

Access or Utilisation – What Triggers User Obligations?

A Comment on the Draft Proposal
of the European Commission on
the Implementation of the Nagoya Protocol
on Access and Benefit Sharing

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Foreword

The main incentive for developing countries to engage in the negotiation of 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 Protocol) was their common understanding that biopiracy, or the misappropriation of genetic resources (GRs) and associated traditional knowledge (TK), could not be successfully fought without the engagement of both provider and user countries. Indeed, many incidences of biopiracy have demonstrated that the best Access and Benefit Sharing (ABS) legal provisions in provider countries are insufficient to ensure compliance with ABS obligations. To effectively fight biopiracy, complimentary legislation in user countries is essential, because if left unpunished, the illegal access and utilization of GRs and TK will continue. In exchange for the user countries' commitment to fight biopiracy, provider countries agreed to facilitate access to GRs in their home countries.

The Nagoya Protocol was developed by member states to the Convention on Biological Diversity (CBD) with the objective of remedying biopiracy. However, after seven years of negotiations, some the most contentious issues remained unresolved and instead of compromise language, the text of the Protocol contains significant gaps allowing for flexible interpretation. It is now up to the ratifying countries, through the enactment of implementing legislation or other forms of regulatory frameworks, to provide clarity on these ambiguous provisions and ensure that the objectives of the Protocol are met.

With this comment, we analyse if the proposed European Commission (EC) Regulation to implement the Nagoya Protocol in the European Union will be able to fulfill its task: ensuring compliance with the ABS laws of provider countries and effectively setting the ground for the fair and equitable distribution of benefits arising from the utilisation of GRs and associated TK. In this regard we focus on a crucial issue, commonly referred to as the temporal scope of the Nagoya Protocol, which relates to two key intertwined questions:

- a) What triggers the users' obligations under ABS law – a new physical access of GRs and TK whether in the country of origin or from an ex-situ source, a new utilisation of such resources, or both?
- b) When do such user obligations become compulsory – post ratification of the Nagoya Protocol in user countries? In provider countries? Both? Or post ratification of the CBD?

Our investigation has shown that in the draft EC Regulation, the rules set out would only apply to GR and associated TK physically accessed after the entry into force of the Nagoya Protocol. This implementation would be in a sharp contrast to existing ABS laws in provider countries where the utilisation of GR and TK also triggers the obligation to share benefits. This difference in interpretation of the Nagoya Protocol and subsequent national implementation is likely to have very serious consequences. First, a significant share of GRs and associated TK used in the EU will not be covered by the Regulations, thereby undermining the spirit of the Nagoya Protocol. Second, individual users of GRs and TK will not be able to receive what they always wanted: legal certainty. In many cases, the utilisation of GR and TK will be legal under EU law, but illegal under the law of the provider country. Although the user has received an approval from European authorities, he or she could be prosecuted in a provider country upon setting foot in that country. Nobody is interested in such scenario.

We therefore urge the EU-Parliament, the Council and the Commission to enact a regulation that is line with the objective of the Nagoya Protocol and ensures that all utilisation that takes place after the Nagoya Protocol comes into force complies with the ABS rules of provider countries. This will build trust between user and provider countries, create legal certainty, and contribute to the conservation and sustainable use of biodiversity.

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Executive Summary

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 Protocol) is a landmark instrument that sets forth important obligations for its signatories. However, the Nagoya Protocol, which has not yet entered into force, does not specify when access and benefit sharing (ABS) obligations are triggered. Once the Nagoya Protocol enters into force, it remains unclear whether ABS obligations are triggered by the *utilisation* of genetic resources (GRs) and traditional knowledge (TK), or only when GRs or TK are newly *accessed*.

This question, often referred to as the question of temporal scope, is of key importance. GRs and TK have already been and are currently being accessed on a large scale. It is entirely possible to *access* GRs and TK prior to the entry into force of the Nagoya Protocol, but for the *use* of these same GRs and TK to take place after the treaty has entered into force. Thus, if the position is taken that access of GRs or TK is what triggers ABS obligations, on-going or new *utilisation* of resources that have been accessed prior to the Nagoya Protocol's entering into force and are now outside their natural habitat would be excluded from the scope of national or regional regulations implementing the Nagoya Protocol. In such cases, a large number of GRs found in local markets, international trade fairs, private collections and gene banks or botanical gardens would be freely usable, without triggering any ABS obligations after the Nagoya Protocol comes into force.

The current European Commission (EC) draft on implementing the Nagoya Protocol within the Union takes the position that access is what triggers ABS obligations, and limits the obligations of users of GRs to uses of resources that have been accessed in provider countries *after* the Nagoya Protocol has been ratified by both the EU and the country of origin. The draft provides that it is the moment of access that triggers compliance requirements for European users. This position contrasts with a majority of ABS systems in place in provider countries, under which any new use of GRs triggers ABS obligations.

The inconsistency between the EC proposal and the majority of existing national ABS systems raises a number of concerns:

- First, under the draft EC proposal, all utilisation of GRs and TK accessed prior to the entry into force of the Nagoya Protocol for the Union will be deemed to be legal irrespective of conflicting provisions of the CBD, the Nagoya Protocol or national laws of providing countries, calling for the fair and equitable sharing of benefits arising from the utilisation of GRs and associated TK. Thus the objective of the Nagoya Protocol, the fair and equitable sharing of benefits arising from the utilization of GRs and associated TK, will not be fulfilled. Article 5 on Fair and Equitable Benefit-sharing, as well as Article 15 on Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing will not be implemented in line with the objective.
- Second, it will lead to greater legal uncertainty for European users of GRs, who may be in compliance with EU laws, but in breach of the ABS laws of the provider country for failing to negotiate prior informed consent (PIC) for access to GRs that took place before, but use that takes place after the Nagoya Protocol comes into force for the Union.
- Third, at the time of access, downstream use is uncertain. It is difficult for countries providing GRs to control their use, including for commercial purposes, once they have left the country. As a result, the EC proposal would encourage provider countries to impose very restrictive ABS procedures since they may not be able to enforce the renegotiation of PIC and mutually agreed terms (MAT) for new uses of their GRs once access has been granted. This reaction, in turn, would raise concerns among the scientific community as well as private companies using GRs, rightly fearing that research would become increasingly regulated and burdensome, thereby potentially undermining one of the other key objectives of the Nagoya Protocol, which aims to facilitate research.

¹ This opinion piece was written by Johanna von Braun, staff member at Natural Justice (www.naturaljustice.org), Alice Bisiaux, associate at Natural Justice and François Meienberg from the Berne Declaration (www.evb.ch). For further questions, please contact Johanna@naturaljustice.org or francois.meienberg@evb.ch.

This paper first provides an overview of the question of sharing benefits from new and continuing uses of GRs and TK accessed prior to the entry into force of the Nagoya Protocol. Second, it reviews ABS regimes in both provider and user countries, examining in particular if the user obligations are triggered by the access or the utilization of the GRs. The third section describes the draft EC proposal on the implementation of the Nagoya Protocol, focusing on the provisions that define what triggers ABS obligations. The last section outlines the implications that are likely to arise from the inconsistency between the existing ABS regimes reviewed and the Draft EC proposal.

In sum, it is our strong belief that the current lack of consistency among different jurisdictions in relation to what triggers ABS obligations is likely to increase confusion with respect to European users. The latter may well find themselves in compliance with EU law but in conflict with the laws of the provider country. In order to increase legal certainty for European users and truly reflect the nature of bioprospecting supply chains while maintaining the spirit of the Nagoya Protocol, we urge European legislators to apply the EU ABS regulations not only to access, but also to on-going or new forms of utilisation taking place after the entry into force of the Nagoya Protocol.

1. Introduction

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 Diversity² (Nagoya Protocol) fails to provide full clarity on whether user obligations to share benefits and corresponding compliance measures are triggered by the utilisation of genetic resources (GRs) and traditional knowledge (TK) or only takes place in cases where GRs or TK are accessed after the coming into force of the Nagoya Protocol (even if the utilisation takes place after the coming into force of the Protocol).³

This question is of critical importance. If the implementing laws and regulations by Parties to the Nagoya Protocol will not apply to the utilisation of GRs and TK accessed before its entry into force, even when their use is newly initiated or on-going, a wide range of activities will be left outside its scope, thereby undermining its objective to fairly and equitably share benefits arising from their utilisation.

It is now up to the signatories of the Protocol to shed some light on this ambiguity through the instruments they enact for its implementation. Many provider countries, who argued for the application of the Nagoya Protocol to GRs accessed before its entrance into force, have enacted ABS provisions that define “access” as including not only physical access to GRs in the first instance, but also the utilisation of such GRs whether they have been accessed in situ or ex situ. In these definitions, the trigger for the application of national ABS obligations is not only the moment of physical access of such resources, but also the new use of resources that are already outside their natural environment, whether in local markets, international trade fairs, private collections and gene banks, or botanical gardens.

In contrast, the current European Commission (EC) draft on implementing the Nagoya Protocol within the Union limits the obligations of users of GRs to uses of resources that have been accessed in provider countries after the Nagoya Protocol has been ratified by

both the EU and the country of origin. According to the draft, it is the moment of access that triggers compliance requirements for European users, thereby limiting the application of the Protocol to utilisation based on new physical access in the provider Party carried out after its entry into force. If this provision is passed, millions of compounds currently available in botanical gardens, gene banks, private and other forms of collections outside the country of origin, originally accessed legally or illegally (but prior to the entry into force of the Nagoya Protocol), would be freely usable, without triggering any ABS obligations after the Nagoya Protocol comes into force in the Union. This would not only undermine the principles of the Protocol in relation to the fair and equitable sharing of benefits, but also the spirit in which the Nagoya Protocol was adopted in 2010 and the objective and balance of the Convention on Biological Diversity (CBD) as a whole.

1.1 Introduction to Temporal Scope

The question whether the Nagoya Protocol would apply to GRs and associated TK that were accessed before its entry into force was one of the most contentious issues in the negotiations leading to its adoption.⁴ Most developing countries supported such an approach, bearing in mind the vast quantities of GRs that were originally accessed in their territories but are now in the possession of botanical gardens, gene banks, and private collections or are available through commodity retailers outside their borders. Developed countries, on the other hand, opposed such an application, arguing that international law cannot be applied retroactively and that the Nagoya Protocol can only apply to GRs and associated TK accessed after the Protocol comes into force.⁵ As no compromise language was reached during the negotiations, the Nagoya Protocol remains silent on the issue of temporal scope, leaving it up to member States to clarify this ambiguity through their implementing legislation.

² <http://www.cbd.int/abs/text/>

³ See Earth Negotiations Bulletin, Vol. 9, N° 544, *Summary of the 10th Conference of the Parties to the Convention on Biological Diversity*, 1 November 2010, at: <http://www.iisd.ca/vol09/enb09544e.html>

⁴ This issue was addressed during negotiations, but the compromise package adopted included no mention of the temporal scope of the Protocol, despite the fact that the African Group argued that there is a moral obligation to share benefits arising from continuing uses of material accessed before the Protocol's entry into force, and the Protocol should “encourage” such benefit-sharing; and there is a legal obligation to share benefits arising from new uses of such material, possibly through a multilateral mechanism. See Earth Negotiations Bulletin, Vol. 9, No. 544, *Summary of the 10th Conference of the Parties to the Convention on Biological Diversity*, 1 November 2010, at: <http://www.iisd.ca/vol09/enb09544e.html>

⁵ Gurdial Singh Nijar (2011) *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysis*, CEBLAW Brief, University of Mayala, Malaysia.

The Vienna Convention on the Law of Treaties provides that a treaty shall not be applied retroactively unless its parties chose to give it that effect.⁶ Since the Nagoya Protocol is silent on this aspect, its retroactive application cannot be expected from member states. However, a related issue remains unsettled: whether new or on-going utilisation of GRs and TK carried out after the implementation of the Nagoya Protocol but accessed before its entry into force would trigger certain obligations under the Protocol.

Article 3 of the Nagoya Protocol on its scope states that *“This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources.”*⁷ Furthermore, according to Article 5(1) of the Protocol: *“In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.”*

Article 5(1) refers to utilisation more generally, without further defining when and where such resources have been originally accessed. Article 5(1) can be interpreted as placing the trigger for sharing benefits on utilisation and not access. The same is true for references to utilisation contained in Article 5(2), which relates to GRs that are held by indigenous and local communities, as well as in Article 5(5), which relates to TK.⁸ According to this reading, a new use would lead to the non-retroactive application of the Protocol, regardless of when physical access took place (i.e., whether it took place before or after the Nagoya Protocol came into force).

A number of legal experts have concluded that while the Nagoya Protocol is silent as to its temporal scope with respect to the utilisation of GRs or associated TK, Article 3 as well as Articles 5(1), 5(2) and 5(5) clearly call for including not only new access to GRs for the purpose of their utilisation after the implementation of the Nagoya Protocol, but also the new and on-going utilisation of GRs and associated TK carried out after the implementation of the Nagoya Protocol.

Gurdial Singh Nijar, a senior practicing lawyer and member of the Malaysian ABS negotiation team, explains that the non-retroactivity principle enshrined in the Vienna Convention on Treaties applies to situations that have ceased to exist, and the Nagoya protocol should not apply to situations that have ceased at the time when it enters into force. However, he argues that the Protocol would apply to situations that have not ceased to exist, for instance when GRs were accessed before its entry into force, but where the situation continues under the new Protocol because the GRs are subject to on-going or new use. Gurdial is of the view that in these cases, the provisions of the Protocol should apply without violating the retroactivity rule in international law.⁹

In a related argument, Veit Koester, a Danish lawyer who headed the Ecological Division of the National Forest and Nature Agency for two decades, writes that *“it is arguable whether the Commission’s interpretation [regarding the non-retroactivity of the Protocol] holds true.”* He specifically questions the fact whether governments who are members of the CBD should be exempt from its obligations until the Nagoya Protocol comes into force. In his view, *“it is hard to explain”* why the commercial utilisation of GRs, for which access was granted only for research purposes prior to the Protocol’s entry into effect, should not be covered by the Protocol given that such obligations already ex-

⁶ See Article 28 on the non-retroactivity of treaties: Unless a different intention appears from the treaty or is otherwise established, its provisions do not bind a party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the treaty with respect to that party.

⁷ Article 15 of the CBD refers to access to GRs.

⁸ Article 5(2) of the Nagoya Protocol: *“Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.”*

Article 5(5) *“Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.”*

⁹ Gurdial Singh Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources:*

An analysis, Ceblaw brief, 2011, Section 2.3.c on the temporal scope of the Protocol.

At: <http://biogov.uclouvain.be/multistakeholder/presentations/Gurdial-Nijar-NagoyaProtocolAnalysis-CEBLAW-Brief.pdf>

isted before. In short, he is of the view that new uses of GRs accessed before the Protocol's entrance into force would be covered by its provisions, especially if such resources were accessed after the CBD was adopted.¹⁰

Finally, a number of users of GRs also argue for such an interpretation. For instance the Union for Ethical Bioproducts (UEBT) recommends to its private sector members the following interpretation:

*"This issue, referred to as 'temporal scope', was not expressly resolved in the Nagoya Protocol. According to international law, provisions of an international instrument are not binding to any act that took place before or any situation that ceased to exist at the date of entry into force of the treaty. New uses of genetic resources entail new instances of access that would thus be covered. New benefits arising from prior or ongoing uses may also be considered as new situations for benefit-sharing requirements – but access requirements would not apply retroactively. Access that has already taken place and benefits that have already been accrued would not be covered by the new requirements."*¹¹

Similarly, the International Plant Exchange Network (IPEN), which was developed by several research projects and initialised by the Association of Botanical Gardens, only allows its members to transfer plant material in compliance with the provisions of the CBD. The "IPEN Code of Conduct for botanic gardens and similar collections"¹² governs the acquisition, maintenance and supply of living plant material. Art. 3(2)(4) of the Code obligates IPEN members to only transfer plant material for commercial use if the potential user has received the prior informed consent (PIC) by the country of origin and can plausibly evidence such con-

sent, no matter when the material originally entered a member's collection. Furthermore, the Code features an article titled "Pre and post CBD material," which provides that: "Botanic gardens are strongly advised to treat all plant material 'as if' acquired after the CBD came into effect and therefore subject to the CBD." (Article 1(3)).

The same is valid for the International Treaty on Plant Genetic Resources for Food and Agriculture. The Standard Material Transfer Agreement regulating ABS is used for all accessions to resources included in the multilateral system of the Treaty, no matter when the resource was accessed in the country of origin. If the Treaty's provisions had only been applied to GR accessed after its entry into force, it would have been emptied of all content.

2. Examples of National ABS Systems

According to the Vienna Convention, one may look to the preparatory work leading up to the adoption of a treaty in order to interpret an ambiguity in that treaty. Thus, to help clarify the definition of the temporal scope of the Nagoya Protocol, one may draw on the preparatory work of this treaty.¹³ This will lead to an examination of national ABS systems currently in place. Indeed, during the negotiations of the Nagoya Protocol Parties recognised the significance of experience with national ABS systems in terms of the reference they set for the negotiation. Often negotiators drew on an analysis of existing legal and other instruments at national, regional and international levels relating to ABS, including access contracts, experiences with their implementation, and compliance and enforcement mechanisms.¹⁴

¹⁰ Veit Koester, *The Nagoya Protocol on ABS: ratification by the EU and its Member States and implementation challenges*, Study No. 03/12 June 2012, (Roskilde University) section 6.3.

At: http://www.iddri.org/Publications/Collections/Analyses/STUDY0312_VK_nagoya%20abs.pdf

¹¹ Nagoya Protocol on Access and Benefit Sharing – Technical Brief (2010) Union for Ethical Bioproducts, page 3, http://www.ethicalbioproducts.org/news/wp-content/uploads/UEBT_ABS_Nagoya_Protocol_TB.pdf

¹³ Vienna convention on the law of treaties, article 32 on the supplementary means of interpretation provides that:

"Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31: (a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable." [Emphasis added]

¹⁴ CBD COP Decision VII/19 at Part D, Annex, para. (a)(i), which provides: "Terms of Reference for the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing"

(a) Process:

(i) To elaborate and negotiate the nature, scope and elements of an international regime on access and benefit-sharing within the framework of the Convention on Biological Diversity, as contained in paragraphs (b), (c) and (d) below, drawing on *inter alia* an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing, including: access contracts; experiences with their implementation; compliance and enforcement mechanisms; and any other options."

2.1 Examples of ABS Systems in Provider Countries:

Since the CBD entered into force in 1993, a significant number of countries have adopted ABS laws. Most of these instruments have been adopted by provider countries and in most cases, it is the use of GRs that triggers the application of the benefit sharing provisions. (A comprehensive list of specific articles in ABS laws can be found in the Annex.) The laws can be classified/grouped as follows:

- a) The definition of access not only includes the physical access to GRs, but also their utilisation, independently from where and when the physical access took place.

Example: Ethiopia

Ethiopia: Proclamation No. 482/2006

Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation:

Art 2 Definitions: In this Proclamation, unless the context requires otherwise:

1/ “access” means the collection, acquisition, transfer or use of genetic resources and/or community knowledge;¹⁵

Example: Andean Community

Andean Community¹⁶: Decision 391 that defines the Common Regime on Access to Genetic Resources for the Andean Community

Art. 1 defines access as the obtaining and use of genetic resources for purposes of research, biological prospecting, conservation, industrial application and commercial use, among others.

Example: Bhutan

The Access and Benefit Sharing Policy¹⁷

Section 6.b: Access to genetic resources means the utilization of genetic resources from Bhutan irrespective of whether they are accessed in situ or ex situ for the purpose of conducting any research and/or development on the genetic and/or biochemical composition of genetic resources including through the application of biotechnology.

Section 6c: Access to traditional knowledge means the utilization of traditional knowledge associated with genetic resources for the purpose of conducting any research and development.

- b) The legal framework is targeted towards the utilisation of GRs, rather than access and benefit sharing.

Example: India¹⁸

The Biological Diversity Act focuses on the activities carried out in relation to the GR, not the access.

Article 3 provides that: *Certain persons not to undertake Biodiversity related activities without approval of National Biodiversity Authority*

3.(1) No person referred to in sub-section (2) shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization.

Example: South Africa¹⁹

The South African national bioprospecting framework does not refer to “access permits” but to bioprospecting permits, whereas bioprospecting is split into a discovery phase and commercial phase, each triggering a different level of obligation. They are defined, respectively, as:

“Discovery phase of a bioprospecting project” means any research on, or development or application of, indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is not sufficiently clear or known to begin the process of commercialisation.

“Commercialisation phase of a bioprospecting project” means any research on, or development or application of, indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is sufficiently established to begin the process of commercialisation.

¹⁵ See: <http://www.cbd.int/doc/measures/abs/msr-abs-et2-en.pdf>

¹⁶ See: Common Regime on Access to Genetic Resources: <http://www.comunidadandina.org/ingles/normativa/d391e.htm>

¹⁷ Still in draft form, but expected to be adopted in Parliament in 2013.

¹⁸ <http://nbaindia.org/content/25/19/2/act.html>

¹⁹ See: Bioprospecting, Access and Benefit Sharing Regulations, 2008, South Africa, Section 1.

“Commercialisation” means a) the filing of a complete intellectual property application, whether in South Africa or elsewhere; b) obtaining or transferring any IPRs or other rights; c) commencing clinical trials and product development, including the conducting of market research and seeking pre-market approval for the sale of resulting products; or d) the multiplication of indigenous biological resources through cultivation, propagation, cloning or other means to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts.

c) The utilisation trigger is recognised through benefit sharing clauses:

Example: Brazil²⁰

Article 24. The benefits arising from the economic use of the product or process developed from samples of genetic heritage components and associated traditional knowledge, obtained by a Brazilian or foreign institution, shall be shared in a fair and equitable manner among the contracting parties, as defined in complementary and relevant legislation.

Article 26. The economic use of a product or process developed from samples of genetic heritage components or from associated traditional knowledge, accessed in a manner contrary to the provisions of this Provisional Act, shall subject the offender to payment of compensation corresponding to at least twenty percent of the gross income obtained in the commercialization of the product or of the royalties obtained from third parties by the offender, as a result of licensing the product or process or use of technology, whether or not they are protected by intellectual property, without prejudice to the administrative sanctions and appropriate penalties.

d) Specific wording within legislation making reference to access and/or utilisation preceding the entrance into force of the national ABS framework

Example: Andean Community

Decision 391 that defines the Common Regime on Access to Genetic Resources of the Andean Community provides, in para.1 of its temporary provisions, that: those who possess, for purposes of access, genetic resources when the Decision enters into force, shall negotiate that access with the Competent National Authority pursuant to the provisions of the Decision, and within a period of two years.

Example: South Africa

Transitional Provisions (Art. 22)

(1) ... any person involved at the commencement of the Regulations in a bioprospecting project, may continue with that project pending the issuing of a bioprospecting permit.

(2) A person involved in a bioprospecting project that has already commenced must, within six months, of these Regulations coming into effect, submit an application for a bioprospecting permit to the Minister in accordance with Chapter 2 of these Regulations.

Example: Panama²¹

Executive Decree No. 25

Art 51: Any holder of a valid permit or contract to access genetic or biological resources at the time of entry into force of this regulation will have to amend their practices and legal instruments in order to abide to the provisions of the present decree within 6 months.

2.2 Examples of ABS Systems in User Countries:

While a number of developing countries are both user and provider of GRs (such as South Africa or India), Norway as a user country stands out as linking its compliance regime to both, import (access) and utilisation:

Example: Norway

Nature Diversity Act²²

Section 60:

The import for utilisation in Norway of genetic material from a state that requires consent for collection or export of such material may only take place in accord-

²⁰ See: Medida Provisoria No. 2.186–16 of 23 August 2001, Brazil.

²¹ See: <http://www.cbd.int/doc/measures/abs/msr-abs-pa5-es.pdf>

²² Nature Diversity Act (2009), Norway, Section 60.

ance 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.

When genetic material from another country is utilised in Norway for research or commercial purposes, it shall be accompanied by information regarding the country from which the genetic material has been received (provider country). If national law in the provider country requires consent for the collection of biological material, it shall be accompanied by information to the effect that such consent has been obtained. [...] Based on the legislative examples listed above and further examples listed in Annex 1, it is clear that utilisation as a trigger point to ABS obligations is common, above all in provider countries. This is especially the case in the most recent pieces of legislation, which were developed as parallel discussions during the Nagoya Protocol negotiations drew further attention to the matter.

3. The Draft EC ABS Regulation

The current EC ABS Draft Regulation²³ takes a different approach than the majority of ABS systems reviewed and described above. Here, the trigger point for user obligations is linked to the point of access.

Art 2 of the current draft states:

This Regulation applies to genetic resources over which states exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union.

“Access” is defined as:

*[...] the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol in accordance with the applicable domestic access and benefit-sharing legislation or regulatory requirements of that Party.*²⁴

The focus on access as the key trigger for user obligations in the EU raises a number of concerns, first and foremost because it effectively means that all access of GRs and TK prior to the entry into force of the Nagoya Protocol for the Union will be deemed to be legal irrespective of:

- a) Article 15 of the CBD, which came into force in 1993 requiring the fair and equitable sharing of benefits arising from the utilisation of GRs;²⁵
- b) The objective of the Nagoya Protocol as well as Articles 5(1), 5(2) and 5(5) calling for fair and equitable sharing of benefits arising from the utilisation of genetic resources; and
- c) The regulatory frameworks already in place in many countries of origin that require PIC and mutually agreed terms (MAT) for utilisation of their GRs and associated TK, regardless of when such GRs and associated TK were accessed.

The current wording could end up legalizing all utilisation of GRs and TK accessed before the entry into force of the Nagoya Protocol – even if the utilisation takes place afterwards. It also raises concerns regarding the obligations of EU members towards GRs and associated TK accessed in countries that are not Parties to the Nagoya Protocol, but who may be Parties to the CBD, or have stand-alone ABS regulations.

Furthermore, from a European perspective, these provisions are likely to lead to a greater inconsistency in relation to trigger points of national ABS systems, thereby increasing legal uncertainty for EU users.

²³ 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 Utilization in the Union, 4 October 2012, available at: http://ec.europa.eu/environment/biodiversity/international/abs/pdf/PROPOSAL_FOR_A_REGULATION_EN.pdf

²⁴ The Swiss law implementing the Nagoya Protocol, an amendment to the Federal Law on the protection of nature and landscape adopted in April 2013, takes a similar view. It provides that:

“Articles 23n and 23o only apply to facts related to an access to genetic resources that occurs after the entrance into force of the said articles” (which outline the ABS obligations of users of GRs).

²⁵ In this respect, Veit Koester notes that the EC’s interpretation appears to be consistent only as far as the relations inter partes are concerned, in accordance with the Vienna Convention on the Law of Treaties. In other words, a Protocol Party may not claim to a non-Protocol Party that is Party to the CBD that the demand for PIC only applies to genetic resources acquired after the entry into force of the Protocol and not to genetic resources acquired after the entry into force of the CBD but prior to the entry into force of the Protocol. See: Veit Koester, *The Nagoya Protocol on ABS: ratification by the EU and its Member States and implementation challenges*, Study No. 03/12 June 2012, (Roskilde University) section 6.3.

At: http://www.iddri.org/Publications/Collections/Analyses/STUDY0312_VK_nagoya%20abs.pdf

4. The Implications of the Draft EU Proposal

4.1 Undermining Legal Certainty

Paragraph 9 of the draft Regulations addresses its temporal scope by stating that:

In order to ensure legal certainty, it is important that the rules implementing the Nagoya Protocol should only apply to genetic resources and traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union.

This paragraph suggests that the current wording regarding temporal scope was a political decision. Likely seeking to provide legal certainty, the drafters of this framework decided to exclude from the scope of the Nagoya Protocol all GRs and TK accessed before its entry into force. The question arises, however, whether the current wording will actually fulfil this aim or whether it will be counterproductive in this regard. Indeed, due to the lack of consistency with an overwhelming body of laws in provider countries in terms of what triggers users' obligations under ABS laws, the draft Regulations would in our view increase legal uncertainty because EU users will have to abide by both the legal framework of the EU, as well as that of the provider country.

The drive towards achieving greater legal certainty in relation to accessing and utilising GRs and TK and sharing the benefits from such utilisation has been one of the strongest engines behind the negotiations leading up to the Nagoya Protocol. Not only providers, but above all users and private sector stakeholders have repeatedly called for the need to develop a framework that increases the legal certainty within which bioprospecting is to take place in the future, and therefore avoiding long mediation processes and public relation scandals. Unfortunately, in spite of the declared intent of increasing legal certainty, by focusing only on access triggers the current wording of the EC draft would actually have the opposite effect, namely increased legal uncertainty.

Under the current draft, a European company may find itself in a situation where the utilisation of a commonly traded resource or medicinal plant for a new bioprospecting lead may be considered legal in the EU, but illegal in the country of origin where such utilisation may have required a permit and an ABS agreement to be in place. While the country of origin may not be able to use the EU compliance regime to press charges, it can still do so within its jurisdiction, which, apart from possible court proceedings, is likely to lead to negative media coverage and other consequences. An example of how criminal charges based on national legal frameworks may be taken forward against a foreign

company is the Indian Monsanto case that is currently unfolding (See Box 1).

4.2 How to reflect the nature of supply chains in the law

An approach with a focus on utilisation would provide greater clarity in terms of the status of material that may have entered the EU through different channels, such as through commodity trade. In these cases, the material is exported without assumption that it will be used for R&D purposes down the supply chain, with no ABS contract negotiated at the moment of access. The EC draft provides no clarity in terms of the obligations of users to demonstrate due diligence in relation to the utilisation of such material, given that the material was not necessarily accessed in the country of origin or for the purpose of utilisation in the sense of the Nagoya Protocol. The EC draft regulations places a large emphasis on regulating ABS at the acquisition phase of GRs/TK, in turn requiring the drafting of relevant contractual arrangements at that moment in time, when a large aspect of its later utilisation remains unknown. In many cases it will be impossible to consider all possible use scenarios at the moment of access before a clearer picture regarding the potential value of the material is available. Nestlé's recent attempt to patent the anti-inflammatory use of Rooibos is an example of such a scenario (see Box 2).

4.3 A disincentive to facilitated access

One of the main incentives for user countries to adopt the Nagoya Protocol was the hope that it would facilitate access to GRs in the Global South where most of the world's biodiversity is found. Facilitated access, however, comes in exchange for user countries to set up a compliance regime that provider countries can rely upon in terms of the appropriate use of any material accessed. Provider countries are likely to make access increasingly difficult if they have no clarity in terms of how the compliance systems of user countries will prevent the utilisation of GRs carried out without MAT. Such would be the case, for example, where the material was accessed before the Nagoya Protocol entered into force, or where its utilisation changes after the material was first accessed and thus is beyond the scope of any contractual arrangements originally negotiated. Given that the EC draft places the large majority of its regulatory burden and user obligations on the moment of physical access and little emphasis on the moment of utilisation of the material, provider countries will likely make their access provisions increasingly onerous, above all in relation to the initial ac-

Box 1: The Monsanto Indian Melon Case – An Example of Legal Uncertainty

The National Biodiversity Authority (NBA) is an autonomous statutory body in India, which has been established under Section 8 of the Biological Diversity Act, 2002 and has been tasked with the implementation of the provisions of the Act.

It was brought to the attention of the NBA by the Berne Declaration that in May 2011 Monsanto was awarded a European patent on conventionally bred melons (EP1962578). Melons have a natural resistance to certain plant viruses. It was known in the case of Cucurbit yellow stunting disorder virus (CYSDV) that certain melons known to occur in nature are resistant to this disease. Using conventional breeding methods, this type of resistance was introduced from an Indian melon (PI313970- registered in the Germplasm Resources Information Network) to other melons and has now been patented by Monsanto. The NBA was also made aware that a patent application on the same invention has been made to the US Patent and Trademark Office (US Patent Application number 20090013435).

DeRuiter, a seed company in the Netherlands, originally developed these new melon varieties. DeRuiter used plants designated PI 313970, a non-sweet melon from India. Monsanto acquired the DeRuiter in 2008 subsequently now owning the European patent and through DeRuiter is the applicant for the US patent.

Section 3 of the Biological Diversity Act requires non-Indian entities (not incorporated or registered in India or having non-Indian participation in its share capital or management) to seek the approval of the NBA prior to obtaining any Indian biological resource for the purposes of research or commercial utilization in accordance with Rule 14 of the Biological Diversity Rules. Section 6 of the Biological Diversity Act 2002 makes it mandatory for any person applying for a patent on any invention based on any research or information on biological resources obtained from India to seek the prior approval of the NBA in accordance with Rule 18 of the Rules.

The actions of Monsanto in using Indian melon varieties to engage in R&D with a commercial intent including application for a patent based on Indian melon varieties amounts to a violation of Section 3 and 6 of the Biological Diversity Act. This is irrespective of whether Monsanto accessed the Indian melon varieties ex-situ. It is not known when De Ruiter acquired these melon varieties from India, but as per the Biodiversity Act, any commercial use of Indian genetic resources that is initiated after the entry force of the Act would require the approval of the NBA.

Section 55 of the Biological Diversity Act makes such violations punishable with imprisonment for a term that may extend to five years or with a fine that may extend to ten lakh rupees. If such violations have occurred through the neglect or consent of any director, manager, secretary or any other officer of a company, then Section 56 of the Biological Diversity Act makes such individuals liable.

The NBA as per the Biological Diversity Act is considering to file a criminal complaint against the Directors of Monsanto for the violation of the Act. The complaint will be filed in the local criminal courts where if a prima facie case of violation of the Act is established, then arrest warrants could be issued against the Directors of Monsanto.

What makes this case relevant for the discussion on temporal scope is that even though Monsanto or DeRuiters may not have violated any laws in Europe since they have accessed Indian melon varieties ex-situ and in the absence of national ABS legislation, it is possible that their chairman or other individuals held responsible will face criminal charges against them in India, a country where they do a significant amount of their business and where they have large amounts of assets.

Source: Interview with Source at NBA

cess contract. Hence, contractual obligations and safety measures and procedures are likely to increase if the EC draft is adopted in its current form.

4.4 Other possible impacts

The European draft regulation may also lead to unfair competition. One could imagine a scenario, for example, where one competitor enjoys access to a certain GR through a (private) collection that may be exempt from EU ABS regulations as the original material was accessed before the Nagoya Protocol was ratified. Others may not enjoy such access and subsequently have

to turn to the country of origin in order to access sufficient quantities of the GR in question in order to engage in R&D. This may lead to a scenario where competing users face very different conditions for utilising the same GR and associated TK. A utilisation trigger would solve this dilemma as both users, whether or not they accessed the material in-situ or ex-situ, would have to follow the respective ABS legislation in the country of origin.

Finally, the European proposal will also pose a significant challenge for enforcing ABS within the EU. The date of acquisition in the country of origin, which

Box 2: The Nestlé Rooibos Case

In May 2010, Nestec, a Nestlé subsidiary, filed five international patent applications for using two endemic South African plants, rooibos and honeybush, or extracts from them (i.e. ‘derivatives’) to treat hair and skin conditions such as acne, wrinkles, hair loss as well as using Rooibos as an anti-inflammatory agent.

The South African Biodiversity Act requires companies to get a bioprospecting permit from the government if they intend to use South African genetic resources for research or patenting or they are exported for that purpose, an obligation Nestlé failed to meet.

Nestlé, having acquired the plants from South African biotradors in Europe, maintained that any claims of misappropriation of genetic resources were baseless since it neither sourced the plants in South Africa nor did research on them there, as that took place in two laboratories in France and Switzerland. The South African biotrader in turn claimed he was not aware of Nestlé’s intention to use the plants for R&D when the material was exported and thus never considered filing for a bioprospecting export permit.

Under the new EC ABS draft regulation such access would fall outside of any user obligations, not only because plenty of Rooibos and Honeybush are already available in the form of tea in European markets, but also because the material was never physically accessed in the country of origin. In South Africa, however, the utilization of the country’s indigenous biological resources for the purpose of bioprospecting, independent of where the material was accessed or the R&D took place, would require a permit.

This example demonstrates how difficult it is for different stakeholders along the supply chain to be aware of what will happen with the material traded along the way. A company is unlikely to communicate to local traders the exact purpose of its demand for raw material due to confidentiality reasons and is thus not inclined to disclose all possible forms of utilization at the moment of access. The trader, in turn, unaware of the intention behind the demand, will not be able to fulfill his obligations for exporting native plants for the purpose of bioprospecting. As the nature of such supply chains are unlikely to change an additional trigger for ABS obligations at the moment of utilization (e.g. engaging in R&D or filing for a patent application) would therefore be much more efficient and reflect the unpredictable nature of trade and utilization of plant genetic material.

Source:

Lessons from the Rooibos Robbery (2010) ICTSD, Bridges Weekly, Vol 14, No. 4, <http://ictsd.org/i/news/bridges/98765/>

is decisive for determining whether or not the GR falls within the scope of the European regulation, is only traceable where access has been legal and documented, e.g. through PIC and MAT or any other appropriate contractual arrangements. Where access has been illegal, no paperwork will exist. The focus on access as the regulatory trigger will subsequently become an incentive for illegal users to claim that the respective material has been accessed pre Nagoya Protocol and is subsequently outside the scope of the framework. It will be impossible to confirm whether such statements are true or not. An access-based system will therefore always be offering loopholes for abuse without an additional trigger based on the utilization of GRs or TK.

5. Conclusion

This paper aims to demonstrate the importance of not placing the principal regulatory burden in relation to ABS on the moment of physical access to GRs and TK, but also to include obligations on the moment of utilising such GRs and TK for the purpose of bioprospecting, research and development. Doing so will likely have the following benefits:

First, in keeping with the spirit of the Nagoya Protocol, it will lead to a fairer and more equitable benefit-sharing regime as it will account for the millions of resources that have already left provider countries but where new uses could trigger new benefits.

Second, it will prevent a misalignment of trigger points and lead to greater policy coherence between European and provider countries' ABS regimes, therefore leading to greater legal certainty of European users when it comes to fulfilling their commitment under both their national laws, as well as that of the provider country.

Third, it will reflect the complex nature of today's supply chains where an increasing amount of research is based on ex-situ sources, and at the moment of physical access most downstream uses remain unknown. Having to draft a contractual relationship between provider and user at the moment of access is likely to not only lead to major loopholes within such agreements but also to very strict conditions being attached to such contracts in order to prevent any loopholes down the line.

Finally, a global ABS system is based on mutual trust between providers and users. If providers feel they have no real oversight over what happens with the material once it leaves their home soil, access conditions will likely become increasingly bureaucratic and burdensome for European users. If, however, Europe's internal compliance regime accounts for changes in utilization within its borders, then provider countries would likely be less fearful and more willing to differentiate between the diverse nature of stakeholders, ranging from commodity traders to botanical gardens to commercial R&D laboratories, seeking access to their GRs and TK.

Annex: The Trigger of User Obligations in Selected ABS Laws and Policies

| Country/Region | Legal Framework | Year of adoption | User obligation trigger | Access | Utilisation | In situ | Ex situ | Specific new use trigger | Entry into force and transitional provisions | Notes |
|------------------|--|---|--|--------|-------------|---------|---------|---|--|---|
| Afghanistan | Environment Act | 2005 | Art. 62.1 on Permitting requirements: “Access to Genetic Resources shall be subject to prior authorisation in the form of an access permit granted by the National Environmental Protection Agency” | Yes | No | Yes | Yes | | 18 December 2005 | |
| Andean Community | Decision 391: Common Regime on Access to Genetic Resources | 1996 | Art 1 defines access as “the obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things.” | Yes | Yes | Yes | Yes | | 7 February 1996 | |
| Australia | Environment Protection and Biodiversity Conservation Amendment Regulations 2005 (No.2) | 2005 | Art. 8A.03 on the meaning of access to biological resources, provides that: “(1) access to biological resources means the taking of biological resources of native species for research and development on any genetic resources, or biochemical compounds, comprising or contained in the biological resources. In the examples of access given, it mentions: collecting living material or analysing and sampling stored material, for various purposes including taxonomic research, other research and potential commercial product development.” | Yes | No | Yes | No | | 1 December 2005 | Australia's legislation currently only includes provider measures. Its in the process of drafting its user measures |
| Bhutan | The Access and Benefit Sharing Policy | 2012 (still in draft form but expected to be approved by Parliament by December 2013) | Section 6.b: “Access to genetic resources means the utilization of genetic resources from Bhutan irrespective of whether they are accessed in situ or ex situ for the purpose of conducting any research and/or development on the genetic and/or biochemical composition of genetic resources including through the application of biotechnology.” Section 6.c: “Access to traditional knowledge means the utilization of traditional knowledge associated with genetic resources for the purpose of conducting any research and development.” | Yes | Yes | Yes | Yes | Yes, indirectly, through Section 8/4.4 on the types of permits required for each use. | | |

| Country/Region | Legal Framework | Year of adoption | User obligation trigger | Access | Utilisation | In situ | Ex situ | Specific new use trigger | Entry into force and transitional provisions | Notes |
|----------------|---|------------------|---|--------|------------------------------------|---------|---------|--------------------------|--|------------------------------------|
| Brazil | Medida Provisoria No. 2.186-16 de 23 de agosto 2001, as clarified by the Genetic Heritage Management Council in their Technical Orientations No 1, 2, 3, 4, 6 and 7; and with the exemptions noted by the Genetic Heritage Management Council in Resolutions No 26, 29 and 21 as amended by Resolutions No 28 and 30. | 2001 | <p>Art. 1 “This Provisional Act provides for assets, rights and obligations concerning: I – Access to components of genetic heritage existing within the Brazilian territory, on the continental shelf and in the exclusive economic zone for purposes of scientific research, technological development or bioprospecting; II – Access to TK associated to genetic heritage, related to the conservation of biological diversity, to the integrity of the country’s genetic heritage and to the use of its components; III – The fair and equitable sharing of the benefits arising from the use of the genetic heritage component and the aTK;”</p> <p>Art. 2 “Access to genetic heritage existing in the country shall only be take place with an authorization from the government and its use, commercialization and employment for any purpose shall be submitted to inspection, restrictions and sharing of benefits in the terms and conditions established in this Provisional Act and its complementary legislation.”</p> <p>Art. 24 “The benefits arising from the economic use of the product or process developed from samples of genetic heritage components and associated traditional knowledge, obtained by a Brazilian or foreign institution, shall be shared in a fair and equitable manner among the contracting parties, as defined in complementary and relevant legislation.”</p> <p>Art. 26 “The economic use of a product or process developed from samples of genetic heritage components or from aTK, accessed in a manner contrary to the provisions of this Provisional Act, shall subject the offender to payment of compensation corresponding to at least twenty percent of the gross income obtained in the commercialization of the product or of the royalties obtained from third parties by the offender, as a result of licensing the product or process or use of technology, whether or not they are protected by intellectual property, without prejudice to the administrative sanctions and appropriate penalties.”</p> | Yes | Indirectly through benefit sharing | Yes | Yes | | 24 August 2001 | The law is currently being revised |

| Country/ Region | Legal Framework | Year of adop- tion | User obligation trigger | Access | Utilisation | In situ | Ex situ | Specific new use trigger | Entry into force and transitional provisions | Notes |
|------------------------------|---|--------------------------|--|--|---|---------|---------|--|--|---|
| Costa Rica | Reglamento sobre las Normas Generales para el Acceso a los Elementos y a los Recursos Genéticos y Bioquímicos de la Biodiversidad, Decreto Ejecutivo No 31.514-MINAE | 2003 | Art 2. Scope – access regulations apply to genetic and biochemical resources and elements of biodiversity, whether in the wild, domesticated, terrestrial or marine, in salt or freshwater, in situ or ex situ within the national territory [...] In the same way, the protection of associated TK and the fair and equitable distribution of the benefits derived from the use of these elements and resources will be regulated. | Yes | Only in relation to resources accessed | Yes | Yes | Indirectly through revocation of permit if conditions of permit are not met (Art. 28) | 15 December 2003 | Three types of permits required – basic research, bioprospecting and economic exploitation |
| Costa Rica | Reglamento para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad en Condiciones ex situ, Decreto Ejecutivo No 33697-MINAE (Regulation on the access to the elements of, and the genetic and biochemical resources of biodiversity (ex situ) | 2007 | Art 7. defines access as activities related to basic research, bioprospecting, or economic activity provides that to apply for the access permit for basic research, bioprospecting, or economic use, to the elements, GR and biochemical resources of biodiversity in ex situ conditions, the interested party or his/her representative will have to properly fill out the forms and documents that are mentioned at Art. 8 and 9 of the Decreto Ejecutivo No 31514-MINAE. | Yes (Art 5. To access the elements and genetic and biochemical resources in any ex situ situation, the obtaining of an access permit by the interested party is required, following the procedure established in this Executive Decree.) | The Model Contract contained in Annex I on the transfer of GRs, Art 2 provides that the provider transfers the GRs to the “interested party” to be used exclusively for the listed purposes, and that it may not be used for a different purpose without written agreement of the provider. | No | Yes | | Article 15 III: the owners of ex situ collections have to register their collections within 10 months of the entrance into force of the regulation. Entered into force: 2007-04-18 | In Annex II to the regulation that contains a Code of Conduct for access to GRs, the parties are to communicate to the national authorities of the successive uses and purposes given to the GRs. |
| Central African Region | Strategy of the Central African Forest Commission (COMIFAC) on access to biological and genetic resources and the fair and equitable sharing of the benefits arising from their utilization | 2010 | Part 5, para d) notes that access to genetic resources can include various steps, including research activities, the promotion of genetic resources, as well as their commercialisation and other uses | Yes | Yes | Yes | Yes | | | The strategy outlines possible elements for the COMIFAC member States to adopt ABS legislation, it is not a binding document. |
| Cuba | Regulaciones sobre la Diversidad Biológica, Resolucion No. 111/96 (Regulations on Biological Diversity) | 1996 | Art. 2 defines access to biological diversity as: the use of biological diversity resources, for scientific or commercial purposes, whether the resources are located in situ or ex situ | Yes | Yes | Yes | Yes | Yes, see Art. 12 that provides that new uses trigger the requirement of new access permits | 28 November 1996 | |

| Country/Region | Legal Framework | Year of adoption | User obligation trigger | Access | Utilisation | In situ | Ex situ | Specific new use trigger | Entry into force and transitional provisions | Notes |
|----------------|--|------------------|--|--------|-------------|---------|---------|---|--|-------|
| Denmark | Greenland Home Rule Parliament Act No. 20 of November 20th 2006 on Commercial and Research-Related Use of Biological Resources | 2006 | <p>Art2. defines the scope of the law as applying to: “all forms of commercial and research-related acquisition, collection, receipt, use and exports of biological resources.”</p> <p>Art 10.1: “Any commercial utilisation of biological resources and survey results from such biological resources shall be subject to prior issue of a commercial licence from the utilisation enterprise.”</p> <p>Art. 6.1 on survey licences, provides that “any acquisition, collection or survey of biological resources in connection with research or with a view to possible subsequent commercial utilisation shall be subject to prior issue of a survey licence.”</p> | Yes | Yes | Yes | Yes | Art6.7: on survey licences provides that “changes in use or application, including changes in collection methods, places or types of biological resources, shall require a new survey licence.” | 01 December 2006 | |
| El Salvador | Ley del Medio Ambiente (Environment Act) | 1998 | Art. 66 on access, protection and use of biological diversity provides that access, research, handling and exploitation of biological diversity can only be carried out through a permit, license or concession. | Yes | Yes | | | | 05 April 1998 | |
| Ethiopia | Proclamation No. 482/2006 – Access to Genetic Resources and Community Knowledge and Community Rights Proclamation | 2006 | <p>Art2.1 “‘access’ means the collection, acquisition, transfer or use of genetic resources and/or community knowledge.”</p> <p>Art. 3 Objectives: “The objective of this Proclamation is to ensure that the country and its communities obtain fair and equitable share from the benefits arising out of the use of genetic resources so as to promote the conservation and sustainable utilization of the country’s biodiversity resources.”</p> | Yes | Yes | Yes | Yes | Yes, see Art35.1.c | <p>Art.33.1 “Access agreements made prior to the coming into force of this Proclamation shall be revised and harmonized with the provisions of this Proclamation.</p> <p>2. The access to genetic resources under agreements concluded prior to the coming into force of this Proclamation shall be suspended until they are revised and harmonized with the provisions of this Proclamation.”</p> <p>27/02/2006</p> | |

| Country/Region | Legal Framework | Year of adoption | User obligation trigger | Access | Utilisation | In situ | Ex situ | Specific new use trigger | Entry into force and transitional provisions | Notes |
|----------------|---|--------------------------------|---|--------|-------------|---------|---------|--|--|--|
| India | The Biodiversity Act | 2002 | Art 3.1: “No person referred to in sub-section (2) shall, without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilization or for bio-survey and bio-utilization.” | Yes | Yes | Yes | Yes | Yes, through what has become common practice in the National Biodiversity Authority in interpreting the Act to how the Act | 5 February 2003 | |
| Kenya | Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations | 2006 | Part 1 Art. 2 “‘access’ means obtaining, possessing and using genetic resources conserved, whether derived products and, where applicable, intangible components, for purposes of research, bioprospecting, conservation, industrial application or commercial use.” | Yes | Yes | | | Art. 15.d (d) “All agreements entered into with respect to access of genetic resources shall be strictly for the purposes for which they were entered into.” And indirectly, through revocation of permit if conditions of permit are not met (Art. 16.1) | 1 December 2006. Part 5: Ongoing utilization at the time of the enforcement of these regulations have to comply within 6 months. | |
| Namibia | Draft Access and Benefit Sharing Bill | Before the Namibian parliament | Section IV a: “Access to genetic resources under this Act means the utilization of genetic resources from Namibia for the purpose of conducting any research and/or development on the genetic and/or biochemical composition of genetic resources including through the application of biotechnology.” | Yes | Yes | Yes | Yes | Yes, indirectly through the revocation of the permit if the GR and/or TK are utilized in a manner that violates the permit (Section VI. 6 and 7) See also Section 13, on penalties. | As of the entry into force of the Access and Benefit Sharing Act | Section VIII.12: additional obligations for users of GRs outside of Namibia: “No person or entity shall utilize in Namibia, genetic resources and/or associated traditional knowledge accessed from other countries without complying with the domestic access and benefit sharing requirements of those countries.” |

| Country/Region | Legal Framework | Year of adoption | User obligation trigger | Access | Utilisation | In situ | Ex situ | Specific new use trigger | Entry into force and transitional provisions | Notes |
|----------------|---|------------------|---|-----------------------------|-------------|---------|---------|---|---|---|
| Norway | Act relating to the management of biological, geological and landscape diversity (Nature Diversity Act) | 2009 | Section 60: “The import for utilisation 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. [...] When genetic material from another country is utilised in Norway for research or commercial purposes, it shall be accompanied by information regarding the country from which the genetic material has been received (provider country). If national law in the provider country requires consent for the collection of biological material, it shall be accompanied by information to the effect that such consent has been obtained.” | Yes (in terms of import) | Yes | Yes | Yes | Indirectly depending on provider country | 19 June 2009 | |
| Panama | Executive Decree No. 25 (Decreto Ejecutivo No 25 de 29 de abril de 2009 que Reglamenta el Artículo 71 de la Ley 41 de 1 Julio de 1998, General de Ambiente) | 2009 | Art. 3 defines access to genetic and or biological resources as “the process that includes the obtaining and use of biological or genetic resources, and or its derivatives, associated with native forest life, in ex situ or in situ conditions, from the prior informed consent of the State or of the owner of the resource, for purposes of basic, scientific, industrial or commercial research.” | Yes | Yes | Yes | Yes | Art 16: Any use that is not foreseen or identified in the original application for access requires the presentation of a new application. | Art51: Any holder of a valid permit or contract to access genetic or biological resources at the time of entry into force of this regulation will have to amend their practices and legal instruments in order to abide to the provisions of the present decree within six months. Entered into force: 2009-10-31 | |
| Philippines | Guidelines for Bioprospecting Activities in the Philippines | 2005 | Section 2.1 Scope “The Guidelines shall apply to bioprospecting activities conducted by any resource user, including government agencies.” Section 5. Definition of bioprospecting: “the research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived therefrom solely from commercial purposes.” | Yes | Yes | Yes | Yes | Indirectly through revocation of permit if conditions of permit are not met (Section 31.1) | 14 January 2005 | Includes bioprospecting fee of USD 3000, later 2 % of total global gross sales to be paid to national government and resource providers |

| Country/Region | Legal Framework | Year of adoption | User obligation trigger | Access | Utilisation | In situ | Ex situ | Specific new use trigger | Entry into force and transitional provisions | Notes |
|----------------|--|------------------|---|--------|-------------|---------|---------|---|---|-------|
| South Africa | National Environmental Management: Biodiversity Act | 2004 | Art. 81 (1) “No person may, without a permit issued in terms of Chapter 7–10 (a) engage in bioprospecting involving any indigenous biological resources; or (b) export from the Republic any indigenous biological resources for the purpose of bioprospecting or any other kind of research.” | Yes | Yes | Yes | Yes | Indirectly through revocation of permit if conditions of permit are not met (Art. 93.b) | As of 1 April 2008 through regulations | |
| South Africa | Regulations on Bio-Prospecting, Access and Benefit-Sharing | 2008 | Art. 4 (1) “discovery phase and/or commercialisation phase of a bioprospecting project may only be carried out with a bioprospecting permit issued by the Minister.” (2) “If the applicant for a bioprospecting permit intends exporting the indigenous biological resources to which the application relates, the applicant must apply to the Minister for an integrated expert and bioprospecting permit.” | Yes | Yes | Yes | Yes | Art. 13.2 An export permit for the export of indigenous biological resources for research purposes other than bioprospecting (f) “must be issued subject to the following conditions: (i) the indigenous biological resources to which the permit relates, may only be used for non-commercial research purposes as specified on the permit; (ii) the indigenous biological resources to which the permit relates may not be used for bioprospecting purposes.” Art.20.b A person is guilty of an offence if that person “performs the activity for which the permit was issued otherwise than in accordance with any conditions subject to which a permit was issued.” | Entrance into force: 1 April 2008 Art. 22.2 Transitional periods. “A person involved in a bioprospecting project that has already commenced must, within six months of these Regulations coming into effect, submit an application for a bioprospecting permit to the Minister in accordance with Chapter 2 of these Regulations.” | |

| Country/Region | Legal Framework | Year of adoption | User obligation trigger | Access | Utilisation | In situ | Ex situ | Specific new use trigger | Entry into force and transitional provisions | Notes |
|----------------|--|--------------------------------------|---|---|---|---------|---------|---|---|-------|
| Sabah | Biodiversity Enactment | 2000 | Art 2. Access defined as “all activities relating to the prospecting, collection, commercial utilisation and research and development of biological resources or associated relevant knowledge.” | Yes | Yes | Yes | Yes | Yes as license may be terminated if against its conditions | | |
| Switzerland | Proposed Amendments to Federal Law on the protection of nature and landscape. Loi fédérale sur la protection de la nature et du paysage. | Currently under Parliamentary Review | Art. 23n Diligence obligations 1. Whomever, in compliance with the Nagoya Protocol, uses genetic resources or draws directly advantages from their use (user) must exercise all the necessary diligence required under the circumstances in order to guarantee: a. that the access to genetic resources occurs legally, and b. that these advantages are shared in a fair and equitable manner. 2. Utilization of genetic resources under paragraph 1 means the research and development activities on the genetic or biochemical composition of the genetic resources, in particular for biotechnological applications. | Yes (see column on transitional provisions) | Yes (see column on transitional provisions) | | | | Art. 25.d Transitional provision: Articles 23.n (on due diligence obligations) and 23.o (on the obligations to notify) only apply to activities related to an access to genetic resources after the entry into force of these articles. | |
| Viet Nam | Biodiversity Law No. 20/2008/QH12 | 2008 | Art 3.29: “Access to genetic resources means activities of investigating and collecting genetic resources for research and development and production of commercial products.” | Yes | Yes | Yes | Yes | Art. 60: 1. “Organizations and individuals licensed for access to genetic resources have the following rights: a) To investigate and collect genetic resources and carry out other activities as indicated in their licenses for access to genetic resources.” | 1 January 2009 | |