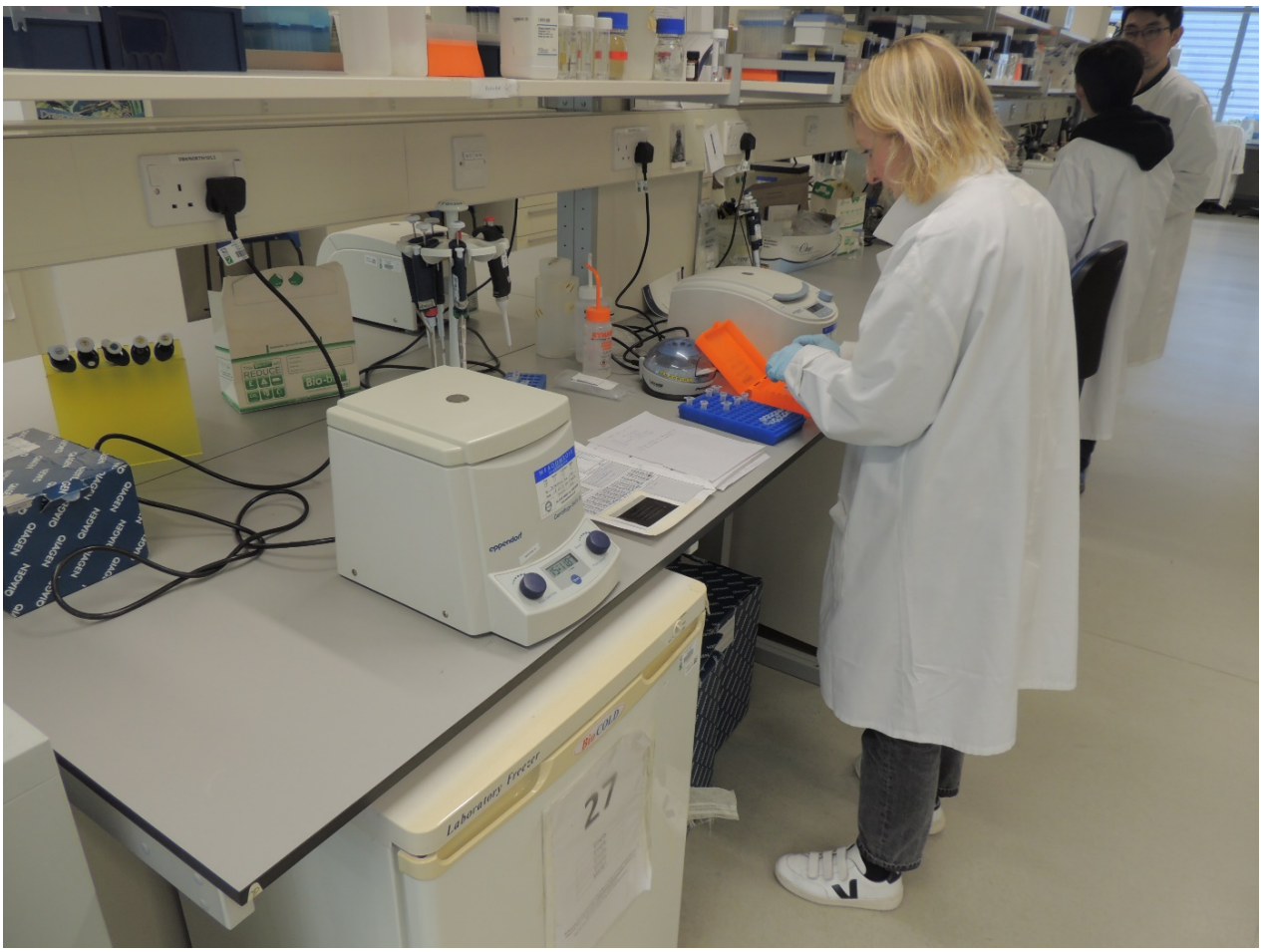
Evanson Chege Kamau (Ed.)

Implementation of the Nagoya Protocol

Fulfilling new obligations among emerging issues



Federal Agency for Nature Conservation

BfN-Skripten 564

2019

Deutsche Forschungsgemeinschaft

Universität Bremen

Implementation of the Nagoya Protocol

Fulfilling new obligations among emerging issues

Edited by
Evanson Chege Kamau

Federal Agency for Nature Conservation

Cover picture: Laboratory at the Natural History Museum, London (Chris Lyal)

Editor's address:

Dr. Evanson Chege Kamau — Universität Bremen
Universitätsallee, GW 1
28359 Bremen
E-Mail: echege@uni-bremen.de

Scientific supervision:

Thomas Greiber — BfN, Division I 1.3 "Competent National Authority for the Nagoya Protocol"

This study was funded by the German Ministry for the Environment, Nature Conservation and Nuclear Safety as Research & Development project (FKZ: 3517 81 010E).

This publication is included in the literature database "DNL-online" (www.dnl-online.de)

BfN-Skripten are not available in book trade. A pdf version can be downloaded from the internet at: http://www.bfn.de/skripten.html.

Publisher: Bundesamt für Naturschutz (BfN)
Federal Agency for Nature Conservation
Konstantinstrasse 110
53179 Bonn, Germany
URL: http://www.bfn.de

Printed by the printing office of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

Printed on 100% recycled paper.

ISBN 978-3-89624-325-6

DOI 10.19217/skr564

Bonn, Germany 2019

Table of Contents

Contributors ..... **iv**

Acknowledgements vi

List of Figures vii

List of Abbreviations / Acronyms viii

PART I: INTRODUCTION 1

Chapter 1
Implementing the Nagoya Protocol and new arising issues: Introduction, observations and conclusions

Evanson Chege Kamau 3

PART II: ABS MEASURES AND IMPLEMENTATION OF NAGOYA PROTOCOL REQUIREMENTS: CASE STUDIES 13

Chapter 2
Viet Nam: New ABS legislation and practice, compliance with the Nagoya Protocol

Tran Thi Huong Trang, Nguyen Ba Tu & Nguyen Dang Thu Cuc 15

Chapter 3
Korean ABS law

Jae-Hyup Lee & Ah Young Cho 23

Chapter 4
The Malaysian ABS law – A big step forward

Evanson Chege Kamau 27

Chapter 5
Implementing ABS in Australia. Failing at the last hurdle?

Geoff Burton 35

Chapter 6
The South African ABS regime: Between old and new

Evanson Chege Kamau 41

Chapter 7
Towards a Nagoya Protocol compliant ABS regulatory framework in Cameroon

Marcelin Tonye Mahop 49

Chapter 8
The Ethiopian ABS regime

Ashenafi Ayenew Hailu 55

Chapter 9
The Kenyan ABS regulations: A static law

Evanson Chege Kamau 59

Chapter 10
Brazil: New ABS legislation and practice

Lilian Massini Mozini 65

Chapter 11
ABS regime in Argentina

Luciana Carla Silvestri 73

Chapter 12
Costa Rican ABS legislation and practice

Jorge Cabrera Medaglia 77

Chapter 13
ABS in Ecuador and Peru: Between the Andean sub-regional regime and the Nagoya Protocol

Maria Victoria Cabrera Ormaza 83

Chapter 14
The post Nagoya Protocol ABS regulatory framework of France

Marcelin Tonye Mahop 91

Chapter 15
ABS regime in Spain

Luciana Carla Silvestri 99

PART III: CRITICAL THEMES AND IMPLEMENTATION 103

Chapter 16
ABS regulation in the European Union

Gerd Winter 105

Chapter 17
Disentangling Due Diligence – Making sense of the EU Regulation 511/2014 transposing the Nagoya Protocol

Christine Godt & Markus Burchardi 111

Chapter 18
Implementation of Due Diligence obligations in Germany

Thomas Greiber 115

Chapter 19
Current situation on Digital Sequence Information (DSI)

Christopher H C Lyal 119

Chapter 20
The persistence of ABS contractual obligations in the context of agricultural breeding

Marie Schloen 125

Chapter 21
Post Nagoya Protocol experiences of academic biodiversity-related research in Ecuador

Erwin Beck 131

Chapter 22
Rights over genetic resources and ways of monitoring the value chain. A case study from the Royal Botanic Gardens, Kew

China Williams 137

Figure 1: Weevil, *Elaeidobius plagiatus Fahraeus* from West Africa, a polinator of oil palm. Photo by Chris Lyal.

Contributors

Ah Young Cho, PhD Candidate, Seoul National University School of Law, South Korea. hasiromi5@snu.ac.kr.

Ashenafi Ayenew Hailu, Director, Genetic Resource Access and Benefit Sharing Directorate, Ethiopian Biodiversity Institute, Addis Ababa, Ethiopia. ayenewashenafi2007@gmail.com.

China Williams, Senior Science Officer (Policy), Royal Botanic Gardens, Kew, UK. c.williams@kew.org.

Christine Godt, Prof. Dr., Chair for European and International Economic Law, Civil Law, Carl von Ossietzky University of Oldenburg; Director Hanse Law School. Germany. christine.godt@uni-oldenburg.de.

Christopher H C Lyal, Dr., Department of Life Sciences, Natural History Museum, Cromwell Road, London SW7 5BD, UK. c.lyal@nhm.ac.uk.

Erwin Beck, Prof. Dr., Department of Plant Physiology and Bayreuth Centre of Ecology and Environmental Research, University of Bayreuth, Bayreuth, Germany. erwin.beck@uni-bayreuth.de.

Evanson Chege Kamau, Dr., Senior Research Fellow, Research Centre for European Environmental Law, University of Bremen, Germany. echege@uni-bremen.de.

Geoff Burton, Principal Consultant, Genetic Resources Management, Jean Shannon & Associates, Australia. geoff@jeanshannon.com.

Gerd Winter, Prof. Dr., Research Professor of public law and sociology of law, University of Bremen, Germany. gwinter@uni-bremen.de.

Jae-Hyup Lee, Prof., Seoul National University School of Law, South Korea. jhyup@snu.ac.kr.

Jorge Cabrera Medaglia, Prof., Professor of Environmental Law, University of Costa; Legal adviser, National Biodiversity Institute, Costa Rica. jorgecmedaglia@hotmail.com.

Lilian Massini Mozini, Legal consultant in environmental law specialising in development of strategies for biodiversity access, innovation and products development for companies and research institutions, Brazil. lmozini@ambiente-global.com.

Luciana Carla Silvestri, Dr., Institute of Human, Social and Environmental Sciences (INCIHUSA) – National Council of Scientific and Technical Research (CONICET), Av. Ruiz Leal s/n, Ciudad de Mendoza, Argentina. lsilvestri@mendoza-conicet.gob.ar.

Marcelin Tonye Mahop, Dr., Research Fellow, Sustainability Research Institute (SRI), School of Earth and Environment (SEE), Faculty of Environment, University of Leeds, UK. tonye2169@gmail.com or m.tonyemahop@leeds.ac.uk.

Maria Victoria Cabrera Ormaza, Dr., Legal Officer at the International Labour Office. Former associate professor and researcher at the Universidad Espiritu Santo-Ecuador. marvic.co@gmail.com.

Marie Schloen, PhD Candidate, University of Bremen, Germany. mschloen@yahoo.com.

Markus Burchardi, PhD candidate and research assistant at the Chair for European and International Economic Law. markus.burchardi@uni-oldenburg.de.

Nguyen Ba Tu, Ministry of Natural Resources and Environment, Hanoi, Viet Nam. tunguyen.bca@gmail.com.

Nguyen Dang Thu Cuc, Ministry of Natural Resources and Environment, Hanoi, Viet Nam. nguyendt.cuc@gmail.com.

Thomas Greiber, Head of Division I 1.3, Federal Agency for Nature Conservation (BfN) – Competent National Authority for the Nagoya Protocol, Bonn, Germany. thomas.greiber@bfn.de.

Tran Thi Huong Trang, Dr., Independent legal consultant in biodiversity, natural resources and environmental law, Viet Nam. tranglpsd@gmail.com.

Acknowledgements

I would like to thank the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz – BfN) for financing the printing of this publication and the workshop which preceded it. The workshop which took place on 27-28 June 2019 in Bremen, Germany, served as a critical meeting point for the review of the progress of an ongoing ABS research project and therefore filled an existing gap in the initially planned project activities. It is hereby acknowledged that the project, which started in February 2017 and hosted at the University of Bremen, is funded by the German Research Foundation (Deutsche Forschungsgemeinschaft – DFG).

Though the workshop was useful in advancing the drafting process its recommendation that the research team draft preliminary results for this publication obviously meant additional workload. Considering that this undertaking was not contemplated in the initial planning and timeline of the project its success depended fully on the team's willingness and commitment. I owe my gratitude to my exceptional team. Thank you so much for an excellent team spirit and cooperation throughout the project, hard work and diligence.

Besides, I would like to thank Ms. Anna Himmelskamp, our secretary at the Research Centre for European Environmental Law (Forschungsstelle fuer Europaeisches Umweltrecht – FEU), for her input in organisational and technical issues which have been critical not only for the success of the workshop but likewise the entire project.

In addition, I would like to thank my student assistant, Ms. Talline Koerner, for her input in research-related issues and in other areas including organisational and the first formatting of the manuscript to this publication.

Further, I am extremely thankful to Ms. Antje Kautz for the final formatting of the print version of the manuscript to this publication and the creation of the accessible (barrier free) pdf version.

Last and not least, my appreciation goes to Ms. Ute Feit and Mr. Thomas Greiber of the BfN for their assistance and guidance during the application process for grant and throughout the ensuing undertaking.

Evanson Chege Kamau

Bremen, December 2019

List of Figures

Figure 1: Weevil, *Elaeidobius plagiatus Fahraeus* from West Africa iii
Figure 2: Damnux new species from *Dipterocarps*. 1
Figure 3: Dobsonfly. 13
Table 3.1: Other laws related to the genetic resources under different Korean ministries .. 35
Table 11.1: Provinces with ABS-related legislation 85
Figure 4: Plant life on a tree in the biodiversity hotspot of South Ecuador 103
Box 22.1: Kew collections in numbers 137
Box 22.2: Summary of Kew's ABS Toolkit 138
Diagram 22.1: Basic principles of RBG Kew operations 139
Figure 5: Project team outside the FEU 142
Figure 6: Project team at the entrance to the University of Bremen 142

List of Abbreviations / Acronyms

A/aTK	Associated traditional knowledge
ABS CH	ABS Clearing House
ABS	Access and Benefit-Sharing
ABSA	Access and Benefit-Sharing Agreement
ABSpc	ABS Permitting Committee
AHTEG	Ad-hoc Technical Expert Group
BABS	RegulationsBioprospecting, Access and Benefit-Sharing Regulations (South Africa)
BfN	Bundesamt für Naturschutz (Federal Agency for Nature Conservation)
BL	Biodiversity Law
BR	Biological Resources
BS	Benefit-sharing
BSA	Benefit-sharing Agreement
BTF	Benefit Trust Fund
c.	Clause
CA	Competent Authority
CAN	Community of Andean Nations
CBD	Convention on Biological Diversity
CGEN	Conselho de Gestão do Patrimônio Genético
CGRFA	FAO Commission on Genetic Resources for Food and Agriculture
CHM	Clearing-House Mechanism
CITES	Convention on International Trade in Endangered Species (of Wild Fauna and Flora)
CNA	Competent National Authority
COA	Código Orgánico del Ambiente en Recursos Naturales, Energía e Infraestructura (Codex of Enviroment – Ecuador)
COI	Codigo Ingenios (Codex of the Social Economy of Knowledge, Creativity and Innovation – Ecuador)
COFEMA	Federal Council of the Environment
COMIFAC	Commission des Forêts d'Afrique Centrale
CONAGEBIO	National Commission for the Management of Biodiversity
COP	Conference of Parties
COP/MOP	Conference of Parties serving as Meeting of Parties
CP	Checkpoint
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CSR	Corporate Social Responsibility
DDD	Declaration of Due Diligence
DEA	Department for Environmental Affairs

DNA	Deoxyribonucleic Acid
DSI	Digital Sequence Information
DSMZ	Deutsche Sammlung von Mikroorganismen und Zellkulturen (German Collection of Microorganisms and Cell Cultures GmbH)
EBI	Ethiopian Biodiversity Institute
EEA	European Economic Area
EFTA	European Free Trade Association
EMCA	Environmental Management and Coordination Act
EPBC Act	Environment Protection Biodiversity Conservation Act
EU	European Union
FAO	Food and Agriculture Organization (of the United Nations)
GAP	General Access Procedure
GEF	Global Environment Facility
GR(s)	Genetic Resources
IBRs	Indigenous Biological Resources
IGBRs	Indigenous Genetic and Biological Resources
ILC(s)	Indigenous and Local Communities
INABIO	Instituto Nacional De Biodiversidad (National Institute of Biodiversity – Ecuador)
INCOPESCA	Instituto Costarricense de Pesca y Acuicultura (Costa Rican Institute of Fishing and Aquaculture)
INTECO	National Standarization Office (Costa Rica)
IP	Intellectual Property
IPR(s)	Intellectual Property Right(s)
IT	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for Conservation of Nature
KEPHIS	Kenya Plant Health Inspectorate Service
KWS	Kenya Wildlife Service
MAE	National Environmental Authority
MARD	Ministry of Agriculture and Rural Development
MAT	Mutually Agreed Terms
MEC	Member of Executive Council
MLS	Multilateral System
MoC	Memoranda of Collaboration
MONRE	Ministry of Natural Resources and Environment
MOU	Memorandum of Understanding
NACOSTI	National Commission for Science, Technology and Innovation
NBS	National Biodiversity Strategy

NCA(s)	National Competent Authority(ies)
NCST	National Council for Science and Technology
NEMBA	National Environmental Management: Biodiversity Act
NFP	National Focal Point
NGO	Non-governmental Organisation
NMK	National Museums of Kenya
NP	Nagoya Protocol
NSD	Nucleotide Sequence Data
OECD	Organisation for Economic Co-operation and Development
PIC	Prior Informed Consent
r./rr.	Regulation(s)
RBG	Royal Botanic Gardens
R&D	Research and Development
RESPECT	Environmental Changes in Biodiversity Hotspot Ecosystems of South Ecuador: Responses & Feedback Effects
RNA	Ribonucleic Acid
s./ss.	Sections
SA	South Africa
SCBD	Secretariat of the Convention on Biological Diversity
SE & SD	Secretariat of Environment and Sustainable Development
SENESCYT	National System of Science, Technology, Innovation and Traditional Knowledge
SUIA	Unique System of Environmental Information
SUMA	Unique System of Environmental Management
TO	Technical Office
TOPS	Threatened or Protected Species
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNCLOS	United Nations Convention on the Law of the Sea
UNDP	United Nations Development Program
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNGA	United Nations General Assembly
WIPO	World Intellectual Property Organization
WWF	World Wide Fund (For Nature)

PART I: INTRODUCTION

Figure 2: Damnux new species from *Dipterocarps*. Photo by Chris Lyal.

Chapter 1
Implementing the Nagoya Protocol and new arising issues: Introduction, observations and conclusions

Evanson Chege Kamau

1 The Nagoya Protocol

The Convention on Biological Diversity (CBD) was adopted in 1992 at the UN Conference on Environment and Development (Earth Summit) in Rio de Janeiro. The Convention came into force in 1993 and has a membership of 196 states and the EU.[1] Its three main objectives are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising from the utilization of genetic resources.[2] Our focus is the third objective on benefit-sharing, which is anchored on articles 15 and 8 j of the CBD. These articles set the rules for access to genetic resources (GR) and traditional knowledge associated to such resources (aTK) and the sharing on benefits arising from their utilisation. Accordingly, access must take place subject to the prior informed consent (PIC) of the party providing the GR and/or aTK and the establishment of mutually agreed terms (MAT) between the parties. In addition, benefits arising from their utilisation must be shared in a fair and equitable manner.

The implementation of the third objective has suffered many setbacks over the years. Although restrictive rules of the providers and lack of compliance measures in user countries bore part of the blame for the debacle, the diffuse nature and often voluntary disposition of the provisions likewise led to this result. To try and resolve the challenges encountered and to operationalize access and benefit-sharing (ABS) the parties to the CBD agreed to negotiate a more concrete and binding instrument under the Convention. Following the negotiations, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity was adopted in Aichi-Nagoya, Japan, in 2010, eighteen years since the adoption of the CBD. The Protocol came into force in 2014 and now has a membership of 123 parties including the EU.[3] Upon becoming party to the Protocol, each member is obliged to put national measures in place to comply with its provisions.[4] However, countries have leeway not to establish any access measures if they choose not to subject access to PIC and MAT, but must ensure compliance with other parties' measures within their territory.[5]

This publication focuses on the implementation of the post-Nagoya Protocol ABS legislation and practice based on a research project of the University of Bremen titled "New ABS legislation and practice and their compliance with the Nagoya Protocol". The project is funded by the DFG (German Research Foundation) and headed by Dr. Evanson Chege Kamau. Among the issues being examined in the project is how countries are coping as well as complying with the Nagoya Protocol (NP) and to what extent available country experiences can provide solutions to similar issues in other countries. In addition it is being examined how some of the issues that remained controversial or unresolved during the negotiations,

---

[1] www.cbd.int.

[2] Article 1 CBD.

[3] https://absch.cbd.int/, as of 22 January 2020.

[4] Article 33 (3) in conjunction with e.g. articles 5, 7, 15 and 16.

[5] See e.g. Greiber, T. et al. (2012), 277.

or that have risen during the implementation phase are being resolved. Examples of such issues include questions about digital sequence information (DSI); scope of provider rights; the role of databases; inadequate definitions of central CBD terminology such as genetic resources and utilization; and incomplete regulations on the necessary proof of compliance with the CBD, e.g. for non-commercial users of GR, as well as the related verification of compliance with international legal requirements.

Apparently, there is a dearth of studies that examine the implementation of the NP not just descriptively, but analytically and in a problem-oriented approach, in particular regarding the issues mentioned above. Our research project attempts to close this gap. The reports presented here are more or less descriptive summaries of the preliminary results of the ongoing examination of legislations and practices of fifteen case studies and six general themes. The case studies make a global representation as they cover five continents of the world. The full reports containing analytical parts and novel ideas on how to resolve challenges with implementation and other relevant issues e.g. DSI will be published shortly in a book volume. Attempting not to repeat much of what is contained in Part II and Part III below we present some of the preliminary observations and conclusions.

2 Cross-cutting implementation issues

Observations on implementation can be placed under two main headings: challenges and new developments.

2.1 Challenges

Fragmentation of legislations

A number of regimes still suffer from fragmented statutes. Most of these are unrevised pre-NP legislations which engage different laws to regulate ABS, e.g. regimes of Kenya and Cameroon. In Kenya, for instance, that results to overlapping mandates of state agencies with power to regulate ABS and multiple, complex procedures,[6] and hence to unclarity and uncertainty. We see countries trying to resolve this problem by giving the jurisdiction over ABS issues to the new stand-alone legislations alone. Maybe article 3 (2) of the Malaysian Act of 2017 could be interpreted as instituting such jurisdiction. It states: “The provisions of this Act shall be in addition to, and not in derogation of, the provisions in any other law for the time being in force, relating to forests, wildlife, animals, fishery and international trade in endangered species, except for matters that fall within the provisions of these Act” (bold added). In our view this would mean that in matters of ABS that are addressed by the Act, the Act has pre-eminence even if it is in derogation of other relevant biodiversity laws. In South Korea, on the other hand, the problem of competition for jurisdiction over ABS-related issues between different national authorities remains in spite of a new stand-alone legislation (of 2017). That means, solely having a new legislation, though stand-alone, cannot solve that problem. Unless the ABS legislation is clear concerning its jurisdiction and the mandates of the national authorities created by it over ABS issues, and, of course, other relevant legislations are revised in order to attain harmonisation, this problem is deemed to recur. Unclarity and uncertainty, however, can also result from another form of fragmentation: post-NP revisions and amendments found in different acts. This is the case with the South African regime, which has undertaken several amendments after the adoption of the NP as well as its entry into force. Scattered bits of statutes make it burdensome for an ap-

[6] See Kamau/Winter (2009), 365-379 on the legal situation (still up-to-date) and ways of improving the regime.

plicant to easily understand the regime, or initiate his/her undertaking with certainty of having full knowledge of its operation.

Incoherent (use of) terms

Although most legislations have embraced different terms, their use across these legislations is very incoherent. One, occasionally the same term is used with different or (slightly) diverging meanings, e.g. 'traditional knowledge'[7], 'local community'[8] and 'access'[9], or different terms used to mean the same thing.[10] That includes at times terms already defined in the Nagoya Protocol e.g. 'derivative'.[11] Second, many times they are used without a definition. For instance, the South Korean, Ecuadorian legislations use the term 'commercial'/'non-commercial', and the Vietnamese 'utilisation', but there is no clue what they mean. Third, at times the term is defined, e.g. 'utilisation' in the Korean and Cameroonian draft bill, 'non-commercial' in the Malaysian and 'commercial' in the Costa Rican legislations, but there are no catalogues of activities considered as such. In such cases it would be hard, for example, to use the definition 'utilisation' to establish when it actually commences and when it terminates. As observed, even with a definition often it is still hard to fathom what the terms allude to. A list of activities considered as utilisation or commercial/non-commercial research would be helpful. Viet Nam, for example, has published a document of the CNA with a list of activities considered as utilisation as a guidance to the implementation of Decree 59. The guidance document is, however, only for reference use and not a normative legal instrument, or administrative document.[12] South African Act provides a non-exhaustive list of activities considered as 'commercialisation' and also defines the term 'commercial exploitation'.

Incoherent approaches

Despite elaborated ABS measures by the Nagoya Protocol, approaches taken by different countries concerning the various issues remain inconsistent. For example, some establish their material scope (for resources, i.e. apart from aTK) as biological resources (Malaysia[13], South Korea, Viet Nam, Costa Rica, Australia, South Africa[14]), others genetic resources (Ethiopia, Kenya, Ecuador, France), and some extend it to genetic information (South Africa, Ethiopia, Malaysia, Brazil). This disparity can be noticed at times within one country, e.g. eight out of the twenty three provinces that have ABS legislations in Argentina, for example, include biological resources and derivatives in the scope and others not. Temporal scope is also established in some countries (e.g. Viet Nam, Malaysia) and not in others. Besides, the requirements for application and procedures for grant of an access permit, conditions of access, use etc. vary from country to country.

---

[7] Compare e.g. Korea, Ethiopia (the latter uses 'community knowledge'), Ecuador (refers to such knowledge as 'intangible component').

[8] Compare e.g. South Africa, Ethiopia, Malaysia.

[9] Compare e.g. Korea, Kenya, Brazil (in the Brazilian law the term 'access' is equivalent to 'utilisation' according to the NP definition in Art. 2), Ethiopia, Costa Rica.

[10] E.g. 'take' in the Malaysian Act and 'access' in the Australian Act.

[11] Compare e.g. Malaysia, Ethiopia.

[12] Tran Thi Huong Trang, *pers. comms*.

[13] Even if the biological resource cannot be put under utilization.

[14] The material scope would include both genetic and biological resources as long as bioprospecting is intended.

No clear facilitation for non-commercial research

Many legislations use the term 'non-commercial research' and consider it as a different type of research but predominantly there are hardly any facilitation measures (e.g. Costa Rica). A few countries have tried to offer such measures of which worth mentioning are Australia and South Africa (see below). Ecuador has adopted new regulations to enhance clarity as well as developed a contract MAE-DNB-2016-0045 to authorise scientific research but as researcher's experience indicate below (Beck, E.) there are still many challenges faced, including slowness in processing of permits.

Over-extension of compliance obligations

According to the Ethiopian regime foreign users must present a letter from the competent authority of their countries assuring that they will uphold and enforce the access obligations. In addition, if the research based on the access cannot be conducted locally for any reason, the institution hosting the research must issue an assurance letter that it shall enforce and observe the obligations related to the access and use. Whereas the regime is attempting to seal violation gaps, it ends up placing the burden on third parties. The competent authority though responsible for enforcement, for instance, cannot be directly connected to or associated with access and use of GR and/or aTK.

Unforeseeable end of provider rights

Due to the ever evolving technology it is difficult to establish the exact scope of provider rights based on GR. This is evident in the issue of digital sequence information (DSI) where providers are asserting their rights over benefits from such information. A number of countries are already inserting provisions in their legislations to deal with this issue (South Africa, Brazil) by generally using the term 'information', which is preferred by many countries as it is regarded as covering all types of information also in the future. Some countries believe the issue is regulated in their pre-NP legislations (Ethiopia, Costa Rica) whereas many, in addition, have expressed their views that DSI is within the scope (Viet Nam, Argentina, Kenya, Costa Rica, Brazil, Ecuador, Malaysia, South Africa). Hence, more and more legislations are expected to insert relevant provisions. However, as the special study on DSI (Lyal, C.) will show, there is still little terminological understanding of what DSI is. In the same vein is the question on rights over the results and data in the public domain. Today many countries are expressing their views that these should be monitored using ABS tools and benefits from their use should be shared. Some already do protect them in their legislations (Costa Rica,[15] Brazil[16]). The reason for this is because commercial research at times accesses results/data of facilitated non-commercial research placed in the public domain to circumvent ABS obligations of the provider. Whilst the concerns of provider countries are genuine, it needs to be considered what the concept of public domain, which seems threatened, means today and the limits of its inviolability. Interminable provider rights are said to have negative effects on R&D as the study of agricultural breeding shows (Schloen, M.).

No user compliance measures in traditional provider countries

Except Malaysia, none of the other legislations of (traditional) provider countries have established compliance measures for users. Traditional provider countries focus on ensuring adherence to their own measures. Other countries considered as providers under examina-

[15] Future uses of materials derived from the samples (extracts, fractions) after the permit expires are protected through the public domain concept. For such use a new permit, PIC and MAT are necessary.

[16] The term 'genetic heritage' covers a broad spectrum of research activities and also reaches to utilisation of information from genetic sequences based on Brazilian genetic heritage published in public databases.

tion that have access and also user compliance measures are EU member states (Spain, France in this publication and Malta, Bulgaria, Croatia).

2.2 Positive developments

New legislations

From sixteen countries investigated and the Australian state of Queensland there are seven stand-alone legislations (Malaysia, South Korea, France, Brazil, Spain, Germany, Viet Nam), one revision (South Africa) and four drafts (Australian state of Queensland, Ethiopia, Cameroon, Argentina). Costa Rica, Ecuador, Peru, Federal Australia, Kenya are still operating old legislations and have no drafts yet. It implies that there is implementation progress in eleven out of sixteen cases which is a good sign. Besides, legislative activities are going on in Ecuador, Australia and Kenya.

Party to Nagoya Protocol

From the investigated sixteen country case studies, only three countries are not party yet, i.e. Australia, Costa Rica and Brazil. But Brazil, as already mentioned, has a post-NP stand-alone legislation. This can be interpreted as a sign of wide acceptability of the instrument as well as readiness to comply.

Establishment of scopes

In spite of varying approaches as mentioned above, generally legislations have established their scopes – in particular geographical and material scopes. In addition, a few have established temporal scope, e.g. Viet Nam, Malaysia, France and Cameroon and Queensland (drafts). According to Decree 59 of Viet Nam GR accessed before 2009 do not require any registration whereas those accessed after 2009 until 2017 without a licence would need registration to obtain an ABS licence. Access after 2017 must be done subject to registration and request for an ABS licence. In the same vein article 63 (3) of the Malaysian ABS law foresees that any person in possession of a biological resource or aTK “After the date of the coming into operation of this Act … in respect of which this Act would apply and there is no benefit sharing agreement entered, shall enter into such agreement with the resource provider if— (a) there is a new use of the biological resource or traditional knowledge associated with the biological resource; or (b) there is development of a new product arising from the biological resource or traditional knowledge associated with the biological resource”. Also the draft of Cameroon establishes temporal scope for new uses and the draft of Queensland allows for retrospective grant of ABS.

Definition of terms

Even though definitions often differ in different legislations, the attempt to understand what they mean by defining them is also a positive sign. For instance, South Korea (Art. 2 (4)) and Viet Nam[17] define the term ‘utilisation’; Viet Nam includes other important definitions, viz. ‘genetic resources’, ‘access to genetic resources’, ‘traditional knowledge on genetic resources’, ‘provider’, ‘user’/‘accessor’; South Africa defines ‘bioprospecting’, which is an important determinant of the application of ABS legislation, its geographical, material and personal scopes as well as the trigger for benefits-sharing, and in addition ‘genetic resources’, which according to the revisions of 2013 expanded its meaning to include information on GR. The Cameroonian draft also defines the terms ‘utilisation’, ‘genetic material’, ‘genetic resources’, ‘customary right’, ‘valorisation of research results’ and ‘vulgarisation of

[17] Adopted from the Nagoya Protocol.

research results'. The new Brazilian law also defines 'genetic heritage' as information of genetic origin from plants, animals, microorganisms or species of other nature, including substances derived from the metabolism of these living beings. Hence it covers a broad spectrum of research activities and also reaches to utilisation of information from genetic sequences based on Brazilian genetic heritage published in public databases. Further, it defines 'access to the genetic patrimony' as research or technological development applied to specimen of the genetic patrimony. This is understood as covering R&D on bulk resources which shows that countries are also trying to address the issue of biological resources accessed as commodities and later used for R&D. Malaysia (Art. 63 (3)) and Cameroon (draft) likewise deal with this issue as mentioned above.

Attempt to comply with the NP access and benefit-sharing rules

Countries have tried to comply with the Nagoya Protocol rules by establishing the requirements and conditions for permit application, PIC, MAT, benefit-sharing, use of material, change of intent, third-party transfer etc. Besides, procedures are established although some are still confusing and cumbersome. Likewise, many have notified internationally recognised certificates of compliance (IRCCs) viz. Peru, Kenya, South Africa, Ethiopia, France, Spain and Viet Nam, which indicates a functioning permitting system. Besides, some countries which have not taken legislative action to comply with the NP e.g. Kenya are finding practical solutions to ease access challenges by creating an ad hoc ABS permitting committee (ABSpc) which has helped cut the application duration tremendously. The ABSpc is made up of different stakeholders who are normally competitors in ABS issues thus eliminating competition. Besides an ABS tool-kit has been published and the creation of a one-stop shop is in the process.

User compliance measures

Due to lack of user compliance measures prior to the NP providers claimed they had to use restrictive measures to deter post-access violations. Although some users installed internal measures to manage the monitoring of the value chain and thus, among other things, win provider trust (Williams, C.), that could not change the general situation. The NP introduced binding measures for users alike. Implementation of compliance measures can be observed in particular in the EU. The EU Regulation 511/2014 implementing the NP user measures has direct effect according to EU law and must be implemented by all member states. One of the studies looks at the ABS approaches of EU member states on the basis of the regulation (Winter, G.). The regulation implements only user compliance measures but gives member states leeway to implement access measures. A close examination of the implementation of its core concept of compliance (i.e. due diligence) in Germany (Greiber, T.) shows much progress has been made and experience gained, but there are also challenges encountered. Some of the challenges are connected to this new concept, which a further study (Godt, C, Burchardi, M.) attempts to unravel.

Differentiated approach for commercial and non-commercial research

One of the most discussed topics in the ABS discourse is about the differentiation of commercial and non-commercial researches. This is critical for the implementation of article 8 (a) of the NP. As seen above, except scanty attempts to produce lists of activities which these researches include there are barely any definitions. However, some regimes have nevertheless tried to create a differentiated approach for non-commercial research. According to article 3 (3) of the South Korean legislation, for instance, the Act shall not apply to any "Utilization of genetic resources for any other purpose than described in Article 2 (4)",

which is the definition of the term 'utilisation'.[18] Further, it establishes under article 10 (2) simplified procedures for access to GR for 'non-commercial research purposes' such as 'pure research' and provides reporting waivers as required under article 9 (1), which must be done if the intent/purpose changes. South Africa and Spain likewise differentiate the types of R&D and consequently the requirements for ABS and procedures. Besides, facilitation of some types of research and the possibility of integration of permits for access and export for bioprospecting are also provided. Also the Malaysian law differentiates between a permit for commercial or potential commercial purpose and one for non-commercial purpose to which it establishes differentiated requirements/conditions and procedure. Cameroonian draft provides for a facilitated access procedure for non-commercial research but with exceptions. The Brazilian law, on the other hand, establishes a system of registration, authorisation and notification depending on the purpose/use with tighter control established at the stage of commercial exploitation of final products or reproductive material. Thus, the approach is considered in principle as simplified and no further simplification is provided for non-commercial research. The Australian and Costa Rican regimes though pre-NP offer good model of dealing with non-commercial research. Australia has a quick processing/granting system whereas Costa Rica had introduced a special access regime for public institutions, but with a deadline.[19]

Exemption of GR under specialised instruments

The only recognised and functioning specialised instrument at the moment is the IT under which countries party to the CBD have agreed to exempt a number of PGRFA listed in its Annex I from the usual ABS rules. Access and benefit-sharing of these GR is regulated through the standard material transfer agreement (SMTA) of the IT. It is appreciable that most regimes abide to this rule, albeit at times with slight nuances. While exempting the same Cameroon (draft), for instance, subjects such GR to a simple declaration to the competent authority and consultation between the authority and the Ministry of Agriculture. Ethiopia likewise does not expressly exempt Annex I GR but creates a facilitated procedure of access which nevertheless still uses SMTA. Among all examined regimes, Malaysian Act of 2017 has gone a step further by inserting article 2 which reads: "This Act shall not apply to the specific biological or genetic resource covered by and for the purpose of any specialized instrument on access to biological resources and benefit sharing to which Malaysia is a party". This does not only expressly exempt GR under Annex I of the IT but fully implements article 4 NP in regard to any specialised instrument on ABS. There are a few instances where CBD/NP member states subject IT Annex I GR to the normal ABS requirements and procedures (e.g. Viet Nam).

Establishment of national authorities and definition of their functions

National authorities have been widely established and often their functions defined according to article 13 of the NP. For example, Viet Nam has established a NFP and two CNAs each responsible for different types of GR. Further, checkpoints have been established to enforce compliance.

[18] "Utilization" (or use) means to conduct, through the application of biotechnology, the research and development on the genetic and biochemical components of genetic resources.

[19] Costa Rica offered a window to public universities but only the University of Costa Rica made use of it in 1999 before it closed.

Benefit distribution approach

All examined provider regimes require in general terms benefits to be shared for utilisation/use of GR. Brazilian law, for example, is more articulate on this and requires benefits to be shared if there has been an economic exploitation of finished product(s) or reproductive material (sale of final products or materials derived from the exploitation of national genetic heritage or aTK). In addition, some state how benefits are to be distributed between the different groups of providers. In Malaysia and Brazil benefits are paid into state funds and used for conservation and sustainable use purposes if the resource provider was the state (federal government or state authority in Malaysia), or applied for the interest of the ILCs if they are from the utilisation of their aTK. In Brazil ILCs also share the benefits of GR accessed from their territories. In Ethiopia 50% of all benefits obtained from GR go to the communities and 50% to conservation of biodiversity whereas 100% of the benefits from aTK go to the communities. The three countries serve as a good example of the implementation of article 9 of the NP.[20] South Africa opens a tiny door for the same: according to s. 40 of the BABS Regulations benefits may be distributed for other purposes which includes conservation and sustainable use of indigenous biological resources, but only if there are monies in the Benefit Trust Fund, which for whatever reasons are not due to any stakeholder in terms of the benefit-sharing agreement (BSA), or when for whatever reason it is not possible to pay such funds due to the stakeholders in terms of the BSA. Not many regimes though fix benefit shares to be distributed from the utilisation of GR and aTK. Brazil does so by establishing shares to be given by companies depending on their annual gross income as well as the source (in-situ, ex-situ GR, or aTK).

Access requests have been reported

There is not much information on this but Viet Nam, for instance, has had over 20 post-NP requests for access to GR for both commercial and non-commercial purposes. There are also ongoing negotiations for the use of different types of GR: plants, insects, microorganisms. The issuing of IRCCs by a number of countries as reported above (France, Spain and Viet Nam having new legislations and South Africa having done some post-NP revisions), however, shows that there are access request and granting activities taking place. We could not establish though whether this is more intense now than before.

3 General conclusion

Much has been done in an effort to implement the Nagoya Protocol obligations. From a surface observation, this conclusion can be drawn based on the number of party states to the Nagoya Protocol out of the investigated lot, and the number of new legislations. When considered together these post-Nagoya Protocol legislations have also implemented many obligations of the Protocol. For instance, scopes have been established, including temporal scopes; many definitions are available even formerly seldom ones e.g. for 'traditional knowledge'; access requirements and procedures e.g. concerning permits, non-commercial research, aTK, and plant genetic resources for food and agriculture have been adjusted in order to achieve compliance; and competent authorities have been established and their mandates defined as required under article 13 NP. Besides some have established user compliance measures; defined criteria for benefit-sharing to ensure the allocation of a share to the conservation and sustainable use of biodiversity according to article 9 NP; and estab-

[20] Article 9 says: "The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components".

lished communication mechanisms with the ABS CH in line with article 14 NP from which notifications have been executed. The wide spectrum of these and other issues covered give an opportunity for cross-fertilisation of legislations and shopping for legal transplants.

However, these advancements are not enough to transform ABS into a regime capable of driving R&D based on genetic resources, and generating adequate benefits for conservation and sustainable use of biodiversity. The reason for this is that there are still many issues hurting it and thus negating the implementation progress that has been made. First, there are issues related to implementation approaches, which include fragmentation of legislations and hence of mandates of national authorities even in jurisdictions with post-NP laws; incoherent use of terms intermittently with different or diverging meanings; disparity in approaches including in regard to the scope of the legislation; unclear *de facto* facilitation of non-commercial research even when legislation separates requirements and approaches for research with commercial and non-commercial purposes thus leading to the maintenance of *status quo*; over-extension of compliance obligations including on monitoring and publication of research results and data; and never-ending provider rights which overburden R&D e.g. in plant breeding. Many of these issues greatly challenge users of genetic resources and aTK who have to adapt to the complex and varying measures of different countries. Likewise, they yield legal uncertainty and unclarity.

Second, in addition to challenges resulting from implementation approaches, there are also issues which were not resolved in the run up to the NP and new issues which have emerged in the implementation phase. They include the post-publication management of data and scope relating to (digital) sequence information. These have no concrete regulation and are a source of legal uncertainty for both providers and users.

Having said that, it is regrettable that the NP has not yet managed to transform ABS into a dynamic regime for R&D and benefit-sharing as awaited, notwithstanding it being a binding instrument. Even though not all shortcomings can be blamed on the Protocol, it is evident that some are rooted in it. For example, it did not strive to achieve harmonisation thus leading to divergent implementation approaches. In the same vein, it neglected vital issues for its adoption leaving points of contention. To ease access and stimulate benefit-sharing it is essential that parties, based on the strength of progress made so far, strive to eliminate the negative phenomena slowing ABS. To begin with it is vital to reach a certain level of harmonisation at least concerning terms, and clear and straightforward requirements and procedures. In addition, a resolution of outstanding pre- and post-adoption issues needs to be quickly reached.

References

E. Chege Kamau, G. Winter, Streamlining access procedures and standards, in: Kamau/Winter (eds) Genetic resources, traditional knowledge and the law: Solutions for access and benefit sharing, London: Earthscan/Routledge, 2009.

T. Greiber, S. Peña Moreno, M. Åhrén, J. Nieto Carrasco, E. Chege Kamau, J. Cabrera Medaglia, M.J. Oliva, F. Perron-Welch in cooperation with N. Ali and C. Williams, An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing, IUCN, Gland, Switzerland, 2012.

PART II: ABS MEASURES AND IMPLEMENTATION OF NAGOYA PROTOCOL REQUIREMENTS: CASE STUDIES

Figure 3: Dobsonfly. Photo by Chris Lyal.

Chapter 2

Viet Nam: New ABS legislation and practice, compliance with the Nagoya Protocol

Tran Thi Huong Trang, Nguyen Ba Tu & Nguyen Dang Thu Cuc

1 Introduction

Being a Southeast Asian country in Indochina peninsula endowed with abundant and rich biodiversity, Viet Nam is classified as one of the world's biodiversity hotspots[1]. Viet Nam has officially become a Party to the Nagoya Protocol since 12 October 2014[2].

Currently, the Biodiversity Law 2008 and Decree No. 59/2017/ND-CP of the Government on the management of access to GRs and the sharing of benefits arising from their utilization (herein after referred to as Decree 59), are the major laws regulating ABS in Viet Nam.

The Biodiversity Law was approved by the National Assembly on 13 November 2008 and came into force on 1 July 2009. It is the first law having provisions on ABS. Section 1 – chapter V of this law (from Article 55 to Article 61) – covers all fundamental elements of ABS. These regulations are consistent with basic principles of the CBD and the Nagoya Protocol.

The Decree 59 was issued on 12 May 2017 and came into effect on 1 July 2017. The decree consists of 28 articles in 5 chapters, detailing orders and procedures of the ABS process from registration and negotiation of an ABS contract to application for access to GRs and benefit-sharing, following up and monitoring compliance through information and reporting. Rights and obligations of the involved parties are also concretized, including the state management responsibility to designate a National Focal Point (NFP) and a National Competent Authority (NCA) to grant licences. To facilitate its implementation, the Decree provides 9 sample forms, which assist the application of the Decree in practice.

2 Scope of ABS regime

2.1 Geographical scope

Vietnamese ABS legislation regulates activities of access to GRs and sharing of benefits arising from their utilization under the sovereignty of the Socialist Republic of Viet Nam. ABS legislation applies to individuals and organizations engaged in activities related to access to GRs for the purpose of utilization for research or development of commercial products.

2.2 Material scope

Under Biodiversity Law 2008, ABS rules cover all biological resources in Viet Nam; native, wild, cultivated GRs, with direct access or indirect access, for example, access to plant directly or access to derivatives. These GRs may be native or exotic. For cultivated species ABS rules apply to exotic species if these have been produced in Viet Nam for a long time.

---

[1] Hotspots of international biodiversity conservation, http://www.biodiversityhotspots.org/xp/hotspots/hotspots_by_region/Pages/default.aspx. Revised as of May 20, 2012. Vietnam Ecology& Nature Protection Handbook, International Business, USA, Washington DC, USA-Viet Nam, 2008, p. 43.

[2] Resolution No.17/NQ-CP of the Vietnam's Government dated March 17th, 2014.

The Biodiversity Law, 2008 has a definition of traditional knowledge associated with genetic resources (TK)[3] and states that "The State protects TK copyrights on GRs and encourages and supports organizations and individuals to register TK copyrights on GRs", but no further detailed provision.

The Decree 59 does not regulate TK but a guidance document on TK is being developed under which the main issues are being considered.

2.3 Scope of utilisation/use

ABS rules focus exclusively on R&D activities which cover not only access to GR but also to derivatives.

The Decree 59 provides some definitions for 'utilisation' which are re-written from those of the Nagoya Protocol. However, like the Nagoya Protocol, Decree 59, or any specific legal instrument does not specify R&D. The Decree 59 does not provide a list of activities as utilisation of ABS, but the existing guidance document for implementation of Decree 59 determines a list of activities within the scope of ABS law of Viet Nam[4].

2.4 Exemptions

In accordance with definitions of Biodiversity Law 2008, Decree 59, the ABS regulation of Viet Nam, does not cover human GRs.

Viet Nam is not a member of the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture. Therefore, GRs for food and agriculture in Viet Nam are also governed by the Nagoya Protocol.[5]

3 National authorities

The Ministry of Natural Resources and Environment (MONRE) is designated as the National Focal Point (NFP) of the Nagoya Protocol under the Decree 59. Its responsibilities include: implementing unified management and monitoring of granting, renewal and withdrawal of licences for access to GRs; acting as a focal point for liaising, providing information and coordinating information exchange with the Secretariat of the CBD via the ABS Clearing-House in accordance with the Nagoya Protocol; leading the development of a national report on the implementation of the Nagoya Protocol in Viet Nam; proposing and implementing decisions of the Conference of the Parties to the Nagoya Protocol; coordinating and organizing the implementation of national obligations to the Nagoya Protocol; coordinating with other countries in implementing measures to comply with the Nagoya Protocol

[3] TK associated with GRs means knowledge, experience and initiatives of native people on the conservation and use of GRs, Article 3.38 of the Law on Biodiversity 2008 of Viet Nam.

[4] These activities include: Carrying out R&D on specific naturally separated compounds, Carrying out research on different extraction processes involved in plant extraction to different potential compounds; Plant and livestock breeding using biotechnology: To create new plant and livestock varieties by recombinant DNA technology, genetic engineering, cell technology; Any biotechnology application that uses systems of biology, living organisms or their derivatives to create or modify certain products or processes for certain uses (including antibiotic production); Any biotechnology application that uses enzymes and protein technology to produce a natural conversion of vegetable oil components to another fatty acid and separate plant cells that allow the separation of hydrophilic and lipophilic fractions from kernels, leaves, seeds ...; Reproduction of genetically modified insects to control diseases as malaria…; Microorganism culture to produce potential chemical compound.

[5] In 2019, the Ministry of Agriculture and Rural Development is cooperating with FAO to assess and consult on adherence of Viet Nam to ITPFGRA.

applied to the utilisation of Vietnamese GRs in foreign countries; organizing the implementation of bilateral and multilateral international cooperation for access to GRs and benefit-sharing.

For the National Competent Authorities (NCAs) the Government assigns the authority to grant, renew and withdraw licences to access GRs to the MONRE and Ministry of Agriculture and Rural Development (MARD), which specifies:

- The MARD shall grant, renew and withdraw licences to access GRs of agricultural crop varieties, livestock, aquatic species, and forest seedlings.
- The MONRE shall grant, renew and withdraw licences to access GRs other than those specified above.

The procedures for access to GRs include:

1. Registering access to GRs with the national competent authorities.
2. Making an agreement and signing the ABS contract with the Provider.
3. Requesting the commune-level People's Committee to certify the contract.
4. Submitting application dossiers for access to GRs to national competent authorities.
5. Implementing license on access to GRs and benefit-sharing

Depending on the purpose of utilization or intention of user, the procedures and requirements are different, namely between commercial and non-commercial purposes, between domestic users and foreign users, and special cases. The difference is in the timeframe of consideration, handling and approval of the dossier. For non-commercial purpose, the timeframe will be shorter by a maximum of 30 days, while for commercial purpose the timeframe is 90 days.

For the domestic users, the utilisation of GR for non-commercial purpose does not need a licence to access GR, but access to GRs for the utilisation with commercial purpose is subject to registration and application of an ABS licence.

Foreign organisations and individuals wishing to access GRs for any purposes should be subject to register and apply for ABS licences. There is an obligatory requirement to enter into cooperation with a domestic scientific and technological organisation for access to GR.

4 Requirements and conditions for access to in situ and ex situ genetic resources

4.1 Access permit

Access permit depends on whether the activity is for a commercial or non-commercial purpose. Access to GRs for commercial purpose is the access for a certain benefit, by developing products, commercialising them to gain a profit. Therefore, the criterion for research to be considered as non-commercial is not gaining a profit.

Decree 59 has separate regulations for Vietnamese students, doctoral students and Vietnamese scientific and technological organisations who wish to transfer GRs abroad. This is a simplified and shortened procedure to promote the scientific researches. Following this procedure, the dossier is handled within 15 days from the date of receiving a valid application.

4.2 Content of the access permit

Decree 59 provides a form of permit, which includes minimum information: name of the competent national authority, information of the licence holder, guarantor organisation, scope of access to and utilisation of GRs, name of accessed GRs; quantity/amount, purpose, duration, place of access to GRs, information of provider, information of the parties utilising the GRs and the place where GR activities will be implemented, information on the use of TK, information on the taking of GRs out of the territory of Viet Nam, responsibility of the license holder (it includes information of implementing signed ABS contract, plan for access to the GR, compliance with reporting obligations and other relevant regulations) date of effect, recipients.

The period of validity of the licence to access GRs shall be decided by a competent national authority based on the proposed objective and the plan of access to GRs but it shall be no longer than 3 years.

Individuals and organisations that have been granted a licence to access GRs have the right to transfer GRs abroad, except for cases where GRs belong to the list of GRs prohibited or limited for exporting.

4.3 Permit conditions – especially most critical/important ones

4.3.1 Third party transfer

The Decree 59 requires that a transfer of accessed GRs or derivatives of accessed GRs to a third party with a change of purpose of utilisation specified by the granted licence must involve the application of a new licence by the third party. This will include a new procedure of negotiation and signing an ABS contract with the provider. The new licence should be obtained prior to receiving GRs or derivatives of GRs. In case the transfer to the third party is without any change of purpose of utilisation, the Decree only requires a written notification to the NCA which granted the licence.

The transfer of accessed GRs to a third party shall include the transfer of the obligations of the accessor under the granted licence, and the signed contract between the accessor/user and provider, including the provisions of the sharing of benefits arising from the utilisation of GRs with the provider.

4.3.2 Change of intent

Decree 59 requires that a licence shall only utilise GRs for the registered purposes. Therefore, in case of a change of purpose of utilisation, the user must apply for a new licence to access the GRs[6].

4.3.3 Claim of IPRs

Registration for intellectual property rights for innovative results from the utilization of GRs and its derivatives must state clearly the source or origin of accessed GRs, and comply with the benefit-sharing obligation under Clause 2, Article 22 of Decree 59.

4.3.4 Other permits

Following Article 16.3 of Decree 59, organisations and individuals who are granted licence to access GRs have the right to transfer them abroad, except for cases where GRs belong

[6] Article 14 of Decree No. 59.

to the list of GRs prohibited or limited for exporting. It may be understood that the licence to access GRs would be replaced with the licence to export GRs, excluding the two last cases of limited or prohibited export.

5 Model transfer agreements, guidelines

There is a model agreement which is called ABS contract form under annex 03 of Decree 59, which is based on the basic requirements of the Biodiversity Law. The contract serves both as the prior informed consent of the provider and the mutually agreed terms on benefit-sharing among parties. The user and provider are obliged to fill the form of ABS contract which, as basic requirements, must: be in writing and signed by the provider of GRs after receiving a written confirmation on accessing GRs from the NCA; be certified by commune-level People's Committees of localities where GRs are accessed or where the registered address of the provider is located; contain the following principal details:

- Purpose of access to GRs;
- GRs to be accessed and volume of GRs to be collected;
- Place of access to GRs;
- Plan on access to GRs;
- The transfer of the results of survey and collection of GRs to a third party;
- Activities of research and development or production of commercial products using GRs;
- Participants in research and development or production of commercial products using GRs;
- Place for conducting research and development or production of commercial products using GRs;

Sharing of benefits with the State and involved parties, including the distribution of intellectual property rights over invention results on the basis of access to GRs and TK copyrights on GRs. Disputes over or complaints about access to GRs and benefit-sharing shall be settled under Vietnamese law and treaties to which Viet Nam is a contracting party. The ABS contract shall be effective only after the NCA grants the license to access GRs. When the licence to access GRs expires, the user will not be allowed to access GRs but benefit-sharing provisions of the contract will remain in force.

6 Benefit sharing

6.1 Types of benefits

ABS law of Viet Nam defines both types of benefits from utilization of GRs: monetary and non-monetary benefits. Monetary benefits may include: Access fees/fee per sample collected; Payment of royalties; License fees in case of commercialisation; Lump sum or milestone payments; Other monetary benefits arising during the utilization of GRs. Non-monetary benefit may include: Sharing of research results; Rights to be involved in collaboration on the research, development and production of commercial products; Rights to have access to scientific and technical information related to the GRs; Technology transfer to providers of GRs; Training and capacity building of providers in research and development of GRs; Joint intellectual property rights corresponding to the percentage of contributions to innovative results based on access to GRs; Other non-monetary benefits.

6.2 Conditions and content of a benefit-sharing agreement

For monetary benefits, Decree 59 stipulates that the share of monetary benefits of the product generated from the utilisation of GRs shall be not less than 1% of the total annual revenue of such product. The share of monetary benefits for the provider when obtained by the transfer of GRs or derivatives thereof, or the utilisation of intellectual property rights based on the GRs, shall be not less than 2% of such total transfer value or total revenue from the use of intellectual property rights.

6.3 Benefit-sharing formula

The total monetary benefit is shared as follows:

- When the provider is Commune-level People's Committees, or Protected Area's Management Board, or state-managed facilities for storing or preserving GRs, or Biodiversity conservation facilities, or institutes for research and technology development assigned by the State: 30% of the shared money shall be paid to the provider of GRs as prescribed in Clauses 1 and 2 of Article 22, Decree 59; and the remaining 70% of the shared money shall be paid into the State Budget to be used for conservation and sustainable use of biodiversity;
- When the provider is an individual or a household or an organisation assigned to manage GRs by the State: 50% of the shared money shall be paid to the provider of GRs as prescribed in Clauses 1 and 2 of Article 22, Decree 59; and 50% of the shared money shall be paid into the State Budget to be used for conservation and sustainable use of biodiversity.

Beneficiaries of non-monetary benefits include domestic providers, domestic partners of the foreign accessor, and other involved organisations and individuals. The origin of the accessed GRs should be clearly stated when publishing any results of the scientific research or applying for intellectual property rights for any innovative results based on accessing and using such GRs.

7 Participation of other public and private entities

Other public and private entities, including non-governmental entities, indigenous people, private individual and land users, participate in the PIC process when they are defined as providers of GRs. The provider refers to the individuals and/or organisations assigned to manage GRs by the State, as specified in Clause 2, Article 55 of the Biodiversity Law[7]. They include: i) Management board of protected areas and organisations assigned to manage conservation zones where GRs are located; ii) Owners of biodiversity conservation facilities, scientific and technological research facilities, GRs preservation and management facilities; iii) Organisations, households and individuals that are assigned to manage and use land, forests and water surface where GRs are located. The above mentioned providers participate in the PIC through the step of negotiation and signing of ABS contract with the user. An ABS contract signed and certified is one of the obligatory documents to obtain an ABS licence.

ABS law of Viet Nam does not differentiate providers being indigenous people and other providers. All the above mentioned providers have the same rights and responsibilities following Article 56 of the Biodiversity Law. The indigenous people, who live in buffer zone of

[7] Article 3.1 of the Decree 59.

protected area where GRs are found, cannot participate in the PIC unless they are assigned to manage and use land, forests and water surface. If the indigenous people are holders of TK, they may participate in the PIC as providers of TK but there is still no legal provision in detail for this case of TK

8 Assessment of the pre- and post-NP situation and conclusions

It has not been long since Viet Nam adhered to the Nagoya Protocol as well as the latter came into effect in Viet Nam. Viet Nam has made progress in developing legislation and policy to implement the Nagoya Protocol. A new Decree on ABS, which meets the requirements of implementing the Nagoya Protocol, was issued and came into force in 2017. This has increased the demand in ABS in practice in the country.

There is no official assessment of implementation of the Decree in practice. However, the number of applications for licences to access GRs, the workshops and seminars that have been held shows the improvement of capacity building, awareness raising and that the Decree is getting life.

The analysis of laws on ABS also raises a number of issues that need to be improved for effective implementation of the national ABS law and the Nagoya Protocol. Recently, the government of Viet Nam has planned to revise its Biodiversity Law, 2008. This will be a good opportunity to amend the provisions on ABS to meet more effectively the requirements of the Nagoya Protocol and fill the gaps of the Decree 59 and overcome existing constraints which cannot be solved by the Decree 59. This is because Decree 59 being a by-law document issued by the government has lower legal validity than the Law on Biodiversity, especially in regard to the demarcation of assignments among the authorities, responsibilities between relevant Ministries, their cooperation in inter-ministerial ABS issues and enhancing compliance and enforcement through checkpoints.

A sound and effective ABS national legal framework will facilitate the implementation of the Nagoya Protocol and also promote GRs, biodiversity conservation and sustainable use in Viet Nam.

Chapter 3
Korean ABS law

Jae-Hyup Lee & Ah Young Cho

1 Introduction

The biodiversity policies of Korea were dispersed throughout the government because wildlife, agriculture, forest, marine and bio-information were handled separately by different ministries. The 'Act on the Conservation and Use of Biodiversity' was enacted in 2012 to remedy such lack of systematic management. The coordinated access and benefit-sharing (ABS) system, however, has not taken shape in spite of specific provisions of the act. Therefore, it was necessary to enact a new law for implementing the Nagoya Protocol. The Ministry of Environment announced the Notice of Legislation 'Act on Access to, Utilization, and Benefit Sharing of Genetic Resources' (ABS Act) on December 19, 2013. Unfortunately, this bill was not passed due to a termination of the term of the National Assembly. Subsequently, on June 15, 2016, the Ministry of Environment again submitted the 'ABS Act bill' to the National Assembly, which was finally passed on December 29, 2016 (promulgated on January 17, 2017).The purpose of the Act is to provide for necessary matters for implementing the Nagoya Protocol on ABS and the Convention on Biological Diversity, thereby contributing to the conservation and sustainable use of biodiversity, improving the lives of the people, and promoting international cooperation.[1] After the enactment, the Ministry of Foreign Affairs deposited the 98th instrument of ratification of the Nagoya Protocol on 19 May 2017 and the Republic of South Korea became an official member of the Nagoya Protocol from 17 August 2017.

Although the ABS Act provides a framework of ABS system of Korea, there are some other laws related to genetic resources (see table 3.1). This ABS legislation was enacted by different ministries based on their jurisdiction.

Table 3.1: Other laws related to genetic resources under different Korean ministries

Ministry	Law related to genetic resources
Ministry of Environment	Biological resources pursuant to the Wildlife Protection and Management Act and the Act on the Conservation and Use of Biodiversity
Ministry of Science and ICT	Biological resources pursuant to the Act on the Securement, Management and Utilization of Biological Research Resources
Ministry of Agriculture, Food and Rural Affairs	Agricultural biological resources pursuant to the Act on the Protection, Management and Use of Agricultural Biological Resources
Ministry of Trade, Industry and Energy	Biological resources pursuant to the Act on the Securement, Management and Utilization of Biological Research Resources
Ministry of Health and Welfare	Pathogen resources pursuant to the Act on the Promotion of Collection, Management and Utilization of Pathogen Resource
Ministry of Oceans and Fisheries	Marine biological resources pursuant to the Act on the Securement, Management and Utilization of Marine Biological Resources

[1] Article 1 of the Act on Access and Utilization of Genetic Resources and Benefit-Sharing.

2 Scope of ABS regime

The geographical scope of the Act is limited within the national jurisdiction since Article 3 of the Act stipulates applicability by stating that the Act shall not apply to genetic resource(s) existing in an area beyond national jurisdiction, such as Antarctica.

The material scope of the act could be deemed by the definition of the terms used in the clauses. According to Article 2, the definition of genetic resource follows Article 2.4 of the Act on the Conservation and Use of Biological Diversity, which defines it as "materials which have practical or potential value, among plants, animals and microorganisms or other genetic material which becomes genetic origins including a genetic functional unit." This definition of genetic resource does not vary much from the one of the CBD and Nagoya Protocol. However, the Act never refers to 'derivatives' nor 'DSI'. In addition, the Act defines traditional knowledge without mentioning 'ILC' which is almost impossible to find in Korea. These can be seen as user-oriented legislation.

The act defines 'utilisation' as "conducting research and development on the genetic and biochemical composition of genetic resource(s), including through the application of biotechnology". This term does not have significant differences compared to the definition used in the Nagoya Protocol. However, it is difficult to find details of the scope of utilization in the law and enforcement decree.

3 National authorities

Korea has two national focal points, the Ministry of Environment and the Ministry of Foreign Affairs. Functions of each ministry are separated. The Ministry of Foreign Affairs liaises with the Secretariat of the Convention on Biological Diversity. On the other hand, the Ministry of Environment disseminates information on access to genetic resource(s) and benefit-sharing.

There are five competent national authorities based on each ministry's field of jurisdiction. The duties of the head of the Competent National Authority is to process a report on access or report on changes, to prohibit or restrict access and utilization of domestic genetic resources, and to support the fair and equitable sharing of benefits from domestic genetic resources. Other necessary matters relating to access and utilization of domestic genetic resources shall be prescribed by Presidential Decree. However, there is no distinction between commercial and non-commercial in the terms appearing in each clause.[2]

In the case of checkpoints, there are six checkpoints in Korea, adding one more organisation compared to CNA. This is because there are some research institutions affiliated to the Ministry of Trade, Industry and Energy which are not included as CNA. The duties of the checkpoints provided by the Act are processing procedural compliance reporting, monitoring and recommending procedural compliance, supporting persons who utilise foreign genetic resource(s) domestically and other matters prescribed by Presidential Decree.

4 Requirements and conditions for access to in situ and ex situ genetic resource

Where foreigners, overseas Koreans, foreign institutions, international organisations, and those other persons designated by Ordinance of the Ministry of Environment seek to access Korean genetic resource(s) for their utilisation, they shall report such access to the

[2] Ibid, Article 8.

head of the Competent National Authority, as prescribed by Presidential Decree.[3] Where a person who has reported in accordance with Article 9 (1), seeks to change any matters prescribed by Presidential Decree, such person shall report the change to the head of the Competent National Authority.[4] The meaning of 'to change any matters prescribed by Presidential Decree' in Article 9 (3) of the Act is any of the following: 1) to change purpose for accessing the declared genetic resource(s); 2) to increase at least 10/100 of the declared genetic resource(s) quantity or concentration (excluding microorganisms); 3) to change the details of mutually agreed terms concerning the relevant genetic resource(s) (only applicable where mutually agreed terms are established).[5]

As aforementioned, each different ministry has its own law related to access to genetic resources and benefit-sharing under their jurisdiction. However, this might be confusing for the people accessing the domestic genetic resources. To minimize confusion from this circumstance, approvals or permissions obtained through another law are deemed to have completed the reporting duty according to Article 10 of the ABS Act.

Indeed, Korean government's role as a party to the Nagoya Protocol was to simplify procedures for the parties accessing the genetic resources. However, even though a clause that allows a simplified procedure in the ABS Act exists[6], the definition of the 'non-commercial research' and the details of the 'simplified procedure' are yet to be clarified. So the question remains: how should commercial and non-commercial use be distinguished and to what extent can these two users be treated differently?

5 Benefit sharing

According to Article 2 of the ABS Act, 'benefits' means both monetary benefits and non-monetary benefits. The range of monetary benefits includes, but are not limited to, royalties and income, from utilising genetic resource(s), and non-monetary benefits include, but are not limited to, sharing of research results and transfer of technology.

In terms of benefit-sharing, the Act stipulates "providers and users of genetic resource(s) shall agree to share the benefits of domestic genetic resource(s)".[7] Originally, the draft of the bill which the Ministry of Environment submitted had required that they "shall try to agree to share" the benefits of domestic genetic resource(s)", but it was amended to "shall agree to share". Using stronger expression would increase importance of the need for benefit-sharing. However, there is no separate sanction for breach of obligation.

6 Assessment of the pre- and post-NP situation and conclusions

The Korean government has adopted various international agreements, but there are some problems and some obstacles to overcome. With regard to ABS of domestic genetic resources, the following limitations are found in the Act: first, it requires prior notification, rather than prior informed consent; second, the establishment of mutually agreed terms is not legally binding. The provision does not actually state that the parties must develop mutually agreed terms (MAT), but rather, that they should strive to establish MAT, and the national

[3] Ibid, Article 9(1).

[4] Ibid, Article 9(3).

[5] A Guide to Act (18 July 2018), 8.

[6] Article 10, Act on Access to and Utilization of Genetic Resources and Benefit-Sharing (2017).

[7] Ibid, Article 11.

authority may assist with reaching a fair and equitable agreement (Article 8(2)-3). Third, there are multiple national competent authorities, and the relevant laws are fragmented.[8]

On the other hand, there are also some limitations relevant to ABS of foreign genetic resources. First, the compliance with procedures that are required by the country providing such genetic resource and the sharing of benefits arising from utilisation of foreign genetic resource is not legally binding. The sanctions on breach of an obligation to report are not strict enough. Second, the investigation of compliance with procedures has no legal force.[9] Third, having multiple checkpoints gives rise to legal uncertainty. Furthermore, the domestic researchers on either commercial or non-commercial purposes using the ex-situ genetic resources can get confused who to contact. There might be a regulatory gap by not having a clear rationale on the division of the checkpoints.

The most serious problem is that the multiple national authorities are competing over the jurisdiction over the ABS related issues. This situation may hinder systematic and effective establishment of the ABS system based on the Nagoya Protocol. For example, each major legislation related to the conservation of biodiversity has different periods of master plan. Even their starting points are all different. This situation should be improved to establish more systemic plans and policies by maintaining coherencies between regulations.

One solution to this problem is the integration of information. However, there are already information centers in each ministry in Korea besides the Clearing house. When the centers serving as hubs of information are distributed or designated as plural, it is difficult to expect administrative efficiency to provide information of the process, which leads to confusion in accessing and using information. In addition, administrative costs can be excessive. That is why the role of the Genetic Resources Information Management Center under Article 17 becomes important. Accordingly, it is highly necessary to establish an integrated information hub center in order to enhance accessibility and efficiency of information to users and maximize the reduction of organisation installation and operation costs. There are two types of genetic resource information centers: the integrated type and the decentralized type. Genetic Resources Information Center was established in March 2018 to expertly perform duties related to access to and utilisation of genetic resources and benefit-sharing in accordance with Article 17 (1) of the Act on Access to and Utilization of Genetic Resources and Benefit-Sharing.

References

Legislation, regulations and Government decisions

Republic of Korea, Act on Access and Utilization of Genetic Resources and Benefit-Sharing, (Amended by Act No. 14839, Jul. 26, 2017).

Articles and reports

A Guide to Act on Access to and Utilization of Genetic Resources and Benefit-Sharing in Republic of Korea, Ministry of Environment and Ministry of Foreign Affairs (18 July 2018).

Park Jong Won, The Significance and Limitations of the “Act on Access to, Utilization and Benefit-Sharing of Genetic Resources”, 40 Environmental Law Review (August 2018) (in Korean).

[8] See generally, Won, P. J. (August 2018).

[9] Ibid.

Chapter 4
The Malaysian ABS law – A big step forward

Evanson Chege Kamau

1 Introduction

Malaysia is party to the Convention on Biological Diversity (CBD) since 22 September 1994 by ratification and the Nagoya Protocol (NP) since 3 February 2019 by accession. Access and benefit-sharing is regulated by the 'Access to Biological Resources and Benefit Sharing Act 2017'. The Act is a stand-alone law hence all sections are relevant for ABS. It aims to implement the CBD and the NP in regard to access to biological resources (BR) and associated traditional knowledge (ATK) and the sharing of benefits arising from their utilisation and for matters connected therewith. The Act is to be read together with any written laws relating to ABS and its provisions shall not be in derogation but in addition to provisions of any other law in force e.g. laws relating to forests, wildlife, animals, fishery and international trade in endangered species, except for matters that fall within the provisions of this Act (s. 3 (1), (2)).

2 Scope of ABS regime

2.1 Geographical scope

The Act applies to all the genetic and biological resources including wild, domesticated and cultivated species of flora and fauna, both in-situ and ex-situ conditions found within the territory of Malaysia,[1] which should be understood as the country's terrestrial and marine jurisdictions.

2.2 Material scope

The Act applies to biological resources and traditional knowledge associated to such biological resources.

2.3 Scope of utilisation/use

The Act applies when BR and/or ATK are accessed for research whether with a commercial or commercial potential purpose or non-commercial purpose. According to s. 4 on definitions the concept of BR is broad and includes:

- (a) the genetic resources, organisms, microorganisms, derivatives and parts of the genetic resources, organisms, microorganisms or derivatives;
- (b) the populations and any other biotic component of an ecosystem with actual or potential use or value for humanity; and
- (c) any information relating to paragraphs (a) and (b);

It does not apply to BR used as a commodity for the purpose of direct use or consumption as determined by the Competent Authority (CA).[2] However, the transitional provisions of s. 63 (3) – (4) suggest that if such a commodity is later used in R&D the person engaging in

[1] Syafira S. (18 December 2012). 2 Ibid.

[2] Ibid.

such activities must enter into a BSA with the resource provider and receive a permit from the CA.

2.4 Exemptions

The Act does not apply to the specific biological or genetic resource covered by and for the purpose of any specialized instrument on access to biological resources and benefit sharing to which Malaysia is a party (s. 2).

3 National authorities

3.1 National competent authority

A national competent authority (NCA) is established under s. 7 (1) of the Act. It consists of the Secretary General of the Ministry responsible for natural resources and environment, who shall be the Chairman, and such number of persons to be appointed by the Minister (s. 2). According to s. 8 the NCA has the following functions:

- (a) to coordinate the implementation and enforcement of the provisions of this Act by the Competent Authorities;
- (b) to determine the fees payable upon consultation with the Competent Authorities;
- (c) to communicate with other countries and the secretariat established under any treaty, agreement, convention or protocol relating to access and benefit sharing in relation to a biological resource, as appropriate, on matters under this Act;
- (d) to implement and to fulfil the requirements under any treaty, agreement, convention or protocol relating to access and benefit sharing in relation to a biological resource to which Malaysia is a party where such treaty, agreement, convention or protocol relates to the purposes of this Act;
- (e) to create awareness and to provide training, education and information relating to access and benefit sharing in relation to a biological resource;
- (f) to keep and maintain a register of permits issued by the Competent Authorities and information relating to the permit;
- (g) to establish measures under subsection 30 (1) with the aim of monitoring and tracking of a biological resource or traditional knowledge associated with a biological resource accessed;
- (h) to support customary laws and practices of indigenous and local communities, and the development of community protocols and procedures by the indigenous and local communities, as the case may be;
- (i) to establish and maintain a clearing house mechanism under section 32;
- (j) to act as Competent Authority for all ex-situ collections where the origin of the biological resource cannot be ascertained with due diligence and which do not come within the jurisdiction of any other Competent Authority; and
- (k) to do such other things as it deems fit to enable it to perform its functions effectively or which are incidental to the performance of its functions.

3.2 Competent authority

'Competent Authority' means the Competent Authority as specified in the First Schedule. There are fourteen competent authorities (CA): one responsible for three regions and the other thirteen for one region each. Each one of them is responsible for all biological resources covered under the Act in the region specified in the first schedule of the Act (s. 9 (1)). A CA has powers to establish an advisory body consisting of indigenous and local communities (ILC) to deal with issues of BR and ATK relating to such communities whose advice shall be sought and taken into account (s. 9 (2)). The CA may establish such committee to facilitate the carrying out of its functions under the Act if it deems it necessary (s. 9 (3)). It shall consult and seek the advice of the NCA in the exercise of its powers and performance of its functions under the Act (s. 9 (5)).

According to s. 10 competent authorities have the following functions:

- (a) to deal with all the applications for access to a biological resource or traditional knowledge associated with a biological resource within its jurisdiction and the sharing of benefits arising from the utilisation of the biological resource or traditional knowledge associated with a biological resource;
- (b) to maintain a record of all access applications and decisions relating to such applications, including the permits issued;
- (c) to prepare an annual report concerning such access applications and decisions relating to such applications including permits issued and to submit the report and copies of the permits to the National Competent Authority on or before such date as the National Competent Authority may determine; and
- (d) to do such other things as it deems fit to enable it to perform its functions effectively or which are incidental to the performance of its functions.

In addition, they have powers to do all things necessary or expedient for or in connection with the performance of their functions under the Act.

3.3 Advisory committee

According to s. 11 (1) and (4) of the Act an advisory committee is established by the NCA from persons with experience, knowledge and expertise on matters relating to the scientific, legal, technical, ethical and other relevant disciplines to provide the NCA with advice related to their expertise. A member of the committee shall hold office for a term not exceeding two years unless such a member resigns or vacates his office or his appointment is revoked (s. 11 (3)).

4 Requirements, procedures and conditions for access to in situ and ex situ genetic resources

Access to BR and/or ATK, including by an authorised intermediary,[3] is subject to an access permit. A permit may be issued either for commercial or potential commercial purpose, or for non-commercial purpose.

[3] 'Authorized intermediary' "means any person named by the applicant for a permit under sections 12 or 15 to take the biological resource or traditional knowledge associated with biological resource on its behalf" (s. 4).

4.1 Permit for commercial or potential commercial purpose

A permit for commercial or potential commercial purpose is issued by the CA with particulars as may be determined by the NCA in consultation with the CA (s. 13 (1)).

An application must be sent to the CA in the form and manner as may be prescribed and the prescribed fee paid (s. 12 (1)). The CA may approve the application if all matters listed under s. 12 (2) are satisfied. Upon approval of the application the CA shall grant an access permit which shall be evidence of PIC of the CA and ILC, the origin of the BR, the person to whom the permit has been granted, the conclusion of a BSA with the resource provider, and the use for which the permit is issued (s. 24). If any of the grounds is not satisfied, the CA shall refuse the application except in regard to §§ (c) and (d)[4] if it is satisfied that the application for permit does not undermine the conservation and sustainable use of biodiversity (s. 12 (4)). The CA may also deny the application if, after consultation with the NCA, it is evident that the applicant is from a jurisdiction that does not have adequate and effective user compliance measures (s. 12 (3) (b)).

The CA must state the grounds for refusal and if the application qualifies approve it with or without conditions and issue a permit (s. 12 (5)). Additional conditions on the permit may be imposed, or amendment or revocation of any conditions any time after the permit has been issued (s. 13 (3)). In such circumstances the CA shall give the permit holder a written notice of its intention within which time the permit holder will have an opportunity to make representations and after which the CA shall decide whether to impose, vary or revoke any of those conditions (s. 13 (4), (5)). The CA shall inform the permit holder of its final decision as soon as practicable and the decision shall take effect on a date specified in the written notice (s. 13 (6)).

If the CA revokes the permit, the person aggrieved may in accordance with s. 29 appeal against the decision in court.[5] The court shall confirm or set the decision of the CA aside.

4.2 Permit for non-commercial purpose

A permit application for non-commercial purpose must be sent to the CA in the form and manner as may be prescribed and shall be accompanied by a copy of a statutory declaration duly completed as specified in the second schedule and the prescribed fee (s. 15 (1)). According to the second schedule the permit holder must swear that s/he shall:

- (a) not use the accessed BR and/or ATK for commercial purposes;
- (b) give a written report of the results of the research to the CA;
- (c) undertake to offer a taxonomic duplicate of the BR collected to the CA;
- (d) undertake not to give the BR to any person other than the CA without its prior written permission; and
- (e) undertake not to carry out, or allow others to carry out, R&D for commercial or potential commercial purposes on any BR, or derivative, or in relation to ATK, unless s/he obtains a permit for commercial or potential commercial purposes in accordance with sec-

[4] (c) the application is not for any threatened taxa; and (d) the application is not for any endemic species, rare species or any species protected under any federal or state law.

[5] For the purposes of s. 29, 'Court' means the High Court of Malaya and the High Court in Sabah and Sarawak or either of the High Court in Malaya and the High Court in Sabah and Sarawak, as the case may require.

tion 12 and a BSA has been entered into in accordance with subsection 22 (1) of the Act.

An undertaking for non-commercial purpose must be carried out in collaboration with a public institution of higher education, public research institution or Government agency (s. 15 (2)). However, the CA may exempt this condition if it is satisfied that:

- (a) the applicant is a non-profit organization based or registered in Malaysia;
- (b) local researchers are involved in the activity; and
- (c) a program for capacity building is included in the activity.

The rest of the procedure from grounds for approval/refusal of the application for permit and penalties (s. 15 (3) – (7)), issuing of the permit (s. 16) and transmitting of the decision is the same as that for commercial or potential commercial purpose, except the grounds under s. 12 (2) (a) and 15 (3) (a)[6] differ due to differing purposes. This also shows that the conclusion of a BSA is not a condition for a permit for non-commercial research. In addition, the procedure is the same but the conditions differ.

Circumstances where a permit is not required are listed under s. 18 of the Act. Accordingly, no permit is required—

- (a) by any person employed or studying and carrying out research for non-commercial purpose in or under the authority of, a public higher education institution, public research institution or Government agency within Malaysia, subject to such conditions as may be prescribed and subject to the prior informed consent of the relevant indigenous and local community for any access to a biological resource and traditional knowledge associated with a biological resource referred to in subsection 23 (1);
- (b) for the exchange of biological resources between persons within a public higher education institution, public research institution or Government agency within Malaysia or between such institutions or agencies within Malaysia for non-commercial purpose, unless otherwise required by a Competent Authority and subject to such conditions as may be prescribed; or
- (c) by any person or institution in or outside Malaysia who accesses a biological resource from a permit holder under subsection 15 (1) or the person or institution under paragraph (a), at the request of such permit holder or the person or institution, for the purpose of carrying out or continuing any research for non-commercial purpose.

4.3 Permit conditions

4.3.1 Third party transfer

4.3.1.1 Commercial or potential commercial purpose

A permit for commercial or potential commercial purpose cannot be transferred or any right, duty, liability or obligation under the permit assigned to a third party (s. 14 (1)).

4.3.1.2 Non-commercial purpose

No person or institution referred to in s. 18 (a) and (b) shall transfer any BR and/or ATK, or results of research in relation to the BR and/or ATK to a person or institution other than that

[6] "… a benefit sharing agreement has been established in accordance with section 22", and "the application is not for commercial or potential commercial purpose".

referred to in s. 18 (a) and (b) without the prior approval of the CA (s. 19 (1)). If the CA approves the transfer it shall prescribe the conditions under which the transfer may take place and, in addition, the transferee shall be required to apply for a permit under the Act unless the CA decides otherwise (s. 19 (2)). Besides, the permit holder or the person or institution referred to in s. 18 (a) and (b) shall notify the CA of the access (s. 19 (3)).

4.3.2 Change of intent

4.3.2.1 Commercial or potential commercial purpose

No change of use is allowed in relation to the BR as specified in the permit issued under s. 13 (1) except upon a fresh application being made and a permit issued under s. 13 (§ 2).

4.3.2.2 Non-commercial purpose

No permit holder, whether the initial holder or a transferee, is permitted to carry out, or allow others to carry out, R&D for commercial purposes on any BR and/or ATK, unless the person obtains a permit for commercial or potential commercial purpose under s. 13 and concludes a BSA in accordance with s. 22 (s. 20).

4.3.3 Records of BR and ATK

A permit holder is obliged to keep a record of the BR and/or ATK accessed for twenty years after the end of the period of use as long as the BR and/or ATK is in his possession (s. 26). The records shall indicate the description of the BR and/or ATK, including available unique identifiers; the date or dates of access; the place of access; the quantity or size of the biological resource (such as weight or physical dimension); the common and scientific name of, or given to, the biological resource; the location where the biological resource is kept; and the particulars about any subsequent physical disposition of the biological resource, including the names and addresses of others having possession of the BR or a part thereof. The permit holder shall furnish the NCA and CA with a copy of the records within thirty days after the BR is taken or within a period determined by the NCA and CA.

4.3.4 Disposal of BR

According to s. 27, the permit holder may offer the BR for which s/he has a record to the CA if s/he does not intend to keep it. However if the CA does not agree to take it, the permit holder shall dispose the BR in a manner as may be determined by the CA and the permit holder shall forthwith furnish a report of the disposal of the BR to the CA. There is no information whether the twenty years' obligation to keep records ceases after disposal.

5 Benefit sharing

As already said and according to s. 22, an applicant for a permit for access to BR and/ATK for commercial or potential commercial purpose must enter into a BSA with the resource provider. The BSA shall be based on mutually agreed terms and must provide for fair and equitable benefit-sharing. Where the Federal Government or State Authority is not the resource provider, it may require the applicant to pay a percentage of any monetary benefits derived under the BSA as it may determine. Such monetary benefits shall be deposited into a fund as may be established by the Federal Government or State Government. The CA shall use any payment or any part of the payment received towards the conservation of biodiversity and the sustainable use of its components and for such other incidental expenses. Benefits shared with the ILC for utilisation of their ATK shall be applied for the in-

terest of ILC taking into account the advice of the advisory body established under s. 9 (2) (s. 23 (5)). Benefits shared can be of a monetary or non-monetary character.

6 Participation of other public and private entities

For access to a BR on land to which an ILC have a right as established by law, or to the ATK of such a community, PIC must be obtained from the relevant community (s. 23). Such PIC shall be obtained in accordance with customary laws and practices, protocols and procedures of ILC, as the case may be. If access is for commercial or potential commercial purposes the applicant must enter into a BSA with the relevant ILC. This process is executed through the representative, organisation or body identified in accordance with the customary laws and practices, protocols and procedures of the said indigenous and local communities. However, if such representation cannot be identified in regard to ATK, the process shall be executed with the holders of the ATK within the ILC and, if the holders of the ATK cannot be identified, with the Federal Government or State Authority.

If the same ATK is shared by more than one ILC, the applicant must obtain PIC and enter into a BSA with the duly identified representative or organization of all the holders of the ATK. However, if it is not practicable in all the circumstances of the case to ascertain all such holders, and this is proven to the satisfaction of the CA, the applicant shall obtain the PIC of, and enter into BSA with the duly identified representatives or organisation of such holders as the applicant may ascertain. Should another ILC also claim ownership, the CA shall determine such claim in consultation with the ILC whose PIC has been obtained and BSA entered into and if it proves the claim, declare such an ILC entitlement to the benefits due. Further, the CA shall determine the quantum or nature of benefits such an ILC is entitled to in consultation with all the ILCs concerned.

7 Assessment of the pre- and post-NP situation and conclusions

Malaysia did not have a specific legislation to regulate ABS before 2017 except the states of Saban and Sarawak, which had enacted stand-alone laws.[7] Thus, that Malaysia has now enacted such a comprehensive stand-alone law, which is already in force, is a big step forwards, including towards compliance with the NP. The Act, as seen above, defines the scope, establishes national authorities to regulate ABS, states the requirements for grant of access permits and lays down procedures for applications and their review, differentiates requirements, conditions and procedures for commercial/potential commercial and non-commercial research etc. Besides what has been examined in this paper, the Act has also defined violations and sanctions thereto, established monitoring and tracking measures, a clearing house mechanism and, unlike most traditional provider countries' laws, has user (compliance) measures. The law has the potential to ease access to biological resources and ensure fair and equitable sharing of benefits. Nonetheless, some issues are still incomplete as the regulations thereto have not yet been enacted. For example, it is not clear which particulars the applicant must submit with the application, the duration, terms, conditions and restrictions to be imposed upon issuance of a permit, the minimum terms for a benefit-sharing agreement, or the fees to be charged for a permit. This should change once the regulations are enacted as foreseen in s. 62 (1) of the Act.

[7] Nordin R. et al. (2012), at185.

References

R. Nordin et al. (2012), Regulating access to genetic resources and the sharing of benefit through the Sarawak access benefit-sharing legislation, Research Journal of Applied Sciences 7 (3), 185-193.

S. Syafira (18 December 2012), I am drafter: Access and benefit sharing law in Malaysia, http://syafi-ct.blogspot.com/2012/12/i-am-drafter-access-and-benefit-sharing.html.

Chapter 5
Implementing ABS in Australia. Failing at the last hurdle?

Geoff Burton

1 Introduction

Australia was the first OECD country to introduce ABS laws to implement the Convention on Biological Diversity's Article 15 – Access to Genetic Resources. In doing so it followed a path of legal and operational innovation. It contributed to the further international evolution of ABS through the development of world's best ABS practice (the CBD'S Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of their Utilization (Bonn Guidelines) and the Nagoya Protocol. Yet to date, while Australia is a signatory to the Protocol, it has yet to ratify the treaty. This paper outlines Australia's progress on ABS, its innovations and contributions, and identifies the remaining steps needed to fulfil its obligations prior to ratification and suggests why progress has stalled.

2 Background

The evolution of ABS in Australia at national level has a long history. Australia's first significant legislative step was to provide for ABS in the country's overarching national environmental law: the Environment Protection Biodiversity Conservation Act 1999 (the EPBC Act).[1] This was followed by the conduct of a national inquiry into ABS (the Voumard Inquiry 2000[2]). The Voumard Inquiry was a top down process established with an independent chairperson and an advisory committee including representatives from the scientific research, biodiversity conservation and Indigenous peoples' communities along with a member of the CBD Secretariat in their private capacity. The Inquiry conducted extensive consultation with all stakeholders groups around Australia before recommending a comprehensive ABS scheme to government.

In parallel with this process, the Australian government actively participated in the development and adoption of the 2002 Bonn Guidelines. The Guidelines' final negotiated terms were consistent with Australian government policy development on ABS so, on 11 October 2002, the national government concluded an agreement with Australia's states and territories for a common implementation of the Bonn Guidelines. This was set out in the Council of Australian Governments' Nationally consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources.[3] Finally in 2005, following a successful tabling in Parliament, the Australian government introduced a new part to the EPBC Regulations – Part 8A, Access to biological resources in Commonwealth areas[4]. The sys-

[1] Section 301 of the Act provides that regulations may control access to biological resources in Commonwealth areas and may contain provisions for the equitable sharing of benefits arising from the use of biological resources, facilitating access, denial of access and granting access on terms and conditions for such access. See: https://www.legislation.gov.au/Details/C2018C00440/Download, accessed 31 August 2019.

[2] See https://www.environment.gov.au/system/files/resources/d0f84da6-eb69-4053-8d96-ec294da649bc/files/abrca.pdf, accessed 31 August 2019.

[3] See http://www.environment.gov.au/system/files/resources/bbfbde06-d13a-4061-b2f9-c115d994de2d/files/nca .pdf, 31 August 2019.

[4] See http://www.environment.gov.au/node/14439 And https://www.legislation.gov.au/Details/F2014C00950, accessed 31 August 2019.

tem introduced by this law has now been operating successfully for 14 years with 47 Access Permits issued in 2017/18[5].

In summary the drivers for that system are:

- Its geographical distribution of land and waters,
- The conservation and sustainable use of biodiversity,
- Facilitating access and use,
- Respecting private and Indigenous land rights,
- Creating legal certainty for access and use, and
- Incentivising investment in research and development and creating new biodiversity knowledge.

3 Ownership of Commonwealth genetic resources

Australia is a common law country. Accordingly, it is constrained from taking any genetic resources it does not own without paying compensation on just terms but may regulate their use.[6] Thus, federal ABS law regulates the taking of resources and guarantees that shared benefits must flow to private landholders where they exist. In this case, with some caveats relating to the operation of Native Title in Australia, privately owned land within Commonwealth administered lands and waters is confined to Indigenously owned or managed lands or waters. With this in mind the regulations set out two pathways for benefit-sharing: one for Commonwealth owned or managed lands and waters, and one for indigenously owned and managed lands and waters but within Commonwealth jurisdiction. In the latter case, the role of the Commonwealth is to protect the interests of indigenous owners by ensuring fair dealing by users.

4 Ownership of State and Territory genetic resources

Australia is a federated nation made up of 6 states and two territories. Only two jurisdictions, Queensland and the Northern Territory have enacted specific ABS laws. In both cases they respect common law principles. In Queensland ABS law applies to public lands and waters but does not apply to private property. In the Northern Territory benefits derived from genetic resources taken from private property owners must flow to the owners.

5 Geography, biodiversity, indigenous people and industry

Australia's continental land area of 7.7 million square kilometres is similar to the USA. Its marine jurisdiction is larger at 10.2 million square kilometres. Australia's states and territories manage the bulk of land while the Commonwealth is responsible for the greater part of its marine jurisdiction. The Commonwealth's terrestrial jurisdiction largely consists of indigenously owned national parks, defence lands and Australian offshore islands.

---

[5] Page 256 of the Department of Environment and Energy 2017/18 Annual Report.

[6] This principle is enacted at Sub-Section 51(31) of the Commonwealth of Australia Constitution Act 1900. See https://www.aph.gov.au/About_Parliament/Senate/Powers_practice_n_procedures/Constitution.aspx, accessed 31 August 2019.

Australia is one of 17 megadiverse countries.[7] Geographical isolation has produced abundant biodiversity, often unique and sometimes ancient or rare. Moreover, Australia's indigenous peoples' 50,000 years of settlement[8] has given them an intimate knowledge of biodiversity and its properties and hence a body of traditional knowledge associated with genetic resources. Indigenous communities own, manage or have recognised land rights over 27 per cent of Australia.[9]

Australia has a growing biotechnology and life sciences industry. In 2016 the sector was valued at AU$100 billion with 1000 companies, including 300 biotechnology companies and 400 medical technology companies. The sector employs 48,000 people.[10] Biodiscovery is an important element as reflected by its inclusion in Australia's National Biotechnology Strategy with a stated objective of enhancing access to Australia's genetic resources.[11]

6 Challenges and innovations

6.1 Definition of terms – utilization

International debates on CBD Article 15 often centred on the difficulty of determining the scope of genetic resources and the limits of their derivatives. Australia took an alternative approach. It focused instead on the intended use of genetic resources i.e. its utilisation. Accordingly, it defined access to biological resources as:

… the taking of biological resources of native species for research and development on any genetic resources, or biochemical compounds, comprising or contained in the biological resources…[12]

Thus the taking and specified use of native species' biological material was regulated. It also reduced the scope of the activity to research and development on genetic resources and on biochemical compounds found within a biological resource.[13] This approach was later adopted in the definition of 'utilisation' in the Nagoya Protocol.

6.2 Electronic verification of permits

To address the difficulty and cost of verifying legal provenance of collected genetic resources it was decided to develop and pilot a low-cost system of electronic verification of access permits. This was achieved by building an internet-accessible verification website. This pilot programme continued until the establishment of the ABS Clearing-house (ABSCH) that serves a similar function. Permit details will be provided to the ABSCH following ratification.

---

[7] See https://www.australianwildlife.org/wildlife, accessed 31 August 2019.

[8] See http://www.australasianscience.com.au/article/science-and-technology/when-did-aboriginal-people-firstarrive-australia.html, accessed 31 August 2019.

[9] See https://aiatsis.gov.au/explore/articles/land-rights, accessed 31 August 2019.

[10] See https://www.ausbiotech.org/biotechnology-industry/fast-facts, accessed 31 August 2019.

[11] See page 26 at: https://www.cbd.int/doc/measures/abs/msr-abs-au4-en.pdf, accessed 31 August 2019.

[12] See https://www.legislation.gov.au/Details/F2014C00950, accessed 31 August 2019.

[13] Australia decided to confine ABS to its native species to avoid deriving benefits from foreign species and thus encouraging countries to obtain benefits from utilization of Australian native species found in their own jurisdictions. Author as director of Australian Access Task Force 1999-2006.

6.3 Commercial and non-commercial use

To facilitate access and reduce cost Australia published two model benefit-sharing agreements, one for indigenously owned land and waters and one for Commonwealth only lands and waters.[14] Significant to any contract for access on indigenous' owned land is the requirement that the Commonwealth Minister be satisfied the owners have given their prior informed consent and that any intended use of traditional knowledge associated with genetic resources has been properly disclosed to the owners.[15] The model contracts also set out how equitable benefit-sharing capacity differs by industry sector and allows for non-financial benefits.

Access permits are free for non-commercial use. Such permits do not require complex benefit sharing agreements.

Instead they must include a Statutory Declaration showing:

- the permission of the provider,
- the use is for non- commercial purposes,
- research results will be published or shared,
- a taxonomic duplicate of any new species will be offered to a public collection, and
- a commercial agreement will be negotiated if there is wish to commercialise.

7 Ratification

7.1 Next steps and ratification

The Australian government signed the Nagoya Protocol in 2012 but has not yet ratified. Compliance options include: requiring government research funding to be conditional on use of lawfully obtained genetic resources, the restriction on the importation of unlawfully obtained genetic resources for research and development, and the creation of international certificates of compliance and increased penalties for breaches of Australian ABS regulations.

Its published position is that its domestic ABS measures are consistent with the Protocol and it is developing its approach to implementation and ratification. This does not explain the delay. Interviews with officials not authorised to speak on behalf of the government offers a more prosaic explanation. This is that the government is reluctant to legislate compliance measures as opening the door for amendment of the EPBC Act may lead to pressure for undesirable amendments promoted by its more conservative members.

7.2 Pressure for ratification

During the May 2019 annual conference of the Australia New Zealand Marine Biotechnology Society, research scientists from the Commonwealth Scientific and Industrial Research Organisation (CSIRO) stated to the author that Chinese researchers advised them that Australia's non-ratification of the Protocol prevented research partnerships. Researchers

[14] A copy can be found on the World Intellectual Property Organization Contractual Data Base at: https://www.wipo.int/tk/en/databases/contracts/texts/australiamodel.html#_Toc170201080, accessed on 31 August 2019.

[15] See Clause 8A-10 Informed Consent at: https://www.legislation.gov.au/Details/F2014C00950, accessed 31 August 2019.

from Tasmania, and South Australia stated that the absence of Protocol implementation was creating difficulties for establishing collaborative research more broadly.

The states of Western Australia, South Australia, Tasmania and New South Wales have indicated in earlier consultations with Commonwealth officials that state ABS legislation will be contingent on the national government implementing its domestic compliance obligations and ratification of the Protocol.

8 Conclusion

Australia's ratification of the Nagoya Protocol and implementation depends on pressure from the biotechnology research communities and state governments overcoming government resistance to amending the EPBC Act. To date Australia's early innovations and contributions to the development of an international ABS system has not provided sufficient momentum to ensure Australia's timely ratification of the Protocol and its domestic implementation.

References

Commonwealth of Australia Constitution Act 1900. Federal Register of Legislation, Constitution - C2013Q00005, https://www.legislation.gov.au/Details/C2013Q00005.

Department of Environment and Energy 2018/19 Annual Report, https://www.environment.gov.au/system/files/resources/1c417884-f855-4411-943b-c284450cfd1b/files/annual-report-2018-19-full.pdf.

Nationally consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources. Decision of the Council of Australian Governments' endorsed 11 October. ISBN 0 6425 1557 X.

Number of Living Species in Australia and the World, Arthur D Chapman, 2006. ABRS Publications, ISBN 978 0 642 568496.

Chapter 6
The South African ABS regime: Between old and new

Evanson Chege Kamau

1 Introduction

South Africa is Party to the CBD and the Nagoya Protocol by ratification since 31.01.1996 and 12.10.2014 respectively. The ABS regime is formed by a number of legislations, but the main ones are two.

The first one is the National Environmental Management: Biodiversity Act, No. 10 of 2004 shortly referred to as NEMBA. It regulates ABS issues mainly under chapters 6 and 7. The purpose of chapter 6 (s. 80 – 86) on Bioprospecting, Access and Benefit-sharing is (a) to regulate bioprospecting involving indigenous biological resources; (b) to regulate the export from the Republic of indigenous biological resources for the purpose of bioprospecting or any other kind of research; and (c) to provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources. Inter alia, it establishes the scope of the Act (material, personal, geographical) stating the exemptions, condition for utilisation of indigenous biological resources (i.e. subject to a permit), pre-conditions for grant of permit, prescribes formats for BSA and MTA and establishes a Benefit-sharing Trust Fund (BTF). Chapter 7 (s. 87 – 93) states its purpose as the regulation of the issuing of permits. It establishes inter alia the procedure for application, issuing of permits, form of permit and timelines. It also establishes an integrated permit system. Equally important are sections 9 on sanctions and section 1 on definitions. NEMBA has been revised severally in 2009 and 2013.

The second is the Bioprospecting, Access and Benefit-Sharing Regulations, 2015. These are referred shortly as BABS Regulations and they elaborate, clarify and specify the ABS provisions of the Act.

2 Scope of ABS regime

2.1 Geographical scope

The geographical scope of the ABS regime is defined in s. 4 (1) (a)-(b) of the Act as the Republic, which should be understood as South Africa (SA), including its territorial waters, exclusive economic zone and continental shelf as described in the Maritime Zones Act No. 15 of 1994, and the Prince Edward Islands referred to in the Prince Edward Islands Act No. 43 of 1948. This means any terrestrial or marine territory under the jurisdiction of SA.

2.2 Material scope

The regime applies to indigenous biological resources (IBRs) for bioprospecting or export for any other kind of research and to access to associated traditional knowledge (ATK). The term ‘indigenous genetic and biological resources’ is defined in the Act and, in connection to bioprospecting, “means any living or dead animal, plant or other organism of an indigenous species and any derivative or genetic material of such animal, plant or organism”. Important to note is that this term was broadened by inclusion of the word ‘genetic’ to the term indigenous biological resources under s. 19 of Act 14, 2013. The term ‘any other kind of research’ was defined in BABS Regulations 2008 but was not taken up when these regulations were appealed following the adoption of the new BABS Regulations 2015. ‘Any other kind of research’ means any other research other than bioprospecting. The term ‘traditional

use/knowledge' as defined in the BABS Regulations 2015 "refers to 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 include discoveries about the relevant indigenous genetic and biological resources by that community or individual".

2.3 Scope of utilisation/use

First, it is important to note that the regime does not use the term 'utilisation' but 'bioprospecting' which is defined under s. 1 in relation to IBRs as "…any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation".[1] Hence together with the definition of the term 'indigenous biological resources', bioprospecting is considered to take place when biological resources and their derivatives or genetic material are used for commercial or industrial purposes (to make profit). Thus, bioprospecting triggers the requirement for an access permit as well as the sharing of benefits. The regime is silent on bulk resources and digital sequence information.

2.4 Exemptions

Excluded from its scope are:

- (ii) genetic material of human origin (s. 80 (2)(b));
- (iii) any exotic animals, plants or other organisms, other than exotic animals, plants or other organisms referred to in s. 80 (2) (a)(iii) (s. 80 (2)(b)); and
- (iv) indigenous biological resources listed in terms of the ITPGRFA (s. 80 (2)(b)).

3 National authorities

NEMBA has established institutions with mandates for ABS. These are the Minister and the Member of Executive Council (MEC). They are referred to as issuing authorities in s. 87A of the Act as they are mandated with the issuing of permits. The Minister is responsible for issuing permits for commercialisation phase of bioprospecting[2] involving any IBRs or their export from SA for the purpose of any type of bioprospecting (commercialisation or discovery phase[3]), for biotrade and for the latter two integrated (r. 4 (1)). This would include any bioprospecting targeting threatened, protected or endangered species (s. 87A (1) (a) & (b)), hence CITES and Threatened or Protected Species (TOPS) permits. For bioprospecting abroad, the Minister can issue an integrated permit for bioprospecting and export (r. 17 (2)). The MEC is responsible for issuing permits for export of IBRs collected, gathered or curated in the province if such IBRs are being exported for research purposes other than bio-

[1] The term 'commercial exploitation' was defined through an insertion under s. 1(c) of Act 14 of 2013 and "means the engaging in any bioprospecting activity with the intention of making a profit". 'Industrial exploitation' is not defined in any of the instruments but in its common usage it should mean any industrial activity based on bioprospecting.

[2] According to s. 1 NEMBA "'commercialisation' phase of bioprospecting means any research on, or development or application of, indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is sufficiently established to begin the process of commercialisation".

[3] According to s. 1 NEMBA "'discovery phase of bioprospecting' means any research on, or development or application of, indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is not sufficiently clear or known to begin the process of commercialisation".

prospecting (r. 4 (2)). This said, the Minister and the MEC may in writing delegate power to each other allowing either of them to take decision concerning application for a permit or type of permit that by law falls under the others' mandate (s. 87 A (3)). Discovery phase of bioprospecting and non-bioprospecting research undertaken in SA do not require a permit, albeit the former must be notified to the Minister prior to commencement (s. 81A (1)).

The Director-General is also established under s. 85 (3) and is important as s/he manages the BTF. The mandates of these institutions are elaborated in the BABS Regulations (r. 4 (1) and (2) and r. 40, resp.). Besides, the functions of National Focal Point (NFP), the Competent National Authority (CNA) and Checkpoint (CP) have been established in line with Articles 13 and 17 of the Nagoya Protocol although these institutions are not mentioned in the Act and the Regulations. The roles of the latter three institutions are played by the National Department for Environmental Affairs (DEA). Thus DEA is responsible for advising on applicable procedures and requirements for obtaining PIC and entering into MAT both at the national and federal level. It is also responsible for granting access to all types of GR as well as issuing written evidence that access requirements have been met. In addition, it is mandated to collect or receive relevant information related to PIC, the source of GR, the establishment of MAT and the utilisation of GR. Such information is provided to the relevant national authorities, the party providing PIC and to the ABS CH.

Applications must be submitted to relevant issuing authority via the prescribed procedure for submission of permit applications (r. 20) which is either by e-mail, registered mail, ordinary mail, hand delivery, fax, or electronically on-line. The applicant must pay attention to the prescribed procedure for submission for the specific purpose of application.

4 Requirements and conditions for access to in situ and ex situ genetic resources

4.1 Access permit

Section 81 (1) of the Act stipulates clearly that no person may engage in the commercialisation phase of bioprospecting involving any IBRs or export from South Africa of such resources for the purpose of bioprospecting or any other kind of research without a permit issued in terms of Ch. 7. Parties interested in accessing IGBRs for any of these purposes must submit a permit application either to the Minister or the MEC in the prescribed forms. Applications for permits under the Minister's mandate must be submitted to DEA (r. 5 (1), (2)), unless the Minister has assigned or delegated powers and duties to the MEC. Applications for permits under the MEC's mandate as well as those assigned or delegated by the Minister to the MEC must be submitted to the relevant provincial department responsible for environmental affairs (r. 5 (4) & 5 (3), resp.).

4.2 Contents and conditions of the access permit

Only contents and conditions of an access permit for commercial phase of bioprospecting will be looked at. These are contained in the form of an access permit in Annexure 9 of the Regulations. There are, however, other types of permits. For example, access to endangered or protected species is subject to CITES and TOPS permits as the case may be. Their forms are contained in Annexures 6. Besides, discovery phase of bioprospecting and research other than bioprospecting conducted abroad require export permits. Their forms are contained in Annexures 7.

4.2.1 General information

Accordingly, the permit contains the following information:

1. The name of the issuing authority and contact details;
2. The details of the permit holder and other permit holder if a joint permit application has been made (i.e. names of the applicants, their ID or PP No. of which a certified copy of the first holder must be attached and their detailed contacts including telephone (land-line and mobile), fax, email and postal/physical addresses); details of the import-er/recipient (i.e. same as permit holder except for a copy of the ID/PP in addition);
3. The nature of the permit specifying the IGBRs the permit holder is allowed to access/use (type of organism, family, genus or species – scientific and common names) as well as the quantities and areas of collection, points of export and import if applicable;
4. Permit validation showing when the duration of validity commences and ends;
5. An entry of the MTAs and BSA entered under the permit and together with which the relevant permit must be read; and
6. At the bottom end, the permit number or permit renew number if applicable, the signa-ture of the issuing officer, date of signing, and the stamp of the issuing authority, and the signature of the permit holder, date of signing, and his/her full names.

4.2.2 Standard conditions

In addition, it contains typical conditions as indicated on a non-exhaustive list, viz.:

1. The bioprospecting purpose for which the IGBRs to which the permit relates may only be used;
2. The obligation of the permit holder(s) to comply with all other legislative requirements for the collection of the IGBRs (if any);
3. The permit holder's(s') liability relating to any costs of mitigating or remedying the impact of the bioprospecting on the environment, in accordance with s. 28 of the National Envi-ronmental Management Act, 1998 (Act No. 107 of 1998);
4. The obligation to pay all money due to stakeholders in terms of the approved BSA into the BTF, as required by s. 85 (1) of the Act;
5. The obligation of the permit holder to notify the Department when money due to stake-holders as specified in the approved BSA will be transferred to or paid into the BTF;
6. The obligation of the permit holder to notify stakeholder or stakeholders entitled to a monetary benefit in terms of the approved BSA that money was transferred or paid into the BTF;
7. The obligation of the permit holder to submit to the issuing authority and in a form de-termined by it a status report on an annual basis or timeframes determined by the issu-ing authority;
8. The obligation of the permit holder not to transfer the IBRs to which the permit relates to any third party without the prior written consent of the issuing authority and then only un-der a written agreement containing terms no less restrictive than those which apply to the permit holder in terms of the relevant permit and any agreements related thereto;
9. The obligation of the permit holder to notify the issuing authority in writing if new collabo-rators join the bioprospecting project for which the permit issued relates;

10. The MTA concluded with the subsequent user of traded IGBR should include a clause stating that the use of SA IGBRs for bioprospecting is subject to the provisions of the NEMBA 2004 (Act No. 10 of 2004) and that a bioprospecting permit is required; and
11. Failure to comply with any of the permit conditions renders the permit invalid and may result in criminal proceedings, cancellation of the permit/s and seizure of the consignment/s.

5 Model transfer agreements, guidelines

5.1 Model transfer agreements

SA operates a MTA and a BSA which are included in the Regulations. These are post-NP agreements being part and parcel of the new Regulations of 2015. The agreements must be entered into by an applicant for a permit and any stakeholders identified in terms of the Act (s. 82 (1)) and the Regulations (r. 38 (1)) for access to any IGBRs and ATK. If the stakeholder is a community, a representative of the community identified in the community resolution will enter into the agreement on behalf of the community (r. 38 (4)). If there are different stakeholders a separate MTA must be entered into with each one of them. Parties can add annexes to the form provided if the space is insufficient or use their own forms as long as the format of the model MTA is followed. There is no indication in the MTA that parties can add other conditions not considered in the provided form but parties to the BSA may include other matters concerning the GR and/or ATK (c. 10). None of the agreements seems to allow parties to expunge some of the existing clauses. In addition, it is not possible to use other models e.g. availed by the recipient/permit applicant. Only critical conditions of the MTA will be looked at.

5.1.1 Third party transfer

The recipient/permit applicant is only allowed to sell, transfer or make available the IGBRs to third parties under condition that the subsequent recipient and other third parties are equally bound by the terms and conditions of the first agreement – with the initial recipient/permit applicant (c. 9). Hence the MTA embraces the viral clause approach.

5.1.2 Change of intent

The recipient/permit applicant must not utilise the IGBRs for other purposes other than those agreed upon and stipulated under c. 5, in particular R&D linked to new and useful properties of the IGBRs, without a (new) PIC and conclusion of a BSA with regards to the proposed utilisation changes (c.7). In addition, s/he must not utilise the IGBRs “for germination, propagation, breeding, tissue breeding, cloning or in any way seek to capture genetic material for the purpose of reproduction without PIC from and MAT with the issuing authority and access provider (c. 8).

5.1.3 Claim of IPRs

The MTA provides for the right of the recipient/permit applicant to claim patents or other IPRs connected or referring to the IGBRs for new methods of utilisation of such resources or new process of their preparation, production or manufacture subject to compliance with the Act and the Regulations as well as prior expression and written permission from the issuing authority (c. 6).

5.2 Guidelines

SA released guidelines for providers, users and regulators in 2012. They explain the Act (up to 2009 amendments) and the Regulations of 2008 and simplify their understanding by using illustrations in the form of boxes, figures and tables, and include other useful information. Likewise they guide each of the groups mentioned into their rights and obligations. However, they are outdated as the Act was revised again in 2013 and the 2008 Regulations were repealed in 2015 with the new ones coming into force the same year. Thus, although they are still useful, they do not consider any changes which have taken place after 2012.

6 Benefit sharing

The BSA contains a non-exhaustive list of non-monetary and monetary benefits that can be shared from bioprospecting projects, which is not verbatim to the Bonn Guidelines/NP list. These benefits will vary depending on the case and nature of the project. The table containing the types of benefits can be found at c. 5 of the BSA.

7 Participation of other public and private entities

The entities that participate in the ABS process are referred to as 'stakeholders'. This term is defined in s. 1 of the Act as any entity contemplated in s. 82 (1), i.e., a person (natural or juristic), including any organ of state or a community, and in regard to traditional use or knowledge associated with the GR, an indigenous community or a specific individual. Thus besides government institutions/organs, indigenous communities and individuals participate. Their interests must be protected by ensuring that their PIC is obtained prior to provision or access and use of GR and/or ATK.

8 Assessment of the pre- and post-NP situation and conclusions

Generally, it is quite hard to explicitly conclude that a regime is not compliant with an obligation of the NP. Take for instance article 6.3 (b) NP on fair, non-arbitrary rules/procedures. How would one judge the rule that foreigners qualify to apply for access only in a joint application with South Africans (r. 12 (c) – a juristic person registered in terms of SA law; a natural person, who is a SA citizen or a permanent resident of SA)? It depends on how different sides judge it. For SA, this might be a way to monitor value chain, ensure her involvement as the provider, and building of her skills. For a user, on the other hand, this rule could be seen as being likely to produce effects that are equivalent to unfairness and arbitrariness. Hence, instead of trying to make conclusions whether the regime complies or not this chapter tries to depict some of the steps taken to comply.

SA has revised its statutes by amending the Act in 2009 and 2013 and releasing the new Regulations in 2015. As a result there is more clarity concerning ABS requirements for access and use of South African GR and ATK. Most terms have been defined and are clear, albeit they are at times long because of being interconnected with other definitions, which makes understanding them complex. The scopes are well-defined, national authorities established and their mandates defined. The requirements and procedures for access are clear. There is also a MTA and a BSA as well as guidelines for the regime. However, the regime still suffers from a number of weaknesses. For instance, there are so many scattered bits of statutes which make it burdensome for an applicant to easily understand the regime, or initiate his/her undertaking with certainty of having full knowledge of its operation. This is a big weakness for the regime. The guidelines which should harmonise, condense and explain the relevant issues into one document were released in 2012 and are outdated. Therefore, they miss on rules related to the amendments and at times contradict

the amended instruments. If the guidelines could be revised they could greatly help improve as well as simplify the regime.

Chapter 7

Towards a Nagoya Protocol compliant ABS regulatory framework in Cameroon

Marcelin Tonye Mahop

1 Introduction

Cameroon became a Party to the Convention on Biological Diversity (CBD) in 1995 and in 2017 to its Protocol on Access and Benefit-Sharing (ABS),[1] which was adopted in Nagoya in 2010 and entered into force in 2014. By ratifying and becoming Party to the CBD, Cameroon demonstrated recognition of the values of its biological and cultural diversity and the necessity for domestic actions to ensure their conservation and sustainability based on the benefits and services they offer to humankind (social, economic and livelihoods benefits) and the environment. Specifically, Cameroon's ratification of the Nagoya Protocol (NP) on ABS is clear indication of the country's commitment to translate the provisions of this international environmental agreement into domestic ABS regulations. The ambition is to ensure that access to and utilisation of the countries genetic resources (GRs) will lead to tangible (monetary or non-monetary) benefits that will be shared between Cameroon and users. The proceeds of these benefits earned by Cameroon can be reinvested in domestic conservation, sustainability and socio economic and livelihoods improvement endeavours.

However, despite being Party to the CBD and the NP on ABS, Cameroon has not yet fully legislated on ABS at the national level. This does not mean that the country has been silent on the ABS front. Quite the contrary. Under the leadership of the ministry in charge of Environment and Nature Protection, which hosts both the focal points of the CBD and the NP, an institutional apparatus was set up in 2013 to domestically handle ABS cases. In addition, with the support of the Cameroon government and international development partners, Cameroon embarked on a journey to formulate a regulatory framework on ABS that is NP compliant. The institutional apparatus that was setup is the National ABS committee. On the regulatory aspect for ABS, progress so far can be described to have led to the formulation and adoption of (1) the National ABS strategy, which mirrors the regional ABS strategy formulated by Commission des Forêts d'Afrique Centrale (COMIFAC)[2], and (2) the ongoing development of the drafts ABS regulatory framework that include the draft ABS Law and draft implementing regulations. Until these instruments are promulgated, Cameroon's handling of ABS cases is based on the national ABS strategy and a raft of past forestry law, environmental framework law, research permitting and phytosanitary regulations that are administered by different government departments.

2 Current ABS regulatory approach and emerging Nagoya Protocol compliant ABS regime in Cameroon

In Cameroon, several pieces of national laws are applied in cases of access to and utilisation of biological and genetic resources and associated traditional knowledge. Central to the raft of instruments currently used is the 1994 Forest Law[3], which asserts State's sovereign-

[1] Cameroon's accession to the Nagoya Protocol: https://www.cbd.int/countries/default.shtml?country=cm.

[2] COMIFAC (2011), Stratégie des Pays de l'Espace COMIFAC Relative à l'Accès aux Ressources Biologiques/Génétiques et au Partage Juste et Equitable des Avantages Découlant de leur Utilisation, Commission des Forest d'Afrique Centrale, Série Politique No4.

[3] La loi No 94-01 du 20 janvier 1994 portant Régime des Forêts, de la Faune et la Pêche.

ty and ownership of all its forestry and genetic resources and stresses the State's sole prerogative to authorise access to and exploitation of biological and genetic resources. Specifically, Article 12.1 of the 1994 Forestry Law stipulates that only the State can authorise access to genetic resources for scientific and commercial use. Furthermore, pursuant to Article 12.2 of the 1994 Forestry Law, should access to and use for scientific and commercial purposes generate any benefits, these should be shared fairly and equitably by the actors involved. Additionally, the 1996 Environmental Framework Law is generally referred to in relation to ABS matters in Cameroon.[4] While this law reinforces the principles of State's sovereignty over its resources and its prerogative to authorise access and use, it brings an additional and critical perspective to ABS processes by stressing the need to always involve local communities when collection and exploitation of biological resources occur in their environments.[5] Alongside these key instruments, specific implementing regulations in the form of ministerial or joint ministerial orders were issued. These implementing orders clarify the agencies responsible for the delivery of plant collection and forest exploitation permits;[6] the research permits[7] especially to overseas scientists working in partnership with domestic research agencies; the certificates of exports and origins for materials destined to exportation, the phytosanitary certificate[8] and the mechanisms for sharing the benefits.[9] Although these instruments have largely been referred to by national actors as very relevant to ABS matters, they are in fact not aligned to some of the key ABS principles of the CBD and the Nagoya Protocol as they fail to uphold the PIC and MAT principles of these global instruments and fail to address benefit-sharing from the utilisation of genetic resources, as defined by the Nagoya Protocol. Furthermore, these instruments fail to accommodate the monitoring of utilisation of genetic resources and compliance issues in the spirit of the Nagoya Protocol.

However, draft access and benefit-sharing instruments are being developed with the intention to make the domestic ABS regulatory framework compliant with the Nagoya Protocol. The 2018 versions of these draft instruments include:[10]

- Draft ABS Law entitled: Loi Relative à l'Accès aux Ressources Génétiques et aux Connaissances Traditionnelles associées et au Partage Juste et Equitable des Avantages découlant de leur Utilisation;
- Draft implementing decree setting the terms of access to genetic resources and associ-

---

[4] La loi No 96/12 du 5 août 1996 portant loi-cadre relative à la gestion de l'Environnement.

[5] Article 65.1 of the loi No 96/12 du 5 août 1996 portant loi-cadre relative à la gestion de l'Environnement.

[6] Pursuant to décret No 95-531 du 23 Août 1995 fixant les modalités d'application du régime des forêts, the Ministry of Fauna and Flora issues plant collection permits as well as certificates of origins for materials destined to exportation.

[7] Pursuant to L'arrêté No 00002/MINRESI/B00/C00 du 18 mai 2006 fixant les conditions d'octroi d'une Autorisation de Recherche, it is the ministry of Scientific and Technical Research and Innovations that issues research permits especially to foreigners who conduct research in Cameroon in partnership to national organisations.

[8] Pursuant to loi No 2003/003 du 21 avril 2003 portant protection Phytosanitaire fixant les principes et règles qui régissent la protection phytosanitaire au Cameroun, it is the ministry of agriculture that is responsible for the issuance of the phytosanitary certificates for materials that are meant for exportation.

[9] The joint ministerial order 'arrêté conjoint N° 0000076 MINATD/MINFI/MINFOF du 26 Juillet 2012 fixant les modalités de planification, d'emploi et de suivi de la gestion des revenus provenant de l'exploitation des ressources forestières et fauniques destinés aux communes et aux communautés villageoises riveraines'.

[10] It is important to stress that the Draft Model ABS permit, Draft Model PIC and Draft Model MAT all have draft templates that are available.

ated traditional knowledge and the fair and equitable sharing of the benefits arising from their utilisation;

- Draft model ABS permit;
- Draft model PIC and;
- Draft model MAT.

3 Scope of and exclusions from the emerging regulatory framework, PIC and MAT requirements for commercial and non-commercial research, IPRs and DSI

The scope of the draft law is very broad. It extends to access and utilisation[11] of the genetic resources and associated traditional knowledge and derivatives including: access to plant, animal and microbial genetic resources in the national territory, access to aTK, conservation of GRs, application for and acquisition of IPRs from the use of GRs and aTK, transfer to third party of GRs and aTK for research and commercial purposes, transboundary cooperation; current use of GRs and/or previously acquired.[12] Included in the draft law's definition of 'utilisation of genetic resources and associated traditional knowledge', are considerations of two broad objectives for such utilisation: (1) enhancement of scientific knowledge and, (2) development of commercial products from the resources, associated traditional knowledge or their derivatives. The draft law however provides for some exemptions from its very broad scope. It does not apply to the biological resources that are accessed from Cameroon but are not utilised as genetic resources in line with the draft law's definition of the term 'utilisation' and excludes from its scope, the exchange of genetic resources and associated traditional knowledge among rural communities for their livelihood.[13] The draft ABS law stresses that the State of Cameroon has sovereign rights over the biological and genetic resources that occur within its territory and that those rights apply to in-situ and ex-situ GRs, derivatives of GRs and information associated with GRs and to the sharing of benefits derived from GRs, which are regulated by international instruments.[14]

Cameroon has chosen to regulate 'access' to its genetic resources by including the requirements of PIC and MAT in its emerging ABS regulatory instruments. According to the draft ABS law, access means: "collection or acquisition including any transaction involving the genetic resources, derivatives or associated traditional knowledge by a user".[15] This definition appears very broad and complex because it encapsulates critical ABS issues that, although defined by the NP, have no consensus on how national laws can operationalise them. They include the issue of derivatives and the terms genetic resources. The complexity of the definition of access in the Cameroon ABS law is exacerbated by its inclusion of a loose notion of 'any transaction' associated with the genetic resources, derivatives and traditional knowledge. While the definition of access does not directly point to access for

[11] Article 7 of the draft law defines utilisation of genetic resources and associated traditional knowledge as research on the properties of plants, animals, micro-organisms and to associated traditional knowledge and derivatives in view to enhancing scientific knowledge or to developing commercial products.

[12] Article 3 of the Draft ABS Law : Loi Relative à l'Accès aux Ressources Génétiques et aux Connaissances Traditionnelles associées et au Partage Juste et Equitable des Avantages découlant de leur Utilisation au Cameroun.

[13] Article 4 of the Draft ABS Law.

[14] Article 5 of the Draft ABS Law of Cameroon.

[15] Article 7 of the draft ABS law on definitions.

utilisation, it is tempting to assume that the inclusion of 'any transaction' include utilisation as defined by the NP. Furthermore, 'any transaction' could also be interpreted to accommodate utilisation of genetic information and DSI linked to Cameroon's materials in this definition. Therefore, it does not matter whether the user collected or acquired the materials themselves directly from Cameroon, or through intermediary or acquired them by any means overseas, utilisation of such materials trigger ABS rules and the obligation to share benefits.[16] Moreover, this definition does not distinguish between in-situ or ex-situ genetic resources, meaning that there is no specific treatment of access to GRs in ex-situ collections by the law. In addition, the draft ABS law does not define or differentiate between 'commercial' or 'non-commercial' utilisation and makes no difference on requirements for these categories of utilisation. According to the draft ABS law, it is only the fact of undertaking fundamental research and research and development in the national territory by an institution of the national research system and provided there is no transfer / export of the materials overseas that leads to avoidance of the rigorous access permit application process with the requirement of PIC and MAT.

As mentioned above, the application for and acquisition of IPRs from the use of GRs and aTK is an important constituent of the scope of the draft ABS law. However, the draft implementing regulations expand on this in a somewhat confusing manner. Concerning the application of IPRs over the products of research based on the materials accessed, the draft ABS implementing decree provides that MAT provisions on IPRs need to address, among others, the objectives for applying IPRs and the risks to local and indigenous communities, regular reporting on research progress and possible industrial developments and capacity building aimed at indigenous and local communities.[17] If this approach is maintained in the final instruments, its operationalisation could prove difficult.

The emerging ABS regulatory framework of Cameroon encapsulates the modalities for the fair and equitable sharing of monetary and non-monetary benefits arising from the utilisation of GRs and aTK. Further details on what non-monetary benefits entail are provided by both the draft ABS law and the draft implementing decree. Non-monetary benefits include technology transfer, training, local development, information exchange, the supply of goods and services and any other elements as may be consensually agreed in the MAT.[18] In turn, the draft implementing decree describes different types of payments of monetary benefits by the user to the beneficiary. They can include payment for access and collection of materials, but also milestone payments, licence payments, salaries of local/community assistants, research funding, payment to trust funds for example those set up for the purpose of conservation and sustainable use of biological diversity.

4 Institutional framework and the monitoring and surveillance approach of the emerging Cameroon ABS regime

The draft ABS law formalises the establishment of the three key agencies of the ABS institutional framework in Cameroon.[19] The draft ABS law designates the Ministry of environ-

[16] It must be stressed that this is an extreme view shared with the author by an anonymous informant. It is not an official interpretation of the definition of access.

[17] Article 24 of the draft ABS implementing decree.

[18] Article 4 of the draft ABS law and article 41 of the draft implementing decree.

[19] Article 8 of the Draft Law establishes the National Competent Authority and outlines its roles and prerogatives; Article 9 of the Draft Law establishes the National ABS committee and outlines its roles and prerogatives and Article 10 of the Draft Law establishes the National ABS Focal Point and outlines its role and prerogatives.

ment and Nature Protection as the Competent National Authority (CNA) for ABS in Cameroon. The draft law assigns to the CNA the responsibilities for the issuance of access permit, supervision of the activities of the national ABS committee, elaboration of the conditions for PIC and MAT negotiations and the supervisory role in all PIC and MAT negotiations including in relation to access to traditional knowledge.[20] In addition, the draft law establishes the national ABS committee, which is placed under the supervision of the Minister in Charge of the Environment and Nature Protection. The ABS committee is set up as an advisory agency to the CNA, with the ability to create internal technical and scientific committees that can enhance its performance and strengthen the value of its recommendations to the CNA on ABS cases.[21] Then, the draft law establishes the National Focal Point (NFP) on ABS, which shall perform the roles earmarked in article 13 of the Nagoya Protocol. In addition, the NFP is responsible for the overall coordination of the secretariat and serves as the technical secretary of the ABS committee.

Regarding the monitoring and surveillance of the utilisation of genetic resources and in view to domesticating Article 17 of the Nagoya Protocol, the draft ABS law of Cameroon encapsulates an approach that stands on three pillars:

- The establishment of checkpoints
- A system of denunciation
- A collaborative or partnership scheme between the Competent National Authority and overseas partners to track the utilisation of GRs, aTK and other derivatives including genetic information used overseas.

5 Conclusions and assessments

Cameroon is committed to designing a domestic ABS regulatory framework which should enable the country to fulfil its obligations under the Nagoya Protocol on ABS and to generate development, conservation and sustainability outcomes for the country. The current draft instruments are evidence of the willingness and efforts that Cameroon is putting in the process that should hopefully deliver a Nagoya Protocol compliant ABS regulatory framework. The law and accompanying implementing instruments attempt to cover all the key obligations NP parties are expected to address in their domestic legislation including obligations pertaining to access to GRs for their utilisation and access to aTK, obligations pertaining to benefit-sharing and obligations pertaining to compliance, monitoring and surveillance of the utilisation of GRs. Upon their finalisation and adoption, the post NP ABS regulatory framework would be more aligned to the letter of the Nagoya Protocol as compared to the pre-NP regulatory framework, which was not properly aligned to the letter and spirit of the ABS principles embedded in the CBD. While the post Nagoya Protocol efforts on ABS regulatory making should be commended, the current versions of the draft instruments have their own deficiencies which need to be addressed prior to their finalisation and adoption as they (1) lack clarity in many respects and (2) include some unrealistic and unpragmatic provisions the implementation of which may not deliver the intended results, especially in respect to benefit-sharing.

[20] Article 8 of the Draft ABS law of August 2018.

[21] Article 9 of the Draft ABS law of August 2018.

References

Documents and websites

Cameroon's accession to the Nagoya Protocol: https://www.cbd.int/countries/default.shtml?country=cm.

COMIFAC (2011), Stratégie des Pays de l'Espace COMIFAC Relative à l'Accès aux Ressources Biologiques/Génétiques et au Partage Juste et Equitable des Avantages Découlant de leur Utilisation, Commission des Forest d'Afrique Centrale, Série Politique No4.

Legal or draft legal texts - Old forestry, environmental, research and benefit-sharing framework

Cameroon forest Law: La loi No 94-01 du 20 janvier 1994 portant Régime des Forêts, de la Faune et la Pêche.

Cameroon environmental Framework Law: La loi No 96/12 du 5 août 1996 portant loi-cadre relative à la gestion de l'Environnement.

Forest Law implementing decree: décret No 95-531 du 23 août 1995 fixant les modalités d'application du régime des forêts.

Research permit regulation: L'arrêté No 00002/MINRESI/B00/C00 du 18 mai 2006 fixant les conditions d'octroi d'une Autorisation de Recherche.

Phytosanitary Law: loi No 2003/003 du 21 avril 2003 portant protection Phytosanitaire fixant les principes et règles qui régissent la protection phytosanitaire au Cameroun.

Benefit sharing regime on forest / timber and NTFPs exploitation: The joint ministerial order 'arrêté conjoint N° 0000076 MINATD/MINFI/MINFOF du 26 Juillet 2012 fixant les modalités de planification, d'emploi et de suivi de la gestion des revenus provenant de l'exploitation des ressources forestières et fauniques destinés aux communes et aux communautés villageoises riveraines.

2018 Drafts/emerging ABS regulatory framework

Draft ABS Law entitled: Loi Relative à l'Accès aux Ressources Génétiques et aux Connaissances Traditionnelles associées et au Partage Juste et Equitable des Avantages découlant de leur Utilisation.

Draft implementing decree setting the terms of access to genetic resources and associated traditional knowledge and the fair and equitable sharing of the benefits arising from their utilisation.

Draft model ABS permit.

Draft model PIC.

Draft model MAT.

Chapter 8
The Ethiopian ABS regime

Ashenafi Ayenew Hailu

1 Introduction

Ethiopia is party to the Nagoya Protocol on ABS, since 2012.[1] Access and Benefit Sharing in Ethiopia is regulated by Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation, No. 482/2006[2] and Regulation, No. 169/2009.[3] The ABS law adopted and entered into force since February 2006 and November 2009 respectively.

The objective of the Ethiopian ABS law is to ensure that the country and its communities obtain fair and equitable share from the benefits arising out of the use of genetic resources and associated community knowledge so as to promote the conservation and sustainable utilization of the country's biodiversity resources.[4]

2 Scope of ABS regime

2.1 Geographical scope

The ABS law applies to all kinds of access to genetic resources and community knowledge found in both in situ and ex situ conditions.[5]

2.2 Material scope

The ABS law applies to all kinds of access to genetic resources and community knowledge.[6]

2.3 Scope of utilisation/use

Any research and development that involves the collection, acquisition, transfer or use of genetic resources and/or community knowledge triggers the ABS measures.[7] It applies also to any derivatives extracted or developed from biological resource[8] and DSI.[9]

2.4 Exemptions

The ABS law does not apply to the customary use and exchange of genetic resources and community knowledge by and among Ethiopian Local communities; and the sale of produce

---

[1] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization Ratification Proclamation No.753/2012.

[2] Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation, (No. 482/2006) [here in after Ethiopian ABS Proclamation 2006].

[3] Access to Genetic Resources and Community Knowledge and Community Rights Council of Minister Regulation, Regulation No. 169/2009 [here in after Ethiopian ABS Regulation 2009].

[4] Ethiopian ABS proclamation (2006), Art.3.

[5] ABS proclamation Article 4(1).

[6] Ibid.

[7] ABS proclamation Article 2(1).

[8] ABS proclamation Article 2(6).

[9] Draft ABS proclamation.

of biological resources for direct consumption, that do not involve the use of the genetic resource thereof.[10]

3 National authorities

Ethiopian Biodiversity Institute (EBI) is responsible to issue access permit, negotiate and enter into access agreements in accordance with the access law, and follow up their implementation.[11] EBI issues access permit as per the different procedures stated for commercial access[12] and non-commercial access.[13]

4 Requirements and conditions for access to in situ and ex situ genetic resources

An access applicant should submit written application, obtain PIC and sign an access agreement.[14] An access applicant who is a foreigner shall present a letter from the competent authority of his national state or that of his domicile assuring that it shall uphold and enforce the access obligations of the applicant.[15]

4.1 Access permit

An access permit granted can be for commercial or non-commercial purpose and should specify the type of genetic resource permitted to be accessed.

4.2 Content of the access permit

An access permit contains the type and quantitative description of the genetic resource permitted to be accessed, the intended use, the locality where the genetic resource is to be collected, the duration of the access permit and the obligations the access permit holder shall have.[16]

4.3 Permit conditions – especially most critical/important ones

4.3.1 Third party transfer

The access permit holder is not allowed to transfer the genetic resource and the community knowledge accessed to any other third party without first notifying and obtaining written authorisation from EBI.[17]

4.3.2 Change of intent

The access permit holder is not allowed to use the genetic resource and the community knowledge accessed for any purpose other than that originally intended, without first notifying and obtaining written authorisation from EBI.[18]

---

[10] ABS proclamation Article 4(2).

[11] Ethiopian Biodiversity Institute Establishment Council of Ministers Regulation No 291/2013, Art.6 (11)..

[12] ABS regulation Article 3-10.

[13] ABS regulation Article 11-13.

[14] ABS proclamation Article 14.

[15] ABS proclamation Article 12(4).

[16] ABS proclamation Article 16.

[17] ABS proclamation Article 17(9).

4.3.3 Claim of IPRs

Where an access permit holder seeks to acquire intellectual property rights over the genetic resources accessed or parts thereof, s/he shall negotiate a new agreement with EBI based on the relevant laws of Ethiopia.[19]

4.3.4 Publication of results

Access permit holder should inform EBI in writing of all the findings of the research and development based on the genetic resource and community knowledge accessed.[20]

4.4 Other permits

No person shall export genetic resources out of Ethiopia unless in possession of export permit granted by EBI to this effect.[21] The research based on the genetic resources accessed shall be carried out in Ethiopia and with the participation of Ethiopian nationals designated by EBI, unless where it is impossible.[22] No person may conduct exploration of genetic resources unless in possession of exploration permit from EBI.[23]

5 Benefit sharing

5.1 Types of benefits

The benefits to be shared from access to genetic resources and community knowledge may be monetary such as license fee, upfront payment, milestone payment, royalty and research funding and/or non-monetary such as joint ownership of intellectual property, employment opportunity, and support of infrastructure and technologies.[24] There is existing experience on sharing benefits of monetary and non-monetary types such as upfront payment, licence fee, royalty and creation of job opportunity.

5.2 Conditions and content of a benefit sharing agreement

A benefit sharing agreement should include non-monetary and/or monetary benefits as a condition to obtain an access permit. The non-commercial access agreement includes non-monetary benefits only, whereas the commercial access agreement includes both non-monetary and monetary benefits.

6 Participation of other public and private entities

Local communities participate by giving PIC for access to their community knowledge and sharing of benefits arising out of the utilization of their genetic resources and community knowledge.[25]

---

[18] Ibid.

[19] ABS proclamation Article 17(12).

[20] ABS proclamation Article 17(8).

[21] ABS proclamation Article 11(3).

[22] ABS proclamation Article 12(6).

[23] ABS proclamation Article 22(1).

[24] ABS proclamation Article 19.

[25] ABS proclamation Article 6.

7 Assessment of the pre- and post-NP situation and conclusions

Transboundary cooperation,[26] compliance with domestic legislation or regulatory requirements on access and benefit sharing,[27] monitoring the utilisation of genetic resources that includes measures such as the designation of one or more checkpoints,[28] compliance with mutually agreed terms[29] of the protocol are new advances beyond the ABS laws of Ethiopia. The Ethiopian ABS law has been revised and the draft document has incorporated most significant and innovative provisions of the Nagoya Protocol. This will harmonize the existing Ethiopian ABS law with the Nagoya Protocol.

In conclusion, the compliance provisions of the Protocol are very important to address long-standing concerns about the difficulty for provider countries alone to prevent, detect or obtain remedy from breaches of their domestic ABS measures related to their genetic resources when they are utilised in another country.

References

Access to Genetic Resources and Community Knowledge and Community Rights Council of Minister Regulation No. 169/2009, Federal Negarit Gazeta Year 15 No. 67, 9 November, 2009, Addis Ababa.

Access to Genetic Resources and Community Knowledge, and Community Rights Proclamation No. 482/2006, Federal Negarit Gazeta Year 13 No. 13, 27 February, 2006, Addis Ababa.

African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Genetic Resources adopted by OAU in Algiers, Algeria on 2000.

Ethiopian Biodiversity Institute Establishment Council of Ministers Regulation, No 291/2013, Federal Negarit Gazette No. 57, 24 July, 2013, Addis Ababa.

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization Ratification Proclamation No.753/2012, Federal Negarit Gazeta, 27th day of July, 2012, Addis Ababa.

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, adopted by COP-10, in Nagoya, Japan on October 29, 2010.

[26] Nagoya Protocol Article 11.

[27] Nagoya Protocol Article 15 and 16.

[28] Nagoya Protocol Article 17.

[29] Nagoya Protocol Article 18.

Chapter 9
The Kenyan ABS regulations: A static law

Evanson Chege Kamau

1 Introduction

Kenya is party to the CBD and its Nagoya Protocol by ratification in 1994 and 2014 respectively. The CBD was implemented in Kenya through the Environmental Management and Coordination Act (EMCA) of 1999. The relevant obligations on conservation and access to genetic resources (GR) and benefit-sharing (BS) were specified in "The Environmental Management and Co-Ordination (Conservation of Biological Diversity and Resources, and Access to Genetic Resources and Benefits Sharing) Regulations, 2006" (hereinafter Regulations). This is a pre-NP legislation which has not been amended since its enactment. It does not explicitly state its objective(s) but that can be derived from the title. Access and benefit sharing is regulated under Part III (r. 9-24).

2 Scope of ABS regime

2.1 Geographical scope

The regime applies to the territorial jurisdiction of Kenya, including marine areas, exclusive economic zone and the continental shelf.

2.2 Material scope

The legislation applies to genetic resources (Part III).[1] It does not mention associated traditional knowledge (ATK) or even indigenous communities. It only stipulates in s. 9 that an applicant for an access permit (for genetic resources) must include in the application the evidence of the prior informed consent (PIC) of interested persons and relevant lead agencies. The term 'interested persons' is not defined. In the annex, however, under Part III of the first schedule (form of an application for access permit) on things to be included in the application for an access permit by all applicants it lists the PIC of the relevant lead agencies, local community or private owner of the genetic resources (First Schedule, 2.0 (g). Thus, it can be concluded that these three entities are the ones referred to in r. 9 (2) as 'interested persons', albeit only in connection to GR. Therefore, it is only from practice we know that ATK is regulated under the ABS regime, not from the Regulations.

2.3 Scope of utilisation

The legislation only uses the term 'utilisation' in connection to benefit-sharing but does not define it or state what it consists. However, the definition of the term 'access' gives a clue as to which uses trigger the ABS measures. According to r. 2 "access means obtaining, possessing and using genetic resources conserved, whether derived products and, where applicable, intangible components, for purposes of research, bioprospecting, conservation, industrial application or commercial use."

2.4 Exemptions (r. 3 (a) – (d))

The regime does not apply to:

[1] The definitions of the terms 'access', 'access permit', 'benefit-sharing' and 'material transfer agreement' likewise relate solely to genetic resources (r. 2).

- Exchange of genetic resources, their derivative products, or intangible components associated with them, carried out by members of any local Kenyan community amongst themselves and for their own consumption;
- Access to genetic resources derived from plant breeders in accordance with Seeds and Plant Varieties Act Cap 326;
- Human genetic resources; and
- Approved research activities intended for educational purposes within recognised Kenyan academic and research institutions governed by relevant intellectual property laws.

These exemptions are not applicable if the biological material is to be taken as well as used abroad.

3 Competent authorities

The National Environmental Management Authority (NEMA) is the competent national authority (CNA). According to the regulations, any person who intends to access GR in Kenya must apply for an access permit from NEMA (r. 9 (1)). However, in practice, review of applications is done corporately with a number of stakeholder institutions (relevant lead agencies) as an antidote to the procedural challenges which existed as a result of fragmented mandates. These are normally entities upon which the law vests functions of control or management of any element of the environment or natural resources[2] and whose PIC might be required before the access permit can be applied for. NEMA together with members drawn from these stakeholder institutions form a committee referred to as ABSpc (access and benefit-sharing permit committee). We shall be mentioning them in the next section.

4 Requirements and procedure for access to in situ and ex situ genetic material

These are regulated under rr. 9-14.

4.1 Application for access permit

The application to NEMA for an access permit must contain the following:

- Completed form set out in the Second Schedule of the Regulations;
- Research clearance from the National Commission for Science, Technology and Innovation (NACOSTI), formerly known as the National Council for Science and Technology (NCST);
- Fee set out in the Third Schedule of the Regulations;
- PIC for genetic resources from public territories granted by the relevant lead agency,[3] which, depending on where access is taking place, could be one or several of the following agencies:
- Kenya Wildlife Service (KWS) for wildlife genetic resources and genetic resources in

[2] See footnote 3.

[3] "… any Government ministry, department, parastatal, state corporation or local authority, in which any law vests functions of control or management of any element of the environment or natural resources" (sect. 2 Environmental Management and Coordination Act).

protected areas. Where possible the permit is granted jointly with recognised local community associations;

- Kenya Wildlife Service (KWS) for genetic resources in forests under its jurisdiction; or
- National Museums of Kenya (NMK) for genetic resources in collections.

4.2 Review of application and grant of the access permit

NEMA has 60 days from the time the application is received to determine the application and communicate its decision to the applicant in writing. Upon receiving the application, NEMA:

- Gives notice in the Gazette and in at least one newspaper with nationwide circulation for purposes of getting comments from any interested persons within a period of 21 days;
- After 21 days NEMA arranges an ABS Permit Committee evaluation meeting to review the application;
- Once the committee is satisfied that the activity will facilitate sustainable management and utilisation of genetic resources, it approves the application and NEMA issues the permit;
- If there are reasonable grounds to deny, the permit is denied.[4]

The permit is valid for both non-commercial and commercial research for a duration of one year and may be renewed for a further period of one year upon payment of the prescribed fee.

4.3 Terms and conditions of an access permit

The following conditions are implied in every access permit (r. 15 (2) (a)-(h)):

- Duplicates and holotypes of all genetic resources collected shall be deposited with relevant lead agency;
- Records of all intangible components of genetic material collected shall be deposited with NEMA;
- Reasonable access to all genetic resources collected shall be guaranteed to all Kenyan citizens whether such genetic resources and intangible components are held locally or abroad;
- All agreements entered into with respect to access of genetic resources shall be strictly for the purposes for which they are entered into;
- Quarterly reports shall be furnished to NEMA on the status of research, including all discoveries from research involving genetic resources and/or intangible components thereof;
- The holder of an access permit shall inform NEMA of all discoveries made during the exercise of the right of access granted under the access permit;
- The holder of an access permit shall abide by the laws of Kenya; and

[4] The permit is denied if the applicant has not complied with the provisions of the law, and in the absence of PIC from the competent lead agency/agencies, or any other relevant stakeholder e.g. an indigenous community.

- The holder of the access permit shall provide the following reports:
- A semi-annual status report on the environmental impacts of any ongoing collection of genetic resources or intangible components thereof; and
- A final report on the environmental impacts of collection of genetic resources or intangible components thereof, in the event that the collection lasts for duration of three months or less.

NEMA is given power to impose other terms and conditions as it may deem necessary (r. 15 (1)) or, on its own volition or on the application by an access permit holder, vary the conditions of an access permit (r. 3). NEMA may also suspend, cancel, etc. an access permit (r. 16) if its holder contravenes any of the conditions imposed on the access permit or those implied under these Regulations, or if its holder contravenes any of the agreements concluded pursuant to its grant.

4.4 Other permits

- CITES permit for endangered species;
- Export permit from KWS;
- Phytosanitary permit before export from Kenya Plant Health Inspectorate Service (KEPHIS).

4.5 Participation of other public or private entities

As mentioned above (under “Application for an access permit”), indigenous or local communities participate by jointly giving their PIC if access shall take place in territories managed together with KWS. In addition, evidence of their PIC will be needed if access to genetic resources shall take place in native territories or if ATK shall be accessed. In the same vein, private land owners participate by giving their PIC either for entry into the land or for access to genetic resources.

5 Benefit sharing

Benefit sharing is regulated under r. 20. The law foresees that access shall be reciprocated through sharing of benefits arising from utilisation. It states that all research activities have to be beneficial to the country, consider elements of IP and traditional knowledge as well as participation of the locals and institutions in the execution of the activities under the permit. It enumerates types of non-commercial and commercial benefits to be considered under r. 20 (3) and (4). The list is adopted from the Bonn Guidelines / Nagoya Protocol.

6 Model agreements, guidelines

Kenya operates a model MTA (referred to as “sample” MTA), but does not have a model BSA. There is no executed BSA available. In addition, there are guidelines for users in the form of an ABS Tool-Kit published in 2014 by NEMA, which also have the model/sample MTA annexed to it as appendix III.

7 Other issues

Violation of the law can result to civil or criminal sanctions.[5] Depending on the nature of the offence and its gravity, violation can be penalised by imprisonment for a term not exceeding eighteen months, or a fine not exceeding Kshs 350,000 (approximately USD 3379 / € 3052 as at 29 August 2019), or both (sect 24).

8 Assessment of the pre- and post-NP situation and conclusions

The pre- and post-NP de jure situation in Kenya has not changed. The requirements and procedures of existing laws have been described above. Ways of improving the regime can be read in Kamau/Winter 2009 (London: Earthscan). Theoretically, the regime still suffers from unclarity and uncertainty caused by overlapping mandates of the state agencies having jurisdiction to regulate ABS and complex procedures. The good news for users is that the de facto functioning of the regime at the moment is more conducive as a number of practical measures have been initiated by the relevant agencies to combat weaknesses that ensue from the legal architecture. That includes the establishment of an ad hoc ABS permitting committee (ABSpc) consisting of different stakeholders which has helped cut the application duration tremendously, and the publication of an ABS tool-kit. The weakness of the ABSpc approach lies in the fact that it is not supported by law and thus creates a new ground for legal uncertainty. These and other weaknesses are being proactively confronted currently and there is even hope of creation of a one-stop shop.

[5] According to the law a violation or offence occurs when a person contravenes or fails to comply with any of the matters provided in the Regulations (sect. 23).

Chapter 10
Brazil: New ABS legislation and practice

Lilian Massini Mozini

1 Introduction

The Convention on Biological Diversity (CBD) was ratified in 1994 by Legislative Decree # 2/94, issued by the National Congress, and incorporated into the Brazilian legal system by Federal Decree # 2,519/1998. On the other hand, the country signed the Nagoya Protocol in 2011. Although it was sent for approval by the National Congress in 2012, it has not yet been endorsed.

In June 2000, the executive branch of the federal government issued a Provisional Measure on access to both Brazilian genetic resources and traditional knowledge associated with biodiversity as well as benefit sharing arising from the commercialisation of products deriving from such access. The main objectives of this Provisional Measure were to regulate rights and obligations relating to: access to the genetic resources or the traditional knowledge of the national territory, the continental shelf and the exclusive economic zone for the purpose of scientific research, technological development or bioprospecting; and fair and equitable sharing of the benefits derived from the economic exploitation of genetic resources and associated traditional knowledge.

As this legislation was very bureaucratic and did not achieve its initial objectives of protecting genetic resources and fair distribution of benefits, it was necessary to have a modern and legitimate legislation approved by the National Congress to replace the Provisional Act. So, Federal Law # 13,123/2015, known as the Biodiversity Act, entered into force on November 17, 2015 and repealed Provisional Act.

2 Scope of ABS regime

2.1 Geographical scope

The Federal Law # 13,123/2015 and implementing Decree # 8,772/2016 provide for rights and obligations related to: (i) access to genetic resources and associated traditional knowledge; (ii) the shipping of samples for the purpose of access to genetic resources abroad; (iii) the economic exploitation of finished products resulting from access; and (iv) the sharing of benefits.[1]

Brazilian law covers the entire national territory and must be complied with by users[2] accessing genetic resource and/or associated traditional knowledge. Legislation also allows access activities to be carried out by a foreign institution only if the foreign institution is associated to a national one. Access to genetic resource or associated traditional knowledge by a foreign natural person is prohibited (the researcher may only perform access activities if he is linked to a research institution).

[1] Article 1.

[2] "Individual or legal entity who makes access to genetic resource or associated traditional knowledge or economically exploits finished product or reproductive material arising from access to genetic resource or associated traditional knowledge" -Article 2, item XV of Law 13,123/2015.

2.2 Material scope

The Federal Law covers access to genetic resources or traditional knowledge associated to plant, animal, microbial or other species making up the country's genetic resource. The law will be applicable if the species are considered native to Brazil, i.e. if they have a centre of origin and dispersion in Brazil, or if the non-native species has been introduced in Brazil and it has over time acquired characteristics that are distinctive to the national territory. In the case of microorganisms, genetic resources existing in the national territory shall be considered as having been isolated from substrata of the national territory, the territorial sea, the exclusive economic zone or the continental shelf.[3]

The Ministry of Agriculture, Livestock and Food Supply has edited lists[4] of animal species, plant species, aquatic animals and plant pest animals that are considered as exotic species introduced into the national territory. These species are exempt from compliance with the Law because they are not considered as native or domesticated. However, such lists are not comprehensive, and the user should always conduct research to check if the species to be accessed is national genetic resource.

2.3 Scope of utilization/use

Brazilian law focuses on access to genetic resource and associated traditional knowledge for the purposes of scientific research and/or technological development, which means that both applied research and the development of derivatives such as intermediate products (raw materials for the cosmetics, pharmaceutical industries, etc.) or finished products (cosmetics, medicines, sanitizing products).

2.4 Exemptions

Law does not apply to access to human genetic resources.[5] Access to genetic resources and associated traditional knowledge for environmental, cultural reproduction and practices that are harmful to human health and for the development of biological and chemical weapons is prohibited.[6]

Some activities, when not integral part of research or technological development, do not constitute access to genetic resource, such as:[7] extraction by grinding method, pressing or bleeding resulting in fixed oils; purification of fixed oils resulting in a product whose characteristics are identical to those of the original raw material; comparison and extraction of genetic information available in national and international databases, comparison and extraction of genetic information available in national and international databases, etc.

3 National authorities

The Genetic Resource/Heritage Management Council (known as Conselho de Gestão do Patrimonio Genético (CGEN), in Portuguese) is the competent national authority at the fed-

---

[3] Article 1st, § 1st, Decree # 8.772/2016.

[4] Normative Instruction # 23/2017 (updated by NI # 3/2019) and Normative Instruction # 19/2018 (updated by NI # 16/2019).

[5] Article 4.

[6] Article 5.

[7] Decree # 8,772/2016, Article 107 and CGEN Technical Guidance # 09/2018 bring all activities which are not considered access to genetic resource, when they are not an integral part of research and technological development.

eral level. It is a collegiate body linked to the Ministry of the Environment, of deliberative, normative, advisory and appeal nature, responsible for coordinating the elaboration and implementation of policies for the management of access to genetic resource and associated traditional knowledge and benefit-sharing. It is formed by representation of federal public service bodies and entities having competence over the several actions dealt with in the Law with a maximum participation of 60 per cent and civil society representation of at least 40 per cent parity between the business, academic and indigenous peoples, traditional communities and traditional farmers ensured.[8]

CGEN is composed of the Plenary, which meets periodically; Thematic and Sectorial Chambers, which may be created aiming to discuss specific issues related to system users that are subsequently referred to the Plenary for deliberation; and the Executive Secretariat, which is responsible, among other topics, for the management of SisGen (National System for the Management of Genetic Resource and Associated Traditional Knowledge).

CGEN is responsible for: (i) establishing technical standards on compliance with the law; (ii) creating guidelines for compliance and elaboration of the benefit-sharing agreement; (iii) monitoring access activities to genetic resource and associated traditional knowledge; (iv) deliberating on accreditation of national institutions maintaining ex situ collections; (v) being the highest court in case of infringement appeals, etc.[9]

4 Requirements and conditions for access to in situ and ex situ genetic resources

4.1 Access permission

Access activities to genetic resource or traditional knowledge must be registered together with SisGen. Registration must be made by a natural or legal person based in Brazil. Access activities performed by a foreign institution based abroad must be registered by a Brazilian partner institution.

Registration must always occur before (i) shipping of genetic resource samples abroad for access purposes, (ii) applying for any intellectual property right, (iii) marketing of an intermediate product (e.g. extracts, butters or fragrances), (iv) publication of results, whether final or partial, in scientific or communication media, and (v) notification of a finished product developed as a result of access.[10]

In case of access to the associated traditional knowledge of identifiable origin, that is, when it is possible to identify the holder of such knowledge, the user must sign the prior informed consent before accessing.

Prior to commencing economic exploitation of the product arising from access to genetic resource or associated traditional knowledge, the user must notify the product in SisGen.

4.2 Content of the access permission

Registration is a statement instrument made at SisGen. The user of the genetic resource and/or associated traditional knowledge should make the registration stating:

---

[8] Article 6.

[9] The jurisdiction and composition of CGEN are described in Article 6, paragraph 1st of Law # 13,123/15 and Chapter II of Decree # 8,772/2016.

[10] See article 12, § 2nd, Law 13,123/2015.

- activities on technological research or development, including: activity abstract and objectives; application sector (if technological development); expected or obtained results; responsible in charge, including partner institutions, if any; period of activities; scientific name of the species accessed; origin of the samples (acquired under in situ, ex situ, in silico conditions, trade or intermediate product – raw material); information about partner institutions in Brazil or abroad, if any.
- Previous access registration number, which allows a traceability system of activities;
- Prior Informed Consent, in cases of access to associated traditional knowledge;
- Requisitioning of confidentiality;
- Statement of adequacy in the event of legal exemption or non-benefit sharing.[11]

After registration, the research institutions are able to file their patent applications, publish and disclose results resulting from access, send samples abroad or market intermediate products.

If institutions intend to market finished products, such as medicines, cosmetics, sanitizing products, etc., they must also notify their products prior to marketing. For this purpose, they must submit:

- commercial identification of the product and the application sector;
- information on whether the genetic resource or associated traditional knowledge is decisive for the formation of marketing appeal or is determinant for the existence of the functional characteristics of the product;
- scope of marketing;
- product registration number with the competent bodies;
- expected date for the beginning of marketing;
- indication of the mode of benefit sharing;
- access registration number which gave rise to the product;
- submission of the benefit-sharing agreement, when appropriate.[12]

4.3 Permission conditions – especially most critical/important ones

4.3.1 Claim of IPRs

The law stipulates that the registration of access activities to genetic resource or associated traditional knowledge must be made prior to the application of any intellectual property rights. In this sense, the Brazilian body responsible for the protection of industrial property – National Institute of Industrial Property requires users to state the number of access registrations made in SisGen to make their patent applications.

[11] Decree # 8,772/2016, Article 22

[12] Decree # 8,772/2016, Article 34.

4.3.2 Publication of results

The law determines the registration of access in the SisGen before the publication of results, whether final or partial, in scientific or communication media. After the registration, the researcher is allowed to publish the results.

4.4 Other permissions

Activities of access to genetic resource or associated traditional knowledge in a field indispensable to national security must be previously authorized by the National Defence Council. If access occurs in Brazilian jurisdictional waters, on the continental shelf and in the exclusive economic zone, the access authorisation will be issued by the maritime authority.

The registration of these activities must be prior to the beginning of the research and development activities, and SisGen itself has a mechanism for the competent areas to agree with the access.

5 Model transfer agreements, guidelines

For submission of samples abroad, CGEN approved a model of transfer agreement (MTA) of samples, through Resolution # 12/2018. National institutions intending to ship samples of genetic resource should sign the MTA with the recipient institutions. MTA clauses are mandatory but clauses of specific interest to the parties may be included by means of an appendix.

The national sender institution and the foreign recipient institution may sign one or more MTAs with a validity of maximum 10 years but can be renewed. In addition, for each of the shipments linked to that term, the sender institution must provide a prior shipping registration on SisGen, including a Shipping Note – which is attached to the MTA. Identification and origin of the genetic resource sample, information on sample type and form of packaging, number of containers, volume or weight, objective, intended uses and project application sector should be informed.

MTA, delivery note, and shipping registration receipt must follow the samples for regular operation.

6 Benefit-sharing

6.1 Types of benefits

Pursuant to Article 17 of Federal Law 13,123/2015, benefits resulting from the economic exploitation of finished products or reproductive material deriving from access to genetic resources and/or associated traditional knowledge shall be shared exclusively by the manufacturer of the finished product or reproductive material if the genetic resource or associated traditional knowledge component of the product is one of the main elements of value aggregation, even if the product was manufactured in foreign countries.

Under Article 20, monetary benefit sharing shall be equivalent to 1 per cent of the net revenue obtained from the economic exploitation of the finished product. The benefits shared must be deposited in the National Benefit-sharing Fund, which is bounded to the Ministry of Environment. The Fund has not been established yet, but it is expected to benefit traditional and indigenous communities with investments in social and environmental projects.

If a company chooses to share non-monetary benefits the amount to be paid shall be equivalent to 0.75 per cent of net revenue resulting from commercialisation (Article 22). The mutually agreed terms (MAT) must establish a benefit-sharing project and the beneficiaries

(as, for example: a conservation area, indigenous or traditional communities or small farmers).

Non-monetary benefit-sharing projects may include:[13] projects for the conservation or sustainable use of biodiversity or for the protection and maintenance of knowledge, innovations or practices of indigenous peoples, traditional communities or traditional farmers; human resources training on topics related to conservation and sustainable use of genetic resource or associated traditional knowledge; free distribution of products in social interest programmes; etc., at the user's discretion.

Regarding associated traditional knowledge, if its origin is identifiable, the provider is entitled to receive benefits under a MAT. It is also necessary to obtain a prior informed consent before beginning the access activities. Thus, the company can freely negotiate with the provider (traditional community, traditional farmer, indigenous population) the distribution of benefits. It is also necessary to allocate half of the benefits (i.e. 0.5 per cent of net revenue) to the National Fund in order to ensure the remuneration of the other communities having the same traditional knowledge (Article 24).

6.2 Conditions and content of a benefit-sharing agreement

The benefit-sharing agreement will be required when there is an economic exploitation of finished products (e.g. cosmetics, medicines) arising from access to genetic resource or associated traditional knowledge.

In case of access to genetic resource, the MAT must be signed by the federal government, represented by the Ministry of the Environment, and the institution that exploits the finished product economically. This agreement is to be submitted within one year as of notification of the product. The user is not required to submit MAT when deciding for monetary benefit-sharing, i.e. payment to the National Benefit-sharing Fund.

In case of economic exploitation of the product arising from access to the associated traditional knowledge, MAT shall be signed between the institution marketing the product and the provider of traditional knowledge from identifiable origin.

The essential clauses of MAT are: the products which are the object of economic exploitation, term of duration, type of benefit-sharing, rights and liability of the parties, intellectual property rights, termination, penalties and jurisdiction in Brazil.[14]

There is legal provision for the Executive Authority to regulate the way of benefit sharing in the non-monetary modality. Therefore, it is expected there is a Ministry of Environment standard with an MTA model, however this standard has not been edited so far.

7 Participation of other public and private entities

Law protects traditional knowledge associated with the genetic resource of indigenous peoples, traditional communities or traditional farmers against illicit use and exploitation. The state recognises the right of indigenous peoples, traditional communities and traditional farmers to participate in national decision-making on subject matters related to conservation

[13] Law # 13,123/15 provides other ways of non-monetary benefit sharing, such as: technology transfer, product availability in the public domain, without protection by intellectual property rights or technological restrictions, and licensing of products free of charge. However, the execution of these projects presupposes the payment of 1% of net revenue from the sale of the finished product. In other cases, the benefit sharing will be 0.75% of net sales revenue from marketing of finished product.

[14] Law # 13,123/2015, Article 26.

and sustainable use of their traditional knowledge associated with the country's genetic resource.

In addition, indigenous peoples, traditional communities and traditional farmers, the academic and business sectors have 40 per cent representation of members in the CGEN Membership. Currently, Decree # 8,772/16 designates 3 counsellors as representatives of traditional peoples and populations; 3 from academic sector and 3 from business sector.[15]

8 Assessment of the pre- and post-NP situation and conclusions

Brazil is not a member of the Nagoya Protocol, although it has adopted federal standards since 2000 in order to promote the protection of genetic resources, associated traditional knowledge and benefit-sharing. We still have no expectation for approval of the protocol in the country. Current legislation has included foreign institutions to develop a benefit-sharing mechanism for products even if produced abroad. In this sense, we can see a tendency of the standard to internationalise its rules. The Ministry of Environment also considers developing a new version of SisGen for access by foreign institutions, aiming at the notification of foreign products and the international benefit-sharing.

In addition, Federal Law # 13,123/2015 aimed to simplify administrative procedures by establishing an electronic registration system, with the duty of previous registration being imposed only in relation to shipping of genetic resource samples, development of intermediate products (raw materials for industry), marketing of finished products, or application for intellectual property. This has been followed by a remarkable adhesion of independent researchers and research institutions, since these account for 88 per cent of the registrations made until August 2019.

Businesses which have the greatest potential to share the benefits resulting from access to Brazilian biodiversity still account for the lowest percentage of adherence to the system. Nevertheless, about 71 per cent of the products notified with SisGen until August 2019 are subject to benefit-sharing, which shall allow for the maintenance of associated traditional knowledge and the conservation and use of the Brazilian biodiversity.

[15] Decree # 8,772/16, Article 7.

Chapter 11
ABS regime in Argentina

Luciana Carla Silvestri

1 Legislation and scope

Argentina is a party to the Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP) since February 20, 1995 and March 9, 2017, respectively. The National Constitution establishes that the federal government, through the National Congress, is competent to enact minimum legal environmental standards that bound all provinces across the country. So far, the federal government has not adopted any access and benefit-sharing (ABS) law that includes minimum standards on the issue.

Instead, at the national level three administrative measures regulate ABS matters. The first one is Administrative Decision No. 226 of 2010, adopted by the Argentinian Secretariat of Environment and Sustainable Development (SE&SD). It regulates the access to genetic resources when they are to be later exported or imported. The second one is Administrative Decision No. 208 of 2011, adopted by the Federal Council of the Environment (COFEMA). Its mandate only requires scientists to obtain an authorization of competent authorities in order to access genetic resources. It does not further elaborate any details of the procedure, permits, etc. The third piece of legislation is Decision No. 81 of 2016 adopted by the National Parks authority. The Decision covers any kind of scientific research conducted in national parks, including the access to genetic resources. The three regulations only cover genetic resources as regulated by article 2 of the CBD. Only genetic resources found in Argentina fall within the scope of the legal framework. In addition, none of the regulations provide a definition of genetic resources, users, access, utilization or commercial and/or non-commercial research. According to Decision No. 226 of 2010 cultivars are exempted from its application.

Access to traditional knowledge associated to the utilisation of genetic resources has not been regulated at the national level.

Provinces in Argentina are also competent to regulate ABS issues. According to the National Constitution, provincial environmental regulations can be more stringent than the national law, in case the latter exits, but not more flexible. At the provincial level 10 out of 23 provinces have adopted ABS related legislation (Table 1). These regulations greatly differ from one another due to the absence of a national law setting minimum standards on ABS that could be used as guidance by the different provinces.

Table 11.1: Provinces with ABS-related legislation

Province	ABS regulation
Misiones	Executive Decree No. 474 of 2002 regulating Provincial Law No. 3337 on conservation and sustainable use of biological diversity and its components
Neuquén	Provincial Law No. 2503 of 2005 on access to genetic and biochemical resources
Santa Cruz	Provincial Law No. 2993 of 2007 on access to genetic and biochemical resources
Tierra del Fuego	Administrative Decision No. 570 of 2012 of the Secretariat of Environment and Sustainable Development establishing the legal regime for conducting research that entails access to genetic material
Catamarca	Administrative Decision No. 90 of 2012 of the Secretariat of Environment and Sustainable Development establishing the legal regime for conducting research that directly or indirectly involves natural and/or genetic resources
Jujuy	Administrative Decision No. 15 of 2013 of the Environment Secretariat establishing the regime for the access to provincial biodiversity
Province	**ABS regulation**
San Luis	Provincial Law No. 9-0851 of 2013 on access and registry of genetic and biochemical resources pertaining to provincial biodiversity and Executive Decree No. 8804 of 2015 that further regulates the before mentioned provincial law
Entre Ríos	Administrative Decision No. 1721 of 2014 of the General Directorate of Natural Resources establishing the regulation on access to genetic resources and its derivatives
Formosa	Administrative Decision No. 40 of 2015 of the Ministry of Production and Environment regulating the requirements for access to biological resources and its derivatives
Buenos Aires	Administrative Decision No. 19 of 2019 of the Ministry of Agroindustry regulating access to genetic resources

2 Authorities, access procedures and permits

According to the National Constitution, Provinces own natural resources found in their jurisdictions. These include genetic resources. Consequently, prior informed consent (PIC) and mutually agreed terms (MAT) must be requested and established, respectively, with the relevant province. Only when resources are located in a national park, the national parks Administration is competent for granting PIC and establishing MAT.

Provincial procedures for access to genetic resources have been regulated to a different extent in the various provinces that do count on ABS legislation. Neuquén and Santa Cruz for example, have no provisions on procedures for access to genetic resources despite the fact that their ABS laws date back to 2005 and 2007, respectively. In contrast, Jujuy, Formosa, Entre Ríos, Tierra del Fuego and San Luis, have regulated in a detailed manner the procedure and the requirements needed to access genetic resources found in their jurisdictions. None of the 10 provinces that have adopted ABS legislation has set a facilitated procedure to access genetic resources for purely scientific research purposes.

Some legal conditions applicable to access permits foreseen by provincial legislations include the following: a) permits cannot be transferred; b) obligation to deposit a sample of the collected biological material in a collection belonging to the province where the sample was obtained; c) obligation to submit to the province in question a report on activities undertaken, including research and developments; d) obligation to acknowledge, in any scientific publication, the geographical origin of the genetic resources and e) obligation to jointly apply with an Argentine scientific institution in case access to genetic resources is required by foreign applicants.

At the national level the competent authority for ABS issues is the SE&SD. The Secretary is only responsible for access procedures when genetic resources are to be later exported or imported. The SE&SD checks that PIC has been granted by the relevant authority (a prov-

ince or the national parks Administration) and that MAT have been established with it. If all legal requirements are satisfied, the SE&SD issues an export permit. At the national level, there is no facilitated administrative procedure for access to genetic resources for non-commercial purposes either.

3 Benefit-sharing

Even though MAT are to be established between the user of genetic resources and the province or national park that grants access to them, in practice, when genetic resources are utilised for purely scientific research purposes, MAT are established with the providing scientific institution. Likewise, if resources are obtained from an ex situ collection, the agreement is concluded with it. In both cases, the province or the national parks still has to grant its PIC.

If resources are obtained from in situ conditions, MAT has to be established with the corresponding province or national park. Some provinces, such as Neuquén, Jujuy, San Luis, Formosa, Santa Cruz, Entre Ríos, Misiones and Tierra del Fuego thoroughly regulate the fair and equitable distribution of benefits obtained from the utilisation of genetic resources. The rest of them do not. Amongst the benefits to be distributed are upfront payments, percentages of royalties, scientific research collaboration, joint technological development, etc.

4 Draft regulation on ABS

The SE&SD has prepared a legislative draft proposal on biodiversity which includes a chapter on ABS matters. The objectives of this endeavour are to satisfy legal provisions set under the NP and help solve uncertainties created due to the absence of a national law setting minimum common standards for ABS issues. The draft has been prepared in the framework of a Global Environment Facility (GEF) / United Nations Development Program (UNDP) project and it is expected to be discussed in 2020 at the National Congress.

5 Assessment of the pre and post Nagoya Protocol situation and conclusions

Argentina has not taken any measures yet to satisfy the obligations set under the NP. The main piece of regulation, namely Administrative Decision No. 226 of 2010, was enacted before the Protocol was adopted. This Decision is in a rudimentary state of development; it was not preceded by a strategic planning process and does not provide minimum ABS standards that could guide provinces in the development of their own ABS regulations. In turn, at the provincial level, the overwhelming proliferation and disparity of regulations seems to be the most urgent issue to be addressed.

On the other hand, the current ABS draft law prepared under a GEF/UNDP project does not appear to sufficiently resolve any of the aforementioned problems. The draft is superficial in its development of the regulation and lacks sufficient technical and scientific rigour to support its provisions. If it were to be submitted to Congress as it stands, it will hardly solve any of the problems it is intended to solve. It will not satisfy on the other hand, the obligations anticipated by the NP.

Chapter 12
Costa Rican ABS legislation and practice

Jorge Cabrera Medaglia

1 Biodiversity importance

Costa Rica holds a significant proportion of the world's known species (4.7 per cent) in a relatively small territory due to its strategic geographic position (constituting a bridge between North and South America), its tropical location and variable topography which contributes to its microclimates. Hence, the country can be regarded as a complex mosaic of terrestrial and marine habitats, each one holding a particular combination of species. However, the distinctiveness of the country does not lie in the total number of described species recorded but in their density, meaning the number of species per unit area. These elements help explain the unique high density of known species found in Costa Rica, which no other country in the region exhibits. Costa Ricans have undertaken several initiatives to conserve and use its biodiversity in a sustainable manner. Today, after successfully reversing a national deforestation trend and creating a number of wildlife protected areas, approximately 52 per cent of Costa Rica's land area is covered with forests and slightly more than one third of its land area is protected through diverse categories of wildlife protected areas. As a result, Costa Ricans have a heightened awareness about the value and contribution of biodiversity to development. It is considered among the 20 megadiverse countries in the world and has a well-known reputation for its efforts to conserve and use its biodiversity in a sustainable manner. The country has created more than 170 protected areas encompassing around a 26 per cent of the terrestrial territory in different management categories.

2 Institutional and legal context

Costa Rica has a longstanding and comprehensive environmental legal framework. The Convention on Biological Diversity (CBD) became effective in Costa Rica in 1994, giving rise to the need to draft a national law that would implement this international agreement in a clear, simple and precise manner. The Biodiversity Law No. 7788 of April 30, 1998 (BL) was published in the Official Gazette No. 101 of May 27, 1998. Presently, there is also a 'General Access Procedure' (GAP) that functions as a by-law of the BL. Also the regulations for access to genetic resources found in ex situ conditions were approved by Decree No. 33677-MINAE of 27 April 2007. These two decrees were recently amended by Decree No 41591-MINAE of May 2019. The decree 39341-MINAE establishing the procedures for the imposition of sanctions for illegal access was approved in 2016. A Memorandum of Understanding (MoU) was signed between the International Treaty on Plant Genetic Resources for Food and Agriculture (IT) Focal Point, the National Commission on Plant Genetic Resources and the National Commission for Biodiversity Management (CONAGEBIO in 2014 clarifying the implementation of the ABS regime under the BL and the CBD and the International Treaty. The MOU addresses grey areas and achieves a common understanding on key issues relating to the implementation of the ABS Multilateral System of the IT and the Biodiversity Law and decrees. Finally, the Nagoya Protocol was signed but has not been ratified yet.

3 Scope and exceptions

The general goal of the BL is to promote the conservation and sustainable use of biodiversity and to ensure the fair and equitable sharing of benefits derived from it (article 1). The entire BL responds to this goal as put forth by the CBD. Likewise, all research or bio-

prospecting programmes on the genetic or biochemical material of biodiversity that are to be carried out in Costa Rican territory require an access permit, unless they fall into one of the exceptions provided by the Law. These exceptions include: access to human genetic resources; the non-profit exchange of genetic and biochemical resources and the associated traditional knowledge of indigenous peoples and local communities; and research by Costa Rican public universities, which had one year (until 7 May 1999) to establish their own controls and regulations for research that implies non-profit access to biodiversity.

The access regulations apply to genetic resources in public or private lands, terrestrial or marine environments, under ex situ or in situ conditions, and in indigenous territories (Article 2 on Scope). The decree No 41591-MINAE of 2019 modifies the article related to the scope and includes expressly the reference to the 'utilization' of the elements of biodiversity providing more clarity on the scope of the activities to be covered requiring research and development activities. The term 'utilization' is also defined in the revised regulations and has the same meaning found in the NP article 2. If none of these exceptions apply, all sectors (pharmaceutical, agriculture, plant protection, biotechnology, ornamental, herbal etc.) that wish to access genetic components are subject to the law and must follow its access procedures.

In accordance to these amendment routines, techniques and teaching activities not resulting in publications are also excluded from the obligation to request an access permit.

4 Competent national authorities (CNA) and national focal point (NFP)

The Biodiversity Law created the National Commission for the Management of Biodiversity (CONAGEBIO) as the Competent National Authority in Costa Rica, to propose policies regarding access to genetic and biochemical elements of biodiversity and related traditional knowledge that ensure proper scientific and technology transfer and the fair and equitable sharing of benefits arising from access. The Commission reports to the Ministry of the Environment and Energy and it is the National Focal Point on ABS under the CBD. It acts through a Technical Office (TO) as the entity that processes, approves or rejects and monitors access-related activities.

Since 2004-2019, the TO has granted access to genetic resources through more than 638 permits and several ABS agreements have been negotiated between private companies, universities, farmers, national and international research centers. Out of the total permits granted, 551 correspond to basic research, 85 to bioprospecting (commercial intention) and 2 to commercial use (the first one granted in 2016 to the international company Chanel and the second in 2019 to a national enterprise involved in natural product development, Lisan Natura).

The Biodiversity Commission of the University of Costa Rica in practice is another CNA for the projects carried out by the researchers or students of the University. The Commission approved approximately 40 projects every year mostly for basic and applied research and few for bioprospecting.

5 Commercial and non-commercial and other special considerations

There are different categories for commercial (bioprospecting and commercial use) and basic research. However, there are very few different requirements between bioprospecting and basic research permits and the procedures and conditions are essentially the same.

If there is a change of intent (from basic research to bioprospecting or from bioprospecting to commercial use) a new permit (and a PIC contract with the provider) must be requested and the conditions of the type of permit must be fulfilled by the applicant.

However, there are no written criteria or milestone to clearly determine where a change of intent has occurred or to distinguish between commercial and basic research. The finalization of framework agreements (article 74 of the BL) are foreseen to facilitate access (some formal requirements are presented only once), but for every single access project a separate permit is necessary (the application and technical guide, the draft project, the main researcher identification and any PIC contract must be submitted).

There are no particular or simplified procedures for access to genetic resources in cases of emergencies (NP article 8 b) or for plant genetic resources for food and agriculture other than those falling under the IT Multilateral System (NP article 8 c).

6 PIC and MAT procedures and templates (model clauses)

There are three types of permits:

1. Basic research: activity to investigate, examine, classify or increase the knowledge about the biological elements or their genetic characteristics without any interest in commercialising its results.
2. Bioprospecting: systematic search, classification and research for commercial purposes of new sources of chemical compounds, genes, proteins and microorganisms and other products with current or potential economic value found in biodiversity.
3. Commercial use: use of genetic or biochemical resources for exploitation or commercialisation purposes, which carries out processes of technological and industrial development.

Under the Costa Rican's law PIC and MAT are both included in a single document named the PIC contract.

PIC procedures and requirements are set in detail in the regulations for the 3 different categories (especially article 9). The decree 41111 simplified some of the documents to be presented (the application and the technical guide) and created more stringent conditions for the commercial use category, including detailed requirements for the economic feasibility study to be prepared.

The providers of genetic resources and associated TK are also clearly identified including the Directors of Conservation Areas; indigenous and local communities authorities; owners of the land; ex situ collections and the fisheries institution (INCOPESCA).

In 2015 online platform to submit applications was launched, including a technical guide, tutorials and other tools for the users.

The decree 31514-2003 provides some recommendations for the content of the PIC contract (where mutually agreed terms are included) and the decree 36174-2007 (access to ex situ collections) provides for a Material Transfer Agreement template and a Code of Conduct for the users.

7 Checkpoints

The Patent Law, Nº 6867, from April 5, 1983, and its amendments, establish as patentable all creations derived from human intellect and which can be applied in industry.

The BL establishes that intellectual property rights shall be congruent with the objectives of the Patent Law by virtue of the principle of integration (Article 79). The Law originally excluded the following: DNA sequences from patent processes; plants and animals; unmodified microorganisms; essential biological processes for plant and animal production; the processes of nature or natural cycles; inventions essentially derived from the knowledge of biological traditional practices or in the public domain; inventions that are produced monopolistically that may affect the processes or basic agricultural products used for food and health purposes (article 78).

However, this article was modified by an amendment of an IPR law which was enacted to comply with the IPR commitments of the Free Trade Agreement with the United States (CAFTA-DR). The amendment indicates that a) DNA and RNA sequences are excluded from patent protection to the extent they do not fulfill the patent requirements; b) microorganisms as they are found in nature are not patentable; c) it was clarified that non biological and microbiological processes can be protected; d) it was added to the exclusion those inventions whose commercial exploitation shall impede the protection of public order, the morality, the health or life of human beings and animals and plants and to prevent serious damages to the environment.

Authorities should consult the TO before granting protection of intellectual or industrial property-related innovations that involve biodiversity elements. The submission of a certificate of origin and prior informed consent is required in order to gain these IP protections. A well-grounded opposition by the TO shall prevent protection from being granted (article 80). The BL provides that beneficiaries enjoying protection of intellectual or industrial property rights are subject to a compulsory license in case of duly justified emergency. In the event of a justified emergency, this license will allow the use of such rights for the benefit of the community. This provision is aimed at solving an emergency, without involving compensation or royalty payment (article 81).

The Biodiversity Law recognizes the existence of the certificate of origin in the case where national genetic resources are accessed and requires the presentation of this certificate before the competent office in order to issue IP rights. Similarly, a consultation is required with the Technical Office of CONAGEBIO in the cases of innovations based on biodiversity elements of Costa Rica. It should be noted that the presentation of the certificate guarantees that the access procedure was followed. This includes the negotiation of prior informed consent, the establishment of mutually agreed terms and the sharing of benefits from the utilisation of genetic and biochemical resources.

However, neither the Plant Variety Protection Law No 8631- nor its regulations- expressly requires the National Seed Office (the competent authority to grant plant breeders rights) to consult with the TO before a plant breeder's rights is issued. Protection exceptions are made for wild plants which are not modified (article 2). Likewise, within the concept of 'notoriously known variety' ('variedad notoriamente conocida' in Spanish) will be included all the varieties that are protected by community sui generis intellectual rights, whether those rights have been registered or not, in accordance with what is established in articles 82 and 84 of the Biodiversity Law No. 7788, to the extent that the variety is adequately described and it is possible to verify its existence (article 4).

To the present date, no patent applications have been identified that have made use of national genetic resources.

The challenges for the duly implementation of the article 80 consultation relates to the fact that the Registry is made up of specialised intellectual property lawyers that are not familiar

with the Biodiversity Law. Another challenge is that this consultation is carried out at the substantive review of the application which delays the completion of the patent processing.

8 Sanctions, monitoring and other relevant developments

In summary the following are the main monitoring mechanisms in place in Costa Rica:

- Periodically reporting as mandated in the access permits (resolutions). The on line system facilitates the monitoring of the permits granted.
- One of the main changes introduced by the decree No. 41591-2019 is the incorporation of a detailed content for the different reports (partial, final and others) to be submitted to the CONAGEBIO and the providers. This approach departs from the prior one when only a general reference to the reporting obligation existed.
- The resolution granting access expressly indicates that the monitoring phase is open. There are no more details about how this monitoring phase will operate.
- The TO has the power to conduct in situ inspections and visits to the facilities of the users and providers.
- The TO does not provide specific guidance to the PIC provider for monitoring. Monitoring in the PIC contract is carried out through reporting.

In 2016 a regulation for the imposition of sanctions established in the BL for illegal access (article 112) was enacted aimed to clarifying the due process of law and other legal matters, including the possibility for an alternative solution (conciliation) of the dispute. This could be understood as some form of regularisation of the illegal access, at least in some cases. So far no cases have been brought and decided for illegal access.

The TO of the CONAGEBIO does regular checks and monitors compliance including through in situ visits, review of publications and similar means.

Finally, an ‘ABS label’ granted to companies in compliance with the ABS regime was made official in 2018 and a natural product company (Lisan Natura) was awarded the first one for a natural product allowing the use of the logo in the packing and marketing. The conditions, criteria and terms of use of the label are not completely clear since the standards were developed recently by the National Standardisation Office of the Country (INTECO).

9 Digital Sequence Information: access permits and contracts

Regarding DSI the position of the Government of Costa Rica indicates: that digital sequence information (DSI) is covered under the definition of access to genetic resources of the BL; but in practice, for non-commercial research, it is not regulated (no PIC and MAT are required). For commercial research, benefit sharing should be established probably through the Global Multilateral Benefit Sharing Mechanism. The legal ground for the differentiation between commercial and non-commercial use is not clear. Until now no access permit has been granted for the commercial use of DSI/genetic information per se not involving access to the physical material (genetic or biochemical compound).

On a case by case basis the TO of the CONAGEBIO has the power/authority to impose restrictions and prohibitions for the further dissemination/deposit in public data bases of genetic information to avoid losing control on the DSI resulting from an authorised access to genetic/biochemical resources by a permit.

However, some cases have been identified which have used this restriction. For instance, in the permit No. R-CM-089.2010-OT of January 9 2010, the following restriction was imposed in the permit granted:

"For the DNA (genetic material) extracted from the requested genetic resources the Technical Office of CONAGEBIO restricts the publication of complete/full genomic information on the national and international data bases, meaning that the entire genomes cannot become public; only the information related to molecular markers. Likewise, before publishing the sequences of DNA of the molecular markers developed or used for the project purposes, the applicant shall inform in advance the TO and later on submit the number of accessions of the sequences". (unofficial translation.)

Finally, it is possible that other restrictions/conditions related to the dissemination/deposit/publication of genomes/gene sequences could have been imposed in the access permit, which exact terms could vary on a case by case basis. There is no information available on these other cases.

10 Conclusion

Costa Rica has taken important legal and institutional steps to implement a fully functional ABS national regime. This experience can be qualified as a learning-by-doing exercise resulting in a number of ABS permits and related developments to facilitate the operation of the system.

The ratification of the NP remains one of the main challenges presented especially considering the advantages offered to a country with a national ABS regime like Costa Rica.

Chapter 13

ABS in Ecuador and Peru: Between the Andean sub-regional regime and the Nagoya Protocol

Maria Victoria Cabrera Ormaza[1]

1 Introduction

Ecuador and Peru are parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol). Both countries are, at the same time, bound by a sub-regional access and benefit-sharing (ABS) regime established within the Community of Andean Nation (CAN) in 1996. The Andean ABS regime is contained in the Decision 391 "Common Regime on Access to Genetic Resources", which was adopted by the Commission of the Cartagena Agreement[2] in 1996. This Decision is based on the understanding that countries are sovereign in the use of genetic resources (GRs), in line with the Convention on Biological Diversity.[3] It prescribes requirements and conditions for accessing GRs, which are aimed at strengthening the authority of the provider country vis-a-vis the user.

In practice, the Andean regime has proven complex and difficult to implement.[4] The ratification of the protocol by Ecuador and Peru has posted challenges to these countries, which are under the obligation to ensure "appropriate access to genetic resources" by, among others, providing for clear, transparent and non-arbitrary ABS rules and procedures.[5] While steps are being taken to achieve this goal, there appear to be critical areas in which the national legislations of these countries continue to reflect the over-regulatory approach embedded in the Andean decision. This contribution explains the current ABS legal framework in Ecuador and Peru, outlining some of these critical areas, in three steps. First, it briefly explains the rationale and the main elements of Decision 391. Second, it describes the existing national ABS legislation of Peru and Ecuador, focusing mainly on the scope of coverage, the definitions of 'genetic resources', 'access', and 'utilisation of GRs'; the difference in the treatment given to commercial and non-commercial research, requirements concerning traditional knowledge and transfer of material, and rules concerning benefit-sharing. This article concludes with an assessment, pointing out the challenges ahead.

2 The Andean ABS regime: Decision 391

The adoption of Decision 391, as a sub-regional instrument on ABS directly applicable in Andean countries,[6] was supposed to help Andean countries to strengthen their political power in international negotiations concerning biodiversity as well as to prevent biopiracy.[7]

---

[1] The author expresses her sincere thanks to the Universidad Espiritu Santo-Ecuador which provided support for the conduction of this research at its early stage and to Deyanira Camacho, Maria Consuelo Velasco, and Lily Rodriguez for their guidance and support in this research. The views expressed in this chapter are the author's own and do not reflect the position of the International Labour Organization or its member states.

[2] At the time of this writing, the countries bound by this regime are Ecuador, Peru, Bolivia and Colombia. Only Colombia has not yet ratified the Nagoya Protocol.

[3] Decision 391, Preamble.

[4] Ruiz Muller M. (2003), 3.

[5] Nagoya Protocol, Art. 6.

[6] Treaty establishing the Tribunal of Justice under the Cartagena Agreement, Art. 2.

[7] Caillaux, J. et al. (1999), 7.

This second aspect was particularly critical at the time of the negotiations of an ABS regime in the CAN, given that the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into effect in 1995, reinforcing the protection of intellectual property rights over scientific inventions.[8]

2.1 Underlying principles and scope

The Preamble of Decision 391 recognises the sovereign right of the state to decide over the use of GRs, the economic and strategic value of GRs, the contribution of indigenous and local communities to biological diversity through their traditional knowledge (referred to as 'intangible component') as well as the intrinsic relation between biodiversity and such knowledge. Overall, Decision 391's approach is strictly regulatory and has as its main objective the establishment of conditions for a just and equitable participation of the state in the benefits derived from the access to GRs (Article 2). As regards its scope, it applies to GRs in respect of which Andean countries are the countries of origin, their derivatives and intangible components; as well as to migratory species which, for natural reasons, are found in the territories of the member countries (Article 3). Human GRs as well as GRs that are used for subsistence of indigenous and local communities are excluded from the scope of the Decision (Article 4).

2.2 Key definitions and basic procedure

Article 1 of Decision 391 provides the definitions of 'access', 'genetic resources' 'derivatives' and 'intangible component'. Access implies both "obtaining and use of GRs", conserved in situ and ex situ, of their derivatives and, if applicable, of their intangible components, for a non-exhaustive list of purposes, including, research, biological prospecting, conservation, industrial application and commercial use. Genetic resources are defined as "all biological material that contains genetic information of value of real or potential use". Derivatives comprise "a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings"; whereas the intangible component is defined as "all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resources, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes".

An important contribution of the Andean Decision is that it provides for general ABS rules and an access procedure, which is to be adapted to national circumstances. This procedure involves a request for access which, if approved, leads to the conclusion of an access agreement. This is followed by the issuance of a resolution granting access that must be registered in a public registry. An indispensable condition for obtaining access is the participation of a local university or research institution in the access activities. This institution is referred to as the 'national support institution' (Article 26). It should be noted that Decision 391 provides for the possibility that the competent national authority in charge of granting access, conclude 'framework access agreements' with individual researchers, research centres or universities (Article 36). In practice, this has been understood and applied at the national level as an abbreviated procedure for obtaining access to GRs for non-commercial purposes.

[8] Gomez Lee, M. (2012), 46.

Based on Decision 391, Ecuador and Peru have designed their own national regulations, defining thereby the roles of the competent national authorities. In doing so, they have further developed important aspects concerning ABS, as described below.

3 Peru

Peru ratified the Nagoya Protocol in October 2014. However, the Peruvian first ABS domestic regulation dates back to 2009, and is primarily based on the Andean Decision 391's regulatory approach. This regulation was drafted by the Ministry of the Environment and approved by the Supreme Decree No. 003-2009. Its main objective, as reflected in its Article 1, is to establish conditions for a fair and equitable sharing of benefits arising out of the access to GRs, in order to implement the Andean Decision. The regulation has the same scope of application as Decision 391, but adds into the list of excluded areas the species covered by the International Treaty on Plant Genetic Resources for Food and Agriculture; use of GRs for plant breeding within the national territory and activities that concern the use of non-wood natural resources to produce nutraceutical products and functional food (Article 5).

The 2009 regulation appoints the Ministry of the Environment as the leading agency on ABS matters (Article 13), accompanied by three executing entities in charge of authorising access depending on the type of GRs: The Ministry of Agriculture with respect to wild species; the National Institute of Agrarian Innovation for domesticated species and the Vice-Ministry of Fisheries with respect to marine species (Articles 14 and 15). The Ministry of the Environment is tasked with designing and adopting the national ABS policy and law, coordinating the activities of the three executing agencies, and monitoring compliance with the national regulation. The executing agencies, for their part, must examine and approve access requests, negotiate and conclude ABS agreement in their respective spheres of competence subject to the favourable opinion of the Ministry of the Environment, adopt ABS sectorial policies, and monitor compliance with access agreements.

Procedurally, the 2009 regulation does not modify the ABS procedure contained in Decision 391. However, it specifies the requirements for the access agreement, such as the recognition of the origin of the GRs, the involvement of locals in the research activities and the transfer of knowledge and technology. Aside from this, access agreements shall contain clauses providing for the user's obligations to report on research outcomes to the authority that granted the permission for access as to give an economic compensation to the country of origin for the benefits arising out of access and utilisation of GRs. In addition, the regulation indicates the requirements for the agreements that need to be concluded by the user with ex situ conservation centres, the holder of the intangible component and the national support institution. With respect to the latter, the Peruvian regulation appears to over emphasise the supervisory role of the national support institution (Articles 18 and 19), arguably giving less attention to its function as research partner as was originally envisaged by Decision 391.[9] The conditions for the conclusion of a framework agreement for non-commercial research are spelled out in the 2009 regulation (Articles 24 to 26). These include the involvement of local researchers in activities of collection, research and the production of scientific data, and reporting obligations to the national authorities. However, no specific procedure addressing change of intent from commercial to non-commercial research can be found. Finally, the 2009 regulation stipulates that transfer of material to ex situ conservation centres is subject to the conclusion of an Agreement of Transfer of Material, which is to

[9] Silvestri L. (2016), 76.

be jointly approved by the Ministry of the Environment and the entity which authorises access (Articles 29 to 33).

Access and use of the collective knowledge of indigenous communities associated to GRs is regulated separately by the Act No. 27.811 of 2002. This Act defines collective knowledge as "the accumulated and transgenerational knowledge developed by indigenous peoples and communities regarding the properties, use and characteristics of biological diversity" and requires the prior and informed consent of the concerned community with regards to its access and utilisation (Articles 1 and 6). To obtain the community's consent, the user shall provide the community with the relevant information on the purposes, risks and consequences of the access activities, including the potential uses of their collective knowledge. Notably, the Act states that when the collective knowledge is used for commercial or industrial application, the user shall negotiate and conclude with the concerned indigenous community a licence agreement stipulating the conditions of the use and the distribution of benefits (Article 7). Benefits for the community shall not be less than 10 per cent of the gross sales resulting from the utilisation of GRs, before tax deductions (Article 8).

A new ABS regulation has been drafted and submitted for nation-wide consultation in July 2019. The proposed legislation is contained in the Resolution No. 205-2019 issued by the Ministry of the Environment. Though it does not substantially modify the existing ABS procedure, it introduces new definitions and modifies some of the existing ones. Interestingly, the proposed legislation seeks to implement both Decision 391 and the Nagoya Protocol (Preamble), which appears to imply an understanding of the two instruments as mutually supportive. It keeps the definition of access as the process of "obtaining and utilizing GRs", but it ambiguously defines 'obtaining' as the process of "extracting the genetic material and/or their derivatives from biological resources or any other source" (Article 3). This leaves the door open to subject the 'genetic information', understood as the "nucleotides sequence obtained from GRs, including sequences digitally stored" (Article 3) to the Peruvian ABS regulation. In doing so, the proposed regulation goes beyond the scope of Decision 391, which does not cover genetic information from digital sources.

Following the requirements of the Nagoya Protocol the proposed regulation incorporates a definition of 'Mutually Agreed Terms' (MAT) as "the agreement containing the conditions of use and the rules for benefit-sharing", and of 'Prior and Informed Consent' as "the process through which the Peruvian States grants its consent to access through the competent national authorities, in line with the Convention on Biological Diversity, the Nagoya Protocol and the Bonn Directives". While a distinction between commercial and non-commercial access is kept, no special procedure has been included to address situations of change of intent.

4 Ecuador

Ecuador ratified the Nagoya Protocol in September 2017. At the time of this ratification, Ecuador had established substantive and procedural ABS rules in different legal instruments including the 2008 National Constitution, legislative and administrative measures, besides the rules contained in Decision 391. Article 400 of the Ecuadorian Constitution declares as part of the national heritage "the biodiversity and its components, in particular … the genetic heritage", which means that access to GRs constitutes a matter of public interest. Notably, the use of GRs is subject to a benefit-sharing rule related to the exploitation of natural resources which is contained in Article 408 of the Constitution. According to this rule, the state shall benefit in an amount which should not be less than the amount of benefits obtained by the person or entity that exploits the natural resources of the state. In prac-

tice, the existence of this rule may create disincentives to users as they may have very limited capacity to bring into the negotiation table other terms of distribution of benefits that take into consideration their concerns and interests.[10]

In October 2011, Ecuador adopted its first ABS regulation with a view to implement Decision 391. This regulation is contained in the Executive Decree No. 905. It restates the definitions of access and of genetic resources contained in the Andean Decision, but incorporates the definition of the term 'benefits' as "both monetary and non-monetary benefits, transfer of technology, royalties, among others, obtained from the utilization of GRs or their derivatives, their application and subsequent commercialization" (Article 6).

In contrast to Peru, where the authority to grant access is dispersed among three entities, in Ecuador such responsibility lies exclusively with one entity. The Executive Decree No. 905 recognised the Ministry of the Environment as the competent national authority in charge of granting access and negotiating terms of distribution of benefits. This, however, changed in 2016 with the adoption of the Organic Code of the Social Economy of Knowledge, Creativity and Innovation, which transferred such competence to the National Institute of Biodiversity - the so-called INABIO – (Article 69), which until today lacks clearly defined rules of procedure for this task.

The access procedure is spelled out in the Executive Decree No. 905 and is primarily based on Decision 391. It begins with the submission and analysis of the access request before the competent national authority. In order to add transparency to the process, the Decree ensures the publicity of the request in order to give third parties the opportunity to oppose it (Article 18). Although a single entity is in charge of granting access, different government agencies (including bodies dealing with indigenous rights, intellectual property rights, endangered species, among others) are supposed to participate and provide their opinion in the analysis of the request (Article 21). Once the resolution that grants access has been issued, the competent national authority shall negotiate the terms of the access agreement with the user (Articles 25 to 30). According to the Decree No. 905, the contract shall contain clauses relating to the participation of local researchers, reporting obligations, monitoring and compliance with the terms of the agreement. Notably, along with the contract, users are required to provide a guarantee (of 5 per cent for non-profit users and of 10 per cent for profit-seeking users of the estimated cost of the project) in favour of the competent national authority (Article 31). Transfer of material is subject to the conclusion of an Agreement of Transfer of Material between the user and an ex situ conservation centre and subject to the approval of the Ministry of the Environment (Article 45).

The Executive Decree No. 905 also contains provisions relating to traditional knowledge, referred to as 'intangible component'. While recognising indigenous peoples' property rights over their traditional knowledge (Article 6), it requires the user to present a plan for obtaining the prior and informed consent of the holder of the intangible component associated to the GRs (Article 20). This is to be followed by the conclusion of an agreement between the community and the user, which is to be considered as an annex and condition of validity to the access agreement (Article 34).

Finally, in 2015 the Ministry of the Environment adopted the Ministerial Agreement 034 which contains a procedure for the conclusion of framework agreements for research on GRs for "exclusive scientific purposes". The procedure is shorter that the access procedure

[10] These views were shared by Lenin Nuñez and Diego Inclan of the National Biodiversity Institute and Ricardo Andrade and Wilson Rojas of the Ministry of the Environment in interviews conducted in March 2018.

contained in the Executive Decree No. 905; however, it also provides for the involvement of a national support institution in the research activities (Article 5). The request for a framework agreement shall be firstly approved by INABIO, while the agreement is to be signed by the user and the Ministry of the Environment (Articles 9 and 13). This agreement has a fixed-term period of three years, which could be extended up to five years (Article 14). In practice, this special regulation has facilitated the conclusion of several framework agreements on generally defined research programmes, which are supposed to incorporate, within the scope of that agreement, future specific projects that could emerge in the course of research activities.[11]

After the ratification of the Protocol, no further regulation has been adopted. According to a press release of the INABIO, the Ministry of the Environment and the National Secretary for High Education, Science, Technology and Research are in the process of developing a new regulation that is supposed to introduce procedural changes aimed at streamlining access procedures in conformity with the Nagoya Protocol.[12]

5 Final assessment and conclusion

In sum, Ecuador's and Peru's ABS regulations have their roots in Decision 391. The Andean Decision provides for the main substantive requirements of ABS, in line with the Protocol, namely the prior and informed consent of the provider country and the mutually agreed terms. On the other hand, the two national regulations continue to reflect -and they are supposed to continue to reflect- the regulatory approach of Decision 391, according to which the state retains the stronger bargaining power in ABS negotiations. In this regard, rules and procedures have been set out in both countries with the overall objective of protecting the interests of the provider country and of local and indigenous communities, while the determination of the rights of users is still absent. In this context, users' negotiation capacity is confined to the distribution of benefits as many clauses of the access contract are pre-established by the current regulation. From the institutional point of view, by delegating the power to grant access to different executive agencies, Peru has attempted to decentralize the ABS system, while keeping the function of designing ABS laws and policy with a central authority. In contrast, in Ecuador, the ABS procedure is centralized on one national authority, while a different authority has been appointed for the conclusion of framework agreements for non-commercial research. While in Ecuador no legislation has been adopted following ratification of the Protocol, in Peru the new proposal of ABS regulation seeks to harmonise national legislation with the Protocol, at least formally. However, it introduces ambiguous definitions that may impede achieving the legal certainty required by the Protocol. The biggest challenge that Ecuador and Peru have ahead of them is to find the way to harmonise, through national legislation and practice, the Nagoya Protocol and the CAN Decision 391, which are both binding in these countries.

References

J. Caillaux, M. Ruiz, B. Tobin, El Regimen Andino de Acceso a los Recursos Genéticos: Lecciones y experiencias, Sociedad Peruana de Derecho Ambiental, 1999.

Ecuador, Constitution of 2008.

[11] Views expressed by Diego Inclan of the National Biodiversity Institute in interviews conducted in March 2018.

[12] See: http://inabio.biodiversidad.gob.ec/2019/01/30/16-protocolo-de-nagoya-en-operacion/ (accessed 8 August 2019).

Ecuador, Executive Decree No. 905, National Regulation on the Common Regime on Access to Genetic Resources in application of the Decision 391 of the Andean Community of Nations, 2011.

Ecuador, Ministry of the Environment, Ministerial Agreement 034, Norms governing the procedure for the conclusion of framework agreements for accessing generic resources, 2015.

Ecuador, National Institute of Biodiversity (press release), http://inabio.biodiversidad.gob.ec

/2019/01/30/16-protocolo-de-nagoya-en-operacion/ (accessed 8 August 2019).

Ecuador, Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016.

Decision 391: “Common Regime on Access to Genetic Resources”, adopted by Parties to the Commission of the Cartagena Agreement in 1996.

M. Gomez Lee, La Comunidad Andina frente al reto del acceso a los recursos genéticos y la distribución de beneficions, Oasis 17, 2012.

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 2010.

Peru, Act establishing the regime for the protection of the collective knowledge of indigenous peoples related to biological resources, 2002.

Peru, Supreme Decree 003 - 2009 containing the Regulation for Accessing Genetic Resources, 2009.

Peru, Ministerial Resolution 205 – 2019 containing the draft Regulation for Accessing Genetic Resources and their Derivatives.

L. Silvestri, Conservación de la diversidad genética en el Perú: desafíos en la implementación del régimen de acceso a recursos genéticos y distribución de beneficios, Revista peruana de biología 23 (1), 2016.

M. Ruiz Muller, Es necesario un nuevo marco jurídico para la bioprospección en la región andina? Breve revisión crítica de la Decisión 391, Serie de Política y Derecho Ambiental No. 14, 2003.

Chapter 14
The post Nagoya Protocol ABS regulatory framework of France

Marcelin Tonye Mahop

1 Introduction

As a sovereign country and as a member of the European Union (EU), France is committed to implementing the 1992 Convention on Biological Diversity (CBD) and its protocols on biosafety and on Access and Benefit-Sharing (ABS). France became party to the CBD by ratification on 29 September 1994, party to the Cartagena Protocol on Biosafety by approval on 11 September 2003 and party to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization by ratification on 29 November 2016. The country's engagement to abide by the objectives and fulfil the obligations of these international environmental instruments draws from its rich and diverse biological resources and cultural heritage, which have led the country to proclaim itself a megadiverse country despite non-recognition as such by the club of megadiverse countries.[1] Nonetheless, according to the fifth National report to the CBD, the unique geographical position of France in Europe and overseas provides it with the amount of biodiversity wealth worth the status of a megadiverse country.[2] Moreover, the French overseas departments, territories and collectivities are situated at different latitudinal ranges and belong to a wide range of biogeographical regions including the islands of Mascareignes, Comoros, the Caribbean, the South Pacific, the Austral and Antarctic Islands, and subboreal North America biome.[3] French territory is thus located in five of the world's 34 terrestrial biodiversity hotspots identified by the WWF and the IUCN.[4]

To protect and ensure sustainability of its rich and diverse biological and cultural heritage, France has taken domestic measures with e.g. the development of the 2011-2020 National Biodiversity Strategy (NBS)[5] whose objectives are firmly aligned with the Aichi Biodiversity Targets of the 2011-2020 CBD Strategic Plan for Biodiversity.[6] In relation to addressing the implementation of the third objective of the CBD on ABS therefore, the central objective of the Nagoya Protocol, the NBS Strategy, comprises 18 objectives among which objective 13 is dedicated to ensuring the fair and equitable sharing of the benefits arising from the utilisation of biodiversity at all levels. This objective is pursued in fulfilment of the Aichi Biodiversity Target 16 which stipulates that: "By 2015, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilisation is in force and operational, consistent with national legislation". As a logical step in the operationalisation of the Aichi Biodiversity target 16 after ratification of the Nagoya Protocol,

---

[1] Megadiverse countries are referred to as countries, which harbour the majority of the earth's species with a large number of endemic species in them. Currently, there are 17 scientifically recognised megadiverse countries, and France (metropolitan or any of its overseas territories) is not in the list. See https://www.worldatlas.com/articles/ecologically-megadiverse-countries-of-the-world.html (accessed 28/05 2019).

[2] Ibid, Page 14.

[3] Ibid.

[4] Ibid.

[5] La Stratégie Nationale pour la Biodiversité 2011-2020: https://www.cbd.int/doc/world/fr/fr-nbsap-v2-fr.pdf (accessed 28/05/2019).

[6] CBD COP 10 Decision X/2. Strategic Plan for Biodiversity 2011-2020.

France introduced domestic ABS regulations, which are designed to be compliant with the NP.

2 The ABS regulatory framework of France

The access and benefit sharing regulatory framework of France stands on two principal pillars:

The first pillar is the access regulations.

Through its access regulations, France theoretically constructs domestic ABS regulatory instruments from the standpoint of a supplier/provider country that is very rich in biological and cultural diversity. This pillar comprises three key instruments notably:

- Loi No2016-1087 du 08 Aout 2016 pour la Reconquête de la Biodiversité, de la Nature et des Paysages, Title V : Accès aux ressources Génétiques et Partage Juste et Equitable des Avantages, codifié aux articles L412-3 à L412-20 du Code de l'environnement.
- Décret No 2017-848 du 09 Mai 2017 Relatif à l'Accès aux Ressources Génétiques et aux connaissances traditionnelles associées au partage des avantages découlant de leur utilisation. This decree provides for the designation of the relevant Competent National Authorities (CNA) responsible for the implementation of the monitoring of utilisation and compliance provision of the 2014 EU ABS regulation and for the registration of collections. It also includes a model contract for benefit sharing from the utilisation of traditional knowledge associated with genetic resources.
- Arrêté du 13 septembre 2017 fixant le contrat type de partage des avantages découlant de l'utilisation de ressources génétiques prélevées sur le territoire national, mentionné à l'article R. 412-20 du code de l'environnement.
- The second pillar of the ABS regulatory framework of France represents the implementation in France of the EU ABS regulations, which are essentially the measures that users of genetic resources and associated traditional knowledge (aTK) must comply with when utilising[7] genetic resources and associated traditional knowledge. The principal instruments attached to this pillar are:
- Regulation (EU) 511/2014 of the European Parliament and of the Council of 16 April 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.
- COMMISSION IMPLEMENTING REGULATION (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council about the register of collections, monitoring user compliance and best practices.
- Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union.

[7] Based on the definition of utilisation of article 2 of the NP.

3 Material and geographical scope of the ABS regulatory framework of France

The 2016 ABS law sets out the conditions of access to the genetic resources of France for their utilisation and for the fair and equitable sharing of the benefits derived from such utilisation.[8] Additionally and when relevant, the 2016 ABS law applies to the utilisation of aTK in accordance with the Convention on Biological Diversity.[9] Access to genetic resources for their utilisation on the one hand and the utilisation of aTK on the other hand are therefore the principal elements that constitute the scope of the 2016 ABS law of France.[10] The current ABS regulatory framework of France does not specifically address the utilisation of digital sequence information or genetic information that may be linked with a given GR. The legal implications the utilisation of DSI in France has on the access measures, benefit-sharing and other compliance measures of either the domestic law regime or the ABS law of the parties to the NP, which may be concerned with such resources, are therefore far from known.

There are several exemptions[11] from the scope of the French ABS law, which among others are:

- human genetic resources;
- genetic resources in areas beyond national jurisdiction;
- genetic resources covered by specialized ABS instruments that are consistent with, and do not run counter to the objectives of, the Convention on Biological Diversity;
- genetic resources of cultivated or domesticated species that are used as models in R&D activities (i.e. model species);
- traditional knowledge associated with genetic resources that may not be attributed to one or more communities of inhabitants;
- traditional knowledge associated with genetic resources, whose properties are well known, and that has been used repeatedly and for a long period of time outside the communities of inhabitants that have initially developed such knowledge;
- traditional knowledge covered by the value enhancement measures that are defined by article 640-2 of the Code rural et de la pêche maritime.

In addition, access to genetic resources for their utilisation and utilisation of aTK in the interest of national defence and national security are exempted from the scope of the law.[12] Furthermore, some categories of genetic resources that are regulated by specific ABS regulations are excluded from the scope of the law.[13] These categories of resources are:

- genetic resources of domesticated or cultivated species;
- genetic resources of wild relatives of cultivated crop and domesticated animal species;

---

[8] Art. L 412-3 of the 2016 France ABS Law.

[9] Ibid.

[10] Art. L 412-5 –I of the 2016 France ABS law.

[11] Art. L 412-5-II of the 2016 France ABS Law.

[12] Art. L 412-5-II-3 of the 2016 ABS Law.

[13] Art. L 412-5-III of the 2016 ABS Law.

- genetic resources used in forestry;
- genetic resources collected by laboratories for the prevention, surveillance and eradication of health risks that threaten plant and animal health as well as the food safety of animals;
- genetic resources collected by laboratories for the prevention, surveillance and eradication of serious health risks that threaten human health.

The access procedures laid down in the 2016 ABS law of France apply when access is sought for genetic resources and / or the utilisation of aTK in French territory, both in the mainland France and in the overseas territories (subject to their competences), after the entry into force of the ABS law on 09 August 2016. Any materials accessed before that cut-off date is not subject to the prescribed ABS rules. The 2016 ABS law empowers the overseas territories, if they so wish, to exercise the functions of Competent National Authorities (CNA)[14], meaning that they can process applications for access to GRs and utilisation of aTK aimed at their territories.[15]

4 Access procedures, commercial vs non-commercial, PIC and MAT, IPRs issues, benefit-sharing

There are two access schemes in the ABS regulatory framework of France:

- the declarative scheme to access
- the authorisation scheme to access

The declarative scheme covers access applications to GRs that are sought to be utilised for the purposes of enhancing the knowledge on and understanding of biodiversity, conservation and valorisation of genetic resources with no specific or direct objective of commercialisation of the outcomes of such utilisation.[16] Furthermore, access to GRs in situations of emergency pertaining to human, animal or plant health other than the public health issues enshrined in Art. L.1413-8 of the Public Health Code, are also eligible for the declarative approach.[17] The authorisation scheme covers access applications for GRs for any type of utilisation other than those considered under the declarative approach, specifically access with commercial intent.[18] Although the ABS law and implementing regulations have not directly addressed the distinction between commercial and non-commercial utilisation, a close examination of the two access schemes, the declarative and authorisation schemes shed some light as to how the ABS regime is approaching these two strands of utilisation. The declarative approach covers access to GRs with no objective of commercialisation of the outcomes of the research process and does thus not require negotiations of an ABS contract. On its part, the authorisation scheme requires negotiation of an ABS contract as it applies to access to GRs for any type of utilisation other than those considered under the

[14] Art. L 412-7 to L 412-9 of the 2016 ABS Law of France.

[15] Art. L 412-15 of the 2016 ABS law of France. The territories concerned are the regional councils of Guadelope and Reunion; the assemblies of French Guyana and Martinique and the overseas departments of Mayotte.

[16] Art. R.412-12 of the 2017 ABS implementing decree. The criteria the applicant must fulfil in the submission / application are detailed in Article R.412-13.

[17] Art. L. 412-7 III of the 2016 ABS Law.

[18] Article R. 412-18 of the 2017 ABS implementing decree.

declarative approach.[19] The 2016 ABS law and 2017 ABS implementing decree do not typically mention commercialisation or commercial utilisation of genetic resources as one of the key features of the authorisation approach. One can however assume that, the inclusion of 'no specific and direct objective of commercialisation'[20] of genetic resources, which excludes commercialisation from the declarative approach, is a signal that commercial use of genetic resources is the principal trigger of the authorisation approach.

Access to GRs for utilisation and utilisation of aTK of the communities of inhabitants via the permitting schemes discussed above is subject to the prior informed consent (PIC) of the Ministry in charge of environment, which is the CNA responsible for the administration of the access schemes. Concerning the declarative scheme, there is no typical mention of the requirement for the PIC of the CNA for access to GRs. But the fact that the CNA is expected to issue a receipt to the applicant as evidence that the application has been thus giving permission to collect the GRs, is perhaps a mark that the PIC of the CNA is equally in force through the declarative scheme. It should be stressed that, neither the 2016 ABS law nor the 2017 ABS implementing decree namely mention the PIC requirement in relation to access to GRs. The requirement for PIC of the CNA appears in the standard ABS contract in the 2017 Arete of the ministry in charge of Environment, which provides that the principal objective of the ABS contract is to materialise the PIC of the CNA for access to GRs for their utilisation.[21] With regards to the MAT requirements, there is no requirement for an ABS contract among the key access requirements under the declarative approach. However, for the CNA to grant an authorisation/access permit either to GRs or for the utilisation of aTK one of the key conditions that the applicant/user must fulfil is to negotiate an ABS agreement and submit it to the CNA. There are two types of model MAT in the current ABS regulatory framework of France. One is a model MAT pertaining to access and the utilisation of GRs, which was promulgated as a separate implementing regulation,[22] and the other is the model MAT pertaining to the utilisation of aTK, which is appended to the 2017 ABS implementing decree.

Two broad types of benefits, non-monetary (non-financial) and monetary (financial) benefits are considered in the model contracts. The model contracts have broken down these two broad types of benefits into five specific types including:[23]

- Enrichment and preservation of biodiversity while ensuring its sustainable use.
- Preservation of traditional knowledge associated with genetic resources through, for example, the development of TK databases with the participation and PIC of the communities of inhabitants.
- At local level, contribution to local development through job creation and the development of value chains.
- Collaboration, cooperation and contribution to research activities, education, training and capacity building.

---

[19] Art. R. 412-18 of the 2017 ABS implementing decree.

[20] Art. R. 412-12-3 of the 2017 implementing decree.

[21] Art. 1 of the 2017 Arrêté du 13 septembre 2017 fixant le contrat type de partage des avantages découlant de l'utilisation de ressources génétiques prélevées sur le territoire national, mentionné à l'article R. 412-20 du code de l'environnement.

[22] Décret no 2017-848 du 9 mai 2017 relatif à l'accès aux ressources génétiques et aux connaissances traditionnelles associées et au partage des avantages découlant de leur utilisation.

[23] Art. 3 of the model contracts for access and utilisation of GRs and of associated traditional knowledge.

- Maintenance, conservation, management, supply or restoration of ecosystems services in a given territory.
- Payment of financial contributions.

The ABS regulatory framework of France has clearly identified the institutions that are responsible for handling applications for access to GRs and aTK, the issuance of the various forms of access permits and the roles and functions of the relevant National Competent Authorities (CNA). The agency with the ultimate responsibility for issuing the access permits[24] is the ministry in charge of the environment.[25] This agency is responsible for 'granting access' which is a role assigned to the CNA in accordance with the NP.[26] When access is sought for GRs in a national park,[27] the ministry in charge of the environment is obliged to share the application with the management of the park and seek their opinion on the permit application. The same applies if access is sought for GRs in the territories of the communities of inhabitants.[28] In this case, the ministry must seek the view of the moral authority identified in Article L.412-10 as the representative of the communities. With regards to access to aTK of the communities of inhabitants, the ministry in charge of environment is obliged to seek the opinion of the moral authority that represents the communities of inhabitants.[29] It is important to stress that the opinion of this moral authority will derive from consultations between the moral authority and the communities of inhabitants.

5 Institutional framework and relevant Competent National Authorities (CNA)

The ABS regulatory framework has also designated the relevant competent authorities in fulfilment of France obligations under Article 6 of the 2014 ABS user regulations of the European Union. In relation to monitoring compliance with access regulations in the context of the utilisation of genetic resources or aTK at the stage of research funding application, the Ministry in charge of research is the CNA to receive the Declaration of Due Diligence (DDD) with all the information identified in Article 4 of the EU ABS regulation.[30] The ministry in charge of the environment is the designated CNA to receive the DDD at the stage of final development of a product based on the GRs or aTK or when seeking market approval for the commercialisation of such products.[31] With regards to the DDD at the final stage of product development, users provide the information required to the National Industrial IP Institute (for example when patents are sought over the product developed on the basis of GRs or aTK) or to the national market approval agency (if market approval is sought for the commercialisation of the products.[32] These agencies cannot use this information in their normal examination processes and should focus on simply transferring this information to the relevant ministry in charge of the environment. Finally, the ministry in charge of re-

[24] More on the different types of permits below.

[25] Art. R.412-13, R.412-18, R.412-28 of the 2017 ABS Implementing Decree of France. It must be stressed that in France, the ministry in charge of the Environment is Le Ministere de la Transition Ecologique et Solidaire.

[26] Art. 13.2 of the Nagoya Protocol.

[27] Art. L.412-8 I of the 2016 ABS law.

[28] Ibid.

[29] Art. L.412-9 and L. 412-10.

[30] Art. D. 412-39-I of the 2017 ABS Implementing Decree.

[31] Art. D. 412-39-II of the 2017 ABS Implementing Decree.

[32] Art. L. 412-18-I-2 of the 2016 ABS law of France.

search is the designated CNA for the registration of collections,[33] therefore, for the implementation at the national level of Article 5 of the 2014 EU ABS regulation on registered collections.

6 Conclusion and assessments

Like Spain as a member of the European Union, France has decided to regulate access to GRs under the country's sovereignty and the utilisation of aTK of the communities of inhabitants. The domestic ABS regulatory framework on access complements the implementation by France of the 2014 EU Regulation, which regulates the utilisation of genetic resources within the EU territorial jurisdiction. Having chosen the path to regulate access to GRs and utilisation of aTK, the ABS regulatory framework of France has clearly laid down the requirements and procedures through either the declarative or the authorisation scheme, depending on whether or not, there will be some element of commercialisation of the outcomes of research. While France did not have an elaborate and clear ABS regime prior to the adoption of the Nagoya Protocol, the post Nagoya Protocol era is marked by the adoption of a pan European approach to regulating the utilisation of GRs and aTK which is in force in France and the elaboration of domestic access measures. All these steps ensure that France fulfils its obligations under the Nagoya Protocol.

References

Documents and websites

CBD and Nagoya Protocol Clearing House Mechanism France: https://absch.cbd.int/countries/FR (last accessed on 29/06/2019).

CBD COP 10 Decision X/2. Strategic Plan for Biodiversity 2011-2020.

Fifth National Report of the Republique of France to the Convention on Biological Diversity, Republic of France, Ministry of Ecology, Sustainable Development, Transport and Housing, October 2014.

La Stratégie Nationale pour la Biodiversité 2011-2020: https://www.cbd.int/doc/world/fr/fr-nbsap-v2-fr.pdf (last accessed 28/05/2019).

UICN France & MNHN (2008-2013). La Liste rouge des espèces menacées en France. Paris, France.

World Megadiverse countries: https://www.worldatlas.com/articles/ecologically-megadiverse-countries-of-the-world.html (last accessed 28/05/2019).

Legal texts

France

Arrêté du 13 septembre 2017 fixant le contrat type de partage des avantages découlant de l'utilisation de ressources génétiques prélevées sur le territoire national, mentionné à l'article R. 412-20 du code de l'environnement.

Décret No 2017-848 du 09 Mai 2017 Relatif à l'Accès aux Ressources Génétiques et aux connaissances traditionnelles associées au partage des avantages découlant de leur utilisation.

Loi No2016-1087 du 08 Aout 2016 pour la Reconquête de la Biodiversité, de la Nature et des Paysages, Title V: Accès aux ressources Génétiques et Partage Juste et Equitable des Avantages, codifié aux articles L412-3 à L412-20 du Code de l'environnement.

[33] Art. D. 412-41 of the 2017 ABS Implementating Decree.

European Union

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council about the register of collections, monitoring user compliance and best practices.

Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union.

Regulation (EU) 511/2014 of the European Parliament and of the Council of 16 April 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.

Chapter 15
ABS regime in Spain

Luciana Carla Silvestri

1 Legislation and scope

Spain has been a Party to the Convention on Biological Diversity (CBD) and to the Nagoya Protocol (NP) since December, 1993 and October, 2014, respectively.

The Spanish legislation applicable to access to genetic resources and benefit-sharing (ABS) includes regulations of community origin - Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, and Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No. 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices – and regulations of strictly Spanish origin - Law No. 42/2007, of 13 December, on Natural Heritage and Biodiversity, modified by Law No. 33/2015, of 21 September and Royal Decree No. 124/2017, of 24 February, related to access to genetic resources deriving from wild taxons and to the control of their utilisation. The Law and the Decree regulate access to genetic resources in Spain and sets forth the compliance measures and sanctions provided for in Regulation (EU) No. 511/2014.

Spanish legislation on access to genetic resources covers those resources deriving from wild taxons found either in in situ or ex situ conditions as long as there is 'utilisation' thereof; that is to say, only when research and/or development on the genetic and/or biochemical composition of the genetic resources is conducted, including the application of biotechnology.

The regime is not applicable to: a) access to genetic resources for exclusive taxonomic purposes; b) plant genetic resources for food and agriculture covered under Law No. 30/2006, of 26 July, on seeds and nursery plants and on plant genetic resources; c) fish genetic resources regulated by Law No. 3/2001, of 26 March, on State Marine Fishing; d) animal genetic resources for food and agriculture; e) collection of materials/samples and their maintenance in germplasm banks or in ex situ collections with the exclusive purpose of their conservation and f) the production and commercialisation of seeds and forest materials/plants covered under Royal Decree No. 289/2003, of 7 March, on commercialisation of reproduction forest materials, as long as there is no utilisation of the genetic resources and no transfer to third parties for a different use.

2 Authorities

Spain is politically and administratively organised in 17 Autonomous Communities. They are competent to manage their own environment. Accordingly, they are responsible for granting the prior informed consent (PIC) and establishing mutually agreed terms (MAT) for the access to genetic resources located within their respective territories. Autonomous Communities are also responsible for authorising access to the genetic resources located in their jurisdictions (issue the corresponding access permit) when resources are endemic only to that region.

On the other hand, the Public National Administration is competent for granting PIC and establishing MAT for access to genetic resources found/located in Spanish maritime jurisdiction (General Directorate for the Sustainability of the Coast and the Sea); state public assets (body of the Public National Administration to which the assets are assigned) and state-owned or state-related institutions for ex situ conservation (the institution's managing body). In such cases, the General Directorate of Environmental and Natural Environment Quality and Assessment (public national Administration) is competent for authorising access to the genetic resources once PIC and MAT have been provided and negotiated. The Directorate is also responsible for granting the access permit in case the genetic resources are geographically scattered on the territory of more than one community, provided the relevant communities have granted their respective PIC and established MAT.

3 Access procedures and permits

The Spanish legal framework foresees two types of procedures for access to genetic resources, depending on whether they are intended to be used for non-commercial or for commercial purposes. In the first case, the access application must be addressed to the competent authority -the relevant Autonomous Community or the General Directorate of Environmental and Natural Environment Quality and Assessment-, then the competent authority will contact the responsible authority for providing PIC and establishing MAT. Once all requirements are fulfilled, the competent authority will grant the access permit within a maximum period of two months.

If resources are to be used for commercial purposes, the user must first, obtain the PIC and negotiate MAT with the relevant body. The user then will apply for an access permit from the competent authority. Once the documentation has been revised, the authority will issue the corresponding permit within a maximum period of six months.

According to existing access procedures, there are two types of access permits in Spain: one for non-commercial purposes, and one for commercial purposes. The law considers that there are non-commercial purposes when the research results do not entail the protection of a product or a process by means of intellectual property rights, or the commercialisation of a product or a process. On the contrary, purposes are considered commercial when access to the genetic resources pursues the development of a product for its commercialisation or sale, or to obtain a patent or a product to which access restrictions will be applied by means of intellectual or industrial property rights.

Once an access permit has been issued, the national focal point, the General Directorate of Biodiversity and Environmental Quality of the Ministry for Ecological Transition, will notify it to the Access and Benefit-Sharing Clearing House designated by the Protocol.

Minimal contents for access permits for non-commercial and commercial purposes are set forth in Appendices 2 and 4 of Royal Decree No. 124/2017.

Permits conditions for non-commercial purposes are included in Appendix 2 and Article 6.2 of Royal Decree No. 124/2017. These conditions also apply to permits for commercial purposes which also have to meet arrangements set in Appendix 4 of the Decree.

4 Benefit-sharing

Spanish legislation mandates that MAT have to be established when access to genetic resources is pursued. They will be negotiated with the responsible body/authority mentioned in sections II and III. Benefits can be freely negotiated and established by the two parties. When access is sought for non-commercial purposes, the body in charge of negotiating

MAT may demand by law the following two additional access conditions: a) to deposit duplicates of the material being accessed in an ex situ collection located in Spain and b) to collaborate with a Spanish scientific institution when the access to the resources is sought by a foreign person.

There are no guidelines for the time being for the establishment of MAT when access to genetic resources is pursued for commercial purposes. However, these are planned to be developed in the near future.

5 Assessment of the pre and post Nagoya Protocol situation and conclusions

Even though Spain had the possibility to regulate access to and utilisation of its genetic resources under the power conferred by Law No.42 of 2007, it had not exercised it until 2017. After the passing of Decree No. 124/2017, following the implementation of the NP and the European legislation on the issue, Spain has been able to effectively regulate access to the genetic resources under its sovereignty.

The Spanish legal framework complies with the obligations imposed by the NP in relation to the characteristics that access measures must feature, the need to designate a national focal point and competent authorities for granting access to genetic resources, and the control of the utilisation of genetic resources and traditional knowledge taking place in Spain. It may take a number of years to gauge its effects, soundness and coherence. However, there are clear signs that ABS will be efficiently and successfully implemented in Spain.

PART III: CRITICAL THEMES AND IMPLEMENTATION

Figure 4: Plant life on a tree in the biodiversity hotspot of South Ecuador. The tree barred the construction of a road. Photo by Erwin Beck (1996).

Chapter 16
ABS regulation in the European Union

Gerd Winter

1 ABS and compliance legislation

Under most legal systems of EU member states the genetic potential of organisms are considered to principally be free goods (res nullius). This means that foreign and domestic researchers are free to use, breed and re-combine the genetic makeup at will. The benefits arising from such research and development (R&D) need not be shared with the state of origin. They are essentially reaped by the subjects entitled to claim exclusive rights on them.

Only a few EU member states have established or are about to establish legislation requiring prior consent for access to their genetic resources and prior consent or mutual agreement on the sharing of benefits derived from R&D on the genetic resources. These so-called provider states are Croatia, France, Bulgaria, Malta and Spain. Within the EEA and EFTA Norway and Switzerland have provider regimes albeit of a more lenient version where the executive is empowered to introduce it occasionally. This has been done for certain organisms such as fish in Norway.

The EU does not provide harmonisation on ABS of provider states, which is therefore left to the competence of member states. In fact, several arguments speak against an access regime. First, such regime could end up imposing a heavy administrative burden on R&D activities. The provider country operating such regime would have to survey accesses internally but also the utilisation of its accessed genetic resources both internally and abroad including R&D up to the marketing of products and the obtaining of intellectual property rights. Second, the financial return is very small according to experiences made by provider states. Although monetary compensations have been envisaged since the implementation of the CBD in 1993, they have hardly ever been paid anywhere in the world. In any case, the transaction costs would probably be higher than the potential returns in the long term. Benefits deriving from cooperation in research and development appears to be more rewarding than monetary benefits.[1]

The Nagoya Protocol to the CBD of 2010 which is in force since 2014 imposes obligations to those contracting states in the territory of which R&D on genetic resources is performed (the so-called user states). The states must ensure that the genetic resources utilised in their territory have been accessed and utilised in compliance with the regulations of the provider states and mutually agreed terms (MATs) have been concluded on the sharing of benefits.[2] Furthermore, user states must provide access to justice and other institutions for the enforcement of the agreed terms.[3]

The EU which is contracting party to the Nagoya Protocol enacted a legislative regulation that lays out the user state obligations for all member states.[4] An executive regulation of the Commission further specifies how these obligations shall be implemented.[5]

---

[1] For empirical case studies of provider-user scientific cooperation see Beck E. (2015), 165-174 and Boga H. I. (2015), 181-192.

[2] Art. 15 Nagoya Protocol.

[3] Art. 18 Nagoya Protocol.

[4] REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April

2 Scope

Concerning its temporal scope the EU ABS compliance regime covers only those genetic resources or traditional knowledge associated with such resources that were accessed after 12 October 2014.[6] This time limit is problematic because compliance with ABS requirements was obligatory already under Article 15 CBD, which entered into force as early as in December 1993.

Concerning geographic scope the EU regime is applicable to any R&D and final preparation of products arising out of genetic resources that occur within the EU.

Concerning material scope the EU regime applies to genetic resources that were accessed from provider states operating an access regime and being contracting parties to the Nagoya Protocol. Insofar as EU member states enacted an ABS provider access regime including a related compliance system this has priority over the EU regime.[7]

3 Basic obligations and monitoring

Researchers and developers (i.e. users in the terminology of the regulation) are subject to a number of legal obligations and measures of administrative supervision.

There is first of all a material duty of users which is laid out as follows:[8]

> "Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise 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."

It is worth noting that this provision does not set out a duty in effect but one in conduct because the user must practice 'due diligence to ascertain' rather than just having to cope with the provider state requirements. Nevertheless, if it is found that the user in effect did act in breach of provider state requirements he/she must correct their conduct.[9] This after all makes the obligation one of effect.

Users must keep the information that is relevant for compliance for 20 years. They must transfer the relevant documents to subsequent users.[10] Included is, inter alia, information about the presence of obligations regarding subsequent applications and commercialisation, access permits, and mutually agreed terms, including benefit-sharing arrangements. The formulation that the documents must be 'transferred' avoids the imposition on the pre-

---

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, OJ 2014 L 150/59.

[5] COMMISSION IMPLEMENTING REGULATION (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices, OJ 2015 L 275/4.

[6] This is the date of entering into force of the Nagoya Protocol to which Art. 17 (2) Regulation (EU) 511/2014 refers.

[7] Art. 2 (3) Regulation (EU) 511/2014.

[8] Art. 4 (1) Regulation (EU) 511/2014.

[9] Art. 4 (5) Regulation (EU) 511/2014. The competent authority is empowered to issue a compliance order (Art. 9 (6) of the same Regulation.

[10] Art. 4 (3) Regulation (EU) 511/2014.

vious user of the responsibility to monitor compliance by the subsequent user. Neither is the previous user obliged to inform the provider state of such transfer. This means that the performance of the said material duty of users to comply with the provider state requirements is to be monitored by competent authorities through formal declaration by the user. These must be made at the stages of research funding and final product development stating that the user practised due diligence in respecting requirements for access and benefit-sharing.[11] In addition, the competent authorities are required to perform checks of users which are either 'systematic' (i.e. according to plans) or 'risk based' (i.e. at random and according to third party information).[12]

Annexes II and III of Commission Regulation (EU) 2015/1866 contain templates for the declaration both at the stages of research funding and final product development. In addition the EU Commission offers an information technology tool called DECLARE that users may employ for their declarations. It is not mandatory because member states are free to operate their own formats. The declaration is addressed to the competent Member State authority but forwarded to the Commission and the ABS Clearing House, as provided by Article 7 (3) Regulation (EU) 511/2014.[13]

Ambitious as this compliance system appears an empirical survey of the EU Commission shows that there are still many shortcomings in actual practice. This is due to the novelty of the ABS regime which is widely unknown to researchers, and the lack of informed supervisory personnel.[14]

4 Traditional knowledge

Both the user duties and monitoring measures are also applicable to traditional knowledge associated with genetic resources. This corresponds to the related provisions of the Nagoya Protocol which extends the safeguarding of compliance also to such traditional knowledge.[15] While the Nagoya Protocol does not give a definition, other than that the knowledge must belong to indigenous or local communities and be related to genetic resources, the EU Regulation goes a bit further by specifying that the knowledge must be "relevant for the utilisation of genetic resources" and "as such described in the mutually agreed terms applying to the utilisation of genetic resources". The latter clause can cause confusion if the knowledge is objectively relevant for the utilisation of genetic resources but not described "as such". According to Nagoya Protocol standards benefit-sharing would probably also apply in this case.

5 Collections

Special provisions have been established on collections of genetic resources and related information. They are regarded by the EU approach to ease the burden of users because they can ensure once for all that the genetic resources they provide have been legally accessed and the users are bound by any conditions of provider states for utilisation and sub-

[11] Art. 7 (1) and (2) Regulation (EU) 511/2014.

[12] Art. 9 Regulation (EU) 511/2014.

[13] See further the contribution by Thomas Greiber in this volume on the practices of monitoring in Germany.

[14] REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 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, COM/2019/13 final.

[15] Art. 7 Nagoya Protocol.

sequent commercialisation. For that purpose collections can obtain the status of registered collection which implies that users are considered to have exercised due diligence concerning any access requirements.[16] One collection, DSMZ, has so far obtained that status. Others have doubts what the advantage for them of that status can be, given the costs of obtaining and maintaining registration.[17] It is probably just a service for their customers which could be remunerated by corresponding fees. From the provider states' perspective it may be considered as a shortcoming that the collections are freed from any duty to monitor whether the users of collections actually obey the conditions transferred to them. That lack of supervisory intermediaries however is a general problem of all ABS PICs and MATs.

6 Commercialisation

A crucial issue is the role of commercialisation in the EU user state regime. Regulation (EU) 511/2014 addresses the issue in different contexts, including the duty of member states to assist non-commercial researchers when searching access to genetic resources and utilising them.[18] More importantly, users must respect any provider requirements concerning commercialisation, and authorities are obliged to monitor their compliance.[19] Like many other legal systems the EU Regulation does not provide a definition of commercialisation. Is it 'commercial' if the user explores the functions of certain genes, or if he/she uses the gene in order to modify an organism, or if he/she obtains a patent on it, or if he/she develops the modified organism into a marketable product, or if he/she actually sells the product? One could argue that not the EU but the provider state is competent to define 'commercialisation' when issuing PIC and concluding MAT with conditions concerning commercialisation. But the provider state would have to observe any binding international definition. The Nagoya Protocol which is insofar pertinent[20] does use the term but does not define it. A definition should however be developed as a matter of international law.

Somewhat diverging from prevailing understanding[21] I suggest that the definition should not be based on the content of the research or development alone because on the one side results of basic research, e.g. a gene and its functions, can be patented and thereby generate revenue while on the other side applied research may be undertaken without any plan of commercialisation. Rather, the definition of commercial/non-commercial R&D should preferably be based on two conditions: the marketability and the marketing of the R&D results. This means that if marketable material or information is generated and steps are taken to bring it on the market this should be considered as commercialisation[22]; if, on the other hand such information is made publicly available in order to enrich the general body of scientific knowledge, this should not be considered as commercialisation. The related R&D would be non-commercial. However, if marketable information is produced and kept secret this should be regarded as a step towards bringing it on the market.

---

[16] Art. 5 Regulation (EU) 511/2014.

[17] See the quite ambitious provisions on requests for inclusion as well as on verification and checks in Arts. 2-4 Commission Regulation (EU) 2015/1866.

[18] Art. 13 (b) and (d) Regulation (EU) 511/2014.

[19] Art. 4 (3) (b) (iv), Art. 7 (1), Art. 9 Regulation (EU) 511/2014.

[20] It for instance in Art. 8 asks for simplification of access procedures for non-commercial research.

[21] See further v Kries C., Winter G. (2015), 60-74.

[22] The user obligation to declare observation of the access conditions at the pre-marketing stage according to Art. 7/2) Regulation (EU) 511/2014 as specified in Art. 6.

This means in terms of PIC and MAT clauses, if an MAT disallows the commercialisation of R&D results this should be understood to mean that the user is entitled to conduct any R&D including the development of marketable material and information as long as he/she does not keep it secret, apply for a patent right or sell it on the market. Should the provider state wish to prohibit even the generation of marketable information it would need to see this specifically set out in its PIC or MAT.

7 Unsolved problems

In the remainder of this contribution a few more problems of the EU user regime shall be sketched out:

- R&D on bulk commodities: It may be that an organism was first bought as a commodity for consumption or other use and only later made an object of R&D on its genetic programme. The problem is if 'access' also covers this or is confined to the taking of a sample from nature, a market or a collection. The Regulation (EU) 511/2014 defines access as acquisition. This appears to exclude later changes of use from consumption to R&D. It is an open question if this is compatible with the terminology of the Nagoya Protocol.
- Multi-causal development of products: R&D on genetic resources can be long and involve a multitude of different genetic resources. This is particularly evident in animal breeding where multiple stages of reproduction may diminish the influence of an original contribution. In such cases, it can be doubted that there is still a 'benefit arising from the utilisation of genetic resources'.[23] The text of Regulation (EU) 511/2014 does not give an explicit answer. But the exclusion of minimal contributions from benefit-sharing claims could be inferred applying the general legal principle "de minimis non curat praetor" and referring to the stipulation in Article 5 Nagoya Protocol that benefit-sharing shall be fair and balanced. Things are different if the original trait and its function are still noticeable, even after a long chain of reproduction.
- Digital sequence information (DSI): It has become common practice to sequence the genome of an organism and upload the data to databases. Most of these are publicly accessible so that anyone can download them, do their own research, synthesise genes and develop their own products. If a provider state in the access agreements prohibits any sequencing, or the uploading of the sequence data to public databases, or the commercialisation of the data, is the EU entitled to doubt or deny that this is compatible with its obligation under Article 8 Nagoya Protocol to facilitate non-commercial research and thus let related clauses in PIC and MAT unenforced? Must the EU develop legislation mandating databases located within the EU (or used by EU based R&D) to transport any use restrictions with the data in order to ensure benefit-sharing with the provider state?[24]

8 Regime alternatives

Given the difficulty in determining the benefits obtained from the use of genetic resources, more thorough reflection is needed on the possible alternatives to the bilateral concept 'benefit-sharing in exchange for access' propounded in the Nagoya Protocol. A number of multilateral approaches to the sharing of benefits from the utilisation of genetic resources should be discussed, such as cooperation in R&D, regional or species specific pools of ge-

[23] See further Marie Schloen in this volume.

[24] See further Chris Lyal in this volume.

netic resources and related information, publicly accessible databases enriched by information about provider conditions, etc.[25] On the long run it appears that systems allowing for free utilisation of any genetic resource, giving up direct links between provider state and final products should be considered. In such system products from genetic resources would be subject to a charge which flows into a global fund or regional or species-related funds from which nature protection is financed and provider states are supported that are engaged in the conservation of genetic resources.[26] The EU may consider to further explore and promote this idea.

References

C. v Kries, G. Winter (2015), Defining commercial and non-commercial research and development under the Nagoya protocol and in other contexts, in: E. Chege Kamau, G. Winter, P.-T. Stoll (eds.) Research and development on genetic resources. Public domain approaches in implementing the Nagoya Protocol, London (Routledge), 60-74.

E. Beck (2015) Experiences in international ecological/biological research in E. Chege Kamau, G. Winter, P.-T. Stoll (eds.) Research and development on genetic resources. Public domain approaches in implementing the Nagoya Protocol, London (Routledge), 165-174.

E. Chege Kamau, G. Winter (2013) (eds.) Common pools of genetic resources. Equity and innovation in international biodiversity law, London (Routledge), 193-223.

G. Winter (2013) Common pools of genetic resources and related traditional and modern knowledge, in E. Chege Kamau, G. Winter (eds.) Common pools of genetic resources. Equity and innovation in international biodiversity law, London (Routledge), 3-25.

H. I. Boga (2015) Local scientist's experience with bioscience research authorization process in Kenya: need for facilitation in E. Chege Kamau, G. Winter, P.-T. Stoll (eds.) Research and development on genetic resources. Public domain approaches in implementing the Nagoya Protocol, London (Routledge), 181-192.

[25] See further the various contributions in Kamau E.C., Winter G. (2013) (eds.) at 221-222.

[26] Winter G. (2013) at 23.

Chapter 17

Disentangling Due Diligence – Making sense of the EU Regulation 511/2014 transposing the Nagoya Protocol

Christine Godt & Markus Burchardi

1 Due Diligence

The European Union transposed the CBD-Nagoya Protocol of 2010 by way of Regulation (EU) No. 511/2014.[1] It rests on the so called 'due diligence' concept. The central norm Art. 4.1 Reg. 511/2014 stipulates:

> "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."

Its rationale is that the EU does not directly apply and enforce provider states' measures.[2] A direct enforcement of provider states' norms would, so the argument goes, violate the territoriality principle.[3] Instead, it installs a 'duty to comply' as a sui generis duty under EU law. Yet, what does this mean? What needs to be done to 'exercise due diligence'? What is the standard of care? Who decides what is necessary and sufficient, especially in the light of Art. 4.5 Reg. 511/2014, which reads:

> "When the information in their possession is insufficient or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation."

2 Different roots and common ground

The due diligence duty came about as a compromise formula which attracted the approval of many stakeholders.[4] It became acceptable to various political camps, industry and non-governmental organisations alike. This was possible because the term 'due diligence' has different connotations for different audiences. For international public lawyers, the term resonates with a long-lasting debate about state liability.[5] For European lawyers, the term has become fashionable in the emerging field of corporate social responsibility (CSR) Regulations in various sectors.[6] Corporate lawyers associate 'due diligence' with the established

---

[1] Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 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, OJ L 150, 20.5.2014, 59–71.

[2] On this earlier idea of how 'user measures' are to be installed: Barber, C. S., Johnson, S., Tobin, B. (2003).

[3] This principle is conceptualised as fundamental to public law. In contrast, private international law is based on comity and regulates via a set of rules ('conflict of law rules') stipulating under which conditions and to which extent a national judge will apply foreign law, see Kegel, G., Schurig, K. (2004), at pp. 135 et seq.

[4] COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT (2012), at pp. 44, 51; ICC Document "Nagoya Protocol Implementation in the EU".

[5] E.g. ILA Study Group on Due Diligence First Report (2014), at pp. 2 et seq. See also Kulesza, J. (2016), at pp. 3, 115 et seq.

[6] Council Regulation (EC) No 2368/2002 of 20 December 2002 implementing the Kimberley Process certification scheme for the international trade in rough diamonds, OJ L 358, 31.12.2002, p.28; Regulation (EU) No

business practice to thoroughly check documentation prior to a transaction, which rests on specific liability rules in International sales law.[7] Thus, while a single term found its way into the Regulation, it is not at all clear what the specific content of due diligence is in the concrete context of the new Regulation 511/2014. The problem of compromise is amplified by the background of the discussion surrounding legal transplants. While some authors conceive the adoption of new legal concepts as the central driver of socio-legal progress, system theory scholars maintain that a legal system cannot 'adopt' a concept. At best, new concepts 'irritate'. Put pointedly, the counter position follows the argument that it is not the transplant, which changes the law, but inversely, it is the surrounding law – in this case EU law – which will change the transplant.

The common ground of the various ideas of the political stakeholders appears to be the notion of due diligence as industrial self-governance. Our ongoing component project to the DFG-project directed by Evanson Kamau looks more profoundly into the various concepts, which were amalgamated in Art. 4.1 Reg. 511/2014. It looks into the adjudication of due diligence by international arbitral courts and tribunals, into the adjudication of the Internal Court of Justice as regards state liability, and, in more depth, into various EU Regulations.

3 A unique European quality sui generis

We scrutinized several EU Regulations[8] that can be identified as 'due diligence regimes'. While sharing certain structural elements, these regimes still differ in their overall architecture and (self-) regulatory thrust. Yet, together they form the background and make up today's legal environment in which Art. 4.1 Reg. 511/2014 is to be interpreted as autonomous EU law sui generis. The central question thus becomes: What exactly constituted the (European) compromise? What is due and who decides in case of a dispute between authorities and industry?

In our research, we identify 'EU due diligence' as a distinct instrument with a unique function, which draws on three distinct normative legacies stemming from public international law, international business law and EU law. Its function is that of a hinge joint: Provider states' laws are not applied as such, but Art. 4.1 Reg. 511/2014 rather 'translates' the 'prohibition' under foreign law into a domestic duty to only utilize 'legally acquired material'. The norm has the function of a (classical) conflict of laws rule. Art. 4.1 Reg. 511/2014 'opens the door' for the application of foreign law and proceduralises its enforcement. Insofar as it does not pre-define the substance/the result/the outcome of said application, and thus only

995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market OJ L 295, 12.11.2010, p. 23–34; Regulation (EU) 2017/821 of the European Parliament and of the Council of 17 May 2017 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and highrisk areas, OJ L 130, 19.5.2017, p. 1–20.

[7] Due diligence in the corporate world can be equated with the defence requirement in Arts. 38-40 United Nations Convention for the International Sale of Goods (UN CISG) to 'give timely notice'. Regarding the structure of the various types of due diligence in the process of acquiring a company or its assets, see Bainbridge, S.M., Anabtawi, I. (2017), at pp. 255 – 263.

[8] Apart from the 'supply chain' Regulations already mentioned under fn. 6 supra, we scrutinized Regulation (EU) 2015/757 of the European Parliament and of the Council of 29 April 2015 on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport, and amending Directive 2009/16/EC OJ L 123, 19.5.2015, p. 55–76; Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, 4.5.2016, p. 1– 88; Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1–175.

provides for a normative yardstick to evaluate user behaviour, we see the influence of the preceding debate on due diligence in public international law. In this sense, Art. 4.5 Reg. 511/2014 provides for time and leeway for communication between the regulator and the user. As such, it installs a vertical (user country sui generis) 'duty to produce (diagonal) compliance'. The user may take efforts to re-negotiate PIC and MAT with foreign agencies. In case of problems, he/she may consult with domestic agencies. The duty to produce compliance finds its limits in the real world, where agencies in other countries do not respond or have fallen apart for political reasons. These considerations are to be taken into account; a nuanced decision can be taken by the responsible user state agency.

In the business world, due diligence denotes the practice of conducting ex ante inquiries into a target company or its assets prior to a takeover. Here, the objective standard of corporate liability prescribes 'what ought to be done, needs to be done'. The subjective standard of 'what ought to be known' is determined ex post. Proving that all reasonable investigative efforts (to identify non-hidden defects) were exhausted can be a valuable defence, thus forcing the buyer to install an appropriate risk-management system. This is the corporate law legacy of EU due diligence.

In addition, EU due diligence sees an added layer of regulatory legacy stemming from the Community's own regulatory environment that the concept of due diligence was transplanted into. Said legacy relates to notions of industrial self-governance, orchestration by the state, the consequences of using regulatory intermediaries (or lack thereof), and here in particular the peculiar role of (registered) collections.

Combining those three legacies mentioned above, we developed five qualifications of the sui generis due diligence duty under Art. 4 Reg. 511/2014:

- First, the duty to discontinue in Art. 4.5 last sentence Reg. 511/2014 is a substantive (not a procedural) obligation, which implies that the time window for efforts to remedy an incompliant situation is not open ended and is not at the discretion of industry.
- Second, there is no shift of responsibilities. Due to a lack of industrial engagement in norm-building and enforcement, a 'risk absorber' for industry is non-existent. These elements translate into a strong role for national competent authorities (NCAs).
- Third, the subjective standard of care ('what ought to be known'), in particular the exact terms of risk evaluation and risk management, depends on the professional standard of the respective industrial sector.
- Fourth, a firm's individual capacities (e.g. experience, time or money) are not seen as valuable defences regarding the procedural duties.
- Fifth, the Regulation creates a double (non-identical) duty as regards the objective standard of care ('what ought to be done'). The duty to comply under foreign law is complemented by a domestic duty to only use legal material. These duties are intertwined. The restricted scope of the EU-Regulation (e.g. material accessed on the territory of a NP-signatory) reduces the pressure of compliance. On the other hand, it creates administrative burden where provider states do not regulate. In turn, the domestic duty may ease the regulatory burden where PIC is not available, but a discontinuation of utilisation would be un-proportional.

References

S.M. Bainbridge, I. Anabtawi (2017). Mergers and Acquisitions. A Transactional Perspective. Foundation Press LEG. St. Paul. Minesota.

C.S. Barber, S. Johnson, B. Tobin. (2003). User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity. UNU-IAS. Tokyo.

European Commission (2012). Commission Staff Working Document Impact Assessment Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, Part 2 - Annexes, SWD(2012)292 final. Available at: https://eur-lex.europa.eu/resource.html?uri=cellar:7ad11d44-b4ea-4684-a519-268a2fc4c0bc.0001.02/DOC_2&format=PDF.

International Chamber of Commerce (ICC) (2012). "Nagoya Protocol Implementation in the EU". Document No. 450/1075. Available at: https://www.icc-portugal.com/images/documentos/Propriedade_Intelectual/2012_Nagoya_Protocol_Implementation_in_the_EU__Comments_on_a_possible_due_diligence_system_and_the_EU_Timber_Regulation.pdf.

International Law Association (ILA) (2014). ILA Study Group on Due Diligence in International Law: First Report. Available at: https://olympereseauinternational.files.wordpress.com/2015/07/due_diligence_-_first_report_2014.pdf.

G. Kegel, K. Schurig (2004). Internationales Privatrecht. 9th ed. München: Beck.

J. Kulesza (2016). Due Diligence in International Law. Nijhoff Brill. Leiden. The Netherlands.

Chapter 18
Implementation of Due Diligence obligations in Germany

Thomas Greiber

1 The Due Diligence system established by the EU ABS Regulation

Regulation (EU) No 511/2014 of the European Parliament and of the Council 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 entered into force on 9 June 2014 and applies as of 12 October 2014, the date the Nagoya Protocol itself entered into force for the European Union. The EU Access and Benefit-sharing (ABS) Regulation aims to implement the compliance provisions of the Nagoya Protocol, in particular its Articles 15–17, through a Due Diligence system which is composed of different measures and instruments:

- A general Due Diligence obligation under Article 4 of the EU ABS Regulation which obliges all users of genetic resources and traditional knowledge associated with genetic resources to ascertain that their utilisation is in accordance with applicable ABS legislation or regulatory requirements of the provider state and that benefits are fairly and equitably shared upon mutually agreed terms (MAT).
- The obligation to file Due Diligence declarations at two different points in time, at the stage of research funding (Article 7.1) and at the last stage of product development (Article 7.2).
- Compliance checks which shall be undertaken by the designated competent authorities of EU member states following risk-based control plans and/or substantiated concerns (Article 9).
- Furthermore, two options are foreseen for users to mitigate their risk of non-compliance. The first option is receiving genetic resources or associated traditional knowledge from a collection which is listed in the voluntary EU register of collections and thereby demonstrates its capacity to provide evidence of legal access and the establishment of MAT (Article 5). The second option is the application of best practices which have been recognised by the European Commission and shall enable users to comply with their Due Diligence obligations (Article 8).

2 Implementation of the EU Due Diligence system under German Law

In Germany, the EU ABS Regulation is supplemented by the Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No 511/2014 which entered into force on 1 July 2016. The German Implementing Act designates the Federal Agency for Nature Conservation (Bundesamt für Naturschutz – BfN) as the competent authority which is in charge of undertaking compliance checks, receiving Due Diligence declarations, handling applications for registration as well as providing ABS advice to users. Furthermore, the Act establishes possible response measures to address situations of non-compliance: orders to remedy breaches of ABS laws, prohibition of utilisation, seizure and confiscation of unlawfully utilised genetic resources as well as sanctions through administrative fines.

Since its designation as the competent authority in 2016, BfN has gained first valuable experiences with the implementation of the different pillars of the Due Diligence system in Germany.

Due Diligence Declarations

The first Due Diligence declarations filed in the EU were submitted to BfN in 2018. Afterwards these declarations became the first checkpoint communiqués worldwide to be published on the ABS Clearing-House. As of September 2019 a total of 11 declarations were submitted to BfN and 7 out of currently 15 checkpoint communiqués on the ABS Clearing-House come from Germany. A critical step that triggered this development was the publishing of a general decree by BfN in May 2018 which made the filing of Due Diligence declarations under Article 7.1 of the EU ABS Regulation mandatory.

It is important to note that so far all Due Diligence declarations submitted in Germany fall under Article 7.1. In contrast, declarations under Article 7.2 of the EU ABS Regulation, which are already obligatory EU-wide since 9 November 2015 when the Implementing Regulation (EU) 2015/1866 entered into force, have not been filed yet. One of the reasons for the lack of Article 7.2 declarations could be that the EU ABS Regulation only applies to genetic resources which were accessed after 12 October 2014, while the final development of products from such resources will probably take longer than 5 years.

After receiving a Due Diligence declaration BfN checks the completeness and timeliness of the declaration. Furthermore, a plausibility check of its content will be undertaken which may lead to further queries. Such plausibility checks, however, can be challenging as ABS permits and agreements are not internationally standardised and therefore differ substantially from one country to another. As a result, it is sometimes difficult to assess whether a document submitted as proof of legal access provides for an actual ABS permit/agreement or not.

Once a Due Diligence declaration is converted into a checkpoint communiqué and thus submitted to the ABS Clearing-House as well as the provider state, a bilateral communication between BfN and the provider state is launched. If the provider state as the recipient of the communiqué reports irregular practices or ABS concerns, BfN may become active again.

Compliance Checks

In 2018, BfN also started with its first round of compliance checks. Up to now, 43 companies from 4 different sectors (pharma, cosmetics, biotechnology as well as food and feed) were identified through a risk-based selection process. 40 additional institutions from the plant breeding, animal breeding, biocontrol as well as academic research sectors will follow in the near future. One further institution from the academic research sector was selected based on substantiated concerns.

Before the institutions are contacted a severe background analysis is undertaken by BfN in order to establish a (potential) user profile. For this, annual reports containing data on R&D company sites, expenses and strategies, databases leading to publications and patents related to genetic resources, as well as company homepages and other internet sites comprising information on products as well as bioinnovation processes are evaluated in view of ABS relevance. Each institution is then approached by mail and provided with a two-part questionnaire containing a set of general as well as specific ABS compliance questions. The general questions on ABS policies, procedures and best practices adopted as well as responsible ABS persons identified aim to raise and at the same time test internal Nagoya Protocol awareness. The more specific questions which follow address the issues of access

to and utilisation of genetic resources in order to find out whether an institution falls within the scope of the EU ABS Regulation or not. The filled out questionnaires may lead to further queries, investigations or even on-the-spot checks to clarify open questions. So far, this written procedure has led to on-the-spot checks in 4 companies from different sectors.

Compliance checks based on substantiated concerns again may be triggered by hints which were given to BfN by provider states or even competitors and NGOs for example. While this type of controls has a higher probability of identifying institutions within scope of the EU ABS Regulation or even detecting irregular practices, for the time being concerns were only raised in one case.

Registration of Collections

The EU register of collections is envisaged as an important tool to bring ABS transparency and legal certainty into R&D chains. Nevertheless, in Germany (and the whole EU) only one collection (the Leibniz Institute DSMZ – German Collection of Microorganisms and Cell Cultures GmbH) has applied for registration so far. Although this first application process was successful, no other collection has followed yet. As a voluntary survey of German collections (undertaken by BfN in 2018) seems to indicate the reasons for this slow start may be manifold ranging from general unawareness about the instrument of registration and its legal requirements to lack of financial resources, fear of increased bureaucracy and lack of clarity about the opportunities and threats in practice. As a consequence, BfN has decided to continue its ABS awareness-raising and capacity-building activities for German collections.

3 Conclusions

While the EU ABS Regulation is already in force for 5 years now, it is still a fairly new legal instrument which requires more time and implementation experiences to reach its full operationalisation. First experiences have already been gained in Germany revealing, however, a number of challenges and open questions which are not only due to the novelty of the instrument but also due to the extraordinary subject matter that it deals with. ABS and particularly ABS monitoring is marked by several complexities: transboundary situations and the objective to uphold third country legislation; very diverse sectors involved in highly innovative research and development activities; complicated and not always transparent supply chains etc.

Nevertheless, some positive developments triggered by the start of the EU ABS Regulation implementation can be noted already at this early stage. For example, suppliers of genetic resources seem to face increasing pressure by institutions that aim to use the resources for research and development activities and therefore require ABS transparency. Within companies and research institutions ABS and Due Diligence frameworks seem to be developing. Clarifying internal ABS responsibilities or developing policies and operation procedures are initial but very important steps in this context.

Overall it can be concluded that ABS awareness-raising is increasing which is the key prerequisite for ABS Due Diligence and Nagoya compliance in the future. Still, more work is ahead of all actors, including BfN as the competent authority in Germany.

Chapter 19
Current situation on Digital Sequence Information (DSI)

Christopher H C Lyal

1 Introduction

For a number of years some countries have been proposing that 'Digital Sequence Information' (DSI) be treated as the equivalent of genetic resources within the Convention on Biological Diversity, and therefore should be covered by the provisions of the Nagoya Protocol. This has led to discussions and protracted negotiations in CBD COP 13 / MOP 2 and CBD COP 14 / MOP 3. To inform these discussions the CBD has sought submissions from governments and other stakeholders, and commissioned reports on aspects of the issue. The latest such reports are currently being prepared, and submissions can be found on the CBD website.[1] The CBD is due to discuss the issue again at the next COP in 2020.

At the same time as CBD Parties have been debating this issue, rights over DSI (or apparently similar concepts) have also been discussed in other fora, particularly the International Treaty on Plant Genetic Resources for Food and Agriculture, the Commission on Genetic Resources for Food and Agriculture, the World Health Organisation [particularly in the context of the Pandemic Influenza Preparedness (PIP) Framework], and the UN-UNCLOS process in developing an international legally binding instrument under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction. Although most of these deliberations are unlikely to reach conclusions before the CBD, and are waiting until such a decision is reached before finalising their understandings, the UN-UNCLOS process is time bound and is likely to reach a decision prior to CBD COP 15. There seems little exchange between key actors in the two negotiations.

The main reason why DSI has been proposed by some providing countries as coming under the CBD and NP is the (disputed) proposition that DSI is the 'intangible equivalent' of physical genetic resource and as such fall under the sovereign rights of the country from which the original genetic resource was accessed. There is an understanding that publicly-available genetic sequences can be downloaded from databases, a physical sequence recovered by use of a DNA printer and synthetic biology techniques used to deliver the gene product. This would potentially avoid benefit-sharing obligations that would be entered into were the gene to be obtained from a genetic resource accessed in a provider country.[2] There are also arguments that DSI can be considered as a derivative in the meaning of the Nagoya Protocol, or even could fall under the Intellectual Property Rights (IPR) of a country. The latter two points will not be discussed here.

2 What is Digital Sequence Information on genetic resources?

A key question that has not yet been answered satisfactorily is on the nature of DSI – just what is it? While the term is a handy catch-all in CBD discussions it is not used anywhere else, at least in the scientific world, and the CBD process has failed to define it. Consequently everyone using the term is free to have a different interpretation. There are two broad approaches to understanding the meaning of DSI, 'inclusive' and 'exclusive'. The inclusive methodology has been followed by many to date, and poses the question "What

[1] SCBD 2019.

[2] Hammond 2017.

are all of the concepts this term could encompass?" In contrast, the exclusive approach asks "If DSI were to be agreed to fall under the CBD as an intangible equivalent to genetic resources, what could it include (and what would have to be excluded)?"

The inclusive approach was followed by the CBD Ad-hoc Technical Expert Group (AHTEG) on DSI in 2017, and led them to produce a long list of types of information that "may be relevant"[3] [which has since been reproduced by Costa Rica in its 2019 submission on DSI[4]]. This list, with the addition of a few aspects raised in the 2019 submissions to the CBD on DSI, includes:

Relating to DNA and RNA. This would include nucleotide sequence data, structural annotation of the DNA in genes, functional annotation (i.e. the properties of the genes) and associated data (technical aspects of sequencing experiments: the sequencing libraries, preparation techniques and data files).

Relating to derivatives. This would include the amino-acid sequence of proteins produced from gene expression and the molecular structures of gene products and derivatives.

Epigenetic heritable elements. Not all heritability is encoded in the genes themselves, but some heritable factors have been found elsewhere in the cells. Mexico and Argentina in the 2019 submissions on DSI mentioned one of these, Methylation patterns.[5]

Contextual information (metadata). This may help interpret the function of the genes, and includes (according to AHTEG) ecological relationships; abiotic factors of the environment; function, such as behavioural data; structure, including morphology and phenotype; taxonomy and modalities of use.

Wider information. The Synthesis of Views document produced by the CBD Secretariat from the submissions on DSI in 2018[6] included even wider concepts; one NGO had included biomimicry. Another inclusion in the list, mentioning even wider concepts (phyllotaxis, colouring etc.) was taken out of context from a submission indicating such things could not be included. In the 2019 submissions of the African Union considered DSI as "a continuum that starts with raw genetic sequence data obtained from primary scans of naturally occurring sequences and then progresses through compiled whole genomes to annotated or isolated functional genes, eventually culminating in useful discoveries and/or inventions that can be patented and/or used for gene editing or other forms of genetic manipulation." It suggests using this "in the context of negotiating differentiated benefit-sharing rates for different classes of natural information utilisation" thus taking a very broad view of 'natural information'.[7] While the negotiation priority of provider countries has focussed increasingly on benefit-sharing, it is still critical for legal certainly to understand the basis on which benefits should be shared – the nature of DSI.

In contrast, the exclusive approach is based on the argument that DSI falls under the sovereign rights of the provider country as the equivalent of a genetic resource. If this argument is to be followed, the concept of a genetic resource as understood under the CBD needs to be examined and a strict analogy between the genetic resource and DSI understood. A genetic resource when accessed in situ is generally an organism (or virus). It is

[3] SCBD 2018b.

[4] SCBD 2019.

[5] SCBD 2019.

[6] SCBD 2018a.

[7] SCBD 2019.

accessed with no visible intrinsic 'information'– it is simply an organism, and data about its 'genetic and/or biochemical composition' (Nagoya Protocol Art. 2) have to be generated using post-access analysis – utilisation. This observation immediately indicates that anything involving gene properties is not the intangible equivalent of a genetic resource, but is rather the result of utilisation. The term 'information' in DSI is of particular significance. Information and data are not strictly synonyms. Information is developed through cognitive processing of data, whereas data may be understood as simple observations. Consequently, information may in some situations be subject to IPR. The sovereign rights of a country do not cover the IPR of someone in another country. IPR is often a component of ABS negotiations[8] and, notably, the Annex to the Nagoya Protocol lists as one of the possible shared benefits: "Joint ownership of relevant intellectual property rights".[9] Although nucleotide sequence data (NSD)[10] cannot be patented, gene functionality can be patented under many jurisdictions (at least when accompanied by a use),[11] and thus by this measure the entity taking out the patent is assigned IPR. From this it is clear that gene functionality cannot a priori fall under the sovereign rights of providers, and because of this should be excluded from the discussion of DSI. To return to the comparison of access to a genetic resource and 'access' to DSI, the key feature of genetic resources (genetic material) in the CBD definition is the inclusion of 'functional units of heredity'. Thus, if 'access' to DSI is to be deemed the equivalent of access to genetic resources then the analogy is with a 'functional unit of heredity', which, when the CBD was negotiated, was understood to be genes. In this case, the closest functional analogy between a genetic resource and an intangible equivalent is with NSD.

Epigenetic heritable factors such as methylation patterns have been mentioned, but rather than include this in current negotiations it might be less confusing to discuss this aspect in a separate negotiation, to be resolved finally once the core decision on whether NSD fall under the CBD or not is resolved.

Another repeated assertion in submissions to the CBD is that the amino acid sequence data in proteins falls within DSI.[12] These are in a way analogous to nucleotide sequence data, but, critically, they are not units of heredity. They should instead be considered as intangible equivalent of derivatives. Derivatives have a somewhat ambiguous position under the Nagoya Protocol, being mentioned in the Use of Terms (Art. 2) but not elsewhere. As with epigenetic heritable factors, it seems useful to consider this as a separate negotiating strand, dependent on the decision taken on NSD.

3 How could DSI fall under the Nagoya Protocol?

The Nagoya Protocol to the CBD must use the same concepts and rationale of the CBD. Currently DSI might be discussed within the CBD as a benefit to be shared following its development through utilisation of a genetic resource, or as a tool to assist implementation of the CBD. However, neither of these are the same as discussing use of DSI as itself re-

[8] WIPO 2018.

[9] SCBD 2010.

[10] Nucleotides are the subunits that are connected into long chains to make nucleic acids (DNA and RNA). The four types of nucleotides in DNA are Adenine, Thymine, Guanine, and Cytosine, and in RNA Thymine is replaced by Uracil. The five nucleotides are usually abbreviated to A, T, G, C and U. The order in which these nucleotides occur in a strand of DNA or RNA is the DNA or RNA sequence or Nucleotide Sequence.

[11] Nicol et al. 2019.

[12] SCBD 2019.

quiring benefit-sharing. Rights to benefit-sharing from the use of DSI can only arise if DSI is itself a natural (biological/genetic) resource. The CBD recognises only one sovereign right: "States have sovereign rights over their own biological resources" (CBD preamble). 'Biological resources' are a contextual subset of 'natural resources', the sovereignty over which was recognised under UN GA resolution 1803 (XVII) – "Permanent Sovereignty over Natural Resources". Biological resources of course include genetic resources under CBD Article 2. If the argument that DSI is the intangible equivalent of genetic resources (or genes) is accepted, DSI would fall under CBD Art. 15 and consequently under the Nagoya Protocol; it cannot in this circumstance be covered by the CBD and not the Nagoya Protocol.

There is no evidence from wider discussions that information (or data) is a natural resource as set out in UN GA resolution 1803 (XVII). The rationale of DSI being accepted as the equivalent of a genetic resource must therefore be interpreted under the terms of the Vienna Convention on the Law of Treaties.[13] Article 31 (1) of that treaty states that "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose" (my underline). However, there is no consensus that the ordinary meaning of gene is 'information', but rather there is considerable disagreement on this point. Article 32 of the Vienna Convention states that "Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion". DSI was discussed (under different terminology) in the development of the Bonn Guidelines,[14] in an expert group on the meaning of 'derivatives' and in the development of the Nagoya Protocol.[15] However, the concept was not included in the final texts, which limited coverage to physical material, suggesting that it was intentionally excluded. If DSI is not covered by the CBD it cannot be covered by the subsidiary Nagoya Protocol. There are legal opinions supporting both alternatives,[16] so the ultimate decision is a political one.

4 DSI under provider country legislations

Some countries, for example Brazil, Ethiopia, Malawi and South Africa, now cover DSI in enacted or draft national legislation. However, there is little explanation of what the term covers in these instruments. Most do not explore practical implementation of their legislation, although in at least some cases the focus is on rights over DSI generated under new access agreements for physical genetic resources, where rights would be in contractual terms (PIC and MAT). However, as stated by Ethiopia in its 2019 submission to the CBD on DSI "it is unclear how PIC would be obtained for sequence information from Ethiopian genetic resources (which may not be identified as such) which are already available in publicly and privately accessible databases hosted outside of Ethiopia. In addition, it is not evident how non-compliance with the PIC requirement for such sequence information would be tracked, or how benefit-sharing obligations apply for both non-commercial and commercial uses of DSI" (Ethiopia in AU submission[17]).

[13] United Nations Conference on the Law of Treaties 1969.

[14] SCBD 2002.

[15] CBD 2008.

[16] Sollberger 2018; Spranger 2017.

[17] SCBD 2019.

5 Conclusion

The concept of Digital Sequence Information should be limited to nucleotide sequence data (NSD) however stored and mediated, and possibly its structural annotation. This would provide clarity for negotiations and in discussion. It includes the main issue for DSI, but excludes (i) elements that may cause contention and confusion in negotiations and (ii) intellectual property rights, which are likely not to be covered by the sovereign rights of provider countries. Rights over data on the composition of derivatives and on epigenetic heritable factors should be discussed separately and ideally finalised only if the principle of DSI (NSD) falling under the CBD is agreed. Because there is no unequivocal inclusion of DSI under the CBD, and hence not under the Nagoya Protocol, under international law this will require a policy decision. National law may explicitly state rights over DSI but means of implementing these are currently vague. Similar difficulties will be attendant on implementing any coverage of the Protocol over DSI, and means to manage this would need to be considered if the COP decides that DSI are, indeed, the equivalent of genetic resources.

References

E. Hammond. 2017. “Gene Sequences and Biopiracy: Protecting Benefit Sharing as Synthetic Biology Changes Access to Genetic Resources.” Third World Network Briefing Paper 93, 1–4.

D. Nicol, C. Rochelle, E. Dreyfuss, R. Gold, Wei Li, J. Liddicoat, and G. Van Overwalle. 2019. “International Divergence in Gene Patenting.” Annual Review of Genomics and Human Genetics 20 (1): 1–23. https://doi.org/10.1146/annurev-genom-083118-015112.

SCBD. 2002. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization. Montreal: Secretariat of the Convention on Biological Diversity. https://doi.org/10.1080/14888386.2007.9712830.

SCBD. 2008. “Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches.” https://www.cbd.int/doc/meetings/abs/abswg-07/official/abswg-07-02-en.pdf.

SCBD. 2010. “The Nagoya Protocol on Access and Benefit-Sharing.” Web Pages. 2010. https://www.cbd.int/abs/.

SCBD. 2018a. “CBD/SBSTTA/22/INF/2: Synthesis of Views and Information on the Potential Implications of the Use of Digital Sequence Information on Genetic Resources for the Three Objectives of the Convention and the Objective of the Nagoya Protocol.” Montreal.

SCBD. 2018b. “CBD/SBSTTA/22/INF/4; CBD/DSI/AHTEG/2018/1/4: Report of the Ad Hoc Technical Expert Group on Digital Sequence Information.” Montreal.

SCBD. 2019. “Submissions of Views and Information on Digital Sequence Information on Genetic Resources.” SCBD Website. 2019. https://www.cbd.int/abs/dsi-gr/2019-2020/submissions.shtml.

K. Sollberger. 2018. “Digital Sequence Information and the Nagoya Protocol. Legal Expert Brief on Behalf of the Swiss Federal Office for the Environment (FOEN).” https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/rechtsgutachten/digitale-sequenzinformationen-nagoya-protokoll-rechtliches-gutachten.pdf.download.pdf/20180407_kurzgutachten-digitale-sequenzinformationen_final.pdf.

T.M. Spranger. 2017. “Expert Opinion on the Applicability of the Convention on Biological Diversity and the Nagoya Protocol to Digital Sequence Information. Submitted on Behalf of the German Federal Ministry of Education and Research, Berlin.”

United Nations Conference on the Law of Treaties. 1969. Vienna Convention on the Law of Treaties. Vienna Convention on the Law of Treaties. https://doi.org/10.1007/978-3-642-19291-3.

WIPO. 2018. A Guide to Intellectual Property Issues in Access and Benefit-Sharing Agreements.

Chapter 20

The persistence of ABS contractual obligations in the context of agricultural breeding

Marie Schloen

1 Applying the contractual ABS approach to agricultural breeding

The Convention on Biological Diversity (CBD) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) establish a contractual approach to access and benefit-sharing (ABS), based on regulating access to genetic resources.

The third objective of the CBD, the fair and equitable sharing of benefits arising out of the utilisation of genetic resources[1], could have been organized in many different ways. One way would, for example, have been to require users of genetic resources to make contributions to an international fund for biodiversity conservation and sustainable use, independent of the specific genetic material used and of its origin. Instead, a so-called bilateral case-by-case approach was followed, based on regulating access to genetic resources. Derived from the principle of national sovereignty over natural resources, the CBD stipulates that the "authority to determine access to genetic resources rests with the national government and is subject to national legislation".[2] While the development of concrete arrangements and mechanisms for granting access to genetic resources and ensuring the sharing of benefits arising out of their use is left to national governments, the CBD introduces two concepts of a more general nature that should govern access to genetic resources. It establishes that access to genetic resources shall be subject to the prior informed consent (PIC) of the Contracting Party providing the resources,[3] and that it is to be granted based on terms agreed mutually between the provider and the recipient of the resource (mutually agreed terms – MAT).[4] Thus, the approach is bilateral in so far as it foresees potential recipients of genetic material seeking PIC and agreeing on the terms and conditions of access and benefit-sharing with those contracting parties actually providing the genetic resources in question. It is a case-by-case approach in so far, as there are no predefined terms of access and benefit-sharing, and they rather have to be agreed upon for each transaction individually. However under the CBD, contracting parties are free to make use of their authority to determine access to genetic resources by entering them in a multilateral system. Under the International Treaty on Plant Genetic Resources for Food and Agriculture, contracting parties have for example pooled some of their genetic resources in a Multilateral System.[5] They grant PIC for all resources within the Multilateral System (MLS) based on MAT that have been agreed upon multilaterally and that are enshrined in a Standard Material Transfer Agreement to be used whenever genetic resources from the MLS are accessed.[6] Apart from the Treaty's notable exception, legal frameworks implementing the CBD's ABS provisions usually pursue a purely bilateral case-by-case approach.

---

[1] CBD, Article 1.

[2] CBD, Article 15.1.

[3] CBD, Article 15.5.

[4] CBD, Article 15.4.

[5] International Treaty on Plant Genetic Resources for Food and Agriculture, Article 10.

[6] International Treaty on Plant Genetic Resources for Food and Agriculture, Article 12.

The Nagoya Protocol aims at furthering the implementation of the third objective of the CBD and sets out far more specific obligations for Contracting Parties, in particular regarding the granting of access to genetic resources and the support of compliance with domestic legislation of the state providing genetic resources and with contractual obligations reflected in MAT.[7] In doing so, the Nagoya Protocol seems to build upon and solidify the contractual approach to ABS that was to a certain extent already implied in the CBD. It relies on private contracts concluded between the national competent authority of the providing country and the natural or legal person receiving the genetic material. The contracts, often called material transfer agreements, contain the MAT, including inter alia: terms of benefit-sharing; monitoring and reporting requirements; terms on subsequent third-party use; terms on changes of intent; dispute settlement clauses. Benefit-sharing obligations can relate both to monetary and to non-monetary benefits. They are usually triggered by benefits being generated through the use of the specific genetic resource in question.

The established contractual approach to ABS implies that every transferred genetic resource is governed by its own set of contractual obligations. It also means that the downstream destiny of every individual genetic resource needs to be tracked and traced as long as the contractual obligations persist, inter alia in order to: determine the benefits that arose from its utilisation; assign the due share of generated benefits to the individual provider; and control further transfers of the genetic resource to third parties. Interestingly, the expiry of contractual obligations is usually not provided for, neither in temporal nor in material terms. The lack of provisions regarding the expiry of contractual obligations can possibly be explained with the envisioned innovation process. If the innovation process in which a transferred genetic resource is used, is assumed to be definite and linear in nature, with a clear beginning (the genetic resource), a clear end (the product) and a known causal chain between them, there are natural limits to the contractual obligations. The challenge in the context of agricultural breeding is that the innovation process is cumulative and dispersed in nature and does, therefore, not provide such natural limits to the contractual obligations stemming from the exchange of a genetic resource, rendering the downstream tracking of the use of a specific genetic resource increasingly complicated.

2 The innovation process in agricultural breeding

Agricultural breeding is the process of targeted genetic improvement of plant and animal populations used in agricultural production systems. For about 10 000 years plant and animal species have been subject to domestication and artificial selection by humans. Historically, the genetic improvement of agricultural species has been carried out by farmers and livestock keepers through selective breeding within the same populations also used for production. The separation of production and breeding populations has only occurred during the course of the 20th century with the development of a highly specialised breeding sector. However, this specialisation has been restricted to some species and geographical regions, while genetic improvement elsewhere is still carried out in tandem with actual production.

Breeding can be described as a continuous process of genetic improvement in which selection gains accumulate from one generation to another. Under the constant selection pressure, the breeding population is gradually shifted towards the desired performance. While selection reduces the genetic variation of the breeding pool over time, new variation is eventually added through the inclusion of ‘external’ genetic diversity, e.g. through crossing.

[7] Greiber et al. 2012, p. 25.

Thus, breeding is characterised by phases of creation of new genetic variation through the combination of different genetic backgrounds and phases of reduction of genetic variation through the selection of the most desirable genotypes. While the breeding pool will always continue to evolve incrementally and never be newly established 'from scratch', 'unimproved' or 'low-performing', genetic diversity may eventually be included, if it contains particular required traits that cannot be found elsewhere (like a pest resistance), or if the genetic base of the breeding pool needs to be broadened. However, the inclusion of diversity with a long genetic distance from the advanced material is a very complex, expensive and time-consuming effort.

Thus, farmers and breeders improve the populations generation by generation and there is no clear beginning or end point to the innovation process. The products of breeding, be it plant propagating material or breeding animals, actually constitute the basis for the next improvement cycle. Where breeding has been specialised and separated from production, the desire or requirement to be able to sell a 'stable' product has led to the development of somewhat artificial static points within this continuous flow of incremental improvement. An example for such static points is commercial plant varieties, which could be described as a genetic sub-set of the breeding population. This sub-set contains minimal genetic variation and therefore displays a high degree of uniformity among individual organisms, and its genotypic composition and phenotypic expression is kept stable over a certain timeframe, usually the commercialisation period. Even though the specific variety is kept stable over a certain time, incremental improvement continuous on the genetic diversity it contains, both by its original breeder, who will come up with a new further improved variety as soon as possible, and by other breeders who introduce the variety or parts thereof within their own breeding pool.

The genetic diversity used by breeders stems from different sources. First and foremost they make use of the genetic variation contained in their own breeding pools and collections. Second, they obtain genetic material from other breeders, both by using commercialised varieties or breeding animals and by directly exchanging material under development among each other. To a much lesser extent they may also use less-advanced genetic material like traditional breeds or varieties, landraces or even crop-wild relatives, obtained both from in situ and ex situ sources. For the purpose of ABS, it is important to note that the whole range of genetic material used in plant and animal breeding can be labelled as genetic resources.

During the breeding cycle, the genetic set-up of the incorporated genetic material does not remain intact. Through crossing and selection it is split up in its components, mixed with other genetic information and recombined into new set-ups. A part of the genetic components will actually be excluded through selection, while other components will reappear in ever changing combinations. Because the genomes of crop and farm animal species are usually very large, breeders do not handle the full-sequence-information of their breeding material. The described process therefore largely takes place in a 'black-box', without breeders tracking the destiny of all the involved genetic parts and components. With the advance of biotechnology it is however feasible to punctually spot into this 'black-box', by identifying and tracking particular genes or sequences of interest.

To conclude, the innovation process in agricultural breeding is of incremental nature, in the sense that the genetic material is being improved continuously over multiple successive generations and the gains are cumulative. One innovative step is added to another and products are not the final result, but rather an intermediate step in an ongoing chain of improvement, as they can themselves be used as an input to further innovation (and thus be-

come a genetic resource again). In the course of this continuous improvement process, genetic material is frequently exchanged and mixed with other genetic resources.[8] [9]

3 The persistence of ABS contractual obligations throughout the breeding process

As described above, one of the characteristics of the innovation process in agricultural breeding is, that the breeding populations are improved generation by generation and that there is no clear beginning or end to the improvement process. The products developed out of this innovation process, e.g. plant varieties or breeding animals, are themselves going to be used as an input to the next innovation cycle. Thus, a genetic resource that has been transferred under an ABS contract and has been incorporated into the breeding population will not only be used in one innovation cycle and for the development of one product. It will afterwards continue to be used in future breeding cycles and contribute to the development of many further products. The ABS contractual obligations attached to the original genetic resource will move on together with the genetic material and continue to be applied to subsequent innovation cycles and the products developed thereof. This onward movement of the genetic resource and the attached contractual obligations from one breeding cycle to another, from one breeder to another and from one product to another will eventually continue indefinitely in time.

As explained above, throughout the breeding cycle the genetic set-up of the incorporated genetic resource will not remain intact. It will rather be split-up in its components, mixed with other genetic information and recombined into new set-ups. While breeders may be able to track some of the very prominent genetic components of the original genetic resource throughout this process, they will certainly not be able to track the destiny of all the genetic parts and components concerned. Thus, products developed with the use of the incorporated genetic resource do not contain the genetic resource in its entirety, but recombined parts and components thereof that may be specifically known or unknown to the breeder. The genetic components stemming from the genetic resource tend to become more and more diluted with every breeding cycle they pass through. ABS contracts do usually include the utilisation of parts and components of the concerned genetic resource under their coverage, while they do normally not address the different degrees of importance or weight those genetic contributions have. That bears the question if the contractual obligations attached to the original genetic resource will persist in their entirety as long as any genetic component of the original genetic resource is utilised.

As described above, in agricultural breeding phases of reduction of genetic variation through selection alternate with phases of creation of genetic variation through the inclusion of external genetic diversity to the breeding pool. This external genetic diversity can stem from different sources, such as other breeders genetic material (including commercialised one) or less-advanced genetic material from genebanks or in situ collection efforts. In any case, a breeding cycle and the products developed thereof do not rely on only one particular genetic resource, but on a whole range of genetic inputs. If several genetic resources under respective ABS contracts are incorporated in the breeding process, all of the different contractual obligations would apply to the resulting breeding pool and the products developed thereof.

---

[8] FAO Commission on Genetic Resources for Food and Agriculture (2015).

[9] Schloen, M. et al. (2011).

These three aspects together mean that a growing set of different ABS contractual obligations will potentially accumulate from one breeding cycle to another. With every generation a new layer of ABS contracts could be added to the breeding population, without ever reducing any of the former contractual obligations.

As the innovation process in agricultural breeding does not provide any natural limits to the contractual obligations stemming from the exchange of a genetic resource, it appears to be necessary to establish legal limits to address the persistence of ABS contractual obligations, both in the material and temporal dimensions, in order to enable the implementation of the Nagoya Protocol in agricultural breeding.

References

T. Greiber et al. (2012) An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing, IUCN, Gland, Switzerland.

FAO Commission on Genetic Resources for Food and Agriculture (2015): Working Document CGRFA-15/15/Inf.10: Explanatory Notes to the Distinctive Features of Genetic Resources for Food and Agriculture. FAO, Rome, Italy.

M. Schloen, et al. (2011) Access and benefit-sharing for genetic resources for food and agriculture – current use and exchange practices, commonalities, differences and user community needs. Background Study Paper No. 59, FAO CGRFA, Rome, Italy.

Chapter 21

Post Nagoya Protocol experiences of academic biodiversity-related research in Ecuador

Erwin Beck[1]

1 Ecuador as a provider country of genetic resources: The legal background

Ecuador belongs to the Community of Andean Nations (CAN) and hence participates in the sub-regional COMMON REGIME ON ACCESS TO GENETIC RESOURCES[2] established in 1996 under the Andean Pact. In 2005 the country agreed to the Regional Biodiversity Strategy for the Tropical Andean Countries (Decision 523 of the Andean Community, 2005[3]), but only in 2011 adopted a national regulation to implement the CAN legal framework. This regime is provider-centred under the principle of sovereignty of states over their natural resources as expressed by Decision 391[4] of the above mentioned common regime.

Ecuador signed the Nagoya Protocol (NP) by 1st of April 2011, but the examination of its compatibility with the country's constitution, the development of the required administrative structures and the subsequent decision to ratify the protocol took then more than six years (September 20th 2017). Finally, on December 19th 2017 Ecuador became a party to the protocol. As detailed in the contribution by Maria Victoria Cabrera Ormaza, the spirit of the mentioned Decision 391[5] of the COMMON REGIME dictates the performance of the state in biodiversity issues and consequently also any subsequent legislation, e.g. Ecuador's new constitution that was enacted in 2008.[6]

Immediately before the ratification of the NP, the Law of Environment and Natural Resources from 2004 has been replaced by a new Codex of Environment (Nuevo "CÓDIGO ORGÁNICO DEL AMBIENTE EN RECURSOS NATURALES, ENERGÍA E INFRAESTRUCTURA", COA, 2018[7]) in conjunction with a new CODEX OF THE SOCIAL ECONOMY OF KNOWLEDGE, CREATIVITY AND INNOVATION ("CODIGO INGENIOS", COI 2018[8]) which both repeal several laws associated with environment and biological diversity, streamlining with the sense of the NP. Among others, the new laws consider "biodiversity and genetic heritage as inalienable, indefeasible and unencumbered property of the State; they cannot be privatized and their access, use and exploitation will be carried out in a strategic manner, seeking the generation of endogenous knowledge and national technological development" (COI, Art 4, No. 16). The task of the governing body of the National System of Science, Technology, Innovation and Traditional Knowledge (currently SENESCYT) is, among many other items "to define the conditions for access, use and ex-

---

[1] The author is a member of a group of German researchers who study ecosystems and their biodiversity of the South Ecuadorian Andes since 1997.

[2] http://www.sice.oas.org/trade/JUNAC/decisiones/DEC391e.asp.

[3] http://www.comunidadandina.org/ingles/treaties/dec/D523e.htm.

[4] http://www.comunidadandina.org/ingles/treaties/dec/d391e.htm.

[5] Ibid.

[6] http://pdba.georgetown.edu/Constitutions/Ecuador/english08.html.

[7] http://www.pichincha.gob.ec/images/xvillamarin/lotaip/anexos/2018/lit_a/a2/codigo_organico_del_ambiente_agosto_2018.pdf.

[8] https://www.wipo.int/edocs/lexdocs/laws/es/ec/ec075es.pdf.

ploitation of knowledge derived from biodiversity, in coordination with the national environmental authority in the scope of its competence, and traditional knowledge (COI Art. 8, No.25); further " to grant the necessary permits for research associated with biodiversity in coordination with the national environmental authority (COI Art.8, No.27); and finally "to issue the necessary regulations and public policy for the signing of contracts for access, use and exploitation of genetic resources associated with biodiversity or traditional knowledge, in coordination with the National Environmental Authority" (MAE).

Among many other items the new codices shall regulate the following issues:

- Environmental Education.
- Environmental Research.
- Forms of Citizen Participation in Environmental Management.
- Unique System of Environmental Information (SUIA).
- Funds for Environmental Management.
- National System of Protected Areas.
- National Forest Regime.
- Unique System of Environmental Management (SUMA).
- Environmental Incentives.

Ecuador's constitution as well as the COA emphasize on a 'Decentralized National System of Environmental Management'. Both compendiums allow for the integration and articulation of state agencies and entities with environmental competence, of citizens and social and community organizations through norms and management instruments (Art. 12). Nevertheless, the National Environmental Authority is the Ministry of Environment (Art. 23). In cooperation with public, private and mixed higher education institutions, as well as with other research institutions it shall compile scientific and technical data on biodiversity and the environment, which must be regularly updated (Art. 17).

2 Ecuador's authorities for research in biodiversity

In Ecuador, several authorities are involved in biodiversity research, especially in the granting procedure for research permission: SENESCYT (Secretaría Nacional de Educación superior, Ciencia, Tecnología e Innovación) for science, the Ministry of Environment (MINISTERIO DEL AMBIENTE DEL ECUADOR, MAE) for biodiversity, and the National Biodiversity Institute (INSTITUTO NACIONAL DE BIODIVERSIDAD, INABIO) for functional supervision. Whereas SENESCYT and INABIO are centralized in Ecuador's capital Quito, the MAE has 24 so-called Direcciones, i.e. provincial ministries. In principle SENESCYT is the authority granting research permission; however, at the moment they are not yet prepared for the extensive issue of biodiversity research. Therefore the competent authority is still the Focal Point MAE (COI, Art. 8) with its provincial Directions. Interestingly the Internet tells us, that the Ministry of Foreign Affairs is in charge of the NP.

INABIO[9] is a research institute that was established by the state of Ecuador in 2014, in the time span between signing the Nagoya Protocol and its ratification. In spite of its written independence it is associated with the MAE. Its mission is to "generate knowledge and de-

[9] http://www.biodiversidad.gob.ec/.

velop science, technology and innovation required by the Ecuadorian State to ensure the conservation of its natural heritage through the sovereign, strategic and sustainable use of biodiversity and its components for the consolidation of the society in a good living". In 2019 INABIO encounters 12 scientific departments, runs biological collections, and is counterpart of those research projects which apply (at the MAE) for transfer of Genetic Resources between Ecuadorian Provinces ('movilización'), or export of biological materials (COI Art. 69). It is as well competent for activities in the scope of REDplus.

For the protection of biological and genetic resources in scientific research article 68 of the COI states that "for the development of scientific research on biological and genetic resources and their derived products in Ecuador's territory, natural persons, legal entities or other associative forms, both national and foreign, must obtain the corresponding authorization for access to biological and genetic resources and their derived products for research purposes".

3 A framework contract for academic biodiversity research in Ecuador

INABIO had entered a framework contract ('contrato marco') on Genetic Biodiversity of Ecuador with the MINISTRY OF ENVIRONMENT for three years (July 2016 – July 2019) with four general aims:

- Identification of floristic and faunistic elements of Ecuador;
- Analysis of the genetic flux and the connectivity of floristic and faunistic communities;
- Assessment of morphological characters for the proper description and delimitation of Ecuadorian plant and animal species; and
- Analysis of biogeographical processes taking place in Ecuador's flora and fauna.

The contract consists of 21 clauses, encompasses 15 individual projects (14 national, 1 external) at the time of establishment, permits INABIO access[10] to and handling of biological and genetic resources (GR) of Ecuador, however exclusively for academic research purposes, and entitles INABIO as the institution from which to apply for mobilisation and export of genetic resources.

The contract excludes all other kinds and aims of research on GRs occupancy and utilisation for other purposes, as well as the access to traditional knowledge. The framework contract authorises the (named) coordinators of the individual projects (in joint responsibility with INABIO) for collection, manipulation and access to biological resources. It states, that these coordinators are responsible for the compliant performance of all persons working in the projects, ensuring that these scientists are familiar with the contract provisions.

4 Changed conditions for biodiversity-related academic research

In 2016 (before Ecuador became party to the NP) each PI (Principal Investigator) of the German research group obtained two documents from the local branch of the MAE: One

[10] The tem "Access to genetic resources" is defined neither by the Constitution of Ecuador nor by the mentioned Codigos Organicos; it is however defined by the COMMON REGIME ON ACCESS TO GENETIC RESOURCES, Art. 1 as: Access: Obtaining and using the genetic resources conserved in ex situ and in situ conditions, their derivative products or, if necessary, their intangible components, for research, biological prospecting, conservation, industrial application or commercial use, among others.

that permitted biodiversity-related academic research and another one for transportation and export of samples.

After Ecuador's ratification of the NP, when our new research unit 'Environmental Changes in Biodiversity Hotspot Ecosystems of South Ecuador: Responses & Feedback Effects (RESPECT)' applied at the MAE for a research permit (2018 – 2020), the type of research was acknowledged as academic not commercially oriented biodiversity research which should come under the roof of INABIO.

RESPECT encompasses 9 individual scientific projects on various ecological and biological topics, including modelling of the natural and man-made ecosystems in the South Ecuadorian Andes. The requested procedure was to affiliate it to INABIO's framework contract on 'Genetic Biodiversity of Ecuador' as additional project. The Application Form required details on:

- The research area(s), province, geographical coordinates.
- Species and exact numbers of specimens used in the research.
- Methods employed in the field and in the lab.
- Place of analysis/mobilization/export.

After examination by INABIO and MAE, RESPECT was approved as a project of INABIO under the framework contract. Inclusion in that contract revealed an interesting finding: Even, if a planned research activity apparently conflicts with general or specific legal regulations (also of the framework contract), it can be permitted as academic research if its impact is small, the aim scientifically sound and the project useful for the gain of knowledge on the biological diversity of Ecuador.

By the framework contract 19 obligations of INABIO were stipulated. Those most important for the affiliated projects are:

- Sharing of data with INABIO and the MAE as contributions to an official data base (COI Art. 71).
- Document of deposition of original samples and /or duplicates in an Ecuadorian and/or internationally recognised collection in Ecuador.
- Deposition of holotypes or unique samples in a registered Ecuadorian collection.
- Annual reports about progress of project.
- Citing of the contract in peer-reviewed publications.
- Timely report to the MAE in case of detection of new species.
- Capacity building measures for the staff of the Ministry of Environment with respect to the objects of the contract.
- Information of the relevant authorities if research is conducted in protected or in private areas or with material from ex-situ collections.
- Consultation of the MAE if contracts or agreements with third parties are planned.

5 Benefit-sharing

COI, Art. 73 is on benefits of the use of biodiversity - According to the public policy issued by the Ministry of Higher Education, Science, Technology and Innovation, the State will participate at least in the same proportion as any natural or legal person that has obtained

monetary or non-monetary benefits derived from the research, use, transfer, development and commercialisation of biological or genetic material, as well as from the information, products or procedures derived from it. Although Ecuador acknowledges intellectual property rights, Art. 93 (COI) states that the State shall participate in the ownership of intellectual property and other rights over processes and derived or synthesized products obtained from biodiversity, in accordance with the provisions of the Constitution. Likewise, it shall participate in the benefits resulting from the economic exploitation of these processes and products, without prejudice to their protection through intellectual property rights. This could indicate that Ecuador will finally demand benefits from digital sequence information on GR.

The research of the German group is performed in cooperation with 4 Ecuadorian universities, with the Ecuadorian branch of the US foundation 'Nature and Culture international', with NGOs, cooperatives and land owners. Surprisingly, scientifically capacity building was neither a request of the framework contract nor of the document of affiliation of the research group with INABIO. The projects encompassed by the contract were – with only one exception – projects of Ecuadorian research groups and that might explain the lacking request of scientific capacity building in Ecuadorian research institutions and universities.

Unfortunately, this framework contract terminated in July 2019 and a new one has been applied for, which will encompass the projects of our research group right from the beginning. We are curious to see the outcome of the still ongoing negotiations.

6 Conclusion

In a juridical respect, the situation for biological research in Ecuador has become more complicated and the administrative work consumes more time. On the other side, the new regulations bring more clarity and consequently security about the legality of scientific ventures in the country and also vis-à-vis the regulations of the EU.

Chapter 22

Rights over genetic resources and ways of monitoring the value chain. A case study from the Royal Botanic Gardens, Kew

China Williams

1 Introduction

As well as being a public visitor attraction the Royal Botanic Gardens, Kew ('Kew') is also a world leading scientific research institute. It employs approximately 700 staff in science and horticulture, has over 1.7 million visitors a year and was designated a UNESCO World Heritage Site in 2003. Kew has nineteen major collections including:

- Preserved plant and fungal collections.
- Living material (seeds, micropropagated and, living plant collections).
- Documentary and visual reference collections (library, art and archives, on-line resources including databases).

RBG Kew's scientific vision is to document and understand global plant and fungal diversity and its uses. Kew's collections, including over 7 million dried plant specimens, over 2 billion seeds and a living collection representing over thirty thousand species (see Box below) increases annually. Kew's scientists make over 60 overseas plant collecting trips each year, bringing in over twenty thousand new specimens, and an active exchange programme with other research institutes accounts for a further annual exchange of over 60,000 herbarium specimens and 10,000 live plants and seeds. In addition, the collections receive over 500 academic visitors each year, amounting to 7000 days of study.

Box 22.1: Kew collections in numbers

Herbarium (7.5 M) & Fungarium (1.25 M)
Living collections (+30,000 species)
Millennium Seed Bank (+30,000 species; c. 2 billion seeds)
Over 40 open access science databases
DNA and tissue bank (+42,000 accessions)
DNA C-value (+7,000 species)
Slide collections (+100,000 slides)
Library (> 750,000 volumes), archives (250,000), artwork (> 175,000), paintings, prints and drawings

Source: Kew Science Collections Strategy 2018

2 Monitoring adherence to provider measures and value chain

2.1 ABS policies and procedures

Consequently, Kew has needed to be proactive in recognising the need to be open and transparent with partners on how it acquires and uses genetic resources and associated traditional knowledge, and how it shares benefits arising from their use. Kew has had a policy on access and benefit-sharing since December 2004 which is designed "to ensure that all material brought into Kew (either collected on fieldwork, or from other institutions and

individuals) has been legally acquired with prior informed consent and on mutually agreed terms, that it is used and supplied by Kew on terms and conditions consistent with those under which it was acquired, and that benefits arising from the use of genetic resources by Kew are shared fairly and equitably as agreed with partners in the country of origin of the material".

Kew has also developed a practical 'ABS Toolkit'[1] (see Box 2 below) of policies and procedures to guide how the policy is implemented internally.

Box 22.2: Summary of Kew's ABS Toolkit

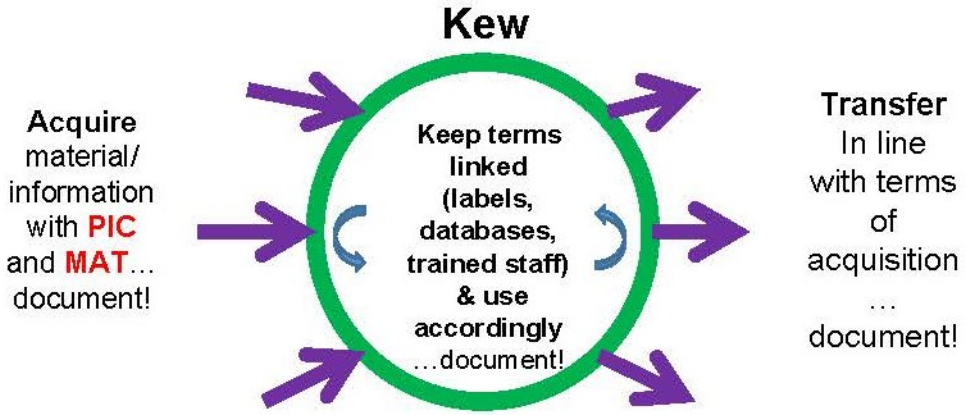
- A dedicated member of staff to implement ABS
- Regular training for staff, and an internet guide to policies and procedures
- A procedure for overseas fieldwork, (an Overseas Fieldwork Committee) including advance planning and follow-up to ensure:
- National laws and legislation are followed
- Appropriate permissions are obtained and kept
- Benefits are agreed and shared fairly
- Staff work according to sectoral best practice standards and models
- Staff are working safely and have adequate advice
- Collections are curated appropriately afterwards, linked to permits and terms of use
- A record of the countries in which Kew is working, and their requirements, is kept and updated
- Policies for:
- visiting researchers in all departments
- use of DNA, data, images and information harvesting
- commercialisation and supply to commercial third parties/change of use and intent
- A suite of model agreements that include:
- Use of material letter, setting out how material will be used by Kew
- Donation letter, for potential donors (if they provide no Material Transfer Agreement)
- Material Transfer Agreements (MTAs) including terms of transfer to third parties (if allowed); different models for different departments if necessary
- Memoranda of Collaboration (MoC) including terms of transfer to third parties (if allowed)
- Access and Benefit-Sharing Agreement (ABSA)
- MoC and ABSA renewal letter
- Approved translations
- A records management system to keep track of key ABS information:
- PIC/MAT documents (agreements, permits, certificates of compliance)

[1] See: www.cbd.int/doc/meetings/abs/icnp-03/presentations/icnp3-Kew.pdf.

- the date of legal extraction of the material from the country of origin
- the country of origin and the provider of the material
- terms of use, including any restrictions and benefit-sharing
- any unique identifiers supplied with the material
- Working with others in non-commercial research sector to develop a sectoral policy.

These policies and procedures are a vital tool to ensure that the rights of the countries of origin of the material or traditional knowledge are protected, that material and associated traditional knowledge (aTK) is obtained with prior informed consent and on mutually agreed terms, that use of the material and aTK is recorded and monitored along the value chain, and that benefits from the use of the material and aTK are shared fairly and equitably with the country of origin. To do this Kew has developed a procedure for staff going on fieldwork that ensures trips are well planned and that all relevant laws are followed. Once the material is back at Kew the terms and conditions of use linked with the GR are recorded in relevant databases, and Kew has policies in place, and collection management systems, to ensure that those resources are used according to those terms. Transfer to third places only takes place in line with the terms of acquisition. To support this regular staff training is essential to ensure that the correct procedures are followed, all terms and conditions are recorded, and that staff and visitors know where to find this information, and that procedures and policies on using the collections, both for staff and visitors, are clear and accessible.

Diagram 22.1: Basic principles of RBG Kew operations



As well as regular training for staff, the guidelines and other relevant policies and procedures (for instance the overseas field work policy and other policies relating to visitors, data collection etc. as well as regularly updated model agreements and clauses) are set out clearly on Kew's internal website accessible to staff.

2.2 Model agreements

In addition, Kew has developed a suite of model agreements to facilitate the exchange of material with partners and stakeholders. Under Kew's standard MoC Kew may loan or supply material transferred or any derivatives from the material and transfer data to other institutions for the purpose of scientific research or education providing that such loan or supply is on terms which prohibit commercialisation. Commercial application here is defined as "applying for, obtaining or transferring IPRs or other tangible or intangible rights by sale or

license or in any other manner, commencement of product development, conducting market research, seeking premarket approval and/or the sale of resulting product". Kew's standard ABSA (Access and Benefit Sharing Agreements) also states that Kew may loan or supply material to a third party for the purpose of scientific research or education, provided that such third party signs a written agreement with Kew prohibiting commercialisation of the material without permission and a further loan and supply for material and associated images or associated data by a third party. Although the terms of agreements can be modified, and in some cases transfer of material to third parties is not allowed, or only with prior informed consent, it is important to note that the exchange of material for identification and verification purposes, for taxonomic study, etc. is vital for the non-commercial conservation research necessary to achieve the objectives of the CBD.

2.3 Donation letter of agreement

Kew has developed a donation letter of agreement which is used when material is donated to Kew and the donating individual or institution has no supply agreement of its own. It is used to set out how Kew may use the material, and if there are any restrictions on use. Standard terms are that material may be made available for scientific study, used for the common good, sent or further distributed to other scientific institutions on terms that allow scientific research and prohibit commercialisation without going back to the original provider to negotiate new PIC.

3 Change of intent

A third party who receives material from Kew under Kew's standard non-commercial material supply agreement and later wishes to use it for commercial purposes must go back to Kew ("the recipient will contact Kew to request prior permission from Kew or, where appropriate, from the provider of the Material to Kew, for any activities not covered under the terms of this agreement") who will go back to the country that provided the material, and negotiate with that country to get the necessary permissions for the change of use.

The key thing to ensure that these obligations are managed, and that material is used on the terms under which it was acquired, is a robust records management system. Kew uses a variety of databases to keep track of the key information – the date of access of the material from the country of origin, the PIC and MAT documents, the agreements, the permits, the certificates of compliance and any other terms and conditions associated with the material. Documents are scanned and kept linked with the material and staff and visitors are trained to use these tools, understand how information is stored and ensure that material is used in line with any recorded restrictions, that benefits are shared with the country of origin of the material and that outputs, such as research and publications can be shared with providers.

Kew, along with other intermediaries, has noted that stricter conditions on use are being imposed by countries of origin in permits and agreements in order to retain control over the use of transferred material. In some cases, providers prohibit further distribution of material for any purpose, even for non-commercial use. In such cases if a third party wants to do research on such material they must go back and ask for it from the country that provided it, and renegotiate specific terms of use. Exchange of material and information in the non-commercial research sector is crucial to enable research that supports the objectives of the CBD and consequently Kew and other non-commercial research organisations work hard to develop internal policies and procedures to increase trust with countries of origin that terms

of access will be followed, change of use will be renegotiated and benefits shared fairly and equitably.

4 Codes of conduct and best practices

In line with others in the non-commercial research sector, Kew bench mark their activities to ensure they are using and following a growing number of best practices and codes of conduct. There are different codes of conduct that have been developed in the non-commercial research sector and give reassurance of best practice being followed in this ever-changing arena.

The ABS Clearing House provides access to Codes of Conduct and guidelines within the Reference Records, under the heading Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and/or Standards.[2]

[2] https://absch.cbd.int/search/reference-records/.

Figure 5: Project team outside the Forschungsstelle fuer Europaeisches Umweltrecht (FEU), University of Bremen (27 June 2019). Front row from left: EC Kamau, JC Medaglia, MV Cabrera Ormaza, M Burchardi, G Burton, E Beck, C Williams, CDT Nguyen, AY Cho. Back row from left: MT Mahop, CHC Lyal, G Winter, T Greiber, Y Ha.

Figure 6: Project team at the entrance to the University of Bremen "Glass Building" (28 June 2019). First row from left: MV Cabrera Ormaza, Y Ha, AY Cho. Second row from left: M Burchardi, G Burton, JC Medaglia, CDT Nguyen. Third row from left: LM Mozini, C Godt, C Williams, G Winter. Fourth row from left: CHC Lyal, MT Mahop, EC Kamau, T Greiber.