obligation at the moment of physical access if the intention to utilise is not declared from the onset. In other words, similar to cases of change of intent, benefits can only be negotiated once utilisation is established. That makes user benefit-sharing measures under Article 5 and compliance and monitoring measures under Articles 15, 16 and 17 extremely important. Nevertheless, nothing speaks against forthwith inclusion of clauses in contracts requiring that benefits are shared in cases of utilisation or change of intent, or obliging the recipient to renegotiate the contract in such cases.

Apart from benefits arising from utilisation, Article 5 (1) states that benefits from subsequent applications and commercialisation shall be shared. The inclusion of these terms in the Protocol was, in a way, a

recognition that benefit sharing cannot be effective if it does not cover products and processes resulting from the downstream chain of value addition.²³ To effectively realise the intended aim it would have been useful to also include the terms under Article 15 on compliance with domestic legislation, which the Protocol did not do. As a consequence it implies that in complying with Article 15, Parties' compliance measures are not required to extend to subsequent applications and commercialisation.²⁴ Instead, Parties will have to address such issues while establishing MAT and, in case of disputes, seek recourse under Article 18,²⁵ as discussed further below.

The temporal scope of the right to benefit sharing is not clearly laid out in the Protocol. Does the right relate to genetic resources and traditional knowledge obtained after the entry into force of the NP or of the CBD? We believe that the CBD is the baseline. This is expressed in Article 3 NP, which states that the NP shall apply to genetic resources and traditional knowledge 'within the scope of Article 15 of the Convention and to the benefits arising from the utilisation of such resources'. It is true that this provision could be read narrowly as simply defining the substantial scope of the Protocol. But its extension to the temporal scope is strongly supported by a historical interpretation: the assumption that the NP shall be the baseline would be tantamount to concluding that the Protocol waives the obligations of Parties under the CBD. It is impossible to assume that this was the general attitude of the Parties negotiating the NP. The CBD as the baseline is also indicated by Article 5 (1) NP which refers to 'a Party that has acquired the genetic resources in accordance with the Convention' as a legitimate provider of genetic resources besides the country of origin of such resources. It also refers to Articles 15 (3) and (7) of the Convention as the background of the benefit-sharing obligation.

Benefits listed under the Protocol include monetary and non-monetary ones (Article 5 (4) and Annex). Monetary benefits include, for instance, upfront payments, royalties and licence fees, whereas non-monetary benefits extend to the sharing of research

21 Evanson Chege Kamau, Bevis Fedder and Gerd Winter, 'The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What Is New and What Are the Implications For Provider and User Countries and the Scientific Community?' 6/3 *Law, Environment and Development Journal* 246, 256 (2010) and Greiber et al., note 8 above, at 66f.
22 See Kamau, Fedder and Winter, *id.* at 251.

23 See Greiber et al., note 8 above, at 85.

24 *Id.*, at 162.

25 *Id.*

and development results and the transfer of knowledge and technology.

While the sharing of these kinds of benefits follows a model of bilateral deal where genetic resources and/or traditional knowledge are exchanged for money and knowledge, the Protocol takes much care to support joint undertakings. The common view has been that provider states shall deliver resources to user states which conduct R&D thus generating benefits, a share of which must flow back to the provider state. This view is sidelined and if appropriate even replaced by another ideal: common projects of provider and user states that allow provider states to develop their own R&D potential. Types of benefits in the Annex that could be shared in such projects include research funding, collaboration in R&D activities (where possible in the provider country), institutional capacity building, training, and joint ownership of intellectual property rights. Although there is room for parties to agree on the kinds of benefits to be shared, the Protocol lays out the Parties' general obligations towards awareness raising, capacity building, technology transfer, and collaboration in technical and scientific R&D (Articles 21-23).

The basic paradigm that maintaining the potential of discovering valuable genetic resources and traditional knowledge stimulates conservation and sustainable use²⁶ is now explicitly complemented by the obligation to encourage the flow of benefits towards conservation and sustainable use (Article 9). The language is however rather weak. It will hardly prevent provider states from using obtained benefits for normal budget purposes, or guide user states to suppress the development of unsustainable products. It is nevertheless a reminder that states are expected to act differently.

3 FACILITATED ACCESS

The procedural facilitation measures under Article 6 (3) apply generally to access that is subjected to

²⁶ See Nagoya Protocol, note 1 above, Preamble considerations 6, 7 and 22.

the PIC requirement. That would include access to genetic resources for the purposes listed under Article 8 if they are not exempted from PIC. During the negotiations, however, there were discussions concerning the importance of certain sectors and their operational difficulties to cope with restrictive ABS requirements. The relevant communities were deeply engaged in promoting a special regime for those sectors. That led to the inclusion of Article 8 on special considerations for non-commercial research, emergency cases related to human, animal or plant health, and genetic resources for food and agriculture.

3.1 Non-commercial Research

The distinct needs of non-commercial research are addressed under Article 8 (a). The transnational research communities are concerned about restrictions on access readily hindering non-commercial research.²⁷ The difficulty provider states have in simplifying access for such research is the existing ambiguity in the dividing line between non-commercial and commercial research. The following reasons on why it is hard to separate the two types of research have been stated:²⁸

- Both the private sector and research institutions (for example, universities) can be involved in commercial as well as non-commercial research.
- Similar research methods and processes are generally used in commercial as well as non-commercial research.
- Both types of research usually require access to the same biological materials and genetic resources.
- Both types of research can be beneficial for conservation and the sustainable use of biological diversity.

²⁷ See Greiber et al., note 8 above, at 117.

²⁸ *Id.*, at 119 and UNEP, 'Report of a Workshop on Access and Benefit-Sharing in Non-Commercial Biodiversity Research' (9 March 2009) UNEP/CBD/WG-ABS/7/INF/6, 5.

Based on the work of a non-commercial research sector workshop in 2008 in Bonn, Germany,²⁹ a Working Group elaborated definitions characterising non-commercial research by a) public availability, b) purely non-commercial intentions, c) results benefit providers, conservation, ecosystem analysis, and characterisation of organisms, and d) generation of near-term, non-monetary benefits. It also characterised commercial research as a) often restricting access, b) generating market products; c) primarily benefiting users, and d) generating long-term, monetary benefits.³⁰ This approach suggests a functional rather than substantial criterion of distinction: if the research aims at enriching the public domain, it is non-commercial, while if it aims at the privatisation of material and knowledge, it is commercial. This means that ‘basic’ research whose substance is taxonomic can nevertheless be commercial, if the result (such as a gene) is patented. On the other hand, ‘applied’ research whose substance is, for example, the development of a marketable product can be non-commercial if the result is made publicly available.

The fact that results of ‘basic’ research can easily be used for proprietary purposes (either by the recipient of genetic resources or third parties) made providers reluctant to concede without an agreement on measures that could counteract violations and abuse. That resulted in the inclusion of a clause on ‘a change of intent’. Thus, the article requires parties to

Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research.

There are thus two underlying messages: the need to create conditions to promote and encourage

²⁹ See UNEP, *id.*

³⁰ CBD GTLE information document 1/INF/2, Concepts, Terms, Working Definitions and Sectoral Approaches Relating to the International Regime on Access and Benefit Sharing, UN Doc. UNEP/CBD/ABS/GTLE/1/INF/2 (2008) at 5 and CBD WG-ABS official document 7/2, note 20 above, Paras. 13 and 43–44.

research for the public domain by providing simplified access rules for research of a non-commercial nature, and the need to address a situation where the initial intent deviates from the MAT at the time of access. To comply with these aims each Party seems to have a wide discretion to decide which actions to undertake.³¹ Even ‘simplified measures’, as a possible action, are very vague. How a change of intention can be dealt with is discussed below under national transposition.

3.2 Emergency Cases

A provision on simplified procedures for expeditious access to genetic resources (especially pathogens) and benefit sharing in cases of emergency was also included under Article 8 (b), after serious controversies in the negotiations. These controversies were centred on questions as to whether viruses or pathogens should, more generally, be included in an ABS instrument negotiated under the auspices of the CBD (which aims at nature conservation), whether special benefit-sharing obligations were feasible and whether expedited access in times of health emergencies should be mandatory.³²

ABS related to pathogens is crucial in addressing human, animal and plant health in a responsible, fair and equitable way.³³ It is therefore critical that genetic resources required for production of medicines and also for building vaccine stocks in preparedness of pandemic outbreaks are made available either expeditiously or with ease depending on the emergency. While most virus samples with pandemic potential are found in developing countries, which are likewise dependent on and keen to support global efforts to combat pandemics by sharing needed virus strains, they have found themselves excluded from the benefits of that process in the past.³⁴ This is because most research and development is conducted in Europe and North

³¹ See Greiber et al., note 8 above, at 119.

³² Marie Wilke, The World Health Organization’s Pandemic Influenza Preparedness Framework as a Public Health Resources Pool, in Evanson Chege Kamau and Gerd Winter eds, *Common Pools of Genetic Resources. Equity and Innovation in International Biodiversity Law* 315 (London: Routledge, 2013).

³³ See Greiber et al., note 8 above, at 117.

³⁴ See Wilke, note 32 above.

America, and countries in these regions at times place a large number of advanced-purchase agreements of vaccines in order to guarantee priority treatment in case of an emergency, and resulting high prices and strong competition for the limited resources bar developing countries from purchasing needed treatments.³⁵

Therefore, while seeking to maintain and ensure the supply of such genetic resources, the provision sought to balance the ABS equation by ensuring that their providers also benefit from the process. The last minute compromise text calls upon each Party, when developing and implementing their access and benefit-sharing legislation or regulatory requirements, to

Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally', and to '... take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries.

Whereas 'present' refers to emergency cases that already exist or that have already occurred, thus demanding immediate action, 'imminent' denotes those that have not yet occurred but are likely or about to occur or reoccur and therefore demand preparedness.³⁶ As to whether a health situation constitutes a present or imminent emergency is to be determined nationally or internationally.

In spite of the likely urgency and health threat, the provision uses very weak language calling upon Parties just to pay due regard to such cases and adding that they may take into consideration the need for expeditious access to genetic resources. This waters down the strong obligation suggested by the term 'shall' in the chapeau to just decisions and actions based on a wide discretion by each Party.³⁷ This also concerns the benefit-sharing obligation. In line with Wilke's observation, the outcome of the negotiations

regarding ABS in health emergencies stays far behind the achieved benefit-sharing obligations under the World Health Organisation's Pandemic Influenza Preparedness (PIP) Framework,³⁸ though she notes that the CBD negotiations were not limited to influenza vaccines and hence had a considerably wider scope.³⁹

3.3 Genetic Resources for Food and Agriculture

The food and agriculture sector with a strong representation in the name of the United Nations Food and Agriculture Organization (FAO) was also deeply engaged in the negotiations in order to protect the interests of the sector. The availability, simplified access and exchange of genetic resources for food and agriculture is core to food production in view of meeting the human food and nutrition supply demand, ensuring food security and coping with the impacts of climatic stress resulting from global warming and other forms of climatic change, in other words, climate adaptation. In the absence of a special regime for such genetic resources, ABS procedures based on the CBD are likely to have a negative impact on this sector. Parties, recognising the interdependence of all countries with regard to genetic resources for food and agriculture (GRFA), their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change,⁴⁰ included the text in Article 8 (c) of the NP in order to reflect these concerns and factors. Article 8 (c) calls on Parties to '[C]onsider the importance of genetic resources for food and agriculture and their special role for food security' in the process of developing and implementing their access and benefit-sharing legislation or regulatory requirements.

There are two situations relating to GRFA that a Party may consider in developing or implementing its ABS legislation or regulatory requirements: relating to plant genetic resources for food and agriculture (PGRFA) included in Annex I of the International Treaty on Plant Genetic Resources for Food and

35 Wilke discusses this problematic in details highlighting the case of Indonesia. *Id.*

36 See Greiber et al., note 8 above, at 122.

37 *Id.*, at 121ff.

38 For an in-depth discussion on the functioning of the PIP Framework see Wilke, note 32 above.

39 *Id.*

40 See Nagoya Protocol, note 1 above, preamble.

Agriculture (ITPGRFA or the Treaty) (Annex I genetic resources), and relating to all other GRFA.⁴¹

Annex I genetic resources relate to 64 crops consisting of 35 food crops and 29 forage genera which Contracting Parties of the ITPGRFA consider extremely vital for food security. They account for 80 per cent of all human consumption and all countries are dependent on them as well as interdependent on each other in this regard. The future of the global agriculture sector highly depends on their conservation and sustainable use. In order to ensure their continual availability, the Treaty makes them the subject of a common pool, widely referred to as the multilateral system (MLS) of the Treaty.⁴²

The Treaty and its objectives, while building on the sovereign rights of resource states and hence being in line with the CBD and the NP, develop the bilateral approach further towards a multilateral concept. In furtherance of conservation and sustainable use objectives, its MLS aims at ensuring that the genetic resources of the 64 crops are accessible and transferable with ease in order to give scientific institutions and private sector plant breeders the opportunity to work with, and potentially improve, the materials stored in gene banks or even crops growing in fields. It also aims at ensuring that the benefits that arise from their utilisation are shared in a fair and equitable way with the participants of the MLS. The ABS regime created by the MLS requires that Contracting Parties of the Treaty facilitate access to their Annex I PGRFA at request by another contracting party and natural or legal persons in their jurisdictions by making them available expeditiously. It also establishes its own criterion of sharing benefits from its benefit-sharing fund based on need for conservation and sustainable use, which is different from the CBD bilateral approach – in other words, the recipient of the benefits is not necessarily the party that provided the genetic resources.

The ITPGRFA is a recognised and specialised instrument for plant genetic resources for food and agriculture. In regard to specialised instruments Article 4 (4) of the Protocol states that:

⁴¹ See Greiber et al., note 8 above, at 123.

⁴² For an in-depth discussion see Evanson Chege Kamau, 'The Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture: Lessons and Room for Further Development', in Kamau and Winter eds, note 32 above, at 342.

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

Accordingly, the Protocol does not apply to the Contracting Parties to the Treaty in regard to the genetic resources covered by it as long as the objectives of the Treaty remain consistent with those of the CBD and the NP and such genetic resources continue to be accessed and exchanged within the scope of Article 12 (3) (a) of the Treaty, that is, solely for the purpose of conservation for research, breeding and training for food and agriculture.

Apart from the PGRFA covered under Annex I of the Treaty, there are also other GRFA which are equally important for food security and nutrition, climate adaptation etc. Currently, there is ongoing work within the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) to identify such resources and to reflect on possibilities of creating a special regime to address their ABS needs. The list of identified GRFA comprises of animal, forest, aquatic and microbial genetic resources, and biochemical agents.⁴³ The NP does not hinder Parties from creating other specialised ABS instruments provided they do not run counter to the objectives of the CBD (Article 4 (2)), which legitimises this ongoing work. Although no specialised ABS instrument exists yet for those resources, Parties may still consider how to develop or implement their ABS legislation or regulatory requirements in a manner that pays due regard to the ongoing work in accordance with Article 4 (3) of

⁴³ See Greiber et al., note 8 above, at 124. The report of the sixth meeting of the AHWG (UNEP/CBD/COP/9/6) recommended that animal genetic resources for food and agriculture are accorded special consideration. In Decision IX/12 of the ninth meeting of the Conference of the Parties to the CBD, a clause was adopted requiring special consideration for '[g]enetic resources within the remit of the FAO Commission on Genetic Resources for Food and Agriculture' in addition to genetic resources for food and agriculture covered by the ITPGRFA and animal genetic resources. See also background study papers, available at www.fao.org/nr/cgrfa/cgrfa-back/en/?no_cache=1.

the Protocol. Anyway, to the extent multilateral systems such as the MLS exist, parties thereto can exempt genetic resources covered by such systems from the ABS requirements of the CBD and its NP.

4 COMPLIANCE WITH ABS MEASURES

The Protocol contains extensive provisions on ensuring compliance (Articles 14-17 NP). These provisions provide major innovations which include, inter alia, the establishment of an ABS Clearing-House (CH) and the duty to ensure compliance by users.

The ABS CH is established under Article 14 NP as a mechanism for collection and provision of information about laws, access permits, model contracts, monitoring policies and codes of practice relevant to ABS for potential users of genetic resources and traditional knowledge associated with genetic resources.⁴⁴ The ABS CH will now also be an important source of any relevant information for the newly established committee on compliance.⁴⁵

Until the Protocol, only a meagre number of countries had measures for compliance with providers' ABS measures for example, Norway, Sweden, Belgium and Denmark in Europe.⁴⁶ Although European states other than Norway have

generally limited themselves until now to recital 27 of the Directive 98/44/EC of the European Union and of the Council of 6 July 1998 on the legal protection of biotechnology inventions, which requires users of genetic material to disclose its origin if known,⁴⁷ more serious measures are expected to emerge with the implementation of the NP.⁴⁸

The duty to ensure compliance is anchored in Articles 15 and 16 on compliance with domestic legislation or regulatory requirements on ABS for both genetic resources and traditional knowledge associated with genetic resources, respectively. It is flanked by obligations to monitor under Article 17 and to provide institutional assistance in relation to breaches of MAT under Article 18. It is unclear why utilisation of traditional knowledge is not covered by Article 17 on monitoring whilst the utilisation of both genetic resources and traditional knowledge is covered by Articles 15 and 16 on compliance with domestic legislation and regulatory requirements.⁴⁹

As for the agencies responsible for ensuring compliance and monitoring, the Protocol only requires that user states must designate them. In contrast to earlier drafts which had envisaged a list of checkpoints such as research institutions, patent offices and regulatory agencies, the Protocol does not specify the kind of checkpoints. Thus, states have discretion as to what agency they nominate for this purpose.

With regard to the stages of utilisation of genetic resources which shall be monitored, the Protocol is very comprehensive requiring that 'relevant information at, inter alia, any stage of research, development, innovation, pre-commercialisation or commercialisation' should be collected (Article 17 (1) (a) (iv)). The use of the term 'should', however, leaves

⁴⁴ For the kind of information that Parties should or may make available to the ABS CH see Greiber et al., note 8 above, Table 5 (156f.).

⁴⁵ See Annex IV of the advance unedited version of the combined decisions of COP 11, available at <http://www.cbd.int/cop/cop-11/doc/2012-10-24-advanced-unedited-cop-11-decisions-en.pdf>.

⁴⁶ Norway offers the best example of compliance measures up-to-date. The Nature Diversity Act 2009 sets out conditions for import of genetic material from other countries under section 60 to ensure that Norwegian users comply with national regulations in provider countries. They are obliged to disclose the country of origin and/or the country from where the material is collected and to follow the PIC conditions of the provider country and MAT. It also foresees the possibility for the Norwegian State enforcing the conditions of access by bringing legal action on behalf of those that set them.

⁴⁷ Evanson Chege Kamau, 'Disclosure Requirement – A Critical Appraisal', in Kamau and Winter eds, note 7 above, at 403 ff.

⁴⁸ For national and regional implementation processes see Jorge Cabrera Medaglia, Frederic Perron-Welch and Olivier Rukundo, *Overview of National and Regional Measures on Access to Genetic Resources and Benefit-Sharing. Challenges and Opportunities in Implementing the Nagoya Protocol* (Montreal: CISDL, 2nd edn July 2012).

⁴⁹ Cf. Nagoya Protocol, note 1 above, Articles 15, 16 and 17.

discretion for user states to identify strategic points. The mandatory disclosure requirement at the stage of patenting of inventions from genetic resources, which had widely been discussed in the run-up to COP 10, was not included in the Protocol.

The kind of information that shall be collected for monitoring is also rather broad. It includes 'relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilisation of genetic resources, as appropriate' (Article 17 (1) (a) (i)). According to the chapeau of Article 17 (1) each Party 'shall take measures, as appropriate, to monitor and to enhance transparency about the utilisation of genetic resources'. This means that not only information about the source and whether it was obtained with PIC and MAT is covered but also, with a view to enhance transparency, information about the utilisation of the genetic resource. Once more, however, the binding force is weakened by the repeated insertion of the words 'as appropriate'.

In relation to documents accepted as proof of compliance, the Protocol refers to the provider state permit and an internationally recognised certificate of compliance, the contours of which are only partially outlined. More resolutions among the Contracting Parties will be required to make it functional.

The main problem however is the scope of user obligations for which the user state shall ensure compliance and the measures the user state shall take to this effect. The Protocol envisages two kinds of measures: authoritative enforcement as assumed in Article 15 (2), and the availability of recourse in case of disputes about MATs (Article 18 (2)).

The reading advocated by EU negotiators,⁵⁰ and also by the IUCN explanatory guide,⁵¹ is that

⁵⁰ Matthias Buck and Clare Hamilton, 'The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Resources' 20/1 *Review of European Community and International Environmental Law* 47 (2011).

⁵¹ See Greiber et al., note 8 above, at 163.

authoritative enforcement is only obligatory in relation to whether PIC was obtained for access to genetic resources and MAT concluded. Cases where the utilisation of an accessed genetic resource is against permit or contractual conditions are regarded to fall in the scope of Article 18. Article 15 does not apply to these cases because, as it is alleged, the clause '...', as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party' in Article 15 (1) refers to the general legislation/regulation but not to the specific conditions in the concrete case. This is indicated by the comma before the cited clause. The narrow reading also excludes from enforcement such cases in which a user does not fulfil benefit-sharing obligations that may be required by the provider state legislation, the reason being that Article 15 only speaks of the utilisation of genetic resources which is defined as research and development, but not benefit sharing.

It is submitted that a more extensive understanding is also possible. This stems from an observation on some embarrassing effects of the ruling opinion: assuming that the monitoring state authority is informed that a user did obtain a provider state permit but clearly performed commercial R&D though the permit only allows non-commercial R&D, shall it really stick to confirming that the access utilisation was in compliance with the PIC requirement and disregard the blunt violation of the permit? Assuming further that the user in this case has obtained various non-monetary or monetary benefits from the utilisation but never shared any of those with the provider state though the permit so required, shall the user state authority still confirm compliance and ignore the breach of law? Should the user state authority not have to order the user to comply with the provider state law and the permit issued on its basis?

As an intermediate solution, it could be suggested that in such cases the user state authority should at least be obliged to inform the provider state of the case. Such obligation could be based on Article 17 (1) (a) (iii). But this offers little help because the enforcement powers of the provider state do not reach into the jurisdictional realm of the user state.

Legal arguments for extending user state enforcement to breaches of permit conditions related to utilisations and of legal requirements concerning benefit sharing include the following:

- The above cited clause ‘as required ...’ can also be understood to refer to the individual permit whenever the provider state legislation requires that the permit shall specify the permissible utilisation, and it can be understood to refer to any precise benefit-sharing requirement established by the same legislation or regulation.
- It would be illogical to extend monitoring to the utilisation of genetic resources but refuse to draw consequences from that information.
- Article 15 (1) when stating that ‘each Party shall take (...) measures to provide that genetic resources utilised within its jurisdiction have been accessed in accordance with prior informed consent’, can be understood to mean that genetic resources utilised in breach of permit conditions were not accessed ‘in accordance with prior informed consent’.
- The duty to ensure compliance with the benefit-sharing obligation can already be derived from Article 5 NP. Article 5 NP refers to Article 15 (7) CBD, which clearly addresses an obligation to ensure benefit sharing both to the provider and user state. Article 5 (3) NP, reading ‘To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate’, can be understood as asking for enforcement measures by the user state.

5 MULTILATERALISM

While ABS is largely conceived as a bilateral undertaking between provider and user states, there are various reasons for more multilateral

concepts.⁵² Regional pools of certain genetic resources and traditional knowledge may emerge because the genetic resource or traditional knowledge is indigenous to more than one state. Networks of *ex situ* collections exist that exchange biological material among themselves and with researchers fostering taxonomic research, but excluding commercialisation and, in consequence, the regulation of benefit sharing. Worldwide pools of certain genetic resources or traditional knowledge – such as the multilateral system of the ITPGRFA – may evolve because the genetic resource or traditional knowledge is felt to be a common good of mankind which must jointly be improved and at the same time be designed to share any monetary and non-monetary benefits with states of primary origin. Taxonomic and genomics data bases exist and spring up in rich variety. Many of them allow for free feeding-in of and free access to data as they consider themselves to be in the public domain. It is also possible to imagine pooling of benefits from intellectual property rights on inventions that are based on genetic resources and traditional knowledge. Article 13 (d) (ii) of the ITPGRFA is exemplary in this regard in that it requires users of the material of the MLS to share monetary benefits if they make a product from it but do not make the product available, and commercialise it.⁵³

The Protocol gives leeway for such endeavours at various points. It encourages cooperation between Parties and communities where genetic resources and/or traditional knowledge associated with genetic resources are transboundary (Article 11). Multilateral systems on a global scale are furthered by Article 10

⁵² See Gerd Winter, ‘Towards Common Pools of Genetic Resources – Improving the Effectiveness and Justice of ABS’, in Kamau and Winter eds, note 7 above, at 19. For a comprehensive analysis of existing pools and their relations with the ABS regime see Kamau and Winter eds, note 32 above. See also the contributions in Michael Halewood, Isabel López Noriega and Selim Louafi eds, *Crop Genetic Resources as a Global Commons. Challenges in International Law and Governance* (London: Routledge, 2013).

⁵³ For case studies of the most characteristic types of common pools and suggestions on how existing pools can be developed further to cope with the requirements of the CBD and the NP and how certain provisions of these conventions can be opened up for commons approaches, see Kamau and Winter eds, note 32 above.

which deals with genetic resources and traditional knowledge occurring in transboundary situations or for which PIC cannot be granted or obtained. The latter clause indicates that a multilateral instrument could also cover genetic resources or traditional knowledge that was obtained prior to the entry into force of the CBD, for instance for *ex situ* collections, an objective which was strongly supported by the African group at the negotiations leading to the NP.⁵⁴

Article 10 could however also be used to pursue the more radical idea of introducing a biodiversity tax on any product that was developed from genetic resources. Such tax would liberate the entire R&D process from many transaction costs and bureaucratic hurdles involved with bilateralism.⁵⁵

Our own suggestion is that the next step towards multilateralism should not depart from legal interpretations of the relevant articles (such as Articles 4, 10 and 11) but rather strive for a framework convention which enables and supports a whole range of common pools of genetic resources and data bases as they actually exist and could be further developed towards integrating the basic principles of ABS.⁵⁶

54 How Article 10 should be construed and operationalised was a subject of discussions in the second meeting of the Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol (ICNP-2) the recommendations of which were adopted by COP 11 in Hyderabad, India (8-19 October 2012) and included in Annex I of Decision XI/1. See <http://www.cbd.int/cop/cop-11/doc/2012-10-24-advanced-unedited-cop-11-decisions-en.pdf>. In the decision, COP 11 decided to reconvene the ICNP for a third meeting to address outstanding issues, in preparation for the first meeting of the Conference of the Parties serving as the Meeting of the Parties (COP-MOP), including, inter alia, the question of the need for and modalities of a global multilateral benefit-sharing mechanism. It also requested the Executive Secretary of the CBD to conduct a broad consultation on this issue in line with which an online discussion was convened through the ABS Clearing-House from 8 April to 25 May 2013.

55 On the advantages and drawbacks of this approach see Joseph H. Vogel, 'From the "Tragedy of the Commons" to the "Tragedy of the Commonplace": Analysis and Synthesis Through the Lens of Economic Theory', in Charles R. McManis ed., *Biodiversity and the Law: Intellectual Property, Biotechnology and Traditional Knowledge* 115 (London: Earthscan, 2007).

56 See further Gerd Winter, 'Common Pools of Genetic Resources and Related Traditional and Modern Knowledge', in Kamau and Winter eds, note 32 above, at 21-23.

6

SUGGESTIONS FOR NATIONAL TRANSPOSITION: THE CASE OF THE EU COMMISSION PROPOSAL FOR AN ABS REGULATION

When transposing the Protocol, states and other actors will have to decide whether to take the provisions in a range between maximum and minimum standards. We propose the establishment of regimes based on reason rather than slavishly copying the provisions. Provider states, for instance, may decide not to make use of the full set of rights granted by the Protocol, while user states may, in an effort to build trust, choose to go further than required to ensure benefit sharing.⁵⁷

In the following section, we will take a closer look at the transposition practices of states that are mainly users of genetic resources and take the upcoming European Union (EU) legislation as an exemplary case.

According to normal EU procedures, the legislative process is initiated by a proposal elaborated by the Commission which is submitted to the European Parliament and the Council. The relevant proposal was submitted on 4 October 2012 as Commission Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, and published as document COM(2012) 576 (the Proposal).⁵⁸ The Proposal is among the first attempts to transform the NP into the law of Contracting Parties and should as such be welcomed. It contains many useful tools, but could also be improved in several aspects. In the following section the content of the Proposal is summarised and evaluated.

57 For further suggestions see Kamau, Fedder and Winter, note 21 above.

58 'Proposal for Regulation of the European Parliament and of Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union', 4 October 2012, COM(2012) 56, available at http://ec.europa.eu/environment/biodiversity/international/abs/pdf/PROPOSAL_FOR_A_REGULATION_EN.pdf.

6.1 Summary of the Proposal

The core of the Proposal is the establishment of a due diligence obligation requiring users to ascertain that genetic resources and traditional knowledge associated with genetic resources have been accessed in conformity with the law of the provider state and that benefits are shared upon mutually agreed terms (Article 4 (1)). In more detail, the obligation comprehends the seeking and keeping of information on the date and place of access, the description of the genetic resources or traditional knowledge, including available unique identifiers, the source of the genetic resources and traditional knowledge, subsequent users of the genetic resources and traditional knowledge, and the general and any specific or unclear legal framework of access (Article 4 (2)). In addition to seeking and keeping information, due diligence includes the duty to effectively obtain a permit and establish mutually agreed terms if required by provider state legislation.

The information obtained under Article 4 (2) must be transferred to subsequent users of the genetic resources or traditional knowledge (Article 4 (1)).

Member States (MS) must establish one or more competent authorities to supervise the due diligence obligation (Article 6). Two methods of supervision are provided:

- The duty of users to declare the exercise of due diligence to the authority. The declaration must be made at the stage of receiving public research funding, market approval or commercialisation if market approval is not required (Article 7).
- The duty of competent authorities to carry out checks to verify compliance of users with the due diligence duty and the duty to declare (Article 9 (1)). In case shortcomings have been detected, the competent authority shall issue a notice of remedial action or take other measures including the suspension of specific use activities, seizure of illegally acquired genetic resources, and fines (Articles 9 (7) & (11)). The information collected from the checks shall be kept in records and is

available to the public according to the Directive on Access to Information (Article 10). The MS shall exchange information on serious shortcomings detected and penalties imposed with the competent authorities of other MS and with the Commission (Article 12 (2)).

The Proposal establishes three ways of alleviating the burden of supervisory activities:

- Concerning genetic resources (but not traditional knowledge), an internationally recognised certificate of compliance is evidence that the genetic resources was accessed in compliance with the provider state law (Article 9 (5)).
- Concerning genetic resources and traditional knowledge the implementation of best practice by a user reduces his/her 'risk of non-compliance' (Article 9 (2)).
- Concerning genetic resources and traditional knowledge accessed from a collection having the status of a trusted collection, users shall be considered to have exercised due diligence as regards the seeking of relevant information (Article 4 (4)).

Best practice of procedures, tools and oversight can be developed by associations of users and can be recognised by the Commission. Collections can also be registered by the Commission as 'Union trusted collection' if they supply samples to third persons with documentation that the genetic resources and related information were accessed in accordance with legal requirements, keep records of supplies to third persons, use unique identifiers for samples supplied to third persons and use tracking and monitoring tools for exchanging samples with other collections (Article 5 (3)).

While most of the monitoring is in the competence of the MS, the EU level also has an important role to play. It intervenes in the following ways: It requires MS to designate competent authorities and notify the Commission accordingly (Article 6 (1)); to transmit biannual reports to the Commission on the declarations received (Article 7 (3)); to notify the

Commission of their rules on penalties (Article 11); and to exchange information on serious shortcomings detected through checks with the Commission (Article 12 (2)). The Commission itself shall establish a register of trusted collections (Article 5 (1)), make public the list of competent authorities (Article 6 (2)), designate an EU focal point (Article 6 (3)), request recipients of EU research grants to declare due diligence (Article 7 (1)), summarise information on due diligence declarations and make it available to the ABS Clearing House (Article 7 (3)), recognise, list and disapprove best practices (Article 8), in due course compile a report on the functioning and effectiveness of the Regulation and report to the Conference of the Parties to the NP (Article 16 (3)). The Commission may adopt implementing acts in relation to the design of Union trusted collections, declaration of user compliance, the requirements of best practices, and the checking of compliance (Articles 5 (6), 7 (4), 8 (7), 9 (8), and 15).

While the Draft Regulation concentrates on the obligations of the user side it leaves the regulation of access to genetic resources and traditional knowledge situated within the EU to the MS. However, it establishes a Union platform serving to streamline access conditions by providing non-binding guidance and opinions.

Both the MS and the Commission have general duties especially in relation to academic researchers and small and medium enterprises (SMEs) to make the obligations under the Regulation known and understood by stakeholders, support the development of codes of conduct and model contractual clauses, support the development of communication tools in support of monitoring and tracking the use of genetic resources and traditional knowledge by collections and users, and provide technical guidance to users (Article 14).

Concerning the temporal scope, the compliance regime applies to those genetic resources and traditional knowledge which were accessed after the entry into force of the NP for the Union and benefits arising from their use (Article 2). The core provisions – those on due diligence (Article 4), monitoring (Article 7) and compliance checks (Article 9) – shall apply one year after entry into force of the Regulation. This means that the grace period extends

beyond the date of entry into force of the NP for the Union if the Regulation enters into force after that date.

6.2 Assessment

As the summary of its provisions shows, the Proposal offers a comprehensive and careful approach to ensure compliance with the NP and implementing provider state legislation. Some critical comments can nevertheless be made, some asking for going beyond the minimal requirements of the NP in a mood contributing to further trust-building with provider states, others arguing that the minimum was not met.⁵⁹

(1) We submit that the objectives of the Proposal as laid out in the preamble are one-sidedly orientated towards enabling economic uses (see especially the 2nd consideration). Research on genetic resources and traditional knowledge as mostly practised is, however, primarily concerned with understanding biological and cultural diversity and aimed at enhancing the public domain, often with the final goal of protecting their conservation or innate dynamics. This kind of research is much more than the commercially orientated research, willing to share resulting benefits, which by nature are non-monetary, with providers and invite providers to participate in the research activities. The Regulation should mention this objective and potential in a separate preamble consideration.

(2) The Proposal does not make clear in what respect MS may go further by taking additional measures. They have a right to do that but only if the measures

⁵⁹ One aspect is more of internal significance for the EU but shall nevertheless be indicated for its indirect implications for provider states: The Commission Proposal is very incommunicative concerning its legal basis and the choice of legal form. One would have expected that the pros and cons of harmonisation by the EU or, alternatively, of competence of the Member States are more openly discussed. Leaving the regulatory competence to the MS would, for instance, enable MS to compete in relation to provider states by offering best conditions of compliance control. This would certainly serve the goals of the NP. Given the economic bias of the Proposal (see above (1)) it is also doubtful if the competence basis for environmental policy (Article 192 TFEU) is appropriate. The Proposal should have given more thought on how an ABS system can serve environmental protection in order to better justify this basis.

taken are more environmentally protective (Article 193, Treaty on the Functioning of the European Union (TFEU)). Does this entail that a MS may introduce more stringent supervisory measures on R&D within its jurisdiction, for instance by checking if the utilisation complies with the permit conditions?

(3) The temporal scope of the envisaged user compliance regime unfairly disadvantages provider states. It is true that the compliance obligations of user states as laid out by the NP will only be binding after entry into force of the NP as such and for a given Contracting Party. The NP however does not rule on the temporal scope of the genetic resources and traditional knowledge and their uses which are subject to the compliance regime. As outlined above it is suggested that the regime should be applicable to all genetic resources and traditional knowledge obtained after the entry into force of the CBD.

(4) The Proposal is focussed on ensuring that the access is in order. It takes care that the user has obtained a permit and established MATs for the access. It also supports the generation of information about the R&D chain throughout which the sample is utilised. The thrust therefore is to assist provider states in implementing their PIC requirement and tracking compliance with permit and MAT conditions down the R&D chain. The Proposal does not however contain a self-standing obligation of MS to supervise whether the utilisation of genetic resources and traditional knowledge complies with the terms of permits and contracts, and in particular, whether the utilisation is kept within the permitted boundaries and whether accruing benefits are shared. As outlined above this is according to the ruling opinion consistent with Articles 15-18 NP, but against the more general promises contained in Articles 5-7 NP. The EU would contribute to trust building if the Regulation went further.⁶⁰

(5) The Proposal must be commended that it extends the due diligence obligation to PIC concerning traditional knowledge (Article 4 (1)), although, as outlined above, Article 17 (1) NP does not command this. However, as far as PIC of ILCs are concerned

the Proposal only requests due diligence insofar as PIC was introduced by provider state national legislation or regulation. This is true not only for access to traditional knowledge but also for access to genetic resources as such. Although this once again corresponds to the wording of Article 16 (1) NP, it disregards the fact that even without national legislation, a PIC requirement may result from the customary law of indigenous and local communities. To observe such customary law is a stand alone obligation resulting from Articles 6 (2), 7 and 12. Therefore, Article 4 (1) of the Proposal should not be interpreted to set this aside.

(6) The Proposal lays an obligation on the user to observe due diligence. It is unclear whether this implies an obligation of result or of procedure. Article 4 (2) (a) (c), stating that users shall obtain proper access permits, speaks in favour of an obligation of result, meaning that, if no permit was obtained, the authority can take appropriate remedial or punishing measures. However, the wording in Article 4 (1) ('due diligence to ascertain') indicates that the obligation is one of procedure, meaning that if the authority finds that in the same case no permit was obtained the authority must nevertheless accept this if the user 'duly' tried but failed to find out what the legal requirements were. In that case the authority cannot order the user to remedy the situation, because this would not be a situation of infringement of Article 4 as required for remedial powers under Article 9 (7). The authority is not even obliged or empowered to pass the information over to the provider state authority, because the information exchange on 'serious shortcomings detected through checks' is confined to authorities of MS and the Commission (Article 12 (2)). This ambiguity should be removed. The NP requires the Contracting Parties to unequivocally establish obligations of result of users.

(7) While it is commendable that users have a declaration duty at the stage of commercialisation (Article 7 (2)), it is unclear what exactly it means to declare 'that they exercised due diligence'. It should not be sufficient that they just posit this by checking a box on a form. Rather, they should have to submit the permit and MAT or other documents. In addition, a provision should be introduced allowing MS authorities to forward this information to

⁶⁰ This view has recently also been forwarded by the European Economic and Social Committee, see its Opinion in OJ C 161, 6 June 2013, 73, sec. 3.8 – 3.10.

provider states if the authority detects an infringement. This would be required by the cooperation duty laid down in Articles 15 (3) and 16 (3) NP. Article 12 of the Proposal appears to be insufficient in this respect.

(8) Collections of genetic resources which do not acquire genetic resources from a country of origin but receive them from other users are not subject to the ABS regime of the NP. They should however seek to ensure that the user who accessed the genetic resources did so, especially by respecting the requirements of the provider state from which the genetic resources were first accessed. They need to do this if they themselves shall be made providers requiring PIC and MAT (Article 5 (1) NP). But they should do that even without such perspective in order to attain the role of trustees of genetic resources entrusted with the care for a fair sharing of benefits between providers and users. The Proposal goes only a small step in that direction. One would have wished that it took a bolder step by making the rules expounded in Article 5 (3) obligatory for all collections.

(9) The scope of users obliged to declare due diligence before accessing genetic resources or traditional knowledge should be broadened. The Proposal only involves users funded from public sources (Article 7 (1)). This should be extended to users receiving private funds, be it funds from private research foundations or from private enterprises and private research organisations.

(10) Concerning EU funded research, the Commission, although tasked with requesting due diligence (Article 7 (1)), is not obliged to further check compliance (cf Article 9 (1)). This should be corrected, most suitably by a separate EU Regulation.

(11) The Proposal largely fails to address the problem of data flow. First, more care should be taken to ensure that a sample can be traced through the often very intertwined R&D process, including data bases. Secondly, just as collections of materials, data bases must also adapt their practices to ABS requirements.⁶¹

The category of a Union trusted data base should be considered as a first step.

7 CONCLUSIONS

Considering how deep the controversy between resource rich and industrialised states was about an equitable sharing of benefits from genetic resources and traditional knowledge, the NP brought with it some major achievements. More precise and binding rules were agreed concerning the definition of core terms, the instruments and modalities of access regulation, the right to and kinds of benefits, the rights of local and indigenous communities, the facilitation of access for non-commercial research to pathogens and to genetic resources for food and agriculture, the obligation to ensure compliance supported by monitoring, the enhancement of capacity building, joint ventures and technology transfer, and the establishment of an ABS Clearing House. While there are concerns that the bilateral approach taken by the Protocol may lead to disappointments on the side of resource-rich states, the Protocol itself does provide for the possibility to seek multilateral solutions, which may include common pools, as alternatives. However, two serious flaws have remained: The temporal scope of the new regime was not clarified, and the provisions on compliance are not strict enough and thus may protract mistrust of providers. The article discusses the recent Proposal of the EU Commission as a test case in this regard.

⁶¹ See further Gerd Winter, 'Knowledge Commons, Intellectual Property and the ABS Regime, in Kamau and Winter eds, note 32 above, at 185-301.

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