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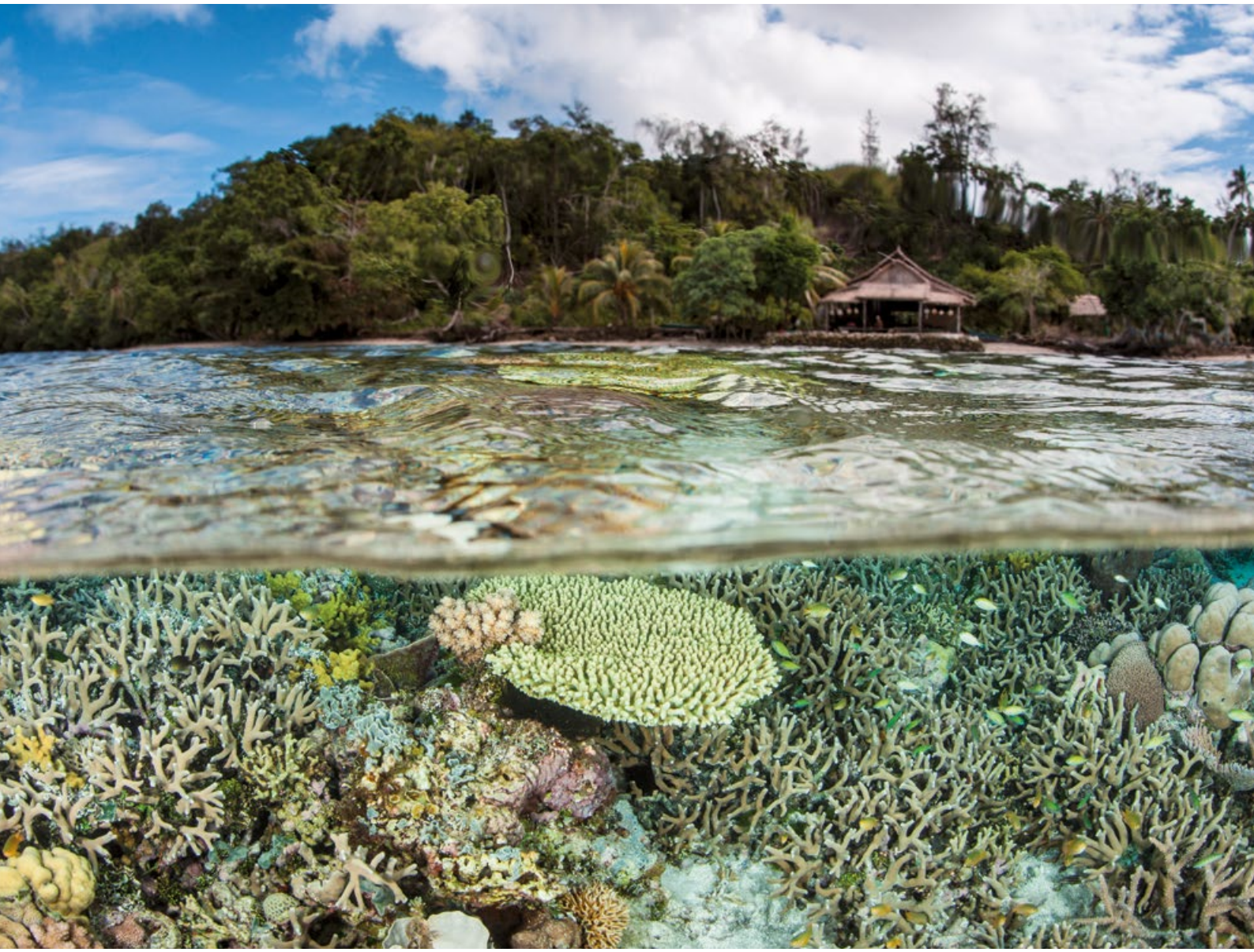


The two worlds of Nagoya

ABS legislation in the EU and provider countries: discrepancies and how to deal with them

NATURAL JUSTICE

Public Eye

IMPRINT The two worlds of Nagoya – ABS legislation in the EU and provider countries: discrepancies and how to deal with them, December 2016 | **PUBLISHERS** Public Eye, Natural Justice | **AUTHOR** Barbara Lassen (Natural Justice) | **WITH CONTRIBUTIONS FROM** François Meienberg (Public Eye), Andreas Drews, Hartmut Meyer, Lucy Mulenkei, María Julia Oliva, Manuel Ruíz, Olivier Rukundo, Mahlet Teshome and Johanna von Braun, Kabir Bavikatte for previous analyses cited | **EDITING** Valerie Kasaiyian | **PHOTO COVER** © Ethan Daniels/Shutterstock.com | **LAYOUT** Karin Hutter

Foreword

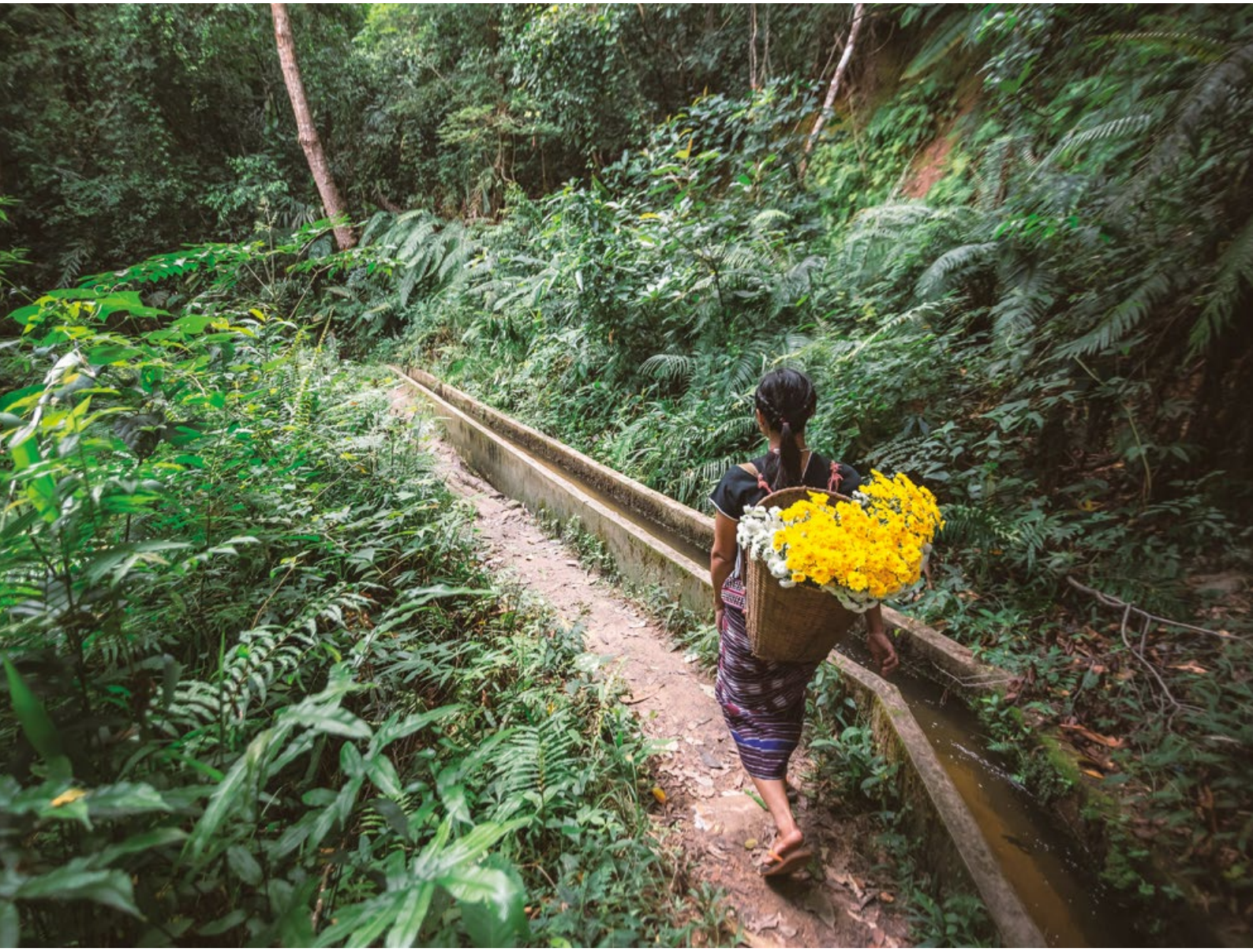
In the last few years, Natural Justice and Public Eye (formerly the Berne Declaration) have repeatedly worked together to support the implementation of the principle of fair and equitable benefit sharing. Examples of this work are our campaign against Nestlé for contravening South African law and the CBD in patent applications for the use of Rooibos and Honeybush in 2010 (which finally led to a Benefit-Sharing Agreement between Nestlé and the Khoi and San People), or our joint input to the European Parliament in 2013 during the debate on the (then) draft EU ABS regulation. Now the ABS frameworks of the EU, Switzerland and other user countries are in place, but also many provider countries have developed new ABS laws to implement the Nagoya Protocol on Access and Benefit Sharing.

What the present study shows, however, is that there are large discrepancies in the way the Nagoya Protocol is implemented through these legal frameworks. This analysis is meant as a contribution to raise the awareness of various actors - governments, holders of traditional knowledge, users of genetic resources and others – of these differences between the EU framework and provider country legislations, and their consequences for access and benefit sharing. We also wanted to present some constructive suggestions on how to deal with the current discrepancies, so that the rights of provider countries and of indigenous peoples and local communities can still be respected and fulfilled, and fair and equitable benefit sharing can be achieved. To this end, we have included contributions from several experts in the field, whom we would like to thank for taking the time to answer our questions.

This study does not claim to be exhaustive. We focused on three specific issues: the trigger of benefit sharing obligations (at the point of access vs. utilisation), the scope of traditional knowledge associated with genetic resources that is covered by the regulations, and the "import loophole", which arises when products based on GR and aTK are developed outside of the European Union but commercialised within. We have tried to include as many provider country legislations as possible that were developed after the Nagoya Protocol, to give a current picture of these issues. Some of these laws and policies are still in draft form, as are others that we were not able to access at the time of publication.

We welcome any feedback and comments on this study. These can be forwarded to: François Meienberg, Public Eye, food@publiceye.ch and Barbara Lassen, Natural Justice, barbara@naturaljustice.org.

François Meienberg, Public Eye & Barbara Lassen, Natural Justice



Executive Summary

The Nagoya Protocol was adopted by the parties to the Convention on Biological Diversity in 2010. Since then, several countries have developed legislation to implement the Protocol. The European Union adopted regulation *(EU) 511/2014* on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (EU ABS Regulation), and developed implementing regulations and a guidance document.

The aim of this study is to analyse the EU ABS regulation, the Implementing Regulations and the Guidance document to showcase several concerns that arise from the narrow scope of the Regulation:

The "temporal scope": The EU Regulation takes the position that benefit sharing obligations are triggered by the *physical access* to a genetic resource (GR) or associated traditional knowledge (aTK) *in the country of origin,* and limits the obligations of users of GRs and aTK 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. This is in contrast with the understanding of most, if not all, provider countries, whose legislations consider that benefit sharing should be triggered by the *utilization* of GR and aTK. This should include any *new utilization* of GR and aTK *after the entry into force* of the Nagoya Protocol or the national ABS law of the provider country, even if the physical access took place before (as is the case with the majority of GR and aTK held in ex-situ collections, for instance). These contradictions concerning the temporal scope between the EU regulations and provider country legislations 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 PIC and MAT for physical access to GRs in the country of origin that took place before, but utilisation that takes place after the Nagoya Protocol comes into force for the Union.

Associated Traditional Knowledge: The EU regulation limits the aTK that falls under its provisions by defining it as *"traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources"*. This definition – i.e. including only aTK that is mentioned in MAT - is concerning because it makes it near impossible to track the illegal access and utilisation of aTK, i.e. the utilisation of aTK which has been accessed without PIC and MAT – which is exactly where user country measures should play a role. Even when MAT are negotiated, this provision opens the door to confusion or even abuse, as TK holders will be wary of including every possible aTK when negotiating MAT, just to make sure that it is covered.

The "import loophole": A significant gap in the EU regulation exists because it requires due diligence only from users of GR and aTK within the EU – not from parties selling or otherwise commercially profiting from products based on GR and aTK which were developed outside of the EU and then imported.

In this analysis, the relevant provisions of the EU documents are compared to provisions in ABS legislations of provider countries that have developed (or are currently developing) national ABS frameworks. This comparison shows several discrepancies between the EU regulation and these frameworks, which, we believe, will lead to legal uncertainty for providers and users alike. This in turn, if solutions are not found, could lead to more restrictive access measures by provider countries.

Potential measures that can be taken by ABS actors to avoid this situation and work towards fair and equitable benefit sharing include:

- Careful drafting of ABS legislations in provider countries
- Actions to monitor and enforce these legislations
- Negotiation of good and comprehensive Mutually Agreed Terms
- National measures to protect Traditional Knowledge
- Developing a list of trusted collections
- Encouraging and publishing best practice by users of GR and aTK

Introduction

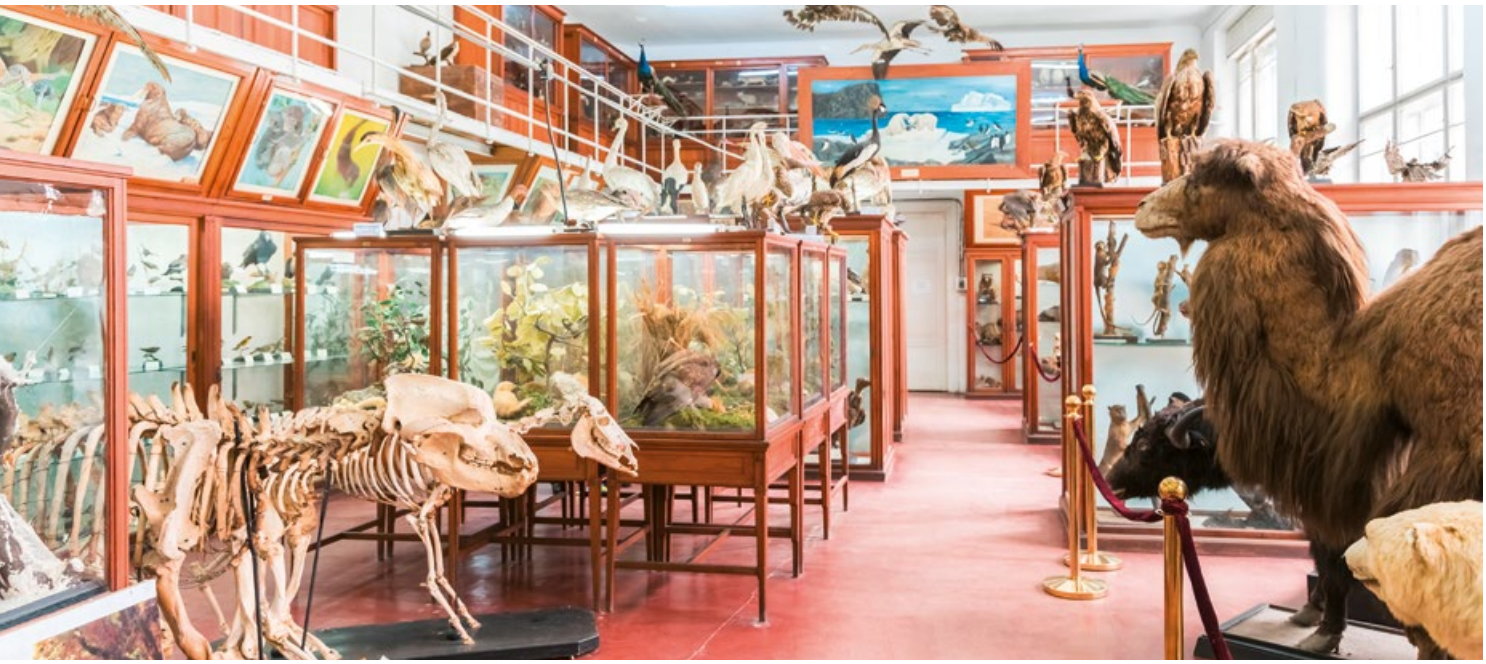
The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Protocol) [1], which entered into force on 14 October 2014 after six years of intense negotiations, contains several "intentional ambiguities" which provided parties with a fair amount of discretion regarding the manner in which they domestically implement their obligations under the protocol and under the Convention on Biological Diversity (CBD)[2].

On 16 April 2014 the European Union adopted *Regulation (EU) 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*[3] (EU ABS regulation). Several concerns were already raised at the time of the drafting and negotiation of the Regulations, especially regarding their scope. The Berne Declaration (now Public Eye) and Natural Justice produced two analyses of the draft Regulations, extracts of which we have used throughout this study.[4]

Since then, the European Commission published the I*mplementing Regulations (EU) 2015/1866 laying down detailed rules for the implementation of Regulation (EU) 511/2014 as regards the register of collections, monitoring user compliance and best practices*[5]; and a *Guidance Document on the scope of application and core obligations of EU regulation (EU) 511/2014*[6].

While these documents clarify some aspects of the EU regulation, the major concerns remain. What follows is an analysis of the discrepancies between the EU ABS framework and several provider country legislations (as well as user countries in the case of the "import loophole").

Despite the EU ABS framework being in place, we believe that it is still important to discuss the difficulties which might arise from it regarding the implementation of the Nagoya Protocol, and how provider countries and other actors can contribute to addressing some of these problems.



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The "Temporal Scope" – Access vs. Utilization

The Nagoya Protocol fails to provide full clarity about *when* benefit sharing obligations are triggered. Indeed, it remains unclear whether these obligations, and corresponding compliance measures, are triggered by *every new and continuing utilization* of Genetic Resources (GR) and associated Traditional Knowledge (aTK), or only when GR or aTK are *newly accessed in the country of origin*. Consequently, it remains open whether there should be benefit sharing obligations for GR or aTK that are physically accessed before, but utilized after the entry into force of the Nagoya Protocol.

This question, often referred to as the question of *temporal scope*, is of key importance. GR and aTK have already been and are currently being accessed on a large scale. It is entirely possible that GR and aTK have been physical accessed in the country of origin prior to the entry into force of the Nagoya Protocol on 12 October 2014, but for the *use* of these same GR and aTK to take place after the treaty has entered into force. Thus, if the position taken is that access of GR or aTK in the country of origin 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 would be excluded from the scope of national or regional regulations implementing the Nagoya Protocol. In such cases, a large number of GR found in private or public collections and gene banks or botanical gardens would be freely usable for eternity, without triggering any ABS obligations. It seems evident that a major part of utilization in the next years will be based on GR and aTK physically accessed before 12 October 2014.

It should be highlighted that the ambiguity here is not about whether the Nagoya Protocol should be applied retroactively[7], but rather about what happens when *new or ongoing utilisation* is carried out on GR or aTK physically accessed in the country of origin before the entry into force of 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[8] of the Convention and to the benefits arising from the utilization of such resources."* In Article 2, the Nagoya Protocol defines utilization of genetic resources as *"to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention"*. 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."* The joint reading of Article 2, Article 3 and Article 5(1) leads to the interpretation that the trigger for benefit sharing is utilization rather than access. The same is true for references to utilisation contained in Article 5(2), which relates to GR that are held by indigenous and local communities, as well as in Article 5(5), which relates to aTK. According to this reading, a new use would lead to the current 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). This understanding was also expressed by the group of like-minded megadiverse countries in a letter to the EU presidency in 2014, which states:

"(...) Article 5(1) of the Nagoya Protocol on ABS recognises the need for fair and equitable sharing with the provider countries of benefits derived from the utilization of genetic resources as well as subsequent applications and commercialization of genetic resources. These provisions apply to new utilization of genetic resources and associated traditional knowledge accessed prior the entry into force of the Nagoya Protocol on ABS and must be addressed in the draft EU regulations on ABS. Finally, it is important to clarify that new utilization of previously accessed GR and ATK does not represent retroactivity of the Nagoya Protocol on ABS provisions, since it applies to future uses of GR and ATK regardless of when the original access occurred."[9]

The question of temporal scope was one of the most contentious issues in the negotiations leading to the adoption of the Nagoya Protocol. Most developing countries supported utilization as the trigger for benefit sharing obligations, whereas developed countries opposed it. 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.

1.1 – THE TEMPORAL SCOPE IN THE EU REGULATION, IMPLEMENTING REGULATION AND GUIDANCE

The EU regulation takes the position that physical access to a genetic resource or associated traditional knowledge in the country of origin is what triggers ABS obligations, and limits the obligations of users of GR and aTK to uses of resources that have been physically accessed in provider countries *after* the Nagoya Protocol has been ratified by *both* the EU *and* the country of origin.

For instance, an EU company would be required to exercise due diligence (see article 4 of the EU regulation concerning the obligations of users) with regards to genetic resources acquired in country X, if such acquisition takes place once the Nagoya Protocol is in force both in the EU and country X, and this country has established access requirements. This due diligence requirement would *not* apply to genetic resources acquired before such a time, even if there is new or continuing research and development.

Specifically, article 2.1. reads *"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"* and access is defined as *"the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol"*.

The Guidance Document further specifies under section 2.2 (temporal scope) that in order to trigger compliance obligations, the GR must be accessed and utilized after 12 October 2014 (the date when the NP entered into force for the Union), and that GR accessed prior to that date fall outside the scope of the Regulation even if utilization occurs after that date.

This focus on access in the country of origin as the key trigger for user obligations in the EU raises a number of concerns: first and foremost, it effectively means that all such access of GR and aTK prior to the entry into force of the Nagoya Protocol for the Union are deemed legal and not covered by the Regulation, even in situations where there is new or continuing utilization of a previously acquired resource.

Article 2.4. of the EU regulation also states that: *"This Regulation applies to genetic resources and traditional knowledge associated with genetic resources to which access and benefit-sharing legislation or regulatory requirements of a Party to the Nagoya Protocol are applicable."* As further explained in the Guidance Document, this means, among other things, that *"provider countries must have ratified the [Nagoya] Protocol and established access measures on genetic resources for them to be in the scope of the Regulation"*, meaning that *"the Regulation only applies to genetic resources from provider countries which have ratified the Nagoya Protocol and established applicable access measures"*.

This in turn raises concerns regarding the obligations of EU users towards GR and associated TK accessed in countries that are not (yet) Parties to the Nagoya Protocol, but who may be parties to the CBD and have national ABS legislation or regulations. Indeed, the Nagoya Protocol is meant to implement the ABS obligations under Article 15 of the CBD, which have been valid since the Convention's entry into force in 1993. A number of countries therefore developed national ABS frameworks before the adoption and entry into force of the Nagoya Protocol. These measures were essentially developed in light of the requirements of article 15 of the CBD.

The Guidance Document does make reference several times to the fact that provider country legislations may go beyond the scope of the EU regulation, and that these remain applicable. It also specifically makes reference to possible rules in provider countries which apply to GR accessed before the entry into force of the Nagoya Protocol, noting that "national legislation or regulatory requirements of the provider country still apply and any mutually agreed terms entered into should be respected, even if not covered by the EU ABS Regulation."[10]

However, the document falls short of giving specific guidance on what to do when there are differences in scope between these legislations and the EU regulation. The guidance only says that the provider legislations "remain applicable" and that "mutually agreed terms entered into should be respected". Most notably, it does not ask or even encourage EU users to seek Prior Informed Consent (PIC) and negotiate Mutually Agreed Terms (MAT) in cases that are beyond the scope of the EU regulation, but where the national provider legislation would demand PIC and MAT. In contrast, and to show the possibilities on the implementation level, one can refer to the language in the Swiss Nagoya Ordinance of 11 December 2015 [11]: the ordinance follows the same logic as the EU Regulation regarding temporal scope, but it states that the Federal Office for the Environment (as the Swiss Competent National Authority) *"encourages users to voluntarily share the benefits arising from the utilisation of genetic resources or associated traditional knowledge in a fair and equitable way even when there is no legal obligation to do so. It aims to ensure that the benefits are used to conserve biological diversity and the sustainable use of their components."* This encouragement certainly includes cases where there is no legal obligation in Switzerland but in the provider country.

1.2 – THE TEMPORAL SCOPE DEFINED IN SELECTED LAWS FROM PROVIDER COUNTRIES

A number of provider countries have developed ABS laws, or revised their existing laws, to implement the provisions of the Nagoya Protocol since its adoption in 2010. Some are still in the process of doing so (including Kenya and South Africa). To our knowledge, in all of these national legislations it is the utilization of GR and not the physical access to it, that triggers obligations for PIC and MAT. This understanding is reflected in provider country laws in a number of ways:

a) The definition of access not only includes the physical access to GR in the country of origin, but also their utilization, independently from where and when the physical access took place.

EXAMPLE: BRAZIL

The Brazilian Law No. 13.123 of May 20, 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional

Knowledge)[12] defines access to "genetic heritage" as research or technological development on a sample of genetic heritage[13]. Further clarifying this interpretation, it distinguishes between *access,* as defined above, and the physical *transfer* of GR out of the country for the purpose of access.[14]

Access to associated traditional knowledge is defined as research or technological development on TK associated with genetic heritage, which allows or facilitates access to genetic heritage (again, based on the definition of access above). This includes aTK that is obtained from secondary sources such as publications, inventories and so on.[15]

Additionally, the law stipulates that benefits arising from economic exploitation of a final product or reproductive material based on access to the genetic resources of species found in *in situ* conditions, or associated traditional knowledge, have to be shared in a fair and equitable manner, even if the plant has been grown and the product produced outside the country (Article 17)[16].

EXAMPLE: ZAMBIA

The Zambian Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act No.16 of 2016[17] defines access as *"the collection, acquisition, transfer or use of traditional knowledge, genetic resources and expressions of folklore".*

EXAMPLE: BHUTAN

The 2014 draft Access and Benefit Sharing Policy of Bhutan[18] defines access as follows:

Section 6.c: 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.

b) The legal framework is targeted towards the utilization of GR, rather than access

EXAMPLE: SOUTH AFRICA

The South African national bioprospecting framework does not refer to "access" or "access permits" but to "bioprospecting permits". Bioprospecting, in the National Environmental Management: Biodiversity Act (10/2004)[19], is defined as:

"any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes

(a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application;

(b) the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; or

(c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation"

Bioprospecting is split into a discovery and a commercial phase each triggering a different level of obligation – and each requiring a separate permit. The Bioprospecting, Access and Benefit-Sharing Regulations (2008, amended in 2015)[20] set out the obligations for users in both phases:

As the temporal scope under the EU regulations only applies to GR and aTK accessed after the entry into force of the Nagoya Protocol for the Union, a large part of the benefits arising from their utilization will not be shared.

Chapter 3 Part 2: Discovery phase of bioprospecting:

14. (1) A person who wishes to export from the Republic any indigenous genetic and biological resources for the purpose of bioprospecting for commercial research must obtain a discovery phase export permit from the issuing authority.

Chapter 3 Part 3: Commercialisation phase of bioprospecting permits

17. (1)A person who engages in bioprospecting involving any indigenous genetic and biological resources within the Republic, must obtain a bioprospecting permit from the issuing authority.

(2) A bioprospecting permit referred to in paragraph (1) above, may also be used for export from the Republic of any indigenous genetic and biological resources covered in the permit application.

EXAMPLE: INDIA

The Indian Biological Diversity Act, 2002[21] focuses on the activities carried out in relation to the GR, as opposed to access. Article 3 provides that:

3. (1) *No person (...) 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.*

The Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014[22] put in place the following procedures, differentiating between access for research and access for commercial utilization:

1. Procedure for access to biological resources and/ or associated traditional knowledge ***for research or bio-survey and bio-utilization for research:***

(1) Any person (...) who intends to have access to biological resources and/or associated traditional knowledge for research or bio-survey and bio-utilization for research shall apply to the National Biodiversity Authority (NBA) (...) for obtaining access to such biological resource and/or associated knowledge, occurring in India.

(2) The NBA shall, on being satisfied with the application (...) enter into a benefit sharing agreement with the applicant which shall be deemed as grant of approval for access to biological resource for research referred to in that sub-regulation.

2. Procedure for access to biological resources, ***for commercial utilization or for bio-survey and bio-utilization for commercial utilization:***

(1) Any person who intends to have access to biological resources including access to biological resources harvested by Joint Forest Management Committee (JFMC)/Forest dweller/Tribal cultiva-

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tor/ Gram Sabha, shall apply to the NBA (...) or to the State Biodiversity Board (SBB), (...)

(2) The NBA or the SBB, as the case may be, shall, on being satisfied with the application (...) enter into a benefit sharing agreement with the applicant which shall be deemed as grant of approval for access to biological resources, for commercial utilization or for bio-survey and bio-utilization for commercial utilization referred to in that sub-regulation.

c) Specific wording within legislation making reference to access and/or utilization preceding enactment of the national ABS framework:

EXAMPLE: BRAZIL

Before adopting the current law, Brazil already had a provisional act since 2000[23]. The transitional provisions of the new law require users who accessed GR or aTK under the previous act (i.e. since 2000), to adapt to the terms of the new law within a year.[24] It also asks users who accessed, utilized or transferred GR or aTK out of the country illegally after 2000 to regularize their situation under the new law within a year.[25]

EXAMPLE: ZAMBIA

The transitional provisions of the Zambian Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act declare that:

(1) Any access agreement made prior to the commencement of this Act shall be revised and harmonised with this Act.

(2) Any access authorised prior to the commencement of this Act shall be suspended and the process for access as provided in this Act shall be followed.

d) Specific wording making reference to genetic resources held *ex-situ*

EXAMPLE: AFRICAN UNION STRATEGIC AND PRACTICAL GUIDELINES[26]

In the section concerning Access for utilization, the Strategic Guidelines state that: *"9) Having or obtaining physical access to (...) genetic resources, including from ex situ collections, does not imply that prior informed consent for their utilisation has been granted or is not required. Utilisations without prior informed consent and without the establishment of mutually agreed terms are considered illegitimate. Member States shall cooperate to enforce their sovereign rights in this regard."*

The Practical Guidelines develop this rationale further by stating under 9. Access for Utilisation that:

"PIC and MAT are needed for utilization even when physical access has already occurred: The NP very clearly governs "access for utilisation" and "sharing of benefits arising from utilisation". This implies that PIC and MAT are needed for utilisation to be legitimate, even when physical access has already occurred (i. e. also applies to GR and aTK accessed from ex situ collections and public sources). PIC should never be granted unless MAT have been concluded."

EXAMPLE: KENYA

The Kenyan 2016 draft Wildlife Conservation and Management (Bio-prospecting) Regulations[27] make direct reference to genetic resources held outside of the country (i.e. including those that were physically accessed before the entry into force of the Nagoya Protocol):

Art.3.2. *These Regulations shall apply to bio-prospecting activities of any wild biological resources found in Kenya including wild*

species of flora and fauna and microorganisms, both (in-situ and ex-situ) and other wild biological resources sourced from Kenya and held in foreign ex-situ collections.

1.3 – ANALYSIS

As mentioned above, the focus on physical access as the key trigger for user obligations in the EU raises a number of concerns.

It runs counter to Article 15 of the CBD requiring the fair and equitable sharing of benefits arising from the utilisation of GR, and the objective of the Nagoya Protocol; as well as to the definition of utilization under Article 2 of the Nagoya Protocol and the join treading of Articles 2 and 5.1, which clearly reinforces that utilization is the trigger for benefit sharing. It also, as demonstrated here, runs counter to a number of provider country frameworks already in place or currently being developed that require PIC and MAT for utilization of their GR and associated TK, regardless of when such GR and associated TK were first accessed in the country of origin.

As the temporal scope under the EU regulations only applies to GR and aTK accessed after the entry into force of the Nagoya Protocol for the Union, a large part of the benefits arising from their utilization will not be shared. Moreover, these contradictions concerning the temporal scope between the EU regulations and provider country legislations will lead to greater legal uncertainty for European users of GR, who may be compliant with EU laws, but in breach of the ABS laws or regulation of the provider country, for failing to negotiate PIC for physical access to GR that took place before but utilization that takes place after the Nagoya Protocol came into force for the Union.

It should be noted that this also impairs the implementation of Article 15 of the Nagoya Protocol, which asks user countries to ensure compliance with provider country legislations in their jurisdiction:

"15(1) Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party."

A further area of concern is that the EU regulations only applies to GR and aTK from countries that have ratified the Nagoya Protocol and established access measures; which creates further legal uncertainty for users of GR or aTK from countries who are still developing their ABS frameworks, or who have not (yet) ratified the Nagoya Protocol but already have national ABS measures in place.

Preambular paragraph 11 of The EU Regulation explains the intent of the choices concerning the temporal and geographical scope: *"In order to ensure legal certainty, it is important that the rules implementing the Nagoya Protocol apply only to genetic resources over which States exercise sovereign rights within the scope of Article 15 of the Convention, and to traditional knowledge associated with genetic resources within the scope of the Convention, which are accessed after the entry into force of the Nagoya Protocol for the Union."*

This paragraph suggests that the wording regarding temporal scope was a political decision. It seeks legal certainty by excluding from the scope of the Regulation all GR and aTK accessed in the country of origin before the entry into force of the Nagoya Protocol. The question arises, however, whether this choice will actually fulfil its aim or whether it will be counterproductive in this regard.

One of the strongest drivers behind the Nagoya Protocol was the necessity to improve legal certainty in relation to access and utilization, and to promote compliance with provider country legislations in user countries. Not only providers, but above all users and private sector stakeholders have repeatedly emphasized 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, the sole focus on access triggers in the EU regulation will actually have the contrary effect:

Under the EU regulation, a European company may find itself in a situation where the utilisation of a genetic resource from a collection or botanical garden 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 institute legal action, 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.

Another issue arises when GR have entered the European Union as trade commodities, but are subsequently used for research and development. The Guidance Document explains under section 2.3. on material scope that:

"if and when research and development is carried out on genetic resources which originally entered the EU as commodities, the intend-

ACCESS VS. UTILIZATION AS TRIGGER FOR BENEFIT SHARING

Manuel Ruiz, Sociedad Peruana de Derecho Ambiental

The only effective and practical trigger for benefit sharing (at least monetary benefits) can occur when and if commercial use is made of products/innovations derived from genetic resources. This is where it becomes evident and visible (at least more so) that genetic resources are being or have been utilized. Anything before that moment becomes rather blurred and confusing, including if there are various utilizations along the R&D chain. As for non-monetary benefits, these are more under control of provider countries and depend on national triggers, which in most cases occur at the point of access or initiation of projects.

The way I see it, regardless of what is established in national (provider country) legislation and when GR were accessed, as long as they are utilized post NP, the benefit sharing obligations should come into play.

ed use has changed and such new use falls within the scope of the EU ABS Regulation (provided the other conditions for application of the Regulation are also met). (...) In the case of such changes in the use of what was until then considered as a commodity, the user is expected to contact the provider country and clarify whether requirements to obtain prior informed consent and establish mutually agreed terms apply to this utilisation of such genetic resources (and if yes, obtain the necessary permits and establish mutually agreed terms).

However, it seems that this only entails that the user should approach the direct provider country of the commodity to obtain PIC and negotiate MAT, if the commodity was provided after the entry into force of the Nagoya Protocol. This is problematic as many genetic resources traded as commodities have long been exported and are being cultivated outside of their country of origin. This means that a GR traded as a commodity today may very well have been originally accessed in the country of origin before the entry into force of the Nagoya Protocol, which would presumably exclude the GR from the scope of the EU regulation. A good example is *Stevia rebaudiana,* on which a lot of research and development is currently being done to develop sweeteners. The plant originates from the border region of Paraguay and Brazil, where it was physically accessed by entities from the North in the seventies. Today *Stevia rebaudiana* grows all over the world and is nearly extinct in its natural biosphere.

Finally, the European Regulation will pose a significant challenge for enforcing ABS within the EU. The date of acquisition in the country of origin, which 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 GR or aTK. Utilization on the other hand is much easier to monitor, for example by using the information provided in patent applications.

> "If a fundamental discrepancy develops between provider and user countries, it will undoubtedly lead to further conflicts, and hence to further delays in facilitating or procuring access."
>
> *African Group of ABS Negotiators*

A further gap for enforcing compliance with provider country legislations is the role given by the EU regulation to collections of GR and aTK which are included in a "register of collections". According to the EU Regulations Art. 4.7, If a user obtains a GR from one of these collections, he "*shall be considered to have exercised due diligence as regards the seeking of information (...)".* The collections that form part of the register have to fulfil a number of criteria, including to have the capacity to *"supply genetic resources and related information to third persons for their utilisation only with documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and, where relevant, with mutually agreed terms (Art. 5.3. (b))".*

In principle, this obligates the holder of the collection to supply GR only with all the relevant information, including whether PIC and MAT was obtained from the country of origin. However, as mentioned before, a large portion of the GR and aTK found in collections has been physically accessed in the country of origin before the entry into force of the Nagoya Protocol – and probably often without PIC or MAT, since it was accessed before ABS regulations were in place, or because the intended use was to store the GR in a collection, not to use it for research and development. The system of registered collection therefore simply passes the due diligence obligation from the user to the collection, without giving provider countries any possibility to demand the negotiation of new PIC and MAT for new uses, when the GR moves from the collection to a commercial user. The Guidance Document acknowledges this in section 3.1. (Due diligence obligations) by noting that *"users need to be aware that when the intended use changes, there might be a need to seek new or updated prior informed consent from the provider country and establish mutually agreed terms for the new use, if it is not covered by the PIC and MAT obtained and relied upon by the registered collection.* But this will be difficult to enforce, and if the GR has been in the collection since before the entry into force of the Nagoya Protocol, there is indeed no obligation to do so.

In a letter dated 9 September 2013 from the African Union to the European Parliament, the African Group of ABS Negotiators voiced their concerns in their comments on the Draft EU Regulations in 2013, most of which retain their validity in the face of the final text of the Regulations, the Implementing Regulation and the Guidance Document:

"African governments are currently establishing or updating national ABS regimes, all of which (will) require obtaining PIC and negotiating MAT for any new access AND all new utilization of GR and aTK. (...) If a fundamental discrepancy develops between provider and user countries in the rules about what kind of utilization triggers ABS compliance obligations for users, it will undoubtedly lead to further conflicts between European users and provider countries, and hence to further delays in facilitating or procuring access. (...)In the absence of a compliance regime that we can trust, African and other provider countries will have no alternative but to impose increasingly burdensome access provisions. The unfortunate result of this will be to undermine one of the key objectives of the Nagoya Protocol, which is to facilitate access to these genetic resources. This will severely limit access of European users to Africa's genetic resources in the future, resulting in less utilization, less benefits to share, and less conservation and sustainable use of biodiversity."[28]

2
The Traditional Knowledge covered

The obligatory protection of traditional knowledge associated with genetic resources (aTK) is one of the key achievements of the Nagoya Protocol. The Nagoya Protocol parties have a set of obligations towards indigenous and local communities (ILCs) regarding ILC rights over traditional knowledge associated with genetic resources and, in certain instances, over genetic resources held by these communities. These include obligations to take measures to ensure that genetic resources and associated traditional knowledge held by ILCs are accessed with their prior informed consent or approval and involvement, and that MAT have been established. In implementing their obligations under the Protocol, Parties are further required, in accordance with domestic law, to take into consideration ILCs' customary laws, community protocols and procedures and, as far as possible, not to restrict the customary use and exchange of genetic resources and associated knowledge within and amongst ILCs.[29] The Nagoya Protocol further obliges user countries to put in place compliance measures to ensure that aTK utilized within their jurisdiction has been access based on PIC and MAT, as required by the domestic legislation of the provider country; and to address situations of non-compliance.[30]

While traditional knowledge associated with genetic resources or associated traditional knowledge for short has now become a term of art, it wasn't always the case. aTK was originally described in Article 8j of the CBD as *"knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity."* Through the various negotiations in the run up to the Nagoya Protocol including a dedicated expert group meeting on aTK in 2009[31], this term of art has now been established – even if the Nagoya Protocol itself does not specifically provide a definition of aTK.

2.1 – THE SCOPE IN THE EU REGULATION

The EU regulation limits the aTK that falls under its provisions by defining it as *"traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources"*.

While the first part of the definition is standard, it is the second part that limits the understanding of aTK to its description in the respective Mutually Agreed Terms – and thereby excludes all traditional knowledge that is not the subject of an access agreement.

Paragraph 20 of the preambular text of the regulations explain the choice of restricting the definition to aTK described in benefit sharing agreements (as opposed to all TK associated with a genetic resource) with the fact that there is currently no internationally-agreed definition of "traditional knowledge associated with genetic resources" and that thus the restriction would ensure flexibility and legal certainty for providers and users.

The Guidance Document reiterates this rationale in paragraph 2.3.2 and further clarifies that *"in order thus to be in scope of the EU ABS Regulation, traditional knowledge associated with genetic resources needs to be related to the utilisation of those resources and it must be covered by the relevant contractual agreements."*

2.2 – THE SCOPE IN SELECTED LAWS FROM PROVIDER COUNTRIES

The restriction of the aTK covered by the EU regulation to aTK described in Mutually Agreed Terms is quite singular, and again contradicts the more encompassing definitions found in recent provider country legislations.

EXAMPLE: BRAZIL

The Brazilian Law on Access and Benefit Sharing of Genetic Resources and Associated Traditional Knowledge defines aTK as *"information or practices of indigenous peoples, traditional communities or traditional farmers on the properties or direct or indirect uses associated with genetic heritage"*.

EXAMPLE: SOUTH AFRICA

The Bioprospecting, Access and Benefit-Sharing Regulations do not give a specific definition of associated TK but they define "traditional use or knowledge" as *"the customary utilisation or knowledge of indigenous genetic and biological resources by an indigenous community or specific individual, in accordance with written or unwritten rules, usages, customs or practices traditionally observed,*

accepted and recognised by them, and [including] discoveries about the relevant indigenous genetic and biological resources by that community or individual"

EXAMPLE: KENYA

The Kenyan Protection of Traditional Knowledge and Cultural Expressions Act, 2016[32] defines traditional knowledge as

"any knowledge (a) originating from an individual, local or traditional community that is the result of intellectual activity and insight in a traditional context, including know-how, skills, innovations, practices and learning, embodied in the traditional lifestyle of a community; or (b) contained in the codified knowledge systems passed on from one generation to another including agricultural, environmental or medical knowledge, knowledge associated with genetic resources or other components of biological diversity, and know-how of traditional architecture, construction technologies, designs, marks and indications."

The draft Wildlife Conservation and Management (Bio-prospecting) Regulations define "associated knowledge" as "any know how or information and skills linked to biological material, genetic resource and derivatives thereof accessed from the provider".

The latter, while linking the definition of aTK to GR that have been accessed by a provider, do not however limit the scope to that aTK which is specifically mentioned in Mutually Agreed Terms.

EXAMPLE: ZAMBIA

In the Zambian Protection of Traditional Knowledge, Genetic Resources and Expressions of Folklore Act, *" traditional knowledge " means "any knowledge, not limited to a specific subject area, technical or medical field associated with genetic resources, originating from a traditional community, individual or group that is the result of intellectual activity and insight in a traditional context and where the knowledge is embodied in the traditional lifestyle of a traditional community or is codified in knowledge systems and passed on from one generation to another".*

EXAMPLE: BHUTAN

The 2014 draft Access and Benefit Sharing Policy defines associated traditional knowledge as follows:

Section 6 (l): *Traditional knowledge associated with genetic resources means the knowledge, innovations and practices of Bhutanese communities that is related to the utilization of biodiversity and is not limited to knowledge relating to genetic structure of biological resources.*

These definitions from provider legislations show that it is perfectly possible to define traditional knowledge, and therefore associated traditional knowledge, without limiting the definition to such aTK that is explicitly described in ABS contracts.

2.3 – ANALYSIS

The EU Regulation defines aTK for the purpose of protection as "described in the mutually agreed terms applying to the use of genetic resources." That is, the regulation only covers traditional knowledge if there is a contract on access to genetic resources that specifically mentioned associated traditional knowledge. Situations where there is no contract relating to access fall out of the scope of the regulation. This makes it near impossible to track the illegal access and use of aTK. Illegal use of aTK for which no PIC and MAT exist is much more likely than for aTK that has been included in mutually agreed terms, and this is exactly where user country measures should play a role.

Illegal use of aTK for which no PIC and MAT exist is much more likely than for aTK that has been included in mutually agreed terms, and this is exactly where user country measures should play a role.

Even where MAT do exist, the definition leaves the understanding of aTK open to speculation and hence interpretation that could go against the interests of the ILCs providing access to it. For one, it would be near impossible to think of all the possible potential uses and hence descriptions of aTK at the time of negotiating the mutually agreed terms. What's more, restricting the rights of ILCs, once they have entered into an ABS agreement, only to the aTK described in the agreement, opens the door to abuse and hair splitting. By limiting its protection to aTK not as how the domestic ABS laws and regulations of provider countries understand it, but as it is described in MAT, more confusion than clarity is added and there is an increase in the possibility of violation of rights of the most vulnerable communities through some crafty drafting of MAT – for example by not specifically mentioning the aTK which will later be used in research and development.

In a letter to the Committee on the Environment, Public Health and Food Safety of the European Parliament[33], representatives of Indigenous Peoples and Local Communities and other groups expressed their concerns with this definition:

"Given that the ABS Regulation foresees access-based' trigger points for user obligations, it is unlikely that all existing TK will be covered in MATs when genetic resources (GR) are accessed. In fact, many governments are unlikely to know of all existing TK associated with particular resources and TK holders are likely to be highly critical of providing a comprehensive list of relevant TK in a general MAT contract just to protect it from illegitimate future use. As a result, a large amount of TK may end up without protection because it will have been excluded from the original contractual terms.

(...)

The definition of TK in the Draft ABS Regulation also stands in direct contrast to the EU Parliamentary Resolution of 15 January 2013, which in paragraph 19 "takes the view that the EU should grant traditional knowledge at least the same level of protection as genetic resources when implementing the Nagoya Protocol" and notes that one way of achieving this is through a binding international instrument that obliges member states to disclose the utilization of GR and TK in patent application."

3
The import loophole

A significant loophole in the EU regulation exists because it requires due diligence only from users of GR and aTK within the EU – not from parties selling or otherwise commercially profiting from products based on GR and aTK which were developed outside of the EU.

3.1 – THE PROVISIONS OF THE EU REGULATION

Article 4 of the EU regulation outlines the obligations of due diligence towards users:

"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."

A "user" is defined as *"a natural or legal person that utilizes genetic resources or traditional knowledge associated with genetic resources "*. The definition of utilization in the EU regulation is the same as in the Nagoya Protocol, namely *"to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention"*.

The Guidance Document spells out what this means under Section 2.5 geographic scope – II: *"The obligations stemming from the EU ABS Regulation apply to all users of genetic resources (falling within the scope of the Regulation) which utilise genetic resources or traditional knowledge associated with genetic resources within the EU territory. Consequently, the utilisation of the genetic resources outside of the EU falls outside of the scope of the Regulation. If a company commercialises in the EU a product that it has developed through utilisation of genetic resources where the utilisation (thus the entire process of research and development) took place outside of the EU, this is not covered by the EU ABS Regulation."*

Concerning the monitoring of user compliance, Article 7 of the EU Regulation establishes two sets of checkpoints:

- when a user requests research funding
- at the stage of final development of a product

The obligation of "declaration of compliance" therefore rests primarily upon those who utilize GR and aTK; not on those who commercialize or profit from the results of the utilization of GR and aTK if they happen to be different from the users. This obligation to declare compliance exclusively on users and not extending it to commercialisers causes certain challenges in establishing checkpoints for compliance with the Regulation, since in many cases the users and commercialisers will not be the same natural or legal person or entity.

The Implementing Regulation seeks to address this difficulty - not altogether successfully – in Art. 6.2. by identifying specific events on the occurrence of which declarations of compliance with the Regulation would have to be made to the competent authorities by users:

"(a) market approval or authorisation is sought for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;

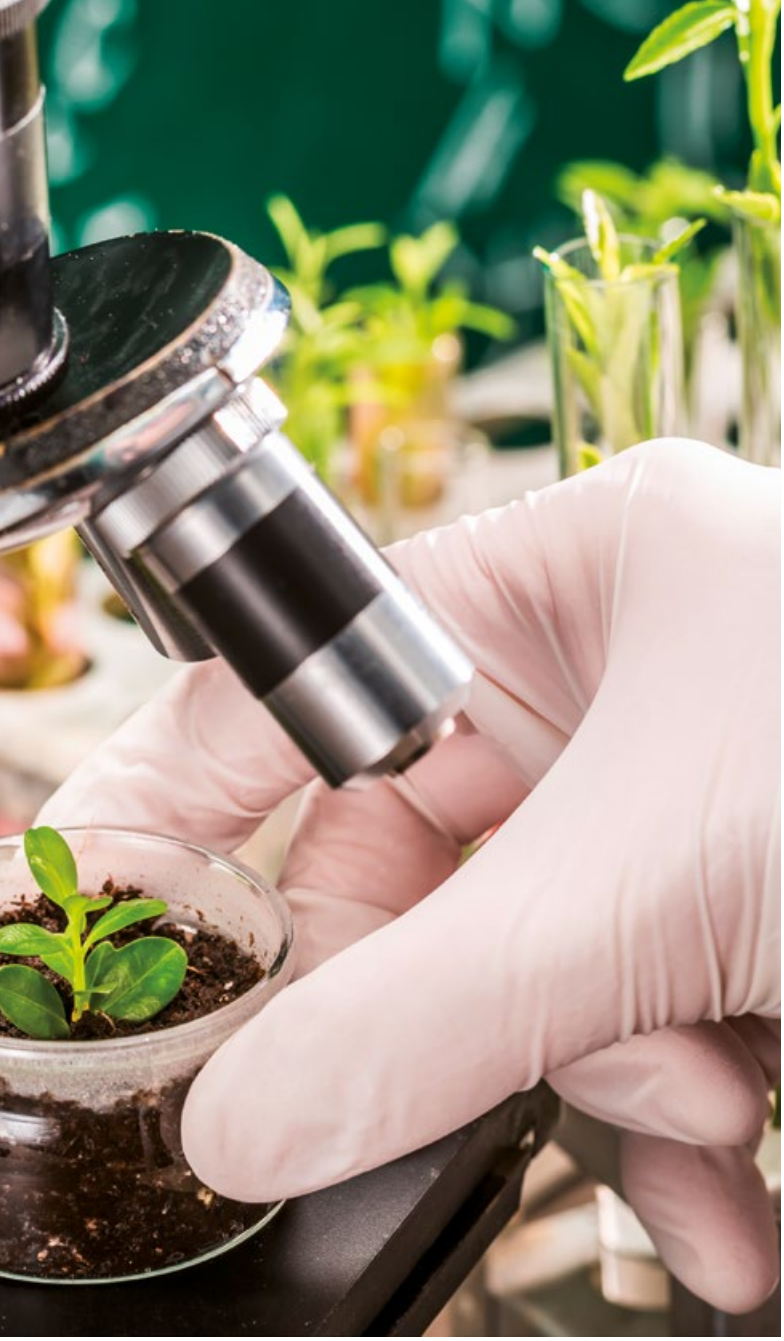
(b) a notification required prior to placing for the first time on the Union market is made for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;

(c) placing on the Union market for the first time a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources for which no market approval, authorisation or notification is required;

(d) the result of the utilisation is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);

(e) the utilisation in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union."

However, unlike events like (a), (b) and (c) which are materially verifiable and hence useful checkpoints, events (d) and (e) are nearly impossible to monitor as they are not regulatory requirements or publicly visible events and hence leave a significant gap in the Union's ability to monitor compliance under the Regulations. Additionally, (d) still only covers instances in which utilization takes place within the EU – not cases where utilization takes places outside and the result is then sold to a company within the EU for commercialization.



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3.2 – COMPARISON WITH OTHER USER COUNTRY LEGISLATIONS

In contrast to the provisions of the EU regulation leaving an "import loophole", we have examined two European provider country legislations below; one outside of the EU (Switzerland) and one from an EU member (Denmark) which chose to extend the scope of it national ABS regulation beyond that of the EU regulation.

EXAMPLE: SWITZERLAND

The Swiss Federal Act on the Protection of Nature and Cultural Heritage (NCHA) of 1 July 1966 (Status as of 12 October 2014)[34]stipulates that:

Any person who in accordance with the Nagoya Protocol utilises genetic resources or benefits directly from their utilisation (users) must apply due diligence appropriate to the circumstances to ensure that:

a. *the resources have been accessed lawfully; and*
b. *mutually agreed terms for the fair and equitable sharing of the benefits have been established.*

The Swiss "Nagoya Ordinance" reinforces this by defining users of GR as *"legal or natural persons who in accordance with the Nagoya Protocol utilise a genetic resource or associated traditional knowledge* ***or benefit directly from their utilisation".***

EXAMPLE: DENMARK

The Danish Act No. 1375 of 23 December 2012 on Sharing of Benefits Arising from the Utilization of Genetic Resources[35] defines utilization as *"conducting research and development on the genetic and/or biochemical composition of genetic resources, including through the use of biotechnology. Utilisation is also understood to mean development and marketing of products based on genetic resources."*

3.3 – ANALYSIS

Requiring due diligence only from users of GR and aTK leaves a gaping hole when it comes to those who utilize the GR and ATK outside the EU to avoid due diligence obligations and subsequently import the products for sale into the EU. The loophole is further reinforced since the only checkpoint provided by the EU for monitoring due diligence is at the final stage of product development, with no checkpoints at the pre-commercialization or commercialization stage (as foreseen in Art. 17.1. (a)(iv) of the Nagoya Protocol).

Activities like this could be fairly common in the EU in the context of multinational companies. For example, a multinational pharmaceutical company headquartered in the EU could engage in research and product development of GR and ATK in its laboratories in the US and it will have no due diligence obligations under the EU Regulations, even if the said product is marketed and sold in the EU. Ironically, through this loophole the EU Regulation pushes research and development activities away from Europe into jurisdictions that have no due diligence obligations and may also result in unfair competition negatively impacting honest European companies, especially small and medium-sized enterprises, conducting their research in Europe and following the requirements of the Regulation. Even in a case where the European Company places the exactly same product on the market, based on the same research and the same Genetic Resource as the multinational company, only the European company has to fulfil due diligence obligations. This could even lead to cases where the European company would not be allowed to sell the product, in contrast to the multinational which is allowed to do so.

Also, an important way in which products based on GR and ATK are commercialized is through sales via Internet. Such products are often "virtually" placed in the Union's market, with direct purchase options for consumers within the Union.

The "import loophole" not only circumvents efforts to ensure compliance with the Regulation in the Union, but also leads to commercial disadvantages; and in so doing, creates perverse incentives for users and commercialisers not to comply with the Regulation.

4
Conclusions and possible ways forward

As outlined in this analysis, the EU ABS framework does not cover a significant portion of cases of utilization of genetic resources and associated traditional knowledge by excluding from it scope the following:

- GR and aTK that were physically accessed in the country of origin before the entry into force of the Nagoya Protocol for the EU, even if utilization takes place afterwards, including any GR and aTK held in collections, botanical gardens, databases etc. in the EU at the time of the Nagoya Protocol's entry into force
- GR and aTK accessed in provider countries that have not (yet) ratified the Nagoya Protocol and/or enacted national ABS measures
- Associated Traditional Knowledge that is not explicitly mentioned in the Mutually Agreed Terms on the GR that it concerns
- Products based on research and development on GR and/or aTK outside of the EU, but then imported and sold on the EU market

As demonstrated above, these exclusions cause significant discrepancies with existing and emerging provider country legislations. They also arguably run counter to the spirit, and the common interpretation, of the CBD and the Nagoya Protocol. Besides hampering a truly fair and equitable sharing of benefits arising from the utilization of GR and aTK, they create legal uncertainty for providers and users alike. Unfortunately, this may lead to less rather than more trust among parties, and generate a push towards more restricted rules for access – both at national level in provider countries and at the level of Indigenous and Local Communities where aTK is concerned.

Of course users of GR and aTK still have to conform with the national legislations of provider countries, and with mutually agreed terms once these are entered into – as is clearly mentioned in the Guidance Document. However, the EU framework will make it quite difficult, in the cases mentioned above, for provider countries to monitor the use of their GR and aTK, and to seek compliance.

WHAT ARE THE CONSEQUENCES OF THE DISCREPANCIES BETWEEN THE EU REGULATION AND PROVIDER COUNTRY REGULATIONS?

Andreas Drews, Manager of the ABS Capacity Development Initiative

Concerning the "temporal scope"

Firstly, I would like to clarify a core issue regarding the question. The EU ABS Regulation does not contain any provisions that deal directly with the benefit obligations its users might have entered into according to their MAT with providers. The Regulation does not impose an obligation on users in the EU to share benefits apart from assuming that users will comply with any contractual agreements as required by other pieces of law. Hence, the EU compliance measures are meant to monitor utilization only and not benefit-sharing. Personally, I had hoped that the EU ABS Regulations would have taken up the core obligation of the Nagoya Protocol – "each Party shall take legislative, administrative or policy measures, as appropriate" to implement the statement of Art. 5.1 that "benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way" – in an explicit way.

The concept that new utilization should serve as trigger to receive MAT and PIC was advocated by the African Group and other developing countries in the negotiations of the Nagoya Protocol. This concept – which in my view is not retroactive because it does not regulate past access but new utilization after the entry into force of the respective law – was taken up in the African Union ABS Guidelines adopted in 2015. It is meant as a measure to ensure that benefit-sharing as one of the three pillars of the CBD is also happening in situations where access was undertaken without PIC and MAT. The concept would only become effective if it was taken up as user obligation in all countries' ABS laws because utilization could take place in any country of the world. During the Parliamentarian discussion on the EU ABS Regulations respective text was suggested by different groups. But in the end – and mostly due to debates that focused on alleged retroactivity and not on the substance of ensuring benefit-sharing – all three EU bodies involved rejected the concept. If now African countries are implementing the AU

ABS Guidelines in this regard – as for example Kenya is aiming at with its draft Wildlife Conservation and Management (Bio-prospecting) Regulations – the effect will most probably be minor because still the majority of all new utilization is situated in the EU and other industrialised countries based on their extensive ex-situ collections.

Concerning the definition of associated traditional knowledge

In my opinion, it is a weak point in the EU ABS Regulation that the compliance measures are only triggered when aTK is defined in the MAT and not when PIC and MAT are required by the provider country's ABS law for access to aTK. The explanation of the EU ABS Regulations for this approach is that *"there is currently no internationally-agreed definition of 'traditional knowledge associated with genetic resources'. Without prejudice to the competence and responsibility of the Member States for matters relating to traditional knowledge associated with genetic resources and the implementation of measures to safeguard indigenous and local communities' interests, in order to ensure flexibility and legal certainty for providers and users, this Regulation should make reference to traditional knowledge associated with genetic resources as described in benefit- sharing agreements."*

In my opinion this explanation disregards the fact that each State is sovereign in defining what aTK is and how access to it has to be dealt with in terms of ABS. The existence of such national legal rules on aTK and ABS should have been reason enough for the EU to deal with aTK at the same level as with GR. Whether this approach actually safeguards the interests of indigenous peoples and local communities and increases legal certainty is disputed by IPLCs and many traditional provider countries.

Concerning the "import loophole"

This "import loophole" in my view directly relates to my first answer on weak implementation of the benefit sharing obligations of the Nagoya Protocol in the EU ABS Regulations. Art. 5 of the Nagoya Protocol clearly includes benefit-sharing from commercialization. However, the scope of the EU ABS Regulation is on the research and development phase only. It is clear that the EU cannot rule on R&D that is undertaken outside of the EU. Following this strict approach, the obligatory checkpoints are only covering the R&D phase. The commercialization of products based on GR and aTK – whether it was undertaken in or outside of the EU – is not governed by the EU ABS system. Therefore, it is well possible that products can be imported into the EU that are based on misappropriation or misuse. And it appears that due to the scope of the EU ABS Regulation the selling of such products cannot be prohibited for the common market. Some EU member countries such as France and Spain do prohibit the sale of products from illegal utilisation through their national ABS law. It is however difficult to judge at this point how effective (or even acceptable) such prohibitions will be in the context of the common market.

CONSEQUENCES FOR COMMERCIAL USERS

Maria Julia Oliva, Union for Ethical BioTrade

The disparity among ABS requirements around the world are of great concern for companies involved in biodiversity-based innovation. The different scope, authorities, procedures and paperwork in various laws and regulations not only increase the complexity and cost of compliance, but also create an inherent legal uncertainty for the many international research projects and value chains.

These differences are particularly relevant when looking at the EU regulation. The EU regulation, as a set of compliance measures, is intrinsically linked to ABS requirements in other countries. Yet it applies to a set of genetic resources and associated traditional knowledge that is significantly more restrictive than those covered in the laws and regulations of provider countries.

This is why, though the EU regulation has greatly contributed to putting ABS high on the agenda of companies involved in biodiversity-based innovation, it is also generating much confusion. Notes explaining the differences and calling for compliance with provider country requirements have been added in official guidance documents. Yet it is evident that many companies in Europe are now under the mistaken impression that compliance with the EU regulation, as the tool to implement the Nagoya Protocol in Europe, is tantamount to a seal of 'ABS-compliant'.

Such confusion risks not only undermining compliance with other laws and regulations, but also weakening the international recognition of ABS principles as best practices in biodiversity-based innovation. Beyond the development and implementation of legal requirements on ABS, it is clear that the days of ethnobotanical studies or screening of plants for new properties and uses without information or benefits flowing back to the providers of samples and related insights should be long gone. Any biodiversity-based innovation should comply with applicable laws and regulations on ABS. Yet even if no such ABS laws and regulations were in place, it would be critical for research and development activities to comprehensively reflect the principles of prior informed consent and fair and equitable benefit sharing based on MAT.

In this regard, the EU regulation is, by focusing on setting such restrictive boundaries for its requirements, not helping to advance ABS principles, but having the opposite effect. Rather than support the inclusion and reflection of ABS principles across company activities such as research, product development, sourcing, intellectual property and sustainability, it is pushing ABS into the exclusive purview of the legal department, which is busy drawing no-go areas for sourcing or innovation. This threatens to undermine countries with ABS requirements. It is also generating a false sense of security for companies, which may not be complying with ABS requirements in provider countries or subject to reputational risks for not following best practices on ABS.

Of course, clarity on who must do what in which situation is critical in any law or regulation, including the EU regulation. Yet such clarity should be part of an approach that seeks to balance practical and meaningful compliance mechanisms. If not, a focus on narrowly defining legal requirements and the basic steps needed to satisfy those requirements may be at the expense of a more purposeful and effective engagement of companies on putting ABS in practice in their activities.

Considering this situation, what can provider countries do to still secure a maximum of benefits from the utilization of their GR and aTK? Which role can other actors, including collections and commercial users, play to somewhat level the playing field again, and fulfil the spirit of the Nagoya Protocol?

4.1 – DEVELOPING NATIONAL ABS LEGISLATION IN PROVIDER COUNTRIES

The first step for provider countries who want to be included in the "geographical scope" of the EU regulation is to rapidly ratify the Nagoya Protocol (for those who have not done so) and to develop "access and benefit sharing legislation or regulatory requirements" (see Art. 2.4. of the EU regulation). Arguably, in some countries existing laws on biodiversity, science, intellectual property rights etc. may be sufficient to fulfil the criteria, without necessarily having to enact new laws on ABS immediately. Several countries have also chosen to put in place interim regulations while developing more comprehensive laws.

As shown in the chapter on temporal scope above, provider countries have explicitly included wording that designates utilization as the trigger point for ABS obligations, rather than physical access. Some have included utilization into their broader definition of what constitutes access, some directly tie user obligations to utilisation activities, and some make direct reference to GR and aTK accessed before the entry into force of the Nagoya Protocol, and/or of GR and aTK held in ex-situ collections outside of the country. It is definitely in the best interest for provider countries to keep including such references, and to demand of users to seek PIC and negotiate MAT for every new or continued utilization of GR and aTK accessed before the entry into force of the Nagoya Protocol.

4.2 – MUTUALLY AGREED TERMS

Another point where provider countries, and communities providing aTK, can avoid losing control over the use of their GR and aTK is at the moment of negotiating mutually agreed terms. Here one option is to prohibit the transfer of the GR or aTK to third parties without authorization. Also, the contracts should include the obligation for the user, and any subsequent users, to seek new PIC and MAT with every change of intent in the utilization of the GR or aTK.

To support compliance with MAT, provider countries should include provisions in MAT to cover dispute resolution, including the jurisdiction in which any dispute resolution processes will be conducted, the applicable law and alternative dispute resolution mechanisms.

To make monitoring of MAT compliance easier, provider countries should also oblige users to disclose the origin or source of GR and aTK in Intellectual Property applications based on the accessed GR or aTK.

Finally, as the African Union Practical Guidelines for the coordinated implementation of the Nagoya Protocol in Africa note: *"The single best piece of advice available on the topic of commercial MAT is to retain the services of a good commercial lawyer to advise the National Focal Point, Competent National Authority, Indigenous or Local Community or other provider stakeholders involved".*[36]

4.3 – ENFORCING NATIONAL ABS LEGISLATION AND MUTUALLY AGREED TERMS

Even if the limited scope of the EU regulation makes it in many cases impossible to enforce compliance with the law of the provider countries in the EU, users of GR and aTK still have the obligation to comply with the national legislation of the country of origin, and with the terms of any ABS contract that they entered into.

It is therefore important for provider countries to put in place legislative, administrative or policy measures to encourage compliance, and to penalise, or where possible prosecute, violators where necessary. This would be an important sign in cases of new utilization where the rights of the provider countries could not be enforced in the EU. It would send a clear mes-

WHAT SHOULD PROVIDER COUNTRIES KEEP IN MIND WHEN DEVELOPING THEIR NATIONAL LEGISLATIONS?

Mahlet Teshome, African Union Commission, Department of Human Resources, Science and Technology

The EU regulations require PIC and MAT only when new access to genetic resources and associated traditional knowledge occur after the Nagoya Protocol comes into force for the Union and its member States. This interpretation of the Protocol's provisions unfortunately excludes new utilization of previously accessed resources which are well covered by the Protocol's focus on new utilization (which was an issue at the heart of the agreement made in Nagoya). This leaves out a very large number of genetic resources that have been taken from provider countries and are currently distributed in private or public collections, legitimizing their otherwise illegal utilization.

The EU regulation does not establish a robust compliance regime, as it only foresees limited user declarations of due diligence, no/weak checks by authorities and long delays in reporting. This may fail to generate the trust that provider countries should have to provide their genetic resources. Hence provider countries, as countries of origin or as countries having acquired genetic resources according to the CBD, should facilitate legal certainty. They should provide in their national laws that PIC is required for access to their GR, including from ex-situ collections. Or in other words, they should make clear that having physical access to their GR does not mean that PIC and MAT are no longer required for new uses. Utilization should always be accompanied by PIC and MAT for the GR covered under the Nagoya Protocol on ABS as appropriate.

GOOD MAT NEGOTIATIONS ARE THE ONLY SOLUTION... IN THE CURRENT SYSTEM

Manuel Ruiz, SPDA

As the ABS system stands at this moment, the only way I see that providers can exercise certain control is good MAT negotiations. However, even these agreements are limited given the extremely complex value adding chain and R&D which takes place nowadays, including through massive use of natural information (or genetic information) and limited need for material support (samples). In many key biotechnological fields, there is no way that controls can be successfully implemented, regardless of how well negotiated a contract is.

On a more positive note: I think the only way for provider countries to effectively exercise more effective control over their GR is through some serious modification to existing frameworks (national, EU, even the CBD as hard as this may be ...), and avoid creating a precedent where it seems that things and situations are inevitable and we need to continue moving in the same direction. I think users and providers should realize that a benefit sharing trigger at the point of commercial success is the only true win-win situation for all – coupled with some form of new international fund. In my mind, it its quite bewildering that provider countries continue to think that invoking sovereignty over (widely diffused) resources and through bilateral contract and MAT, they are "safeguarding" their interests in regards to their GR ... it is quite the opposite. Just take a look at the multi-billion dollar industry in biotechnology and related products, and see whether participation for providers is in fact fair and equitable in any form. Professor Peter Drahos put it very bluntly: countries are receiving peanuts for their biodiversity .... I tend to agree.

EMPOWER INDIGENOUS PEOPLES AND LOCAL COMMUNITIES SO THAT THEY CAN DEFEND THEIR RIGHTS ON ATK

Lucy Mulenkei, Indigenous Information Network

The EU regulations in my view do not give enough importance to the role of Indigenous Peoples and Local Communities (IPLCs), and are mainly focused on national governments. However, users of GR and aTK have to work with all providers and key players, including communities. Ideally, the EU regulations should be revised to accommodate the provider perspective and ensure that IPLCs are fully recognized.

There is still a lot to be done by the governments of provider countries. The national ABS regulations that they are developing should be in line with the Nagoya Protocol but at the same time, governments need to keenly understand the EU regulations and other user country regulations.

Most governments are not involving IPLCs fully in the process. There has to be a comprehensive capacity building effort which includes the raising of awareness about ABS in the communities. Most of them have no knowledge yet of their national ABS regulations. There will be no fair and equitable sharing of benefits if IPLCs are not fully involved and understand how to negotiate MAT. Only providing PIC is not sufficient. National governments and the EU should set aside funding to build the capacities and strengthen IPLCs so that they can successfully participate in ABS negotiations. A human rights based approach should be used to ensure recognition and respect for the rights of IPLCs. All key players should work together, be open to dialogue and negotiation so that during the process success stories can be told and where there are weaknesses, these can be addressed together.

sage to users all over the world (including in states which have not ratified the CBD).

One option to address non-compliance with national legislation is to use relevant regional dispute settlement bodies. Also, although developing countries did not succeed in getting mandatory disclosure of origin in intellectual property (IP) applications included as a compliance measure in the Nagoya Protocol, the readily searchable information of the international IP system remains a potential and very cost-effective tool for tracking and monitoring utilisation of GR and aTK.

In cases where MAT have been negotiated, an important aspect of monitoring compliance is for the competent national authority or the national focal point to follow up on fulfilment of MAT, including regular reporting requirements. If a user fails to comply with agreed reporting obligations, the intervention of relevant ABS authorities in the user country should be sought. Another option is to provide sanctions in national ABS laws for failing to report as agreed in MAT.[37]

4.4 – PUTTING IN PLACE MEASURES TO PROTECT TRADITIONAL KNOWLEDGE

Considering the narrow scope of the aTK included in the EU regulation, it becomes even more crucial for indigenous peoples and local communities and provider country governments to put in place measures to protect TK. Access to TK (e.g. through databases or field interviews) must be regulated, and it is imperative that countries put in place national laws to regulate such access where no suitable legal basis exists.[38] Databases of Traditional Knowledge can be another useful measure, especially for preventing bad IP grants, but they are costly to implement and bear their own set of risks if they are not appropriately secured.

4.5 – A LIST OF TRUSTED COLLECTIONS?

Collections such as botanical gardens, gene banks or private collections hold a large number GR and aTK accessed in the country of origin before the entry into force of the Nagoya Pro-

tocol. They can therefore play a key role in ensuring that the GR or aTK in their keep are not utilized without the PIC and MAT of the provider country and the respective indigenous or local community. Collections can put rules in place which do not allow the supply of GR and aTK for commercial users without first obtaining a new PIC from the provider country. That way, the provider country has the chance to negotiate MAT and obtain the fair sharing of benefits on their GR and aTK even if these were accessed before the entry into force of the Nagoya Protocol, and were held in these collections. The goal should be that collections do not support the circumvention of laws and requirements from provider countries. Unfortunately, this is not an obligation so far, even for the collections which will form part of the EU's voluntary register of collections.

Several collections, for instance botanical gardens, have already put in place their own policies to this effect. The International Plant Exchange Network (IPEN), an exchange system for botanical gardens for non-commercial exchange of plant material based on the CBD, developed a code of conduct[39] for its members regarding access to genetic resources and sharing of the resulting benefits. For instance, the members commit to transferring plant material outside of the network only if *"the recipients commit themselves to act in compliance with the CBD and its agreed provisions on Access and Benefit Sharing. This includes a new Prior Informed Consent (PIC) of the country of origin for any uses not covered by terms under which it has been acquired (such as commercialisation)."* Another (albeit weaker) example are the Principles on Access to Genetic Resources and Benefit-Shar-

WHAT CAN PROVIDER COUNTRIES, IPLCS AND OTHER ACTORS DO TO ADDRESS SOME OF THE CHALLENGES RAISED?

Andreas Drews, ABS Capacity Building Initiative

National ABS frameworks

National ABS Frameworks in Africa – the main focus of our work – should take up Art. 9 of the African Union Strategic Guidelines on ABS and state that "having or obtaining physical access to such genetic resources, including from *ex situ* collections, does not imply that prior informed consent for their utilisation has been granted or is not required. Utilisations without prior informed consent and without the establishment of mutually agreed terms are considered illegitimate." Without respective legally binding user measures this call will have no immediate effect, but it will send a strong political message to all ABS actors to cooperate in ensuring benefit-sharing for new and possibly ongoing utilization.

With regard to aTK, national ABS frameworks should contain definitions and require provider and user to include these definitions in any MAT.

ABS frameworks should also contain provisions that each MAT must – beside benefit-sharing provisions – deal with other key issues related to utilization in response to the user measures and compliance rules in other countries. Amongst these issues there are e.g. kind(s) of utilization allowed, third party transfer, clear ways of communication.

Furthermore, I would like to suggest that ABS frameworks should implement a system for simplified access for non-commercial research. Access for non-commercial research is essential for supporting the aims of the CBD to conserve biodiversity and use it sustainably. I expect that the extent to which this will happen strongly depends on the confidence of provider countries in the effectiveness of the compliance systems set up by traditional user countries such as the EU. The most critical aspect will be in this context the uncontrolled and unwanted transfer of GR, aTK and research results from non-commercial into applied and commercial research.

Mutually Agreed Terms

As said above, MAT must contain a definition of aTK; furthermore, effective provisions on third party transfer, on allowed kind(s) of utilisation and specifically on the development of products and their commercialisation. Benefit-sharing clauses must be specific for all phases of the value chain. MAT need to set clear and legally enforceable conditions determining the actions to be undertaken if provisions of the MAT are not followed by the user.

In general, it is necessary to increase the capacities of providers and specifically the Competent National Authorities (CNAs) to negotiate ABS contracts that comply with the general requirements of commercial contract law and are legally enforceable in the provider and the user country. Capacity building and development in this field is urgently required as at this stage, capacities in negotiating commercial international contracts are limited in such authorities which are normally national environmental institutions.

Indigenous Peoples and Local Communities

As mentioned above for the CNAs, IPLCs are in general not familiar with negotiating commercial international contracts. IPLCs should seek competent legal advice and enter into cooperation with appropriate capacity development programs. If it becomes known that utilization with their GR and aTK is ongoing without the necessary PIC and MAT, IPLCs should seek the support of their national CNA and contact the CNA in the country of the user. CNAs in the user countries should be the first stop for IPLCs to trigger activities leading to the halt of such utilization and, if still wished so, negotiating proper ABS documents. Ideally, national CNAs should support IPLCs in such cases with legal advice and through additional communication with user country CNAs.

Users (including commercial users, researchers, collections etc.)

The mentioned actors should develop sound ABS codes of conducts based on the principles of the CBD, its Nagoya Protocol and the UN Declaration for the Rights of Indigenous Peoples. Such codes of conducts should specifically deal with the above mentioned issues that according to the analysis of many provider countries and IPLCs are not dealt with satisfactorily in the EU ABS Regulations.

ing[40] developed by an international group of 28 botanical gardens and herbaria from 21 countries, which provide a framework upon which individual institutions can design their own policies. The principles encourage their members, for example, to prepare a transparent policy on the commercialisation of GR acquired before and since the CBD entered into force, and to share benefits arising from the use of genetic resources acquired prior to the entry into force of the CBD, as far as possible, in the same manner as for those acquired thereafter.

It is entirely conceivable to establish a list or register of collections which will have such policies in place, and conversely, another register of those whose access to their material does not require renewed PIC and MAT, thereby allowing the circumvention of provider country laws. Such a list would allow provider countries to choose to collaborate only with collections that have ABS policies in place which support the compliance with their national ABS law and regulations.

> "Many companies in Europe are now under the mistaken impression that compliance with the EU regulation, as the tool to implement the Nagoya Protocol in Europe, is tantamount to a seal of 'ABS-compliant'."
>
> *Maria Julia Oliva, UEBT*

4.6 – ENCOURAGE AND PUBLISH BEST PRACTICE BY COMMERCIAL USERS

Companies should always strive to comply with all national legislations which impact their activities, which includes provider country legislations, even if they are utilizing GR and aTK which fall outside of the scope of the EU regulation. Of course companies could choose to use the various discrepancies mentioned to avoid their obligations towards the provider country, hoping that their biopiracy will not be discovered and penalised. Or, on the contrary, they can choose to lead by example by striving for best practice, as much as possible. Standards of best practice and codes of conduct can include provisions on ABS, and thus make fair and equitable benefit sharing part of a company's corporate social responsibility commitments. For example, the Ethical Biotrade Standards[41] developed by the Union for Ethical Biotrade include a set of standards on the "fair and equitable sharing of benefits derived from the use of biodiversity", including the commitment to seek PIC and MAT for research and development, the compliance with relevant legislation, and the respect for the rights of traditional knowledge holders, among others.

Endnotes

1 www.cbd.int/abs
2 www.cbd.int/convention/text
3 http://eur-lex.europa.eu/eli/reg/2014/511/oj
4 See: Berne Declaration and Natural Justice, 2013: Access or Utilisation – What Triggers User Obligations? Available at: www.publiceye.ch/fileadmin/files/documents/Biodiversitaet/130618_Access_or_Utilisation.pdf and also: Berne Declaration, Natural Justice and UNU-IAS, 2014: The Ambiguous March to Equity, available at www.publiceye.ch/fileadmin/files/documents/Biodiversitaet/KORR_The_Ambiguous_March_to_Equity.pdf
5 http://eur-lex.europa.eu/eli/reg_impl/2015/1866/oj
6 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC0827(01)
7 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 (see Article 28 of the Vienna Convention). Since the Nagoya Protocol is silent on this aspect, its retroactive application cannot be expected. The Vienna Convention is available at: https://treaties.un.org/doc/Publication/UNTS/Volume%201155/volume-1155-I-18232-English.pdf
8 Article 15 of the CBD refers to access to GRs and reads:
"Article 15. Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing
1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.
2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.
3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above."
9 Letter sent on 20 February 2014 by the South African Department of Environmental Affairs, titled „Submission of comments on the draft EU regulations on Access and Benefit Sharing by the Like-Minded Mega-Diverse Countries" (letter in possession of the authors).
10 See section 2.2 on temporal scope of the Guidance Document
11 www.admin.ch/opc/en/classified-compilation/20150120/index.html
12 In Portuguese: www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Lei/L13123.htm
13 Art. 2 VIII - acesso ao patrimônio genético - pesquisa ou desenvolvimento tecnológico realizado sobre amostra de patrimônio genético;
14 Art. 2 XIII - remessa - transferência de amostra de patrimônio genético para instituição localizada fora do País com a finalidade de acesso, na qual a responsabilidade sobre a amostra é transferida para a destinatária;
15 Art.2 IX - acesso ao conhecimento tradicional associado - pesquisa ou desenvolvimento tecnológico realizado sobre conhecimento tradicional associado ao patrimônio genético que possibilite ou facilite o acesso ao patrimônio genético, ainda que obtido de fontes secundárias tais como feiras, publicações, inventários, filmes, artigos científicos, cadastros e outras formas de sistematização e registro de conhecimentos tradicionais associados;
16 Art. 17. Os benefícios resultantes da exploração econômica de produto acabado ou de material reprodutivo oriundo de acesso ao patrimônio genético de espécies encontradas em condições *in situ* ou ao conhecimento tradicional associado, ainda que produzido fora do País, serão repartidos, de forma justa e equitativa, sendo que no caso do produto acabado o componente do patrimônio genético ou do conhecimento tradicional associado deve ser um dos elementos principais de agregação de valor, em conformidade ao que estabelece esta Lei.
17 www.parliament.gov.zm/sites/default/files/documents/acts/The%20Protection%20of%20Traditional%20Knowledge%2C%20Genetic%20Resources%20and%20Expressions%20of%20Folklore%20Act%20No.%2016%20of%20%202016.pdf
18 Accessed on 18.11.2016 at www.moaf.gov.bt/.../ABS%20Policy%20of%20Bhutan%20-2014%20(Draft).docx
19 www.environment.gov.za/sites/default/files/legislations/nema_amendment_act10.pdf
20 www.environment.gov.za/sites/default/files/legislations/nemba10of2004_babsregulations_amendments.pdf
21 http://nbaindia.org/content/25/19/1/act.html
22 https://absch.cbd.int/api/v2013/documents/E9B01EDF-9973-167E-AEDD-5C988379E29F/attachments/Guidelines%20on%20Access%20and%20Benefit%20Sharing_%20India%202014.pdf
23 Medida Provisoria No. 2.186-16 of 23 August 2001: www.planalto.gov.br/ccivil_03/mpv/2186-16.htm
24 Art. 37. Deverá adequar-se aos termos desta Lei, no prazo de 1 (um) ano, contado da data da disponibilização do cadastro pelo CGen, o usuário que realizou, a partir de 30 de junho de 2000, as seguintes atividades de acordo com a Medida Provisória no 2.186-16, de 23 de agosto de 2001:
I – acesso a patrimônio genético ou conhecimento tradicional associado;
II – exploração econômica de produto acabado ou de material reprodutivo oriundo de acesso a patrimônio genético ou ao conhecimento tradicional associado.
25 Art. 38. Deverá regularizar-se nos termos desta Lei, no prazo de 1 (um) ano, contado da data da disponibilização do Cadastro pelo CGen, o usuário que, entre 30 de junho de 2000 e a data de entrada em vigor desta Lei, realizou as seguintes atividades em desacordo com a legislação em vigor à época:
I – acesso a patrimônio genético ou a conhecimento tradicional associado;
II – acesso e exploração econômica de produto ou processo oriundo do acesso a patrimônio genético ou a conhecimento tradicional associado, de que trata a Medida Provisória no 2.186-16, de 23 de agosto de 2001;
III –remessa ao exterior de amostra de patrimônio genético; ou
IV–divulgação, transmissão ou retransmissão de dados ou informações que integram ou constituem conhecimento tradicional associado.
26 www.abs-initiative.info/countries-and-regions/africa/african-union-commission-auc/
27 Draft accessed on 16.11.2016 at: www.kws.go.ke/download/file/fid/2217
28 African Union, 9th September 2013, reference: HRST/ST/8/2924/9.13
29 See articles 6,7 and 12 of the Nagoya Protocol
30 See article 16 of the Nagoya Protocol
31 Group of Technical and Legal Experts on Traditional Knowledge associated with Genetic Resources, 16 - 19 June 2009 - Hyderabad, India. See: www.cbd.int/doc/?meeting=ABSGTLE-03
32 www.wipo.int/edocs/lexdocs/laws/en/ke/ke030en.pdf
33 Letter sent on 2 July 2013 on behalf of the International Indigenous Forum on Biodiversity, the Indigenous Information Network and Natural Justice, co-signed by 49 organizations and individuals (letter in possession of the autors)
34 www.admin.ch/opc/en/classified-compilation/19660144/index.html
35 Unofficial translation of Danish: www.cbd.int/doc/measures/abs/post-protocol/msr-abs-dnk-en.pdf
36 See African Union, 2015: African Union Practical Guidelines fort he Coordinated Implementation oft he Nagoya Protocol in Africa, www.abs-initiative.info/fileadmin//media/Knowledge_Center/Pulications/African_Union_Guidelines/AU_Practical_Guidelines_On_ABS_-_20150215.pdf
37 Ibid.
38 Ibid.
39 www.bgci.org/files/ABS/IPEN/ipencodeofconduct.doc
40 www.bgci.org/policy/abs_principles
41 http://ethicalbiotrade.org/verification/ethical-biotrade-standard

This study shows the large discrepancies between the EU ABS framework and provider country legislations in how they implement the Nagoya Protocol, and the consequences for access and benefit sharing. The study also presents some constructive suggestions on how to deal with the current discrepancies, so that the rights of provider countries and of indigenous peoples and local communities can still be respected and fulfilled, and fair and equitable benefit sharing can be achieved.

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