19 Points to consider for national legislation on access to genetic resources and benefit sharing

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Introduction

Although there is currently a global trend of states to introduce ABS regimes, states should be aware that their sovereign rights over their GR[1] enable them to not do this (Greiber et al., 2012, 96). States are only obliged – as user states – to establish compliance control.[2]

States which host potentially highly valuable GR would rather opt in favour of an ABS regime. States poor in such resources should weigh the possibly modest benefit expectation against the transaction costs of an ABS regime, which include PIC and contracting procedures, administrative oversight of GR and TK utilization, costs of enforcing contracts in foreign jurisdictions, etc. They might consider desisting from introducing an ABS regime at all, or confine it to a limited list of GR, the compilation of which may be delegated to a competent body.[3] Another reason to desist from an ABS regime can be that a state regards its free access as a service for the global community or that it considers receiving sufficient benefits from the participation in common pools that exchange, study, and develop genetic resources. This attitude explains why only very few industrialised states have introduced ABS regimes after 1993. The exceptions, such as Australia (Burton, 2009), should reconsider this.

National legislation on ABS should draw a distinction between rules for access to and utilization of domestic GR and TK on the one hand and rules on the utilization of imported GR and TK on the other. As outlined, states have discretion whether to introduce the first, while if adhering to the NP they are obliged to introduce the second. In the following, we assume that a state wishes to introduce rules in both regards. This would suggest an overall structure of the law as follows:

I General Provisions
II Access to and Utilization of domestic GR and TK
III Utilization of imported GR and TK

1 Art. 15 (1) CBD. States have however an obligation to establish some kind of ABS regime concerning the TK of their indigenous and local communities, see Art. 8 (j) CBD.
2 Arts. 15–19 NP.
3 This is the solution adopted by the Norwegian Nature Diversity Act, section 57, and the Swiss Bundesgesetz über den Natur- und Heimatschutz, as amended on 21 March 2014, section 23q.

We will now discuss these three parts in more detail.

I. General provisions

1. Objectives

The first article of the law will contain the primary objectives of the law. These will be access control and assurance of benefit sharing, with a view to use the benefits for the conservation and sustainable use of biological resources.

2. Legal status of genetic resources and traditional knowledge

It is recommended that the national law clearly determine the legal status of genetic resources and traditional knowledge. In some countries this will already be decided by the constitution, but even then some kind of specification on the level of legislative act may be necessary.

The law should use the notion of property in order to facilitate legal action recovering damage to that property by illegal access and utilization. The damage could then be calculated in analogy to damage recovered by holders of IPRs (Godt, 2009).

There are three options of determination:

- Private property of the owner of the organism carrying the genetic resource, such as the landowner, owner of *ex situ* collections, etc.,
- Collective property of indigenous or local communities or property of individuals embedded in such communities, and
- State ownership.

We submit that traditional knowledge should be conceived as property either of an indigenous/local community or of an individual belonging to that community subject to the customary rules of the same.[4] The same should apply to landraces[5] cultivated or domesticated by indigenous and local communities. In contrast, genetic resources should in general be regarded as property entrusted to the state as a common good of the entire people.[6] It is true that in some countries genetic resources are deemed to be private property of landowners etc. South Africa appears to be a case in point,[7] but we believe that the property in an

4 On the international law status of property in traditional knowledge see Greiber et al., (2012), 101.

5 For the term see *infra* section 3.

6 Cf. the Norwegian Nature Diversity Act, section 57 1st sentence which reads: "Genetic material obtained from the natural environment is a common resource belonging to Norwegian society as a whole and managed by the state."

7 Cf. the National Environmental Management: Biodiversity Act 2004, section 82, which says that a bioprospector needs to enter into a material transfer and benefit-sharing agreement with "a person" "providing or giving access to the indigenous biological resources to which the application relates."

organism does not automatically include property in the genetic potential of the same. The plant grown by a landowner is a specimen which can be sold and consumed, but its genome reaches beyond the specimen; it is not produced by the landowner but given to him or her and thus is a public good.

3. Definitions

Insofar as the terms used in the law are defined in the CBD and the NP, their definitions should be used. However, some of these definitions lack clarity. The law should then step in and clarify the issue. The following terms should be included and defined in the national law:

- "Biological resources," as defined in Art. 2 CBD, "includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity."
- "Genetic material," as defined in Art. 2 CBD, means "any material of plant, animal, microbial or other origin containing functional units of heredity."
- "Genetic resources," as equally defined in Art. 2 CBD, means "genetic material of actual or potential value."
- "Traditional knowledge" or "associated TK" is defined neither by the CBD nor by the NP. According to Art. 3 EU-Regulation 511/2014 "traditional knowledge associated with genetic resources" means traditional knowledge held by an indigenous or local community that is relevant for the utilization of genetic resources and that is as such described in the mutually agreed terms applying to the utilization of genetic resources." We suggest that the term should be defined without reference to mutually agreed terms, because if TK exclusively is mutually agreed TK, there cannot be illegal access to TK. Moreover, the definition lacks specification of what indigenous and local community means. It is suggested to follow the Brazilian definition which reads: "traditional peoples and communities are culturally differentiated groups, who identify themselves as such, possess their own forms of social organization, occupy and use territories and natural resources as a condition for their cultural, social, religious, ancestral and economic reproduction, using knowledge, innovations and practices that are generated and transmitted through tradition."[8] In addition, the terms "traditional" and "associated" need to be defined. Once more, the Brazilian terminology may be followed, which defines associated TK as "information on individual or collective knowledge or practice associated to the genetic heritage."[9]
- "Access" to GR or associated TK is defined neither by the CBD nor by the NP. According to Regulation 511/2014/EU, access means "the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol." This includes a variety of

8 Decreto 6040/2007 Art. 3 (1).
9 Brazilian Medida Provisoria No. 2.186–16 of August 2001, Art. 7 V.

activities including the taking of samples, the purchase of an organism (such as a seed) on a local market, the recording of traditional knowledge, etc. It does not, however, include a situation where someone acquires a biological resource for consumption but later on decides to apply R&D on its genetic potential. Some authors therefore understand access to mean any R&D on the genetic resource. This would suggest defining "access" to mean not only the acquisition but also the examination of biological resources in their quality as GR. The legislating state will have to take a position on that difference of understandings. We suggest following the first opinion, because the second appears to deny the term access any function apart from the term utilization. The state may, however, insert a provision stating that PIC shall also be required if R&D on GR or TK is initiated to already accessed biological resources (see *infra*).

- "Utilization of genetic resources," as defined in Art. 2 NP, means "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology."
- "Biotechnology," as defined in Art. 2 NP, means "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use," while "derivative" means "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity." In order to distinguish derivatives from compounds that are not biochemical but just chemical (such as crystallised coral reefs or shells), it should be added that "chemicals which were *in situ* separated from the organic cycle of an organism (such as crystallised corals or shells of snakes) are not considered biochemicals."
- According to Art. 6.1 NP, access to GR is only subject to PIC if it is made "for their utilization," i.e. for R&D on the GR or TK. In order to further clarify what is not meant by R&D, the term "consumption of a biological resource" should be introduced. Consumption might be defined as "the direct or processed use as food, feed, construction material, burning, or similar use, but not, however, for medicinal or cosmetic purposes."
- If the law provides for specific protection of plant or animal varieties that were domesticated or cultivated by or within indigenous or local communities, it may be advisable to introduce the term "landraces." "Landraces" may then be defined as "plant or animal varieties that were domesticated or cultivated by or within indigenous or local communities."
- "*Ex situ* conservation" means the conservation of components of biological diversity outside their natural habitats.
- "*In situ* conditions" means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.
- "Sustainable use" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological

diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

- Some state legislation has definitions of "prior informed consent (PIC)," "mutually agreed terms (MAT)," and "material transfer agreement (MTA)," which are the legal forms used in the NP. It is submitted that national legislation should translate them into the corresponding domestic legal forms. These will be a permit with attached conditions and a contract containing the same and/or additional conditions.
- If the law, following Art. 8 (a) NP, provides different access tracks for non-commercial and commercial research, these terms must be defined. "Commercial" is often regarded as a stage in the R&D process aimed at a marketable product or service, "marketable" including through sales or through IPRs yielding royalties. Such R&D is also called "applied." It produces results which have a market value. In contrast, non-commercial is then understood as "basic," i.e. not meant or not yet ready for the market. The problem of this traditional distinction along market value is the fact that today "basic" research not only generates common taxonomic knowledge (such as about the anatomy or living conditions of an organism) but reaches to the genome of the organism. The new situation is that with the ever-expanding biotechnology, even individual genes whose function has been discovered can be marketable. Sequencing the genome is therefore at the same time "basic" and "applied" research. The discovered gene has a market value. The crucial question is therefore not if there is a market value at all but if the market value is intended to be realized. This depends on whether the R&D result is privatised or made public. Privatisation includes keeping it secret, obtaining IPRs and thus establishing exclusive use rights, or manufacturing products the property of which is sold on the market. Privatisation is the precondition for bringing a product to the market and generating a price for it. In contrast, publication means to submit R&D results to the public so that anyone can make use of it at no price (or at a low price which reflects the costs of publication; see further von Kries and Winter, Ch. 3 of this volume). The distinction along privatisation/publication is also in line with the intention behind Art. 8 (a) NP, which is that the sovereign rights of states should not hinder the enhancement of global biological knowledge which is a prerequisite for the conservation of global biodiversity. In the same vein, the UN Convention on the Law of the Sea (UNCLOS) has established the principle of free marine scientific research and the publication of its results (von Kries and Winter, Ch. 4 in this volume).

Based on these reflections, non-commercial research should be defined as "research aimed at making its results publicly available at not more than incremental costs," incremental cost meaning the cost of publication, copying, etc., but excluding remuneration for the cost of producing the research results and for the market value of the research results. Commercial research would then be

"research for proprietary purposes, such as through keeping research results secret, obtaining IPRs, and bringing products and services on the market."

4. Geographical scope of the law

The geographical scope of the ABS regime extends to all organisms found *in situ* or *ex situ* on the territory of the state, including the territorial sea, as well as (if declared) the exclusive economic zone and the continental shelf. It also extends to the associated traditional knowledge of indigenous and local communities living within the territory of the state. In terms of regulatory technique, the geographical scope can be indicated by the term "geographical jurisdiction." The law could read: "The law applies to the GR and associated TK under the geographical jurisdiction of the state. This includes GR found within the territorial sea, the exclusive economic zone, and on the continental shelf of the state."

5. Temporal scope of the law

Provider states have had sovereign rights over their genetic resources and traditional knowledge since the entering into force of the CBD, i.e. December 1993. Since then they have had the possibility of establishing an ABS regime as have done a number of states, but by far not all of them. Those access activities are captured by national laws which were initiated after the entering into force of the same laws, according to their specification of temporal scope. Such specification cannot, however, be retroactive; in other words, it cannot include GR or TK accessed before the date of validity of the law. According to – contested – legal opinion, the law can however extend to new utilizations of GR or TK that were obtained at an earlier date.[10] Of course, proof of that will not be easy so, in realistic terms, we recommend to let the law cover access and benefit sharing concerning only GR and TK accessed after the date of validity of the given law.

6. Material scope of the law

The ABS regime should not be applicable to

- human genetic resources
- the exchange and use of GR and associated TK within and between indigenous and local communities for their own benefit and based on customary practices[11]

10 Kamau, Fedder, and Winter (2010) 255; in contrast, Regulation (EU) 511/2014, Art. 17, makes its regulation of user countries duties applicable only to GR or TK acquired after the entering into force of the Nagoya Protocol, plus one year for new acquisitions.

11 Cf. the Brazilian Medida Provisoria No. 2.186–16 of August 2001, Art. 4. See also Sect. 3 (a) of the Kenyan ABS Regs 2006: exchange ". . . amongst themselves and for their own consumption."

- access to GR or TK for educational purposes at schools and higher education institutions[12]
- crops covered by the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), if they are in the possession of public collections and institutions
- nonprofit exchange of genetic and biochemical resources and the traditional associated knowledge resulting from the traditional practices of indigenous peoples and local communities[13]

The legislating state may exclude further kinds of GR that it deems to be organized in a way that ensures adequate benefit sharing. For instance, exchange systems of cattle breeders may be considered beneficial for the participating countries even without a costly ABS system (Louafi & Schloen, 2013). Given the fact that in the farm animal sector, germplasm flows from the North to the South rather than its inverse, it can even be counterproductive if a southern state introduces ABS requirements for a transfer from its country because the northern partner may do the same and thus put the southern country in a worse position than it was before.

Considering that Art. 15 CBD relates the sovereign rights of states to "their" genetic resources, it could be discussed whether the legislating state should confine the ABS regime to those GR which have their evolutionary origin within its territory. Some countries indeed speak of "indigenous" genetic resources as objects of their access and benefit-sharing regulation.[14] However, given common migrations and multiple genetic influxes, the evolutionary origin of species is often uncertain and diverse. It is therefore not recommended to introduce limitations as to the origin of genetic resources.

One more problem concerns the fact that traditional knowledge is often shared by multiple communities and may also be disseminated to the modern sector (Kleba, 2009). Shared and disseminated knowledge should however not categorically be exempted from the scope of the ABS regime. Rather, in relation to shared knowledge provisions on involving other communities in the PIC procedure could be designed (see *infra* section 15). Concerning disseminated knowledge a distinction could be introduced between TK that can still be traced to a specific community and TK that lost any such connection.

12 Cf. the Kenyan Environmental Management and Co-Ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006, section 3 (d) which exempts "approved research activities intended for educational purposes within recognized Kenyan academic and research institutions. . . ."

13 Formulation borrowed from the Costa Rican law.

14 See, e.g. the South African National Environmental Management: Biodiversity Act section 80, according to which the ABS regime applies to "indigenous biological resources" that are specimens and derivatives of "indigenous species" that are in section 1 defined as "a species that occurs, or has historically occurred, naturally in a free state in nature within the borders of the Republic, but excludes a species that has been introduced in the Republic as a result of human activity."

II. Access to and utilization of genetic resources and associated traditional knowledge

The situation of access is the one of which the provider state has the most effective control. The subsequent stages of the handling of the accessed genetic resources are more difficult to control, especially if the material was shipped to and is utilized in other countries. Access regulation must therefore be the starting point of any provider state legislation. Its provisions will cover the following themes:

- the obligation to obtain prior informed consent
- the competent authority
- the forms of consent
- the preconditions and content of consent
- the application procedure, including the form of applications, and the involvement of other authorities and the public
- special provisions on access to traditional knowledge
- special provisions on access to collections

The provider state should, besides regulating access, also establish self-standing obligations concerning the utilization of genetic resources and traditional knowledge independently of whether access consent was obtained. This has the effect that the obligations under Articles 15–18 NP of user states are reinforced. The appropriate provisions would address topics such as

- duties concerning utilization
- duties concerning benefit sharing
- monitoring
- the legalization of activities violating access conditions
- sanctions

7. *Obligation of researcher/developer to obtain prior informed consent (PIC) for access*

The provision should state that anyone wanting to have access to GR for their utilization (that is, according to Art. 6 NP, research and development on the genetic resource) must obtain the consent of the competent authority. As to access to associated traditional knowledge, the NP does not restrict the PIC requirement to access for utilization. This means that access for other purposes, such as touristic or artistic, could be included into the scope of the law. We are of the opinion, however, that this would extend the scope far beyond the intention of the ABS idea. The broader the scope, the more difficult the supervision of its application would be. We therefore recommend confining the consent requirement to access to TK for utilization.

8. Competent authority

The law should specify what authority is competent to provide the consent. This will normally be an administrative agency, but the competence could also be delegated to other actors such as a university or other trustworthy body.[15]

Besides the authority competent to provide prior consent, a focal point must be designated (which can be identical with the competent authority) that is responsible for informing access seekers about access conditions.[16]

The obligation to obtain PIC should be accompanied by rules on what happens in case of unlawful access. The competent authority should be empowered to issue an enforcement order asking the actor to apply for a permit within a specified term. It should also have the power to stop utilization activities and order the delivery of the material and R&D results, including normal ways of enforcing such orders. Due to the limits of jurisdiction of the provider state, these measures do not, however, have an effect outside its borders. It can nevertheless be provided that the competent authority may send a request to the user state to assist in the prosecution of the order.

9. Form of the access consent

The consent can have the form of an administrative permit or a contract.[17] Permits are administrative acts which in many legal systems imply powers of administrative authorities to enforce them, e.g. by ordering the researcher who does not abide by the permit conditions to act accordingly and, if he/she does not follow suit to impose a fine, stop utilization activities, withdraw the permit, or take other measures.[18] Where administrative agencies have such powers, the permit is more effective than a contract whose enforcement can only be pursued through the courts. The contract is however more effective if the GR or TK is taken to other countries, because contracts can be enforced through foreign courts, while permits are only enforceable within the jurisdiction of the provider state (unless the user state offers administrative enforcement assistance). We therefore suggest that for utilizations of GR and TK within the legislating state, a permit is the best form of consent. If GR or TK shall be transferred to another country, a contract should be concluded in addition or as an alternative to the permit.

15 In Costa Rica, for instance, the National Biodiversity Institute was by contract with the Technical Office (the authority competent for access consents) entrusted with such competence. The institute has signed more than 60 bioprospecting contracts. A similar setting has been introduced in Brazil where the National Council for Scientific and Technological Development was endowed with powers to provide consent with access for non-commercial research (Cabrera Medaglia, 2012, 346 and 340).

16 See Art. 13 NP.

17 It should be noted that PIC does not mean permit. Also, a contract is a form of consent.

18 In other legal systems the authority must involve a court to impose enforcement measures. For a comparison see Macrory (2010) 79 *et seq*.

10. Preconditions and content of the access consent

No matter if a permit or contract is chosen as the form of consent, the law should specify what the minimum preconditions of the consent and the main content of permit conditions or contract clauses shall be.

There are procedural and material preconditions.

As to procedure, the law will provide that an application must be filed and a procedure followed. This will be addressed below.

The application must include information on the project requesting access and triggering benefit sharing. The scope of information will depend on the conditions/clauses to be negotiated.

As to material preconditions, it should be noted that according to the definition of sovereign rights, these are not unlimited. According to Art. 15.2 CBD, the provider state shall "endeavour to create conditions facilitating access," and according to Art. 8 (a) NP this shall at least be done for non-commercial research. This means that the provider state does not have full discretion whether or not to grant consent. Rather it should fix the preconditions and set a framework for the permit conditions and contract clauses. If these requirements are met, the authority should be obliged to grant consent. Such obligation would also serve to enhance legal certainty as postulated by Art. 6.2 NP and be a means to reduce opportunities for bribery. The preconditions could be

- that the access activities do not cause adverse effects to human health or the environment, and that an environmental impact statement is required if there is indication of such adverse effects
- in case of access to traditional knowledge and landraces, that the prior consent of the indigenous or local community was obtained; the law should set certain requirements in this regard such as that customary rules on responsibilities of authorities and common ownership are obeyed, possibly based on community protocols in difficult cases
- if the legislating state so desires, that a foreign researcher or developer may only be granted access if he/she acts in cooperation with an internal researcher/developer; the law may even require that the internal researcher/developer must be the responsible applicant.[19]
- that in case of export of the accessed GR or TK for R&D in foreign countries, a contract must be concluded (rather than only a permit obtained). We suggest that in such cases the consent should only be granted if the user state has appropriate legislation and practices in place implementing the compliance obligations under Art. 15–18 NP.[20]

19 See the Brazilian Medida Provisoria No. 2.186–16 of August 2001 which in Art. 16 para 6 sets out: "The participation of a foreign juridical person in the collection in situ of samples of the genetic patrimonium and in the access to associated traditional knowledge may only be authorized if this is done in combination with a national public institution that is finally responsible for the coordination of the activities and if all involved institutions exercise research and development in biology and related areas." [author's translation]

20 This would also be an incentive for user states to ratify and implement the NP.

As to the permit conditions/contract clauses, the legislating state should set a framework requiring that reasonable agreement should be reached between authority and applicant on the following issues (see further Kamau, Ch. 17 of this volume):

- The geographical site and time frame where and when the sample may be taken or GR/TK may otherwise be acquired.
- The kinds of GR and TK that shall be accessed.
- The allowable research and development: The state must make a decision here whether it aims at predetermining the allowed utilization or opts for free R&D. We suggest that the kinds of R&D (taxonomic, genome sequencing and functional analysis, product development) should not be regulated because otherwise the creative potential of R&D may be lost. Art. 15.2 CBD and Art. 8 (a) NP, which ask for facilitation of access, should be kept in mind in this respect.
- However, determination should indeed be made in relation to whether commercial or only non-commercial R&D shall be allowed, and in the latter case, a new consent must be obtained in case of a change of intention. It should be kept in mind that according to our definition non-commercial/commercial refers to whether the R&D results are put to the public domain or kept private.
- Whether a duplication of the acquired GR or TK shall be sent to a collection to be specified by the law and/or the permit or contract.
- Whether the GR or TK shall be transferable to third parties; it is advisable to require a so called viral clause in that respect, i.e. a condition/clause obliging the applicant to ensure that the third party signs a commitment to bind herself to the same permit conditions or contract clauses.
- Whether the GR or TK may be moved to other countries; as said in this case a contract must be concluded between the provider state authority and the foreign researcher.
- What non-monetary benefits shall accrue to the state. We suggest that the law should ask for participation of domestic personnel in R&D projects and project publications, albeit only as a principle, not as an absolute requirement, because much depends on the character of the project and the availability of domestic experts. The law should require that obligations and terms for reporting on R&D results shall be determined. It should also require that any publication shall indicate the origin of the GR or TK, and that a copy of the publication itself shall be delivered to the provider state.
- How monetary benefits shall be handled. In case of non-commercial R&D, some revenue may nevertheless be obtained by the researcher/developer for the publication of the R&D results. We suggest that this should not be regarded as monetary benefits that must be shared with the provider state. The phrasing of this issue might be such that any incremental revenue from the publication of R&D results shall not be subject to sharing with the provider state. In contrast, if commercial R&D shall be allowed, then the law might require that a formula for benefit sharing shall be agreed upon

in the contract. The formula will be highly dependent on the contribution the GR or TK is anticipated to make to the final product. If the chain of development is short (e.g. if a drug is made from the extraction of a biochemical from an accessed plant), the percentage of participation in the revenue from sales can be higher than if the chain is long involving many steps and many kinds of intellectual inputs and of GR or TK from other countries. The law should also acknowledge the possibility that the contribution of its GR or TK disappears during the development chain (see further below section 18).

- How the interface between the public domain and commercial use of data should be organized. The underlying problem is that information that was published through print media or stored in open access databases may be used for commercial purposes. This is common allowed practice of the public information domain, but such practice does not reflect the fact that some information may be subject to the benefit-sharing right of provider states of the GR from which the data were derived. For instance, information on a gene of an organism from state A, coding for a certain function (e.g. a commercially interest enzyme), may have been put into an open access database. Some user retrieves the information and uses it for the production of a valuable chemical substance which he or she brings on the market. Benefit sharing can be approached in such cases if the provider state law requires as the content of access contracts:

    - a clause obliging the researcher/developer and, through the viral clause, any third party to ensure that any information that is made public must note the origin of the organism on which it informs, and that commercial use of the information is only allowed upon PIC of the provider state

This will allow the tracking of the original organism through the chain of R&D and help the provider state to obtain benefit sharing even under conditions of the public domain. However, this is admittedly a very ambitious requirement. It is becoming common practice with regard to standard agreements on the transfer of material,[21] but necessitates fundamental changes of practices with regard to the transfer of data. This is notably the case for databases. They would need to ensure that the origin of the GR travels with the R&D information they store, and they would need to oblige commercial users to respect the rights of the provider state. And even if the databases were prepared to change their practices accordingly, it would still be very difficult for provider states to discover breaches of the rules. They would need to check what databases host what information belonging to them, what users have retrieved such information for commercial purposes, what products have been developed on that basis, and what revenue was obtained from

21 See, as an example, the standard material transfer agreement used by the Deutsche Sammlung von mikroorganismen und Zellkulturen (DSMZ) (Fritze and Oumard, Ch. 15 of this volume)

the sales of the product. This is almost impossible for normal provider states. It shows that provider states are in a weak position if they agree to the public domain. But the alternative – tight control of the R&D chain – equally requires enormous effort of administrative supervision. Therefore, the better way out is to introduce the said clause into access contracts and trust that the requested change of practice will take place. For the rest, the problem shows that the best strategy of the provider state is to insist that its scientists are involved in the R&D projects so that the state can develop its own R&D capacity.

- Conditions/clauses should be laid down that allow the authority to withdraw the permit or terminate the contract if they are breached.
- How disputes between the competent authority and the applicant shall be settled. According to customary international law, the courts under jurisdiction of the legislating state will be responsible, if the access and utilization happens within the state's realm, no matter if the researcher/developer is a citizen of the provider state or of a foreign state.

11. The application for access consent

As said, the law will provide that an application must be submitted together with the information the competent authority needs in order to assess if and how the access can be admitted. The information to be submitted may include

- coordinates of the applicant institution
- outline of the project (what shall be researched and developed, non-commercial and/or commercial intentions)
- partner institutions and their role in the project
- coordinates of the persons who will perform the access
- location(s) and time frame of access
- modality of access (sample, purchase, etc.)
- in case of access to genetic material: description of what species and about how many specimens shall be accessed
- in case of traditional knowledge: description of its kind and of the community from which it shall be received and an account of steps taken to ensure PIC of the community (customary law, community protocols)
- possible risks of the access for human health or the environment

The authority should be given a fixed timeline for checking the completeness of the application and be empowered to ask the applicant to complete the required information.

After consultation with other responsible agencies (see No. 9), the competent authority should still be entitled to ask for further information if the information does not suffice to assess whether the requirements for granting the consent have been met. It should also be entitled to hold a meeting of stakeholders in controversial cases.

12. Involving other responsible agencies in the consent procedure

The authority should be required to forward the application to other competent authorities for comment and/or approval. It is recommended that a one-stop-shop concept is realized in that regard. Sometimes national legislation requires more permits, such as one for doing research in the country, one (if applicable) for entering a nature reserve, one (if applicable) for doing research in the marine realm, one (if applicable) for entering into and acting within the area of indigenous communities, one (if applicable) for the exportation of the genetic material, one (if applicable) for entering realms of state security, etc. In addition, other agencies may need to be informed about the project and are empowered to intervene if their realm is adversely affected by the project. The access seeker is thus confronted with often lengthy and frustrating procedures in front of many different administrative bodies. A one-stop shop would charge the authority competent for ABS with obtaining consents and comments from the other agencies. The law might even go further and remove one or the other consent requirement considering that the underlying concern can as well be cared for by the ABS authority (Kamau & Winter, 2009: 375). This is, for instance, the case with the general research permit and the marine research permit: as the ABS regime has also to do with research and looks even closer at the planned project, the other permit requirements can be waived. Alternatively, the permit requirement could be transformed into a right of the responsible agency to comment on the ABS application. To the extent that the other permit is based on criteria that substantially differ from those of ABS, the ABS authority could be charged to also apply the other criteria. For instance, the ABS authority could be mandated to also protect indigenous communities, check environmental risks, and even see to security concerns. It is true that some agencies wish to keep their competences, not the least if the fees charged flow into their individual budgets, but the thrust for enabling R&D should have priority over such concerns. In the law, the one-stop-shop concept could be expressed as follows:

> "The competent authority (i.e. the one competent for ABS consent) forwards the application within [. . .] (term to be fixed) after its reception or completion to the authorities responsible for a permit under laws X, Y, Z. These authorities may file their comments within [. . .] (term to be fixed). The competent authority, taking the comments into consideration, assesses if the legal requirements established by the laws X, Y, Z are respected. No additional permit under these laws is required."

13. Involving the public in the consent procedure

The legislating state will have to decide if other private persons or the public at large should be involved in the consent procedure.[22] We suggest that this is not necessary because the ABS regime primarily manages R&D activities which

22 See for an example the Kenyan Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006, section 10, according to which any application for consent must be published and objections can be made to the competent authority.

hardly affect the individual interests of others. Only competing interests of concurrent researchers and developers may make these requests to be informed. But such interest is hardly well founded, because it is legitimate that a researcher or developer initiates his/her project confidentially in order to prevent the research idea from being stolen by someone else before it could be elaborated. However, in any case, a summary of the final decision – the permit and/or contract – should be made public.

14. Involving the landowner in the consent procedure

The consent of the landowner will have to be obtained in those legal systems which consider genetic resources to be the property of the landowner. In the other legal systems, the taking of a sample may be part of common uses of the land. If it is not covered by common use rights, the consent of the landowner is necessary, but only for entering the land and taking the specimen, not for the utilization of the genetic resource.

It is open to question if the ABS legislation needs to deal with the landowners' rights at all. These rights are ruled by civil law. Their enforcement could be left to legal interaction between the access seeker and the landowner.

Alternatively, the ABS law could at least provide that the landowner is informed about the application for access consent. It could also make the consent of the landowner a precondition of the authority's consent,[23] although this appears to us to be too much of a public intervention into civil law relationships.

15. Special provisions on access to associated traditional knowledge

If the legislating state acknowledges (as we suggested above sub No. 2) that the indigenous or local communities and/or individuals of the communities shall be *sui generis* proprietors of their traditional knowledge and their landraces, the provision of consent to the proprietors could be left to them. The law would then just lay down the condition that such consent must be obtained. However, considering the possibly weak capacity of indigenous and local communities to negotiate with well-equipped researchers and developers, the provider state should put in place some kind of supervision to establish if the consent was obtained under fair conditions. Therefore, various legal systems have established that the state must give its consent to the consent of holders of associated TK and landraces.[24]

In addition, special preconditions of the consent of holders of TK or landraces should be laid down. Often, it will not be easy to identify them. Customary law of local authority structures will have to be consulted, which should be made

23 Such is the regulation in South Africa, see National Environmental Management: Biodiversity Act 2004, section 82 para. (2). The competent authority must even approve the agreements.

24 See the South African National Environmental Management: Biodiversity Act section 82; the also the Brazilian Medida Provisoria No. 2.186–16 of August 2001, Art. 12 and Art. 8 § 1°.

obligatory by the law. The researcher or developer, when applying for an access permit or contract, should be asked to explain what steps were taken in identifying and negotiating with the competent local authority. The law should also specify minimum points that any access permit or agreement should contain. These may include those provisions suggested above (No. 10) for the normal access permit and agreement but could be complemented by more specialised points, including e.g.

- that certain non-monetary benefits shall be agreed upon, such as the involvement of locals in the collection and R&D activities
- the naming of the holder of the TK or landrace in any publication on it
- transfer of adapted R&D technologies to the indigenous or local community
- lump-sum payments
- special reporting obligations
- obligations to explain R&D results
- free use of information and products based on the TK or landrace

Special provision is necessary for TK or landraces that are shared by several indigenous/local communities or by several individuals (such as herbalists) from several communities. We suggest that there is no other way than to let the communities or individuals decide this question themselves. The law might however set certain criteria for these cases, including ancestry in generating the knowledge or landrace, input into its further development, involvement in the planned R&D, etc.

Finally the law should also deal with the problem of disseminated TK and landraces. This is, once more, difficult to solve. The law should accept that widely disseminated TK or landraces are outside the scope of the TK/landraces regime, but that this does not apply if TK/landraces can be traced to identifiable communities and the utilization of TK/landraces is against the intention of the communities or individuals who allow the dissemination take place.

16. Special provisions on access to collections of genetic resources

States are provider states not only concerning genetic resources they possess in *in situ* conditions, but also insofar they possess GR in *ex situ* collections. The GR can be indigenous or acquired from other states. In the latter case, the GR must have been obtained in accordance with requirements set by provider states after entering into force of the CBD.[25] The legislating state can decide to regulate access to and utilization of genetic resources held in collections. It may require prior consent of the competent authority, like in the case of access to *in situ* genetic resources. Alternatively, in order not to hinder the exchange of biological

25 Cf. Art. 6.1 NP.

material, the state may desist from a PIC requirement and set rules that the collections must observe by themselves, such as that a material transfer agreement must be concluded with the access seeker restricting any R&D on the genetic resource to non-commercial purposes and requiring prior consent of the host state in case of change of intent to commercial uses. It is also possible to establish a self-standing obligation to that effect which is applicable even if no agreement was signed. Such an example can be found in Norway.[26]

17. Certificate of compliance

According to Art. 17 paragraphs 2–4 NP "a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-Sharing Clearing-House, shall constitute an internationally recognized certificate of compliance," which serves as evidence that the provider state requirements were fulfilled. In implementing this provision, the ABS law should contain an article providing that the permit does have the quality of such a certificate. If – as in the case of commercial R&D – an access contract had to be agreed upon, the permit should be amended by a statement declaring that such contract was indeed concluded. If the permit is replaced by a contract, a separate formal statement should be handed out containing the information listed in Art. 17.4 NP, i.e. the issuing authority, date of issuance, the provider, identifier of the certificate, addressee of the consent, genetic resource or TK covered, confirmation that a contract was concluded and prior consent obtained, and the commercial or non-commercial intention of the planned R&D. The law should also provide that the certificate must be forwarded to the Access and Benefit-Sharing Clearing-House.

18. Obligations concerning utilization and benefit sharing

As said above (sub II), the provider state should, besides requiring PIC for access, also establish self-standing obligations concerning the utilization and the commercialisation of genetic resources and traditional knowledge independently of whether access consent was obtained or not. This has the effect that a researcher or developer who utilizes or commercialises GR or TK without prior consent, or does this disrespecting permit conditions or contract clauses, acts in violation of the law of the provider state. If the R&D is performed in the provider state, such

26 See Nature Diversity Act section 59 paras. 3–5 which read: "Any person that receives genetic material derived from a public collection shall refrain, in Norway or abroad, from claiming intellectual property rights or other rights to the material that would limit use of the material, such as use for food or agriculture, unless the material has been modified in a way that results in a substantial change. If intellectual property rights over genetic material are established contrary to the third paragraph, the competent authorities under the Act shall consider taking measures, including bringing legal action, to ensure promotion of the objective set out in section 57."

"Any person may invoke conditions under the third paragraph, or other conditions that have been set for collection, against any person that, contrary to such conditions, seeks to enforce an intellectual property right."

violation can trigger remedial action by the competent authority. If the R&D is performed in another state, this state must take measures beyond mere control in case access requirements of the provider state were observed. The user state must then also ensure that the utilization and generation of benefits are compliant with the material obligations set by the provider state legislation.

The first material obligation should be that no utilization of GR or TK accessed in the provider state shall be allowed without prior consent of the competent authority, and that if consent was obtained, any utilization must be performed in accordance with the conditions and clauses of ABS permits and contracts.

Another obligation should concern the generation and sharing of benefits. This could be phrased such that any monetary benefit from IPRs on GR or TK accessed in the provider country shall be shared with the same or, in case of associated TK and landraces, with the pertinent indigenous of local community. The precise amount of the share should be the one agreed in a permit or contract. If the commercialisation was not allowed or not determined in that way, the law should fix a certain percentage of the revenue from royalties or sales.

The law should also address the possibility that the contribution of the provider state's GR or TK disappears during the chain of R&D. In that case the final product cannot anymore be regarded to as "arising from" the GR or TK, as Art. 5.1 and 5.5 NP postulate. For instance, a bioinformatics project may compare genes of organism A with genes of organism B in order to identify functions of those of B. The gene of B and its functions are then used for product development, not that of A. It is true that in very abstract terms the gene of organism A has also contributed to the product, but this appears as very artificial. Another pathway of disappearance of the contribution of the original GR or TK would be that the functional trait taken from the original GR or TK is not anymore identifiable as a distinct feature of the final product. A third pathway would be time related: products arising from an original GR or TK should be freed from monetary benefit sharing after expiry of a certain time. The CBD/NP regime failed to fix such a term, but provider states should fill the gap as an implication of the principle that benefit sharing should be fair and equitable. In analogy to the timelines of patent and copyright laws, 30 years might be considered as a fair solution.

19. Monitoring and sanctions

The competent authority should also be mandated to conduct administrative oversight of activities involving access to GR or TK, R&D, publications, IPRs, and the marketing of products based on GR or TK. Such monitoring, of course, is a very demanding task which the law may facilitate by allowing the authority to take action at random or upon notice from other agencies or persons. In order to perform, the authority should be empowered to ask for information, enter premises, and study files. It should also be entitled to issue cease and desist orders and withdraw the permit in case of breaches of permit conditions. It should be mandated to go to court in case of breaches of access contracts.

III. Utilization of imported GR and TK and benefit sharing

If the legislating state is party to the Nagoya Protocol, it bears obligations under Articles 15–18 NP with regard to imported GR and TK. In that regard, the legislating state is acting as the state in whose realm the utilization of GR and TK takes place, hence as a user state. Its legislation as a user state supports the ABS regime of the provider state. As the provider state will have difficulties in monitoring whether its ABS requirements are observed by researchers and developers in the user state, the latter is called to establish its own supervisory regime.

20. Obligations and administrative checking concerning access, utilization, and benefit generation on GR and TK

Articles 15–18 NP ask the user state to ensure that for R&D on imported GR or TK conducted within its jurisdiction, prior informed consent of the provider state was obtained. There are different options how to implement this. We suggest six of them in an order of increasing intervention:

1 The researcher and developer are obliged to exercise (and are supervised to have exercised) due diligence by obtaining prior consent for access of the provider state; due diligence means, *inter alia*, that if the legal requirements of the provider state are unclear and the researcher diligently tried to find them out, that he/she is regarded to have complied even if according to thorough analysis prior consent was required. This solution was introduced in the EU.[27]
2 The researcher and developer is obliged to obtain (and is supervised to have obtained) prior consent for access to GR and TK if required by the provider state. This means that the user state must in effect ensure that consent was obtained. This solution was adopted by Norway.[28]
3 The researcher and developer is obliged to apply (and supervised to apply) due diligence to obtain prior consent of the provider state and, when conducting research and development, to comply with any permit and contract conditions if this is required by provider state regulation. This solution was adopted by the EU.[29] It is unclear if Articles 15–18 NP actually require

27 See Regulation (EU) 511/2014 which reads: "Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilize have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, [. . .]".

28 See Nature Diversity Act Art. 60 para. 1 which reads: "The import for utilization in Norway of genetic material from a state that requires consent for collection or export of such material may only take place in accordance with such consent. The person that has control of the material is bound by the conditions that have been set for consent. The state may enforce the conditions by bringing legal action on behalf of the person that set them."

29 See Art. 4.2 Regulation (EU) 511/2014 which reads: "Genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilized in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements." Concerning administrative supervision see Art. 9.4 (b): "The checks referred to in paragraph 1 of this Article may include an examination of:

(a) [. . .]; (b) documentation and records that demonstrate the exercise of due diligence in accordance with Article 4 in relation to specific use activities;" [Emphasis added.]

going that far. Art. 15.1 and 16.1 only require that the GR and TK was accessed in accordance with provider state rules, not that it is also utilized in accordance with such rules and the permit and contract conditions, but the monitoring duties under Art. 17.1 NP[30] appear to extend to the utilization. It is true, though, that according to Art. 18.2 NP dispute resolution must be available concerning mutually agreed terms. But this need not be read to exclude unilateral enforcement action of the user state if due to the ignorance of the provider state no bilateral dispute has emerged.

4 The researcher and developer is obliged to obtain (and supervised to obtain) prior consent of the provider state and, when conducting research and development, to comply with any permit and contract conditions if this is required by the provider state regulation. This would once more be an obligation in effect. Whether it is prescribed by the NP is subject to the same reasoning as above at (4). This solution was introduced by Norway.[31]

5 Those who draw monetary benefits from GR and TK are obliged to exercise (and are supervised to exercise) due diligence to share the benefits with the provider state upon mutually agreed terms. This solution was introduced in the EU.[32] The NP however does not require contracting states to adopt it.[33]

6 Those who draw monetary benefits from GR and TK are obliged to share (and are supervised to share) the benefits with the provider state upon mutually agreed terms. The Norwegian law has adopted this variant, or could be understood to that effect.[34] Concerning the NP, the considerations under (5) apply.

The ruling interpretation of Art. 6 NP is that the NP only requires a checking by user states if utilized GR and TK was accessed in accordance with provider state

30 Art. 17.1 (a) reads in (i): „Designated checkpoints would collect or receive, as appropriate, 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 utilization of genetic resources, as appropriate;", and in (iv): "Check points must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization." Why should check points "be relevant to the utilization" if not by ensuring its compliance with provider state requirements?

31 See Art. 60 para. 1 Norwegian Nature Diversity Act.

32 See Regulation (EU) 511/2014 Art. 7.2 which reads:" At the stage of final development of a product developed via the utilization of genetic resources or traditional knowledge associated with such resources, users shall declare to the competent authorities referred to in Article 6(1) that they have fulfilled the obligations under Article 4 [. . .]". Article 4.1 reads: "Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilize have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements." Genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilized in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements." [Emphasis added.]

33 For a critique of this reticence see Kamau, Fedder, and Winter (2010).

34 See Art. 60 para. 1 Nature Diversity Act, cited above Fn.

requirements (above nos. (1) and (2).[35] No matter what the correct understanding of the NP is, the user state is free to go beyond a minimal reading. For provider states which export more than import GR and TK, it is wise to go beyond and thus demonstrate what they would also expect from user states. Hence, following the Norwegian example, the basic provision might be formulated, for example, as follows:

1 The import into [. . .] (legislating state) of genetic resources and associated traditional knowledge from a state that requires consent for access to such material may only take place if such consent was obtained.
2 The person that utilizes or commercialises the genetic resource or associated traditional knowledge imported from a state that requires consent for access is bound by the conditions that have been set for consent.
3 The person importing genetic resources or associated traditional knowledge for utilization from a state that requires consent for access shall inform the competent authority accordingly and submit the documents containing the consent of the provider state.
4 The person bringing a product based on a genetic resource or associated traditional knowledge imported from a state that requires consent for access to the market or derives monetary benefits from them in other ways (such as through royalties in IPRs) shall inform the competent authority accordingly and submit the documents containing the consent of the provider state.
5 The competent authority shall carry out checks to verify whether persons utilising or commercialising genetic resources or associated traditional knowledge imported from a state that requires consent for access comply with the conditions set for consent.
6 The competent authority shall serve compliance orders in cases of noncompliance. It shall inform the provider state of cases of alleged significant noncompliance and cooperate with it in taking appropriate measures.

21. Trusted collections

Collections that receive, store, and transfer genetic resources will also be subject to the rules set out under No. 15 above. This means that they need to comply with the ABS regime of provider states if they import genetic resources or receive genetic resources that were imported by other persons. However, the legislating state may wish to desist from supervising collections if they can be trusted to comply by themselves. This presupposes that trusted collections must fulfil certain requirements for being recognised as such. The EU operates such a system.[36] Such collection must demonstrate its capacity to

35 See e.g. Greiber et al. (2012), 163.
36 See Regulation (EU) 511/2014, Art. 5.

- accept samples only with documentation evidencing that they were accessed in compliance with provider state requirements and can be forwarded in compliance with any consent conditions
- ensure that genetic material is stored with documentation of the provider state where it was acquired
- supply genetic resources and related information to third persons only in compliance with any conditions set by the provider state consent, such as, for instance, that only non-commercial utilization shall be allowed.

22. Sanctions

Finally the law will need to lay down rules on penalties applicable to the more serious infringements which were not cured by enforcement orders or which are to be considered severe.

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