Ius Gentium: Comparative Perspectives on Law and Justice 95

Evanson Chege Kamau *Editor*

Global Transformations in the Use of Biodiversity for Research and Development

Post Nagoya Protocol Implementation Amid Unresolved and Arising Issues

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Foreword

It has been 10 years already since the international community agreed in Nagoya, Japan on a groundbreaking agreement, which aims to ensure the fair and equitable sharing of benefits arising from genetic resources. This has been ten years during which the underlying principles of equity, justice and fairness found in the Convention on Biological Diversity (CBD) have been put at the forefront of international discussions. The Nagoya Protocol, the result of years of negotiations amongst Parties of the CBD, presents means of implementation for Article 15 of the Convention, the main Article addressing the third objective of the Convention. The adoption of the Nagoya Protocol demonstrates how countries can come together in an innovative spirit to uphold the principles of solidarity, equality and fairness.

The Nagoya Protocol is a legal instrument through which Parties commit to having clear rules at the national level on access to genetic resources and associated traditional knowledge, and on ensuring the sharing of benefits, including through putting in place compliance measures. Parties are also required to share information through the Access and Benefit-Sharing Clearing-House (ABS-CH), which is accessible to all.

The 10th anniversary of the adoption of the Protocol is an excellent opportunity for the international community to look at what has been accomplished, what challenges have been encountered on the way and what are the next steps for this important agenda. There are numerous successes in its implementation to celebrate. At the time of the writing of this foreword, 130 countries are parties to the Protocol. Almost 70 of those Parties had shared on the ABS Clearing-House their legal framework on access and benefit-sharing, and close to 2000 international recognized certificates of compliance have been published on the ABS Clearing-House.

However, implementation of the Nagoya Protocol also faces several challenges. The Protocol provides flexibility for countries to implement it in light of their national circumstances. Therefore, implementation at the national level has taken many paths in terms of scope, type of measures taken and approaches. But implementation is also dynamic, not stagnant, and there is a need for a constant dialogue with all stakeholders involved to ensure that implementation of the Protocol achieves

its objectives and contributes to conservation and sustainable use of biodiversity. This book will present a few examples.

As a community, we need to exchange ideas and views on what we can do to advance on pending and emerging issues so that together we can move in the right direction. This book aims to contribute to those discussions by presenting various case studies on how countries are implementing the different obligations of the Protocol, and in what way some unresolved and emerging issues are being addressed. I hope that perusing through those pages will help the reader gain insight on potential ways to address those issues to let us advance together on achieving our common objective.

CBD, Montreal, QC, Canada Elizabeth Maruma Mrema

Preface

Almost twenty years have passed since the Nagoya Protocol was adopted on 29 October 2010 and six years since it entered into force on 12 October 2014. The instrument has been termed a game changer in the quid pro quo relationship between providers of genetic resources and associated traditional knowledge and users of such resources and knowledge in what is termed as access and benefit-sharing. It was agreed to bindingly enforce the obligations of parties in order to operationalize a system that had failed to achieve its goals since the adoption of the Convention on Biological Diversity in 1992. The Convention entered into force in 1993. With the implementation of the Nagoya Protocol being several years old, it was time to examine how countries were coping with the new rules of the Protocol in terms of complying with it, how research and development were reacting to the new national laws and practice, whether new challenges had cropped up during the implementation and which solutions had been found. The research project titled "New ABS legislation and practice and their compliance with the Nagoya Protocol", from which the results of this book emanate, was conceived mainly with this in mind. The aim was to offer an opportunity for cross-cutting learning from the implemented measures as well as solutions to unresolved issues. In order to give a picture that represents the current implementation situation, country case studies were selected from five continents of the world: Africa, the Americas, Asia, Australia and Europe. The research project started in February 2017 and was concluded in May 2021. It is acknowledged that the project was funded by the German Research Foundation (DFG), which I hereby greatly appreciate!

I am very proud of my team for the hard work accomplished to ensure that these results are achieved and for the remarkable cooperation. It cannot be forgotten that the pandemic (COVID-19) came at a very sensitive time of drafting, carrying out revisions and completing the final bits of the research. Thankfully the entire team remained resilient and showed great commitment and determination to deliver. I appreciate all of you! My very special appreciation goes to Prof. Gerd Winter, Dr. Luciana Silvestri, Dr. Chris Lyal, Thomas Greiber, Prof. Christine Godt and

Dr. Marcelin Mahop who formed a small team to review the draft papers. Without you, the burden upon me would have been extremely big. Thank you very much!

This project was steered through three events which were the main milestones—a kick-off workshop (19 April 2017), an international conference (19–21 September 2018) and a review workshop (27–28 June 2019). It is acknowledged that the review workshop was funded by the German Federal Agency for Nature Conservation (Bundesamt fuer Naturschutz, BfN), which I hereby appreciate! Likewise, I thank all participants of the international conference of 2018 for all the useful comments and feedback and our special guests, Dr. Joachim Lohse, the Senator for Environment, Housing and Transport of the Hanseatic State of Bremen and the Dean of the Law Faculty of the University of Bremen, Prof. Lorenz Kähler, for their great support.

Finally, my thanks go to the Secretary of the Research Center for European Environmental Law (FEU), Anna Himmelskamp, for extraordinary logistical support throughout the research project, and to my student assistants Christin Reinke, Talline Koerner and Michel Barongo Chege for their great support in research and organizational tasks.

This book does not only give insight into the current status of national implementation of the Nagoya Protocol but offers solutions for horizontal cross-fertilization of national ABS laws and practice as well as for unresolved issues. It is noteworthy that it also attempts to propose solutions to questions on ABS based on real-life and hypothetical cases. Whilst it contributes to the existing knowledge of the former issues, it is hoped that it will likewise provoke practice and litigation in the area of ABS, an area I strongly believe has reached a stage of solving relevant cases.

Bremen, Germany
September 2021

Evanson Chege Kamau

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Abbreviations and Acronyms

3TG	Tin, Tantalum, Tungsten and Gold
ABNJ	Areas Beyond National Jurisdiction
ABRS	Australian Biological Resources Study
ABS CH/ABSCH	Access and Benefit Sharing Clearing-House
ABS TC	ABS Technical Committee
ABS	Access and Benefit-Sharing
AC	Advisory Committee
ACT	Australian Capital Territory
AHTEG	Ad Hoc Technical Expert Group
ARIPO	Intellectual Property Organization
Art.	Article
ASEAN	Association of Southeast Asian Nations
aTK	Associated traditional knowledge
AVH	Australasian Virtual Herbarium, and formerly the Australian Virtual Herbarium
BABS Regulations	Bioprospecting, Access and Benefit-Sharing Regulations
BBNJ	Biodiversity Beyond National Jurisdiction
BCA	Nature and Biodiversity Conservation Agency
BCP	Biocultural Protocol
BfN	Bundesamt für Naturschutz
BL	Biodiversity Law
BNDES	National Bank for Economic and Social Development
BR	Biological resource(s)
BS	Benefit-sharing
BSA	Benefit-Sharing Agreement
BTF	Bioprospecting Trust Fund
c.	clause
CA	Competent Authority
CAN	Andean Community of Nations
CBD	Convention on Biological Diversity
CETAF	Consortium of European Taxonomic Facilities

CGEN	Genetic Heritage Governing Council
CGIAR	Consultative Group of International Agricultural Research
Ch./ch.	Chapter
CHAR	Council of Heads of Australasian Herbaria
CHM	Clearing House Mechanism
CISG	UN Convention on Contracts for the International Sale of Goods
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CJEU	Court of Justice of the European Union
CK	Community Knowledge
cl.	clause
CNA(s)	Competent National Authority(ies)
COA	Nuevo Código Orgánico del Ambiente en Recursos Naturales, Energía e Infraestructura
COFEMA	Federal Council of the Environment
COGTA	Cooperative Governance and Traditional Affairs
COMIFA	Commission des Forêts d'Afrique Centrale (Central African Forest Commission)
CONAGEBIO	National Commission for the Biodiversity Management
CONCYTEC	National Council for Science, Technology and Technological Innovation
CONICET	National Scientific and Technical Research Council
COP	Conference of the Parties (to the CBD)
COP-MOP	Meeting of the Parties to the Nagoya Protocol
CPs	Checkpoints
CS	Cabinet Secretary
CSIRO	Commonwealth Scientific Industrial and Research Organisation
CSR	Corporate social responsibility
CV	Curriculum vitae
DAFF	Department of Agriculture, Forestry and Fisheries
DD	Due diligence
DDD	Declaration of Due Diligence
DEA	Department for Environmental Affairs
DEFF	Department of Environment, Forestry and Fisheries
DFG	German Research Foundation
DG	Director-General
DNA	Deoxyribonucleic Acid
DoI	Department of Immigration
DSI	Digital Sequence Information
DSMZ	Deutsche Sammlung von Mikroorganismen und Zellkulturen (German Collection of Microorganisms and Cell Cultures)

DST	Department of Science and Technology
DVS	Department of Veterinary Services
DWS	Department of Water and Sanitation
E.g.	Exempli gratia (for example)
EAC	East Africa Community
EBI	Ethiopian Biodiversity Institute
ECPTA	Eastern Cape Parks and Tourism Agency
ECSF	Estación Científica san Francisco (Ecuador)
EEA	European Economic Area
EEZ	Exclusive Economic Zone
EFCCC	Environment, Forest and Climate Change Commission
EFTA	European Free Trade Area
EMCA	Environment Management and Coordination Act
EPA	Environmental Protection Authority
EPBC Act regulations	Environment Protection Biodiversity Conservation Act regulations
EPBC Act	Environment Protection Biodiversity Conservation Act
ERUDEF	Environment and Rural Development Foundation
EU	European Union
FAO	Food and Agriculture Organization
FCMA	The Forest Conservation and Management Act
FLEGT	Forest Law, Enforcement, Governance and Trade Action Plan of the European Union
Fn/fn	Footnote
FNRB	National Fund for the Benefit-Sharing
GDPR	General Data Protection Regulation of the European Union
GEF	Global Environment Facility
GIZ	German Technical Cooperation Agency
GMAC	Genetic Modification Advisory Committee
GMO(s)	Genetically modified organism(s)
GoC	Government of Cameroon
GPA	General Access Procedures
GPS	Global Positioning System
GR	Genetic resource(s)
GRAIN	Genetic Resources Action International
GRSD	Genetic Resource Sequence Data
GSD	Genetic Sequence Data
GSPC	Global Strategy for Plant Conservation
GTI	Global Taxonomy Initiative
iA	Issuing Authority
IARC	International Agricultural Research Centre(s)
ICJ	International Court of Justice
ICMBio	Chico Mendes Institute for Biodiversity Conservation

ICSWGSB	International Civil Society Working Group on Synthetic Biology
ID (No)	Identification (number)
IGBRs	Indigenous genetic and biological resources
IKS	Indigenous Knowledge Systems
ILA	International Law Association
ILC	International Law Commission
ILCs	Indigenous and local communities
ILO	International Labour Organization
IMCE	Interministerial Committee on Environment
INABIO	Instituto Nacional de Biodiversidad (National Biodiversity Institute)
INBio	National Biodiversity Institute
INDECOPI	National Institute for the Defense of Competence and Protection of Intellectual Property
INIA	National Institute of Agrarian Innovation
INSDC	International Nucelotide Sequence Database Consortium
INTA	National Institute of Agricultural Technology
IP	Intellectual Property
IPR	Intellectual property rights
IPRs	Intellectual property rights
IRCC	Internationally Recognized Certificate of Compliance
ITPGRFA/IT	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for Conservation of Nature
KALRO	Kenya Agricultural and Livestock Research Organization
KECOBO	Kenya Copyright Board
KEPHIS	Kenya Plant Health Inspectorate Service
KFS	Kenya Forest Service
KIPI	Kenya Industrial Property Institute
KWS	Kenya Wildlife Service
LA(s)	Lead agency(ies)
MAA	Material Acquisition Agreement
MAAE	Ministerio del Ambiente y Aqua del Ecuador, formerly MAE (Ministerio del Ambiente del Ecuador)
MARD	Ministry of Agriculture and Rural Development
MAT	Mutually Agreed Terms (in Brazil known as Benefit-sharing Agreement)
MEAs	Multilateral Environmental Agreements
MEC	Member of the Executive Council
MINAE	Ministry of Environment and Energy
MINAGRI	Ministry of Agriculture
MinMEC	Ministers and Members of Executive Councils
MITECO	Ministry for Ecological Transition

MLS	Multilateral System
MO	Monitoring Organization
MoC	Memorandum of Collaboration
MONRE	Ministry of Nature Resources and Environment
MOST	Ministry of Science and Technology
MOSTE	Ministry of Science, Technology and the Environment
MoU	Memorandum of Understanding
MRV	Monitoring, Reporting and Verification of CO_2 Emissions from Large Vessels
MSA	Material Supply Agreement
MSBP	Millennium Seed Bank Partnership
MTA	Material transfer agreement
NACOSTI	National Commission for Science, Technology and Innovation
NBS	National Biodiversity Strategy
NBSAP	National Biodiversity Strategy and Action Plan
NCA	National Competent Authority
NCBD	National Committee on Biological Diversity
NCBI	National Center for Biotechnology Information
NCI	Nature and Culture International/Natura y Cultura Internacional
NEMA	National Environment Management Authority
NEMBA	National Environmental Management: Biodiversity Act
NEMLA	National Environmental Management Laws Amendment Act
NES	National Environment Secretariat
NFP	National Focal Point
NGO(s)	Non-governmental Organization(s)
NMK	National Museums of Kenya
No.	Number
NP	Nagoya Protocol
NSBA	National Spatial Biodiversity Assessment
NSD	Nucleotide Sequence Data
NT	Northern Territory
NTFPs	Non-Timber Forest Products
OECD	Organization for Economic Co-operation and Development
OED	Oxford English Dictionary
OFC	Overseas Fieldwork Committee
ORF	Open Reading Frame (portion of a DNA molecule that, when translated into amino acids, contains no stop codons)
Para./para.	Paragraph(s)
PGRFA	Plant Genetic Resources for Food and Agriculture
PI(s)	Principal Investigator(s)

PIC	Prior informed consent
PIN	Personal identification number
PIP	The WHO Pandemic Influenza Preparedness Framework
PM	Provisional Measure 2.186-16/2001 (Brazil)
PMSEIC	Prime Minister's Science and Engineering Council
PP	Passport
PRODUCE	Ministry of Production
PTKCEA	Protection of Traditional Knowledge and Cultural Expressions Act
R&D	Research and development
r./rr.	Regulation(s)
RBS	Regional Biodiversity Strategy for the Tropical Andean Countries
REDD+	Reducing Emissions from Deforestation and Forest Degradation
Reg.	Regulation
RNA	Ribonucleic Acid
s./ss.	Section(s)
SA	South Africa
SANBI	South African National Biodiversity Institute
SANParks	South African National Parks
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
SCBD	Secretariat of the Convention on Biological Diversity
SE&SD	Secretariat of Environment and Sustainable Development
SENADI	Servicio Nacional de Derechos Intelectuales (National Service of Intellectual Property Rights)
SENASA	Argentine Agri-Food Health and Quality Service
SENESCYT	Secretaría Nacional de Educación superior, Ciencia, Tecnología e Innovación/National Secretariat for High Level Education
SERFOR	National Forestry Service
SINAC	National System of Conservation Areas
SisGen	National Genetic Heritage and Associated Traditional Knowledge Management System
SMTA	Standard Material Transfer Agreement
SUIA	Unique System of Environmental Information
SUMA	Unique System of Environmental Management
TK	Traditional Knowledge
TO	Technical Office of the CONAGEBIO
TOPS	Threatened or Protected Species
TWN	Third World Network
UN	United Nations
UNCLOS	UN Convention on the Law of the Sea

UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNFCCC	United Nations Framework Convention on Climate Change
UNGA	General Assembly of the United Nations
UPOV	International Union for the Protection of New Varieties of Plants Convention
US	United States
USDA	United States Department of Agriculture
USFDA	United States Food and Drug Administration
UTPL	Universidad Tecnica Particular de Loja
VACNE	Viet Nam Association for Conservation of Nature and Environment
WCMA	Wildlife Conservation and Management Act 2013
WEF	Wildlife Endowment Fund
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WRTI	Wildlife Research and Training Institute
WWF	World Wide Fund for Nature

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Part I
Introduction

Transformations in International Law on Access to Genetic Resources and Benefit-Sharing and Domestic Implementation. Introduction, Synthesis, Observations, Recommendations and Conclusions

Evanson Chege Kamau

Abstract The chapter describes the new rules on access to genetic resources and associated traditional knowledge (aTK). The Nagoya Protocol, an instrument of the Convention on Biological Diversity (CBD), created globally binding rules in order to operationalize its third objective, i.e. the fair and equitable sharing of the benefits arising from the utilization of genetic resources (GR) and aTK. The chapter starts by describing the new transformations that have changed the landscape for research and development (R&D) based on genetic resources and aTK. Further, it identifies implementation issues that were unresolved in the negotiations leading to the adoption of the Protocol and those that have emerged during the implementation phase, and shows which challenges they present for the implementation process. An example of such issues is the current disagreement between the providers of GR and their users as to whether Digital Sequence Information falls under the definition of 'genetic resources' and consequently the scope of the access and benefit-sharing (ABS) legislation. Besides, it summarizes each chapter. For chapters with case study examination the focus is laid on how the laws are coping with the ABS obligations of the Protocol, how the salient (unresolved and emerging) issues identified are addressed and whether conformity with the Nagoya Protocol is paid attention to. For general themes, challenges, opportunities and lessons from practical experiences are identified and solutions for enriching the implementation process proposed. Finally, the chapter produces some synthesis, observations and recommendations and reaches some conclusions.

Keywords Transformations in international law on access to genetic resources · Access and benefit-sharing · Nagoya Protocol · Domestic implementation · New legislation and practice

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1 About the Subject

Prior to the CBD, access to genetic resources was unrestricted, uncontrolled and free as they were considered a common heritage of mankind.[1] The users of such resources who were mainly located in developed countries did not have any obligation to share the gains of research and development (R&D) with countries from where they were taken, which are mainly developing countries—so-called provider States.[2] That led to a number of repercussions including the overuse of biodiversity[3] and an imbalance in the conservation burden which had to be borne by provider States alone.[4] The General Assembly resolution 1803 (XVII) of 14 December 1962 declared that States have permanent sovereignty over (their) natural resources, i.e. the right of States to decide freely and independently on the use and exploitation of their natural resources.[5] This became the springboard from which debates on among others the deterrence of the misappropriation of genetic resources (GR) and associated traditional knowledge (aTK) of developing countries[6] and the fair distribution of wealth were launched, eventually leading to negotiations for a treaty.[7] The Convention on Biological Diversity (CBD) was adopted in 1992 in Rio de Janeiro, Brazil, and entered into force on 29 December 1993. The Convention overturned the 'common heritage of mankind' principle, reaffirmed the (sovereign) rights of States over their natural resources and declared that ". . . the authority to determine access to genetic resources rests with the national governments and is subject to national legislation" (Art. 15.1). The Convention's 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 (Art. 1 CBD). Access to GR and aTK and benefit-sharing are built on the third objective which comprises the focus of this book. According to the formula foreseen under article 15 CBD, access to GR is subject to the prior informed consent (PIC) of the contracting party to the CBD that is providing such GR, unless that party determines otherwise (Art. 15.5). Where granted, access shall be on mutually agreed terms (Art. 15.4). Access to aTK is subject to the PIC or approval and involvement of indigenous and local communities that hold such knowledge (Art. 8 (j)). Users of GR must share in a fair and equitable way benefits arising from the utilization with their providers upon mutually agreed terms (Art. 15.7). Due to *inter alia* poor implementation of access and benefit-sharing (ABS) as a result of e.g. too restrictive provider

[1] Kamau (2014), p. 143; Reichman et al. (2016), p. 39ff.

[2] Kamau, ibid.

[3] The international debates since the early 1980s implicated intellectual property rights especially patents for the erosion of genetic resources, biodiversity loss and biopiracy of traditional knowledge. For more see Dutfield and Suthersanen (2020), p. 463ff. Also Reichman et al. (2016), p. 52ff.

[4] Kamau (2014).

[5] Scholtz (2008), p. 288; Cabrera Medaglia and Welch (2018), p. 182ff.

[6] See also Reichman et al. (2016), p. 43.

[7] Cabrera Medaglia and Welch (2018), p. 181ff.

measures and too loose or no compliance measures on the side of users, this formula became somehow a failure, and led to a standoff between the two sides.[8] To alleviate the situation, the international community under the intergovernmental umbrella institution known as the Conference of the Parties (COP) initiated a process to push parties to respect and obey their ABS obligations under the CBD.[9] This led to the adoption of a binding instrument, 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 (NP).[10]

The adoption of the Nagoya Protocol in October 2010 and its entry into force in October 2014 became the game changer in the law on access to GR and aTK and benefit-sharing. With it the obligations of the CBD attained an obligatory and binding nature. On the provider side States were taken to task to establish concrete measures in order to facilitate access to GR and aTK as well as create legal certainty, clarity and transparency for users. In the same vein, on the user side States were obliged to put compliance measures in place in order to ascertain that domestic ABS requirements of the providing party are complied with in their jurisdictions and benefits arising from the utilization of accessed GR and aTK are shared (with providers) in a fair and equitable manner. The contributions in this volume focus on the two dynamics. The said measures are considered as key in achieving what is referred to as the ABC (Access, Benefit-sharing and Compliance) of ABS. To that end, countries will need to have ABS frameworks and the required institutional structures (national focal points, competent national authorities, checkpoints) in place and concurrently organize or reorganize their administrative procedures. This has transformed the ABS landscape. But, the Nagoya Protocol (NP) does not prescribe a strict formula of implementation; it gives States leeway as far as the implementation approach they should employ is concerned. For example, they are to decide whether to take legislative, administrative or policy measures, whether to revise or amend old measures, or develop new ones, whether to develop stand-alone laws or integrate ABS provisions in other existing laws, for instance in environmental laws. Likewise, it gives them a big discretion in deciding what and what not to regulate, in taking a narrow or broad interpretation of terms, establishing far-reaching or modest obligations, in determining how to organize administrative procedures, etc. They are also free not to establish any ABS measures altogether for access to their GR and/or aTK. What seems important to the NP, however, is that, if provider/access measures are established, they must meet, *inter alia*, the standards of article 6.3 of the Nagoya Protocol—legal certainty, clarity and transparency. User measures must ensure compliance with domestic ABS laws of provider States and

[8] Kamau (2014), pp. 146–158.

[9] Ibid. For details see Kamau et al. (2010).

[10] For details of the process leading to the Nagoya Protocol see Kamau et al. (2010), pp. 248–250. For an in-depth explanation of and commentary on the Nagoya Protocol see Greiber et al. (2012) and Morgera et al. (2014).

mutually agreed terms—in order to guarantee benefit-sharing as required by articles 5 and 6 NP. In implication, the new post Nagoya Protocol measures are diverse.

Apart from the NP obligations other issues also play out in the implementation process and have the potential of either slowing or crippling, or facilitating it as well as determining the level at which it can be operationalized effectively and efficiently. Such include arising and unresolved issues e.g. the question on (Digital Sequence) Information (DSI) based on GR; possible limits (cut-off points) to provider rights; rights over GR initially accessed as bulk commodities and later utilized in research and development (R&D); availability of sectorial practices; practical tools e.g. well drafted contracts; and the possibility to resolve disputes in court.

2 About the Book

The volume therefore delves on a post Nagoya Protocol study to interrogate some of these issues which are dealt with under three parts of the book.

1. Under **Part II** post NP measures on access and benefit-sharing and domestic implementation are presented. This is the largest part of the book and occupies chapters 2–16. It examines case studies of legislation and practice featuring five continents: South America, Africa, Asia, Australia and Europe. The focus is on establishing how domestic laws have implemented the obligations of the Protocol and how they are coping, their *de jure* and *de facto* compliance with the NP and how they are dealing with arising and unresolved issues, which is critical for learning across the different regimes. In total 15 national legislations and the EU Regulation and their practices have been examined. Only Costa Rica and Australia have not ratified the NP. From the 16 case studies 12 concern post Nagoya Protocol measures with 10 adopted (Argentina, Brazil, Ecuador, Viet Nam, Malaysia, South Korea, Spain, France, Cameroon and the EU) and 2 drafts (Peru and Ethiopia). Of the remaining 4 case studies (Costa Rica, Kenya, South Africa and Australia) old measures are still in operation although some have undertaken a few revisions after the NP (Costa Rica and South Africa) and in Australia one of its States, Queensland, has enacted a post NP law.
2. Following an investigation of the implementation of the NP by national legislations it is important to examine how they are affecting the practical ABS landscape. Therefore under **Part III** covering chapters 17-20 we look at the experiences and lessons from the application of post NP measures by pure biodiversity researchers, an enforcement agency and a botanical garden on the user side. The pre and post NP activities of the researchers (as users) and a botanical garden (as both a user and intermediary) show the changes the new access requirements and procedures have brought in practice and how they have eased or made restrictive the work of research. On the whole the situation seems to have become more difficult. However, their effort to create trust is identified as a critical tool to ameliorate the situation. Besides, the practice of the botanical

garden has shown that having a good policy to guide the behavior of its researchers and their activities as well as having in place exemplary agreements can by far alleviate difficulties with stakeholders and also add to confident dealings. On the other hand activities of an enforcing agency are presented to show how checks are conducted in order to establish violations by users and ensure benefit-sharing. The example of a competent national authority of a European Union Member State, which must take action according to the due diligence compliance concept of the Regulation (EU) 511/2014, is taken as an example. Another question examined under Part III is how successful this concept is in effecting compliance. For that, its origin and nature are also investigated.

3. Affecting the implementation of ABS and its effectivity are not only how the obligations of the NP are transposed nationally and what stakeholders are doing to make it work but likewise critical issues that have arisen and that are unresolved. Some of the most important currently are the issues on DSI, lack of well-thought contractual solutions and lack of litigation. The relevant questions are discussed under **Part IV** in chapters 21–23 and solutions to identified challenges suggested.

3 Further Research Questions

There are many questions than this book can handle requiring research and for which solutions are needed. Four that are considered critical in making ABS dynamic, workable and practical shall be named.

1. Alternative models of ABS.

The current system of exchange of GR and aTK and sharing of benefits is still performing dismally[11] 29 and 10 years since the adoption of the CBD and the NP respectively. Even with the new laws attempting to reach conformity with the NP, access and benefit-sharing (ABS) retain a myriad of challenges. The monetary benefit-sharing project in particular, which is consequential for conservation and sustainable use of biodiversity, has been poorly realized and is considered by some authors as having failed.[12] Our hypothesis is that the core of these challenges lies with the bilateral *quid pro quo* arrangement. Besides, bilateralism is considered a poor fit to modalities of access to, use of and benefit-sharing from DSI[13] which is a basis for the real source of (monetary) benefits, and the ownership of which is currently a major issue of contention between providers and users. A solution to these challenges could be alternative models with the substantial question of linking

[11] Prip and Rosendal (2015).

[12] Muller et al. December (2019); Winter (2021).

[13] Laird et al. (2020); Scholz et al. (2020).

or delinking sovereign rights and benefit-sharing. The theme is very topical and timely given the current discussions about multilateral benefit-sharing in several fora, and the decisions that will be taken over the next few years. Indeed, deliberations in this regard have started at the CBD level.

2. Cut-off points

Ad infinitum provider rights are said to have negative effects on R&D.[14] Notably in the agricultural breeding sector the value chain can be protracted and involve genetic resources from different sources.[15] This can have a number of consequences identified here being two: (1) Due to multiple stages of reproduction within a single (long) value chain sets of different ABS contractual obligations accumulate continuously all of which will apply to the breeding pool and the products developed thereof.[16] This does not only enlarge the bundle of contracts to be monitored, but maintains contracts for which *de facto* obligations have been blurred. Concerning blurred obligations this could be the case e.g. regarding obligations to share benefits arising from utilization if the final commercial variety contains no components of the original sequence of a GR exchanged under the relevant contract. (2) The original contribution of the GR may reduce progressively diminishing its influence.[17] At the end it might be doubtful that there will still be left any benefits to be shared.[18] In such cases it could be alluded that the benefit-sharing rights of the provider no longer existed. For this Winter (2019)[19] suggests the application of the general legal principle "de minimis non curat praetor" and in reference to the stipulation of article 5 NP that benefit-sharing shall be fair and balanced. However, the question should be treated differently if the original trait and its functions are still noticeable even after a long value chain.[20] Concerning the first challenge, a study is required to search for ways of establishing cut-off points of ABS rights in the value chain and regarding the second, to determine which level of contribution could still be considered for benefit-sharing.

3. Practical approaches for improving ABS

At the present stage of the implementation of the NP, the EU Regulation and the national implementation law, it is apparent that a number of legal and practical questions remain unanswered. The answers to these questions are indispensable for legally secure implementation of the instruments in question, such as the availability of necessary information on the actors concerned, protection of secrets, data protection and access to information, burden of proof, content and limits of due diligence

[14] Schloen (2019).
[15] Schloen (2019, p. 128).
[16] Ibid.
[17] Winter (2019, p. 109).
[18] Schloen (2019).
[19] Winter (2019).
[20] Ibid.

obligations, treatment of DSI, advice to users, enforcement of access agreements (mutually agreed terms, MAT), control of benefit-sharing, planning of administrative controls, powers for administrative orders, use of sanctions, cooperation with foreign enforcement authorities and the ABS Clearing House, legal protection of users and providing institutions. On a level of doctrinal systematization it can be asked, how the individual problems that arise can be condensed to more general overarching problems, such as due diligence of users, institutional networking in the multi-level system, the relationship between administrative and contractual instruments, the relationship between the rights of disposal over GR as material and as information, etc. It can also be explored how the practical implementation of the ABS regime is to be assessed with regard to pertinent principles of constitutional and international law, in particular freedom of research and of enterprise, the sovereign rights of the provider states, and fair compensation of non-monetary and monetary benefits.

With a view to improving implementation practices the role of standardization and harmonization of prior informed consent (PIC) and MAT procedures can be further investigated. Currently parties to the NP have different legal, policy and administrative frameworks implementing the Protocol at the national level. As a consequence, the international ABS landscape is marked by highly divergent national ABS procedures and obligations leading to a continuous implementation problem for users. Standardization and harmonization can be done at the global level but more realistically would be at the regional level. This is critical in addressing the prevailing lack of legal certainty, clarity and transparency and would be very supportive to users in implementation of ABS and compliance in practice.

Related to standardization and harmonization is the possibility of developing specialized ABS instruments under article 4.4 NP. Such specialized instruments have the potential to create uniform ABS conditions for a specific set of genetic resources, specific types of utilization or in other contexts. Thus, if standardization and harmonization are not possible under the Nagoya Protocol, specialized instruments provide an option to push for standardization in certain sectors and/or amongst e.g. a coalition of the willing who understand the problem of individualized national ABS approaches.

4. The role of informal suppliers of GR as important ABS players

Parataxonomists, private land owners, traders and research partners act as intermediaries of genetic resources. With the coming into force of the NP, users of genetic resources from such intermediaries are required to prove that the material utilized in R&D was legally accessed from the country of origin of such resources and that MAT were established. That means while accessing GR from an informal intermediary, a user has to ask for corresponding certification. Unlike most mainstream intermediaries, in particular *ex-situ* collections which possess structures for certifying access of material for further research and monitoring downstream use, or can easily adjust to such requirements, informal intermediaries lack such structures. The following questions therefore arise: If materials are accessed from such intermediaries, how will a user be able to prove that the ABS law of the provider was

complied with? How will such intermediaries cope with the need to provide users with evidence that such material was legally accessed? What format of certification would be considered acceptable to (user) checkpoints and enforcement agencies? How can access be organized in the provider country to hinder trade with genetic resources belonging to the provider state and/or indigenous and local communities and also to prevent overharvesting? These questions need to be confronted. The Malaysian Act, for instance, creates a formal opening for suppliers of GR to get involved in the ABS process as long as they are named by the permit applicant and appointed to take the biological resource and/or aTK on their behalf and thus acknowledged as "authorized intermediaries".[21] It could be examined using such examples how that would operate in practice. Other questions could probably be answered by looking at existing certification systems e.g. of the Forest Stewardship Council (FSC) and Marine Stewardship Council (MSC) and drawing lessons from them.

These questions are suggested as important themes for further research and will not be discussed in more detail in this book.

Presented below are the summaries of individual contributions covered in the book and synthesis, observations, recommendations and general conclusions made at the end of this introductory chapter.

4 Summaries of Contributions

PART II: Post Nagoya Protocol Measures on Access and Benefit-Sharing and Domestic Implementation

A. *South American Continent*

In Chapter "Access and Benefit-Sharing Regime in Argentina: Experiences and Perspectives", Luciana C. Silvestri probes the framework for the management of biological resources in Argentina. Argentina has rich and high endemic biodiversity making it an attractive destination for research and development (R&D) based on genetic resources. Besides, in recent years it proactively utilizes its own biodiversity making it a *de facto* user. Hence, it is for the interest of the country to have a comprehensive and effective access and benefit-sharing (ABS) legal framework. The author, however, indicates the contrary. Although a national post Nagoya Protocol (NP) legislation was adopted in October 2019 (Administrative Decision No. 410 of 2019) to rectify the ambiguity created by previous laws and establish uniform minimum standards in all 23 provinces, the law did not create the desired environment for a flawless exchange of genetic resources (GR) and sharing of benefits. This is attributed to the fact that, although the Constitution also foresees that the federal government (national congress) shall enact a formal law that sets minimum

[21] Malaysian Act of 2017, s. 4.

environmental legal standards in order to guarantee a uniform level of environmental protection across the country, it also gives ownership of natural resources to the provinces and hence the competency to define the terms and conditions for access to and utilization of their resources. This has resulted to lack of measures in more than half of the provinces as well as divergent measures and varying requirements and procedures in the 10 provinces which have so far enacted ABS rules. In addition, Administrative Decision No. 410 does not regulate associated traditional knowledge (aTK) and also excludes domesticated or cultivated species from its scope thus neglecting the constitutional rights of the indigenous peoples. It is also void of compliance measures for utilization of GR and aTK from other countries while these are being utilized in Argentina. Likewise, it does not address the issue of digital sequence information (DSI) in spite of Argentina being of the opinion that DSI falls under the scope of GR, and thus makes no contribution to the current debate in this issue. However, it has also brought about some innovations e.g. by including important definitions spelling out the requirements, procedures and authorities responsible, including for which GR. Another vital innovation is the introduction of differentiated conditions and procedure for non-commercial research the effectiveness of which could be minimized by the fact that the Decision introduces checking for access authorizations including for taxonomic purposes. The current situation in Argentina is caused by a lack of national formal law that according to the Constitution must be issued by the national congress. The current administrative Decision No. 410 of 2019 establishes minimum common standards for ABS which betters the situation at the national level but is not binding to the provinces. Its effect and success depend on their willingness to adhere to it a situation which can lead to legal uncertainty and unclarity. This and other factors including the neglect of aTK and lack of user compliance measures are indications that the existing legal situation in Argentina is still below NP standards.

In chapter "Brazilian Biodiversity Law: Challenges and Opportunities for Industries and Research Institutions", Lilian Massini Mozini looks at the Brazilian Biodiversity Act, Federal Law No. 13,123/2015, which regulates access to Brazilian genetic heritage, associated traditional knowledge (aTK) and their utilization and benefit-sharing therefrom and is elaborated by the implementing Decree No. 8,772/2016. Mozini states that it was necessary to adopt a new law which was able to counteract the failures of the previous law, the Provisional Measure No. 2.186/2001, the complex and bureaucratic environment it created leading to the circumvention of the established ABS measures by users. Some of the regime's innovations include the elaboration of key definitions. One of the terms defined that lacks uniform international understanding though being part and parcel of the ABS system is 'access'. From this definition two main factors are revealed: (1) 'Access' according to the Brazilian regime implies not physical taking of a specimen, but rather an intellectual operation involving research and development (R&D) activities. This means that any such activity on Brazilian genetic heritage wherever it may be located falls under the scope of the regime. That includes genetic heritage found in *ex-situ* conditions as long as they originated in Brazilian *in-situ* conditions. (2) Specimens acquired for bulk uses but later used in R&D are also covered by the legislation. In

its elaboration of terms, 'research' and 'technological development' also differentiate work on genetic heritage meant for or not meant for economic exploitation. Consequently the new law also establishes different procedures. Interestingly foreigners cannot undertake access and hence these procedures must be executed by a local entity. Therefore, a foreign entity must enter into partnership with a national institution, which will also be responsible for other formalities including notification of finished products developed from the access whether they are to be marketed abroad or in Brazil, application for intellectual property right, commercialization of the intermediate product, or publication of results. The new Brazilian law differentiates itself from most provider States' measures in a number of ways: (1) It does not only address access to genetic resources (genetic heritage) and aTK and benefit-sharing from their uses but also delves into issues regarding access to and transfer of technology and economic exploitation of finished product or reproductive material and the fair and equitable sharing of the benefits from their exploitation. (2) It allows foreign recipients of samples of genetic heritage to make transfers to third persons provided that these agree to comply with the requirements of the law before the transfer is made and thus introduces into the ABS legislation a viral instead of a come-back clause. (3) It differentiates between prior informed consent (PIC) for aTK of identifiable and unidentifiable origin thus subjecting only the former to the PIC of the indigenous and traditional peoples. Apropos aTK, such communities and peoples must be acknowledged in publications for their contribution to conservation of genetic heritage as well as the origin of aTK indicated. (4) It only requires benefit-sharing if there is economic exploitation of reproductive material. (5) It allows the choice of benefits to be shared whether monetary or non-monetary benefits including from economic exploitation. (6) It is articulate that benefits deposited in the National Fund for Benefit-Sharing shall be used for the purposes of conservation and sustainable use of genetic heritage and aTK. As the author conclusively remarks, although the new biodiversity law presents some difficulties e.g. for the intermediate products' industry, which finds it hard to understand the nature and responsibilities regarding the development of such products, and to users in general in the operations of the electronic registration system, SisGen (the National System of Genetic Resource Management and Associated Traditional Knowledge), it has introduced a new way of management of ABS that gives users more flexibility. The suggestions made in this book will help improve the ABS situation further.

In Chapter "Towards Mutual Supportiveness Between the Nagoya Protocol and the Andean Sub-regional ABS Regime: The Cases of Ecuador and Peru", Maria Victoria Cabrera Ormaza analyzes the access and benefit-sharing (ABS) regimes of Ecuador and Peru. Both countries belong to the so-called megadiverse countries. They are also members of a pre-NP sub-regional common regime on ABS established under Decision 391 (1996) of the Commission of the Cartagena Agreement of the Andean Community of Nations (CAN) upon which their ABS rules and principles are built. As a result their ABS legal frameworks reflect its complexity and discretionary power accorded to the State, which was seen as a way of controlling the presumed high economic value of their genetic resources (GR) and expected economic benefits. This can be seen e.g. in its definition of the term 'access' which is

open-ended and encompasses any form of use leading to multiple negotiations and conclusion of contracts during the entire duration of use. Besides, it does not allow access to foreigners unless they involve an officially recognized national support institution or individual who must participate in the project from its planning phase to conclusion. However unlike Brazil, the applicant is permitted to negotiate the terms of access and benefit-sharing. To ameliorate the situation for non-commercial research though the regime introduces the so-called contrato marco, a 'framework agreement', as a special access procedure for such research. This has been further regulated by both Ecuador and Peru. As the author notes, Decision 391 was a milestone in the development of a multilateral ABS regime, but it is ambiguous and lacks guidance on post-access monitoring of the value chain. During the debates preceding the implementation of the Nagoya Protocol (NP), Decision 391 was still considered in Ecuador as the basic ABS framework to be complemented by the NP whilst in Peru it did not feature in the debates. Consequently, Ecuador in its Executive Decree (No. 905) of 2011 basically just adopted the same stringent requirements and procedures of Decision 391 and elaborated them. An implementing regulation of 2017 established a one-stop counter with the aim of streamlining procedures in order to improve the situation, but no procedure exists as yet on access to GR for non-commercial research or associated traditional knowledge (aTK). On the other hand although Peru's law Supreme Decree No. 003-2009-MINAM that transposed Decision 391 reflected similar stringiness, its draft of 2019 for a new regulation to implement both Decision 391 and the NP shows some difference. Besides introducing new definitions including from the NP as well as reformulating those adopted from Decision 391 it only requires authorization for non-commercial research to access GR from the competent authority and eliminates the requirement to conclude a framework agreement. The applicant must only identify at least three non-monetary benefits for the country of origin. It also designates checkpoints with functions as required by the NP which is recognition of its obligations to control value chain for use of other countries' GR and aTK in Peru. ABS regulation in both Ecuador and Peru still presents many challenges due to their strict attachment to Decision 391, which could probably explain why no contract for commercial purposes has been concluded up-to-date. A fair improvement seems evident once this bond is avoided. This suggests that to have an effective and efficient ABS regulation and to fully comply with the NP parties to Decision 391 must either develop new domestic regimes independent from it or initiate a radical process to completely transform it in order to reconcile the two systems. Until now the process to revise it has failed.

In chapter "New ABS Legislation and Practice in Compliance with the Nagoya Protocol: Current Situation and Perspectives in Costa Rica", Jorge Cabrera Medaglia examines the access and benefit-sharing framework of Costa Rica. The Biodiversity Law No. 7788 (BL) and the ABS regulations of 2003 and 2007 precede the Nagoya Protocol (NP), but the Costa Rican regime has been applauded as having one of the most complete and functioning frameworks through which a huge amount of experience necessary for providing relevant lessons on how to implement ABS in practice has been produced thus justifying its choice. This is testified by the over

650 permits issued between 2004 and 2020 and numerous negotiated and concluded agreements. It is also quite innovative. For example, a label was created recently to certify that a product has been produced in consistency with the permit and national regulatory framework. Likewise, an applicant can request that a certificate of legal provenance for export purposes be granted, which, although is not an internationally recognized certificate of compliance, can provide legal certainty about the rightful acquisition and transfer of the materials. Nonetheless, some post NP work has been done to improve and clarify the ABS situation, *viz*. the regulations of 2003 and 2007 were revised in 2019 by Decree No. 41591-MINAE, a Memorandum of Understanding was signed in 2014 to clarify and address grey areas as well as achieve a common understanding on key areas regarding access to plant genetic resources for food and agriculture (PGRFA) falling under the multilateral system (MLS) of the International Treaty (IT) and the Decree No. 39341-MINAE was adopted in 2016 to establish procedures for imposition of sanctions for illegal access. In addition, a bill has been submitted to parliament to amend several provisions of the BL, which includes exclusion of most basic research from an access permit requirement and instead creating a notification procedure. Based on the public domain approach established by the law the State controls the entire ABS process by means of the procedure established in Chapter V of the BL, *albeit* the customary rules of the communities and any existing *sui generis* intellectual rights must be taken into account when access is taking place in indigenous territories. The rules established by the regime apply equally to all types of research despite the fact that 'basic research', 'bioprospecting' and 'commercial use' are considered as different activities, but the requirements for commercial purposes are very detailed and royalties mandatory. Only a lean exemption from the obligation to obtain an access permit is provided to basic research activities by Decree No. 31514 of 2003 (regulations) in its amendments of 2019. The regime applies equally to foreign and local entities and does not oblige the former to cooperate with a local institution, but a foreign entity if domiciled abroad must have a national representative for the sake of receiving notifications from the Technical Office (TO). It has a full online platform/system for access for which the National Commission for Biodiversity Management (CONAGEBIO), which is the Competent National Authority, provides a guiding manual for users. In spite of its forerunner position, however, the regime still needs improvements. The validity of 3 years for permits despite the conditions of periodic reporting, monitoring and control, for instance, is considered very short bearing in mind that commercial investigations can take many years before a final product is produced. Although the permits can be renewed, the uncertainty related to the danger of failure of renewal and the burden of the work connected to this still persist. It is also not very bold in committing shared benefits to conservation of biodiversity. Although it mentions the percentage to be shared it does not make it an obligation to invest such shares into conservation. Besides, it establishes registration of *ex-situ* collections as providers of GR but still requires users to negotiate PIC with the collections. This installs a kind-of double PIC negotiation procedure: between the collection and the initial provider of GR and between the collection and the user. In addition, it has no measures for compliance with ABS legislations of other countries

when GR and/or aTK are being utilized in Costa Rica. To bring the regime into full compliance with the NP and incorporate some of its innovative provisions more revision work is necessary. For that Costa Rica maybe also needs to ratify the Protocol in order to get the intuition for the urge.

B. *African Continent*

In Chapter "The South African ABS Regime: New Wine in Old Wine Skins?", Evanson Chege Kamau discusses the regulation of access to genetic resources, traditional knowledge associated to such resources and benefit-sharing in South Africa. In putting its regime in place South Africa had a high demand on its biodiversity for research and development (R&D) by both local and foreign industries, demand for local non-industrial uses, unconstrained access under the notion of common heritage for humankind and the encroachment on associated traditional knowledge (aTK) to contend with. It was therefore necessary for the country to develop a comprehensive biodiversity policy to regulate its use and aTK in line with the international legal framework. Apart from the Act of 2004 regulating access and benefit-sharing (ABS), regulations thereto have been developed (2015) and guidelines for both providers and users (2012). A number of revisions have been done on some of the instruments including after the adoption as well as entry into force of the Nagoya Protocol (NP), *albeit* not in response to the need for compliance with it. But work is underway to bring them into full compliance with the NP. The regime has a number of interesting elements, for example: (1) It has a distinct way of defining terms *viz*. 'indigenous genetic and biological resources', 'bioprospecting', 'any other kind of research' and 'traditional use or knowledge', which makes it clear to what exactly and to which activities it applies. From the definition of 'indigenous genetic and biological resources' in the amendment Act of 2013, for example, it is clear that 'genetic information' and any export of biological resources including by traders for bioprospecting purposes also fall under the scope of the regime; (2) It separates phases of bioprospecting giving ease to early stages of R&D—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 commercialization—in terms of permits and benefit-sharing; (3) It establishes a clear institutional framework; and (4) It provides a fixed timeframe for permit issuing authorities to decide on applications with consequences for failure to meet the set deadlines. But the regime also has some flaws. For instance there are many scattered bits of statutes which make it burdensome to understand the regime with certainty yet the guidelines of 2012 are outdated; the rules meant to differentiate requirements and procedures for the sake of facilitation of non-commercial research are a bit obscure and confusing; model MTA and BSA are provided without an option to expunge, replace or rectify any of the clauses or use another agreement e.g. one proposed by the applicant; and it does not have compliance measures for R&D undertaken in South Africa based on other countries' genetic resources and/or aTK. Among others it is recommended that a kit is developed which brings together the rules, requirements and procedures into one document with references to the different relevant laws and that the guidelines are updated. Currently it is left to wonder whether the

new changes which have been continually made fit/sit well with the old law or are like new wine in old wine skins.

In Chapter "The Post Nagoya Protocol ABS Regime in Cameroon: Exploring the Extent to Which Ongoing Policy, Regulatory Developments and ABS Practices Uphold the Obligations of the Protocol", Marcelin Tonye Mahop presents the current situation in the regulation of access to genetic resources, associated traditional knowledge and sharing of benefits arising from their utilization in Cameroon. Cameroon's rich biological diversity has been subjected to different threats hence the importance for an effective legislation which is able to promote its conservation and sustainable use and benefit-sharing from its utilization. Until recently Cameroon was regulating access and benefit-sharing (ABS) through sectoral laws but now a new law has been adopted and it is hoped that the draft implementing instruments which were developed along the law will be adopted soon. The author discusses this new law and the draft instruments. One of the greatest strengths of the framework is that it closely involves the indigenous and local communities in the ABS process including through the use of their bio-cultural protocols and making them the managers of the benefits shared for, among others, the conservation of biodiversity. Of course it is doubtable that such communities have the ability to manage as well as apply scientific non-monetary benefits. Besides, the law makes it a condition to publish the permit issued together with PIC and MAT on the ABS Clearing-House which should help to create certainty of legal access for users. Also according to the author, the elements of the PIC developed within the new framework align themselves with the minimum requirements of an internationally recognized certificate of compliance in accordance with article 17.4 of the Nagoya Protocol (NP). Likewise, it differentiates between permits for commercial and non-commercial purposes, *albeit* the difference made for access is only the exemption from PIC and MAT for fundamental research and research and development undertaken locally by national research institutions without transfer of materials abroad. In addition, it provides clauses on resolution of conflicts. However, it also has several weaknesses. For instance it says that "previously accessed resources" fall under its scope but does not define a temporal scope. This makes the scope extremely broad but it is assumed that could have been intentional. Also it complicates the permit issuing process by creating a double authorization procedure which requires the applicant to seek authorization or consent to negotiate prior informed consent (PIC), which is a pre-condition for the obtainment of a permit. Likewise, it fails to address the issue of mutual recognition and enforcement of foreign judgements and arbitral awards. In addition, established checkpoints do not embrace the functions of checkpoints as foreseen by article 17 NP, but are focused on monitoring and surveillance of the utilization of Cameroonian genetic resources. This is evident too in the way the draft framework empowers the ABS committee created as an advisory body to the CNA to monitor the value chain of genetic resources utilized abroad including those held in international *ex-situ* collections without an afterthought on how possible that is. That kind of too much focus on control comprises one of the major weaknesses of the regime.

In Chapter "The Ethiopian Access and Benefit-Sharing Regime: Stringent with a Purpose", Ashenafi Ayenew Hailu and Evanson Chege Kamau discuss the regime regulating access to genetic resources and associated traditional knowledge and benefit-sharing in Ethiopia. Being one of the high-ranking biodiversity rich countries of the world Ethiopia in passing its access and benefit-sharing legislation aimed *inter alia* to ensure that the country and its people benefit from its biodiversity, terminate uncontrolled access to it and the knowledge of the local communities, and encourage conservation and sustainable use. Ethiopia regulates access and benefit-sharing (ABS) through a pre Nagoya Protocol (NP) framework which though developed to implement the main pre NP international legal framework was greatly influenced by a Teff biopiracy case. Its stringent measures and a more prudently regulated legal regime to control ABS was therefore intentional. This is reflected, for example, in the condition that foreign institutions and competent national authorities guarantee compliance of users or accept liability for enforcement of their obligations. Nonetheless, the current regime has been revised in order to bring it into compliance with the NP, in particular in regards to user and fully compliant monitoring measures, as well as to expunge measures that are hard to implement. As this book was written a draft law had been sent to the Council of Ministers for scrutiny before submission to parliament for adoption. Therefore, the authors examine the current regime in parallel with the revised draft law. This is useful in particular in establishing the level of compliance of the to-be regime with the NP. For instance, the old law did not have user (compliance) measures but these have been included in the revised draft law; the old law included the wording 'genetic information' in its definition of 'genetic resources' and believed that this included 'digital sequence information' (DSI) but the draft law uses the latter term in the revised definition of 'genetic resources', which makes it clear that DSI falls under its scope. The authors also look at the strengths and weaknesses of the revised draft law. Among strengths other than those mentioned above the draft law is clear concerning bulk resources used eventually in research and development (R&D), which will then fall under its scope, and establishes a temporal scope from 27 February 2006; it maintains a kind-of one-stop shop with Ethiopian Biodiversity Institute (EBI) being the national focal point and the competent national authority; although the old law also differentiates between access for commercial and non-commercial purposes and their requirements and procedures the terms 'commercial' and 'non-commercial' were not defined, but have been defined now in the draft law; it exempts plant genetic resources for food and agriculture under Annex I of the International Treaty from its regulation unlike the old law; and it is specific concerning allocation of benefits for conservation and sustainable use purposes. The main weakness of the Ethiopian regime including the revised draft law is its restrictive and protective nature which tries to regulate every aspect touching on genetic resources in an attempt to close every window of misappropriation and misuse and guarantee the country's sovereign rights over its resources. The revised draft law's architecture, however, is out to *inter alia* promote research and the fair and equitable sharing of benefits. This it is hoped will contribute to the conservation and sustainable use of biological diversity in line with the Nagoya Protocol.

In Chapter "Abracadabra! Or When and How Will the Kenyan ABS Law Be Born?", Evanson Chege Kamau presents the Kenyan access and benefit-sharing regime. As one of the megadiverse countries Kenya in developing an access and benefit-sharing (ABS) regime aspired to advance conservation and sustainable utilization of its biodiversity, contribute to fair and equitable sharing of benefits arising therefrom and curb its overexploitation and unregulated bioprospecting. In the process a number of challenges have been encountered the main one having a negative effect on the legislation being lack of a concerted approach by the different lead agencies leading to fragmentation and sectoralism. ABS is still regulated through a pre Nagoya Protocol (NP) biodiversity framework legislation of 2006 and sectoral laws. Without need to say the biodiversity legislation is one of the post CBD laws passed with the aim of instilling control rather than enabling research. Though it is an old law the choice of the case study is justified by the fact that sectoral laws have always played a major role in regulation of ABS in Kenya of which one has been revised and one legislated post NP. The author examines the interplay between the relevant laws and how ABS functions and is affected as a result. It is established that, despite some of the sectoral laws being post NP legislations, the complexity and unclarity of the regime persist or is occasionally hiked. Apart from the procedural complexes and challenges the regime has other weaknesses, *inter alia*: The definitions of 'biological/genetic resources' as well as activities contemplated under the definition of 'access' are very broad; the biodiversity legislation does not provide complaint channels against applications granted by the competent national authority although opposed by the public, *albeit* the Constitution of 2010 as well as Environmental Management and Coordination Act grant standing on public matters; it is not clear to which fund the benefits shared shall be put or how they shall be shared; there are no user compliance measures; designated checkpoints have no functions in line with the NP; county governments have been created in the new Constitution but their roles in ABS are not concretized; and terms are used inconsistently across the different laws. Maybe the strength of the Kenyan regime lies in the approach of the new practice of finding ways to ameliorate the challenges created by the relevant laws, although the author warns that such an approach can also cause legal uncertainty e.g. if applied measures are later challenged. Existing challenges are a cause for legal uncertainty, unclarity and intransparency which at the end are a stumbling block to Kenya's initial aspirations. There is need for the law to catch up with practice although the many years of attempts to revise the biodiversity law of 2006 as well as develop a stand-alone law without tangible results makes questionable the ability of these efforts to bring forth a "healthy product".

C. *Asian Continent*

In Chapter "The New Law and Practice on ABS in Viet Nam: Innovations and Compliance with the Nagoya Protocol", Tran Thi Huong Trang Guihou, Nguyen Ba Tu and Nguyen Dang Thu Cuc look at the regime regulating access to genetic resources, associated traditional knowledge and benefit-sharing (ABS) arising from their utilization in Viet Nam. In response to conserve and sustainably use its

rich biodiversity, being one of the world's biodiversity hotspots and based on the key role biodiversity plays to its development Viet Nam has promulgated relevant policies in line with international treaties. After becoming party to the Nagoya Protocol (NP) it adopted a new law, Decree No. 59 of 2017, replacing Decree No. 65 of 2010 which had been issued in order to elaborate and guide the implementation of the Biodiversity Law (BL) of 2008, but its provisions were still limited and inconcrete to be applied directly into practice. During its seven years lifetime (2010–2017) there was no applicant for a permit of access. Decree No. 59 was adopted in order to deal with these shortcomings, implement the NP and clarify the conformity situation/question with the NP and the ABS provisions of the BL. The Decree was developed in collaboration with a number of international partners and therefore the Viet Nam case study like the Argentinian and Malaysian also foreshows the role of foreign international partners in the development of domestic laws. This is not the focus of the case study but just to mention, this could maybe explain whether the interests of foreign entities are better represented following such collaborations (according to the authors one of the aims of the regime is to "create a system of ABS for foreign entities"), or whether the rights of the relevant country are muffled, or if the resulting laws are well balanced. One of the notable characteristics of the regime is that its model contract also serves as the prior informed consent and mutually agreed terms. Its weaknesses include the very broad definition of the term 'genetic resources' (in the BL) that puts biological resources in general under scope, but lacks a list of activities it considers as 'utilization'; there are no measures to regulate associated traditional knowledge but a guidance document on the same is being developed; the practice allows supply of genetic resources (GR) by "informal" intermediaries (parataxonomists) but users may not interact directly with them which is a cause for legal uncertainty; it does not exempt plant genetic resources for food and agriculture under Annex I of the International Treaty, *albeit* Viet Nam is not party to the treaty; it does not establish user compliance measures; and it lacks a financial mechanism to receive and distribute shared benefits as well as guide on the use of benefits for biodiversity conservation and sustainable use purposes. It also has strengths, e.g. it establishes a clear temporal scope of 1 July 2009 when the BL came into effect; it gives the possibility of regularization for users who accessed GR from this date up to the date Decree No. 59 entered into force and would wish to continue utilizing the GR but had not obtained a permit/license; it defines clearly which authority is responsible for which GR with clear procedures and has a relatively short timeline for application decisions to be taken both for non-commercial and commercial purposes; it establishes an online application procedure; it offers an option to share benefits either in monetary form or non-monetary also for commercial uses. In general the law looks relatively comprehensive and many of its attributes comply with the NP, but the regime is prone to implementation challenges due to potential conflicts within the regime as some provisions of the BL became outdated with the issuing of Decree No. 59. Whilst the latter is more specific on the subject area, it must be consistent with the former being a by-law. It is recommended

that the BL be revised in order to eradicate these conflicts and simultaneously the opportunity be whisked to fix other shortcomings of the regime.

In Chapter "The Fastest Animals Are Not the Fastest Over Time: Malaysia Adopts a Comprehensive ABS Legislation After a Long Steady Effort", Evanson Chege Kamau discusses the Malaysian legislation on access to genetic resources, associated traditional knowledge (aTK) and benefit-sharing. Despite being a megadiverse country and ratifying the Convention on Biological Diversity (CBD) early followed by an immediate and a focused initiative to implement it, Malaysia did not have an access and benefit-sharing (ABS) legislation at a national/Federal level until the adoption of the Act of 2017. Efforts at the national level had produced the first national/Federal draft framework as early as 1999 but this study could not establish with certainty why such a long delay followed afterwards. Collaboration with international partners that began in 2010 seems to have played a decisive role in the final success. The Malaysian Act applies to genetic and biological resources and information thereof, associated traditional knowledge (aTK) and, contrary to the CBD, human genetic resources. Besides its application to human genetic resources other peculiar features are its retroactive application to biological resources (BR) and aTK if no benefit-sharing agreement (BSA) had been entered into prior to its entry into force and the possibility for the competent authority (CA) to deny an access permit if the jurisdiction of the user does not have effective user compliance measures. Although BR for bulk uses are exempted from its application the provisions of the Act will be triggered if they are later used in research and development (R&D) obliging the person involved in the activity to enter into a BSA with the resource provider and receive a permit from the competent authority. Among its strengths, unlike most traditional provider countries' legislation, the Malaysian Act establishes user compliance and monitoring measures; defines critical terms e.g. non-commercial research even though the procedure is not differentiated; provides a provision to direct benefits deposited in the fund to conservation and sustainable use of biodiversity; establishes a clear temporal scope; exempts specialized instruments for ABS from its scope; recognizes the rights of the indigenous and local communities (ILCs) as providers of BR on land to which they have a right as established by law and to their aTK and establishes that the process of obtaining prior informed consent and concluding benefit-sharing agreements must occur according to the customary laws and practices, protocols and procedures of such communities; and foresees as well as provides solutions for situations where the representation of ILCs does not exist or where the aTK is shared by more than one community. However, it misses a mark concerning the requirements of article 18 of the Nagoya Protocol as it has not addressed the questions of access to justice in case of disputes arising from mutually agreed terms or mutual recognition and enforcement of foreign judgements. Also, it does not say to which jurisdiction disputes shall be subjected to or give options for dispute resolution, or which will be the applicable law. Without denying that the new law has slightly more flaws, observation is made that the law is clear and to a great extent gives a sense of legal certainty, which the author attributes to the long duration and steady effort taken by Malaysia to legislate.

In Chapter "Access and Benefit-Sharing Law and Policy in South Korea", Jae-Hyup Lee and Ah Young Cho examine the new law regulating the access and use of genetic resources in South Korea. Until the adoption of the Act on access to and utilization of genetic resources and benefit-sharing of 2017 (Act), Korea did not have a comprehensive law to address ABS. The laws and regulations for the protection of the environment and species, some predating the CBD, did not protect biological diversity directly, were fragmented and were not sufficient to implement the Nagoya Protocol (NP). Unlike most case studies examined in the book, Korea is more a user of genetic resources (GR) than a provider with the biotechnology industry having grown into a major industry. Besides, a large amount of GR is imported from overseas due to a lack of domestic alternative resources, insufficient supply and a high cost of domestic GR. Therefore, the delay in ratifying the NP, which only took place in 2017, and putting access and benefit-sharing (ABS) measures in place is criticized by the authors as having disadvantaged local industries because provider countries would be reluctant to export GR to Korea. However, this could have been a calculated move to avoid or delay compliance with measures of provider countries as it was also evidenced in other industrialized countries. The current Act likewise exhibits some signs of alignment with user perspectives, e.g. it does not mention derivatives and digital sequence information (DSI), establishes a temporal scope of 17 August 2018 which is post its entry into force and a list of the Regulation (EU) No 511/2014 is reproduced in a guideline published in 2019 as examples of activities considered as utilization. Some of the strengths of the Act are that it exempts GR subject to international treaties on ABS from its scope which is in line with article 4 NP; by defining the term 'benefit' to mean monetary or non-monetary it opens the opportunity for parties to agree on any kind of benefits including from commercial uses; it establishes user compliance measures including for tracking and enforcing in line with articles 15, 16 and 5 NP; it designates checkpoints in line with article 17 NP; it eliminates the requirement for an application, prior informed consent or conclusion of a benefit-sharing agreement for access to GR and requires only a report to the head of the competent national authority (CNA); it creates a short duration of 30 days from the date of receipt of the report for the CNA to inform the person seeking access of the outcome; it has given power for waiver of the requirement of a report or simplification of procedures; has provided for expeditious access for utilization related to human, plant or animal health in line with article 8 (a) and (b) of the NP; and has installed a simple and easy integrated online reporting system. However, it also has weaknesses, e.g. no distinction is made between research of a commercial and non-commercial nature; two national focal points have been established contrary to article 13 NP which states "Each Party shall designate a national focal point on access and benefit-sharing" and unlike any other party to the NP; no sanctions are offered against violations relating to foreign GR utilized in South Korea thus weakening enforcement; and except mentioning traditional knowledge in the declaration of the purpose (Art. 1) of the Act and in definitions (Art. 2) there are no measures to regulate associated traditional knowledge but its argued that the mention might be just precautionary as such knowledge is non-existent in Korea; it exempts privately held GR from its scope and thus leaves

a gap concerning regulation of such resources. But the greatest weaknesses of the regime maybe is the fragmentation of relevant laws and national authorities with jurisdiction over ABS issues thus making it hard for users to understand the procedures, increasing administrative tasks and raising costs and management burdens. It is advised that the government issues guidelines for users, researchers and companies with a clear interpretation of representative cases which they can use as a basis for consultation and negotiation.

D. *Australian Continent*

In Chapter "ABS in Australia: A Story of Early Success and Faltering Progress", Geoffrey Burton describes the situation with the access and benefit-sharing (ABS) legislation in Australia. Being a megadiverse country with an extensive body of traditional knowledge associated with genetic resources and also a growing biotechnology and life sciences industry, Australia is a developed-economy user of genetic resources (GR) and associated traditional knowledge (aTK) and a rich provider of the same. An interesting observation would be to see how it reconciles the interests of both sides domestically as well as address them internationally making it a good choice for our study in spite of not having a post Nagoya Protocol (NP) federal legislation. It is apparent that Australia became party to the Convention on Biological Diversity (CBD) immediately when it entered into force on 29 December 1993. However, the implementation domestically of its ABS measures by including a general provision in the biodiversity law of 1999 did not detail how ABS should be undertaken, an issue which was left to yet to be developed subordinate legislation (regulations). The top-down process which was initiated to do this, the so-called Voumard Inquiry of 2000, had to ensure the enactment of a robust legislation that addressed the different stakeholder interests and likewise that social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia. Another thing that makes complex the implementation of ABS measures is the form of government being federal with 6 sovereign States and 2 States that are accorded self-governance, and strong indigenous peoples' rights which the Government at the same time must protect. The inquiry made recommendations to the Government of the legal framework and legal scheme advocated based on principles it developed in response to stakeholder concerns. Parallel to the inquiry and the development of a draft law, Australia was actively involved in the development and adoption of the Bonn Guidelines of 2002. Being consistent with the Government's ABS policy, the emerging draft Environment Protection Biodiversity Conservation (EPBC) Act regulations and the national Strategy of 1996, the national Government in an agreement with all States and territories agreed on a uniform implementation in the same year. The so-called Nationally Consistent Approach comprised 14 principles and 11 common elements which were to be reflected in each jurisdiction's subsequent ABS law and administration. The draft law was finalized in 2005 and included in the regulations of the Biodiversity Act as "Access to biological resources in Commonwealth areas" and had the aim of giving effect to the Bonn Guidelines and the Nationally Consistent Approach. It serves as a model ABS law with the purpose of among others

conservation of biological resources and their sustainable use, equitable benefit-sharing, respecting indigenous peoples' traditional knowledge, and providing legal certainty. For non-commercial research the permit is free and for commercial purposes only a nominal fee of AU$50 is charged. For the former there are arrangements for facilitated access and exemption from benefit-sharing agreement (BSA). For the latter a permit and BSA are necessary but the approval of applications is provided rapidly within 2–10 days. A permit of access from the territories of the indigenous peoples is granted on condition of evidence of a BSA between them and the prospective user based on prior informed consent (PIC) and mutually agreed terms. The current system has been functioning successfully for 14 years with the granting of permits taking place at the rate of 2–3 permits per month. Australia also went on to solve the challenges of operationalization of the regime e.g. the uncertainty created by international and domestic debates on the scope of GR, the difficulty in verifying the legal provenance of GR, disclosure of use of GR to the indigenous peoples and proper grant of their PIC, and facilitation of access. Further improvements to the regime have been introduced as recently as 2020 through an amendment to the biodiversity law in order to devolve Commonwealth environmental approvals down to states and territories. Nonetheless, Australia has not yet ratified the Nagoya Protocol (NP) although it signed it in 2012. Options for complying with the NP were published and the initial progress towards ratification made in 2014 but no further development of a model system for implementing the NP has occurred since then. It is noted that Australia's ratification of the NP is dependent on continued pressure from its biotechnology research communities and from its state and territory governments, which is indicated by some of them undertaking their own initiatives. The State of Queensland, for example, passed the Biodiscovery and Other Legislation Amendment Act on 20 August 2020, with its amendments coming into force on 30 September 2020.

E. *European Continent*

The book enters a new section of studies examining the regulation of ABS in the European continent. The focus of the studies is limited to the European Union (EU). The EU transposes international treaties as a block. Following this pattern the EU implemented the Nagoya Protocol through Regulation (EU) 511/2014.[22] The EU adopted the Regulation on 16 April 2014 and it applies as of 12 October 2014, which is the date of entry into force of the Nagoya Protocol (NP). It aims to implement the compliance pillar of the NP in the EU which means that it does not regulate access to genetic resources (GR), associated traditional knowledge (aTK) and related benefit-sharing in the Member States (MS) of the EU. However, it gives them leeway to implement provider/access measures. The Regulation has direct effect in MS and therefore each MS must implement it nationally. Up to date only 5 out of the 27 MS have put in place (in addition to the obligatory user measures) provider measures for

[22]For a thorough scrutiny of the implementation ('due diligence') model of the Regulation and suggestion for an alternative ('integrative') model see Godt et al. (2020).

access to GR and aTK, i.e. Spain, France, Croatia, Malta, Bulgaria. Two more, Finland and Sweden, have provider measures only for associated traditional knowledge. This section examines Regulation (EU) 511/2014 which consists of the compliance regime of the EU and then presents two case studies of Spain and France as examples of MS with a dual provider and user State role.

In Chapter "The ABS Compliance Regime of the European Union", Gerd Winter scrutinizes the regime of compliance with the obligations of the Nagoya Protocol in the European Union. The genetic potential of organisms living *in-situ* within the borders of most legal systems of the EU Member States (MS) are considered in principle as *res nullius*, i.e. free goods. This implies that both foreign and domestic researchers are free to access and utilize them in research and development without any restrictions as well as obligations on benefit-sharing. It is not surprising that Regulation (EU) 511/2014 that transposes the Nagoya Protocol (NP) in the EU only considered user measures for complying with provider measures. Apart from excluding provider measures, the Regulation does not include transfer of relevant technologies, capacity building and appropriate funding which are also objectives of the CBD and its NP, a failure Winter criticizes. The Regulation uses basic duties as instruments to ensure that access to genetic resources (GR) and associated traditional knowledge (aTK) and their utilization take place in a legal manner/in compliance with provider access and benefit-sharing (ABS) measures. These duties are placed on users of GR and administrative oversight. Besides, there are additional provisions on registered collections and recognized best practices with the aim of simplifying the obligations of users and administrative bodies. How this system is meant to function from access to benefit-sharing is summarized in a table by the author. The Regulation enforces its obligations on users through its concept of compliance called due diligence. Users must ascertain that first, they exercise due diligence and second, they declare due diligence at specified stages. This burden is alleviated if the GR is accessed from a registered collection as due diligence is considered to have been exercised. Administrative/enforcement authorities on the other hand must conduct checks to ensure that users are complying or have complied of which the author suggests must go beyond the normal practice and extend to the bringing on the market of products developed on the basis of accessed genetic resources, as well as to the sharing of benefits therefrom. Administrative/enforcement authorities are also empowered and mandated to receive due diligence declarations from users. In addition, other important issues examined concern the scope of application of the Regulation—material, personal, geographical, temporal. Regulation (EU) 511/2014 is an exemplary step forward of user States which tries to ensure compliance with the ABS regimes of provider countries but the compliance scheme it establishes suffers a number of shortcomings in practice e.g. in regard to declarations, basic duties of users and checking for which the author suggests ways of solving.

In Chapter "Access and Benefit-Sharing Regime of Spain: Striking the Right Balance Between Its Interests as a Provider and a User of Genetic Resources", Luciana C. Silvestri presents the regime of access and benefit-sharing of Spain. Spain is the most biodiverse country in Europe with one of the greatest cultural

diversity endowing it with a wealth of traditional knowledge associated with genetic resources (aTK). At the same time, Spain has a fast-growing biotechnology industry and is a Member State of the European Union making it an important user country. Thus, Spain's interests cut across both provider and user sides. It supports effective access and benefit-sharing (ABS) regimes that enable providers to benefit from the utilization of their genetic resources (GR) and aTK while facilitating research and development by users and simultaneously strong (user) compliance regimes which are able to curb violations against provider interests/measures. This bestows on Spain a double role as a provider and a user and has put in place provider measures and, in implementing its obligations based on Regulation (EU) 511/2014 and Commission Implementing Regulation (EU) 2015/1866, user measures. The features of both provider and user measures are evident in its ABS regime. In regard to provider measures, for example, prior informed consent (PIC) must be obtained, mutually agreed terms (MAT) established and an access permit sought for access to *in-situ* or *ex-situ* GR from the date of entry into force of Royal Decree No. 124/2017, i.e. 15 March 2017, as a general rule. Spain consists of 17 autonomous communities each of which is responsible for granting PIC and establishing MAT for access to GR from their jurisdictions and, in addition, authorizing access if the GR is endemic to their community/territory. There are variations of the rule e.g. if the GR is located in the territory of more than one community, or falls under the jurisdiction of the State, or is intended for non-commercial purposes or for commercial purposes. It is also notable that the duration for review of an application for commercial purposes is relatively long taking up to six months. Concerning user measures the temporal scope, for instance, follows the usual trend of user countries' approach. Besides, it does not apply retroactivity in regards to entities that at the date of entry into force of Royal Decree No. 124/2017 had GR already under their control even if their activities concern new utilization, it exempts pure scientific biodiversity research from its regulation, and it embraces user compliance measures built on the concept of due diligence as foreseen by the EU instruments on ABS. It can be observed that Spain has managed to comply with the obligations of the NP and the EU Regulation and has even been more ambitious than the latter, a sign that ABS has a chance of being efficiently and successfully implemented in Spain. Although it will take some years to assess its effects the author concludes rightly that the current regime of Spain may serve as a model for countries with a dual provider and user role.

In Chapter "The Post Nagoya Protocol ABS Regime in France: Exploring the Extent to Which It Upholds the Obligations of the Protocol", Marcelin Tonye Mahop explores the regime that domesticates the Nagoya Protocol on access and benefit-sharing (ABS) and also, since France is a Member State of the European Union (EU), implements European Union law on ABS according to Regulation (EU) 511/2014 and Commission Implementing Regulation (EU) 2015/1866 in France. France considers itself a megadiverse country based on its unique position in Europe and the rich biodiversity found in its overseas territories. France is equally a major user of genetic resources (GR) being a technologically developed country. Therefore like Spain, it is committed to implementing these agreements and laws in order to consolidate its position as a provider of GR and a user of GR and associated

traditional knowledge (aTK). France formulated its domestic ABS regulatory framework to comply with the NP following its ratification. France comprises the mainland and the overseas departments and regions, but according to the Constitution the ABS law Code de l'Environnement (Loi No 2016-1087 of 2016), its implementing Decree No 2017-848 of 2017 and the model contract for utilization of aTK annexed thereto would equally apply to mainland France as well as the overseas regions and territories. There is a second model contract for access and utilization of GR which was promulgated as a separate implementing regulation (Arrêté (Order) of 2017). With two different approaches for access it installs provider measures for access to GR. Through a "declarative approach" access for non-commercial uses is allowed without need for an access permit. In the contrary, an "authorization approach" is used for access for commercial uses with the applicant required to obtain an access permit after the relevant authority is satisfied with the application and the applicant having first successfully negotiated a benefit-sharing agreement (BSA)/contract which is based on the PIC of the communities. A BSA is meant to materialize the prior informed consent of the relevant authority, which will either be the national competent authority or the relevant authority of an overseas territory. A special application process is foreseen for utilization of aTK of the communities of inhabitants of Guyana and Wallis and Futuna Islands. The access permit contains the usual provider conditions on third party transfers, change of intent etc. In fulfilling its obligations under Regulation (EU) 511/2014 France also puts in place user measures following the concept of due diligence. User characteristics include the application of the ABS regime from the date of its entry into force on 9 August 2016 and non-applicability to resources accessed as bulk commodities and used later for research and development. It is strange that it subjects subsequent access to resources held in collections that were constituted before that date and any new uses of those resources to the law as a highly industrialized EU State, but again it shows its provider inclination. Although the regime is clear, contains transparent procedures and is generally *de jure* compliant with the NP, it lacks a mechanism for bringing corrective and punitive actions against users for non-compliance. This has the potential of lowering the degree of its compliance and hence should be corrected.

Part III: Implementation Experiences and Lessons

In Chapter "Post Nagoya Protocol Experiences of Basic Research in Ecuador", Erwin Beck looks at the circumstances and experiences of doing research in Ecuador for basic biodiversity research before and after the ratification of the Nagoya Protocol. This is reported from first-hand information of the author's work within German research groups which have been engaged in ecosystem studies in South Ecuador since 1997. The groups cooperate with local (Ecuadorian) partner institutions under Memorandums of Cooperation since the last 22 years and are mainly funded by the German Research Foundation (DFG). The implementation of the regulations of the Nagoya Protocol (NP) turned out to be a difficult and still ongoing process in Ecuador. This, according to the group's experience, is based on a number of reasons, *inter alia*, that its 24 provincial governments practice a relatively high level of autonomy in particular with respect to biodiversity issues. As a result, the research group's projects located in different provinces are accorded different

treatment in administrative supervision, including in regard to details of permits. With the implementation of the NP, 6 focal points have been recorded. Competences are not centralized and there is a shortage of experts in the Federal ministries. Biological research as a field reaching into several administrative responsibilities is also not easy to handle by the authorities. Three governmental authorities are relevant for granting access to genetic resources (GR) and permission for basic/academic/non-commercial research with biological materials. The Secretaría Nacional de Educación superior, Ciencia, Tecnología e Innovación (SENESCYT) is the authority competent for issuing research permits. Concerning biological materials the Ministry of Water and Environment (Ministerio de Agua y Ambiente del Ecuador, MAAE) (and its provincial branches) has to agree and decide whether the project has a commercial purpose. If it does have a commercial purpose it will need a so-called framework contract (contrato marco) with prior informed consent (PIC), mutually agreed terms (MAT) and an Internationally Recognized Certificate of Compliance (IRCC). If it is only for basic research then it could benefit from facilitated procedure of granting research permission in line with article 8 (a) NP. This differentiation is also valid for Ecuadorian research institutions. Considered as an interim regulation, the authority of granting access to GR and issuing research permits is currently with MAAE with counselling by the National Biodiversity Institute (Instituto Nacional de Biodiversidad, INABIO). For the research group's projects in South Ecuador, ministerial supervision has been transferred to the provincial branches of MAAE, however, permission to transport biological materials between provinces ('movilización') requires also approval by INABIO. MAAE is competent for export permits of biological materials and also for activities in the scope of RED+. Prior to the adoption of regulations to ratify the NP the groups worked on group research permits. Thereafter each subproject had to obtain a separate research permission with the responsibility for compliance given to the speaker of the entire group in cooperation with an official of INABIO. Besides, research permits were initially issued according to funding duration of the projects but after 2006 they were valid for one year only. In addition, annual reports and annual applications were obligatory. Other obligations have been maintained in the new post NP contract following the ratification of the NP in 2017. In the post NP era the responsibility of ensuring conformity with the permission has been taken from the local partner to INABIO under its framework contract on access to GR with MAAE which was established in 2016. The agreement allows *inter alia* access to GR exclusively for academic research purposes to increase basic knowledge, excludes other types and aims of research, possession and utilization for other purposes, and excludes access to traditional knowledge. The group received its post NP research permit from INABIO (with agreement by MAAE) and was registered under the title "RESPECT: Environmental Changes in Biodiversity Hotspot Ecosystems of South Ecuador: Response and Feedback Effects" in June 2018. The rights and obligations of the group are defined in individual permits. Accordingly, research is only granted on those biological resources which have been specified in advance in the group's projects. Export and mobilization permits can be applied for under these permits. To show the obligations of former research permits and changes following the

incorporation of the research group in the framework contract the author makes reference to his own projects carried out in the period of 2013–2018 and 2018–2020 mentioning concrete conditions and obligations. Since his project was a subproject of the program of a research group some points of general importance were also mentioned in the research permit. For example, the mobilization document could be used in the export process if the German University was declared as the final destination of the samples. For the research unit RESPECT (2018–2020) its subprojects are legally viewed as projects of INABIO ("Genetic Biodiversity of Ecuador") under the framework contract which, however, expired in July 2019. The application form contains information on details to be provided while the framework contract contains more general provisions. Most importantly, it authorizes the named coordinators of the projects (in joint responsibility with the INABIO) for the execution of the collection, manipulation and access to biological resources. They are responsible to ensure that all persons working in the projects perform in compliance with the contract and that they are familiar with its provisions. Any change of the coordinators must be immediately reported to MAAE. The contract allows fresh material to be analyzed only in Ecuador but for specified analysis (e.g. stable isotope signals) dry samples may be exported subject to a mobilization permit from the relevant provincial branch of MAAE and an export permit by the Federal MAAE in Quito, applied for the group by INABIO. Whilst GR rights are under the sovereign rights of Ecuador, property rights of the authors over their data is recognized by the current legislation. The framework contract does not mention digital sequence information. Except capacity building for the staff of MAAE and the sharing of results it does not impose other forms of benefit-sharing. It is presupposed that this is because the contract was negotiated on the basis of an Ecuadorian institution with 7 Ecuadorian and only 1 external group. After the termination of the framework contract in 2019 the group works on the basis of a "simple" research permit which does not involve access to GR. In spite of constraints arising from the implementation of the NP a number of things have been critical in the groups success in doing research in Ecuador, among them the group's declaration to abstain from any bioprospecting from the onset and in the unlikely case its commitment to leave any promising organism with the Ecuadorian partner, collaboration with several partners which has developed into a sustainable fundament of mutual support, and the trust built over the years based on transparency.

In Chapter "Rights Over Genetic Resources and Ways of Monitoring the Value Chain: A Case Study from the Royal Botanic Gardens, Kew", China Williams describes Kew's experiences monitoring the utilization of genetic resources down the value chain to ensure that the access requirements and national measures of provider countries are adhered to and benefits are shared. Ensuring that the measures of the party providing genetic resources (GR) are observed and benefits are shared has been a major challenge for users and providers alike because "use and actors change along the value chain as the resources are used in different ways". In spite of the Nagoya Protocol (NP) obliging all parties to put in place compliance and monitoring/checking measures as well as establishing the ABS Clearing-House, there are still challenges and variations in implementation. Such challenges vary

according to the kind of intermediaries involved and their roles. This raises practical questions, for instance, how should restrictions and conditions imposed by the provider of the material stay linked with the material and how can the value chain be tracked? How should future users be bound by terms of what was initially a bilateral agreement? These questions are addressed through the practices and experiences of Kew. Research undertaken at Kew does not generally have a commercial application; it is largely fundamental, exploratory, research focused on enhancing understanding of plant and fungal diversity. A small area of research focusses on the exploration of phytochemicals and their biological activity. With new ABS legislations following the adoption of the Convention on Biological Diversity (CBD) and resulting challenges, Kew developed an Access and Benefit Sharing (ABS) Policy in 1998. The policy was designed to ensure that all material brought into Kew (whether collected on fieldwork or from other institutions or individuals) has been legally acquired on mutually agreed terms (MAT), that it is used and supplied on terms that are consistent with those under which it was acquired, and that benefits arising from use are fairly and equitably shared. To this end, Kew staff at the newly created 'CBD Unit' started working with science staff to create templates for more formal collaborative agreements with partners, with specific terms on the acquisition, use and supply of genetic resources. The author reports that in October 2019 Kew had over 140 active research agreements with a wide range of international partners in over a hundred countries. These agreements ensure that Kew is working legally, within the national and international laws and regulations, and have become a vital tool in ensuring agreed best practice is followed. These agreements include Memoranda of Collaboration (MoC) and model Access and Benefit Sharing Agreement (ABSA). MoC are considered low risk and are the primary agreements used by Kew and its partners whilst the model ABSA represents a more formal style of agreement and is used where the material is considered more 'high risk'. The latter confirms that prior informed consent (PIC) was obtained and MAT have been negotiated. Kew's ABSAs are usually signed, or counter signed by the government authority in the partner country responsible for granting access. Apart from the MoCs and ABSAs, Kew has developed a suite of other model agreements to be used to ensure that terms and conditions relating to the use of the plant material it has accessed, used or supplied, are monitored and passed on to third parties. The main terms of model agreements used by Kew for monitoring the value chain include conditions on use of material, purpose of acquisition (non-commercial), transfer to third parties, benefit-sharing and reporting. Any material brought back from overseas fieldwork trips by Kew's scientific staff is incorporated into Kew's diverse collections according to terms and conditions of permits and agreements with provider countries. Likewise, fieldwork is planned well in advance in accordance with the Kew's ABS policy to ensure that all aspects of legal collection are adequately prepared. In addition to having its own ABS policy, Kew ensures that its internal policies and processes are in line with sectoral best practice in the area. All these efforts attempt to fill the existing policy gap on both user and provider sides. Their aim is to set out, what is fair and equitable, standard setting and working with others in the sector to ensure there is an agreed understanding of what is 'best practice'. Kew has taken

commendable steps to ensure compliance with provider measures and benefit-sharing but work is still needed to improve long-term use tracking to which a number of recommendations have been made.

In Chapter "First Experiences in the Implementation of the EU ABS Regulation in Germany", Thomas Greiber and Ellen Frederichs look at the implementation of Regulation (EU) No 511/2014 in Germany, which transposes the Nagoya Protocol (NP) compliance provisions, or so-called user measures, in the European Union (EU). The NP compliance provisions are articles 15 and 16 on prior informed consent (PIC) and mutually agreed terms (MAT) requirements of the country providing GR and aTK, article 17 on monitoring the value chain meant to support articles 15 and 16, article 18 on compliance with MAT and articles 19 and 20 to promote the development of compliance support tools. Except article 18 which is left to the individual MS to implement, the EU Regulation implements these provisions through the so-called due diligence (DD) system. This is comprised of the obligation of users to exercise DD and file different DD declarations, the obligation of competent authorities of EU MS to check user compliance with the DD obligations, and a voluntary EU register of collections and recognition of best practices by the European Commission. Germany is a NP party since 2016. It does not regulate access to GR and arising benefits and therefore does not require PIC and MAT for GR collected *in-situ* but there are the general public and private law restrictions to be observed. Concerning access to *ex-situ* GR it would depend on their *in-situ* origin and whether there are any conditions attached thereto. As such Germany focuses on the compliance obligations on the basis of the EU Regulation (EU) No 511/2014. Germany has implemented the NP and Regulation (EU) No 511/2014 through the German Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No 511/2014 of 2016. The Act designates the Federal Agency for Nature Conservation (Bundesamt für Naturschutz—BfN) as the competent national authority (CNA). The BfN is empowered to conduct compliance checks, receive DD declarations, handle applications for registration of collections, provide relevant advice to users in Germany, and cooperate with CNAs of provider states to ensure user compliance. In addition, the Act regulates other possible measures that the BfN can undertake in order to address situations of non-compliance. The national focal point (NFP) is the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz und nukleare Sicherheit—BMU). The authors give an overview of the activities of the BfN to implement the Act and the EU Regulation in the period of 2016 to 2019. In Germany, declarations are mandatory at both stages of research funding and product development. Once the BfN has received a DD declaration it checks its completeness, timeliness and plausibility. A number of difficulties have been encountered with checking the plausibility due to unstandardized forms of agreements and permits and also because these are issued in different languages. It is therefore vital to think about harmonization to which Internationally Recognized Certificates of Compliance (IRCC) are critical. After checking, the BfN in collaboration with the NFP submits information provided/declared by users as required by Annexes II and III of the Implementing Regulation

(EU) 2015/1866 to the ABS Clearing-House after which it is published as a checkpoint communiqué. A copy of this is forwarded to the provider country which may open a bilateral communication between the BfN and the (competent) authorities of the provider country. If the provider country reports irregularities in the communiqué the BfN may become active again to try and investigate the allegations. This kind of communication was helpful is bringing further clarification in the first DD declaration/checkpoint communiqué. Germany was the first country to receive DD declarations in the EU in mid-2018. These became the first checkpoint communiqués in the world. By December 2019 BfN had received 11 DD declarations and from the 17 checkpoint communiqués 10 were from Germany. All 11 fall in the first category of DD declarations, i.e. at the stage of research funding. The lack of DD declarations at the stage of commercialization is perceived to be due to first, the temporal scope of the EU Regulation which means it only applies to GR accessed after 12 October 2014 and yet the final development of a product can take long and second, because products can be developed on the basis of old materials which fall out of its temporal scope. But how effective are the DD declarations as a tool to monitor compliance with the NP in practice and do they not only lead to bureaucracy? The authors observe that users making DD declarations have nothing to hide while those who violate the DD obligation will not file the declarations. That makes checkpoints only a means to confirm compliance or to detect negligent non-compliance. Thus, first experiences with DD declarations indicate that their ability to detect severe and urgent cases of ABS non-compliance is limited. Apart from receiving DD declarations, checkpoints have a duty to undertake compliance checks in order to verify whether DD obligations are being/have been fulfilled according to the two triggers foreseen by the EU Regulation: periodically reviewed risk-based plans and substantiated concerns. The German Act specifies the rights of BfN concerning compliance checks and stipulates sanctions. BfN began its first risk-based checks in 2018. The experiences by the BfN point to a number of challenges in enforcing the DD obligations. There is a lack of relevant ABS/user data which could facilitate *a priori* selection and reliable assessment of institutions falling within the scope of the Regulation in connection to their activities. The scope requirements of the Regulation that must be fulfilled for it to apply give many options for users to find their way out of the scope. In this case putting the burden of proof on the competent authorities the EU Regulation thus makes the determination of its applicability a real difficulty. Besides, the highly differentiated, small-sized interpretation of what is to be considered as utilization or not adds complexity to compliance checks and limits the scope of the Regulation. In addition, the use of bio-innovation as a marketing strategy gives misleading information of institutions/companies involved in *de facto* bio-based R&D. Thus, in conclusion, compliance checks show that clarifying the applicability of the EU Regulation is not only challenging but an integral part of the control process which cannot be anticipated. In spite of the challenges mentioned above compliance checks by the BfN have led to the detection of due diligence violations in both cases of risk-based compliance checks and substantiated concerns. These have led to administrative processes requiring retroactive remedy as a first step failure to which the institutions will be

sanctioned. Additionally to monitoring compliance the EU Regulation aims to support users with the implementation of their DD obligations. Hence, it envisages a register of collections and best practices. Application for registration as a registered collection is submitted to the BfN. By the end of 2019 (and in the entire EU) only one collection had been approved as a registered collection, i.e. the Leibniz Institute DSMZ—German Collection of Microorganisms and Cell Cultures GmbH. However, despite this first success, no other collection has applied for registration in Germany possibly due to a lack of awareness about the instrument of registration including its legal requirements, lack of financial resources, fear of increased bureaucracy etc. Hence, BfN has undertaken a series of awareness-raising and capacity-building activities. In the same vein associations of users or other interested parties may have their combination of procedures, tools or mechanisms, developed and overseen by them recognized as best practices. The MS provide comments to the application and the Commission makes the decision. From 3 applications submitted by the end of 2019 only 1 succeeded while the other 2 applicants did not follow up their applications after comments by MS and the Commission's request for improvements. Besides awareness-raising for the collections, BfN has undertaken general awareness-raising campaigns to promote and encourage information, awareness-raising and training to help stakeholders to understand the Protocol, ABS and the EU DD system as foreseen in article 13 etc. As a general conclusion the authors state, *inter alia*, that it is far from clear whether the implementation of the NP and the EU Regulation has facilitated R&D activities in the EU or at least created legal clarity and hence certainty, whereby industry and public research indicate the opposite. However, in spite of the criticism on both ABS sides of the provider and the EU and noting a number of positive developments that have already been provoked by the initiation of the implementation of the EU Regulation, it is acknowledged that the NP and EU Regulation are young and require more time and implementation experiences to reach their full operationalization.

In Chapter "Due Diligence and the Regulation of Transnational Economic Activity: Regulation (EU) No 511/2014 Compared to Other EU Due Diligence Schemes", Christine Godt and Markus Burchardi examine the genealogy of due diligence (DD) and compare its use in the European Union's (EU) ABS Regulation No. 511/2014 to other EU Regulations that likewise built on DD as a concept. With this concept Regulation (EU) 511/2014 stipulates a self-standing duty of care concerning lawful access unlike earlier thoughts which had envisioned a direct enforcement of provider States' rules by the user State. This self-standing duty functions as a 'regulatory hinge-joint', mitigating what would otherwise have been seen as an encroachment on the territoriality principle, restricting user States' sovereignty. DD had already been embraced in other policy areas before the adoption of the EU Regulation, e.g. in the regulation of trade in tropical timber (EU Timber Regulation 995/2010). Today various regulations subscribe to it, covering a wide range of subjects. Following an inquiry into the genealogy of DD the authors examine the insertion of the remaining legacy of the 'forerunner models of DD' as a 'legal transplant' into a new EU legal environment with questions whether the transplant changes the environment or *vice versa* and how those changes look

like having in mind that the EU Regulation contains further elements of industry self- and co-regulation. A comparative study of 'parallel' Regulations (tropical timber, maritime transport emissions, data protection, conflict minerals/metals) is carried out asking: What is the amount of self- and co-regulation, i.e. what role is foreseen for the regulator and the user (industry/importers)? How is risk distributed? What needs to be done in order to produce compliance? When are efforts exhausted? When do national competent authorities intervene? These questions are asked with a view to the 'crystallization point' of converging interests in Regulation (EU) 511/2014, namely the formulation "or discontinue [use]" in its article 4.5. It is concluded that Regulation (EU) 511/2014 first, leans more towards a command and control style of regulation; common features of self- and co-regulation are underdeveloped. In essence, the Regulation embraces a strong role for competent authorities and a higher risk of compliance failure for industry (=higher duties). Second, "best practices" come with extremely limited monitoring and enforcement duties. Third, Regulation (EU) 511/2014 does not separate procedural obligations and substantial obligations, which is particularly troubling for crystallization. Article 4.5 links procedure and substance in quite a novel fashion. Its formulation is understood by the EU Commission as an "obligation of result" which according to the authors means procedural efforts to produce compliance may not last indefinitely. Hence, they ask themselves: When does the procedural element come to an end and the competent national authority (CNA) steps in? Since the "duty to discontinue" is integrated into the program of duties in article 4, one may also say that it has the effect of 'proceduralizing' what would otherwise have amounted to a straightforward prohibition—meaning there is leeway for CNA discretion and room to produce compliance for users that are found to be incompliant. This leeway is a legacy of the "New Approach". Consecutively they produce a number of insights. For the actual content of EU DD, it can be said that it neither derives from the model forerunners nor from any particular legal family. It is also not simply a management tool. It must be read autonomously, with the intent of the EU lawmaker in mind. Apart from that, some legacy remains most notably with regard to the standard of care, which can be split up into two dimensions: the 'objective standard of care' (or what a user 'ought to do' to produce compliance) and the 'subjective standard of care' (what a user 'should have known' at a certain point in time, i.e. when the user could have known that the use is non-compliant). While irrelevant for the procedural duties, it makes sense to take certain user attributes (role as global player, prior dealings with provider State authorities) into account with regard to the substantive duty ("to discontinue"). The authors conclude that ultimately, it will be up to the Court of Justice of the European Union (CJEU) to determine the exact extent of the standard of care under article 4 Regulation (EU) 511/2014.

Part IV: Unresolved Issues and Solutions to Implementation Challenges

In Chapter "Digital Sequence Information on Genetic Resources and the Convention on Biological Diversity", Christopher H C Lyal discusses the issue of digital sequence information (DSI), based on existing arguments for its inclusion or exclusion from the scope of the Convention on Biological Diversity (CBD) and its Nagoya Protocol (NP). Discussions on this matter are full of misunderstandings,

the terminology is confused and legal views are conflicting. The following questions thus arise: Do sovereign rights of the provider country extend to DSI? If yes, is DSI within the scope of the CBD and NP? Would the NP apply to DSI held in foreign databases? What exactly is DSI? According to the jurisdictional scope of contracting parties under article 4 of the CBD based on their sovereign rights as foreseen in article 3, it is the components of biodiversity envisaged under article 4 that come under the sovereign rights of parties. This is reinforced by article 15 CBD which reaffirms sovereign rights of states over their natural resources and their authority to determine access to genetic resources (GR) subject to national legislation. Further, the GR provided by parties should be those for which the providing country is either a country of origin or has acquired in accordance with the Convention. Therefore this relationship between the scope of the CBD and sovereign rights are critical to interpreting DSI and resolving the questions on scope. The conceptual framework of the CBD and its NP anticipate access to physical GR followed by research and development (R&D) resulting to benefits to be shared fairly and equitably. This model, which the author dubs "simple linear model" has little relationship "to the complex interactions that often characterize supply and value chains of physical genetic resources", not to mention modalities of sharing 'DSI'. The term is not used anywhere in the Convention or under definitions in article 2, which also seem to restrict the article's scope to physical material. However, there are views that a "teleological interpretation of the Protocol (and the CBD) suggests that benefits generated through the use of DSI must be shared 'by the terms of the Nagoya Protocol'". One argument for such inclusion would be that the definition of GR under article 2 CBD needs to be dynamic in order to meet the overall object of access and benefit-sharing (ABS). But an agreement on whether DSI falls under the scope of CBD partly depends on understanding what it comprises. This term was developed in the CBD process and is not used anywhere else and the ultimate decision on its scope can only come from negotiations under the CBD. Work within the CBD began after the Conference of Parties (COP) 13 in 2016 and is ongoing with technical groups and studies trying to deal with different issues relating to DSI. Examining what DSI actually is the author, considering the present challenges and the questions initially raised above, looks at the terminology and scope of the concept according to processes under the CBD and scholarly work. Under the question of DSI as a component of ABS the following are interrogated: sovereign rights as reflected in the CBD and NP; whether DSI falls under the sovereign rights of the country providing GR; and whether DSI can be within the scope of the CBD. Finally, the questions concerning implementation of national legislation covering DSI looking at its inclusion in prior informed consent and mutually agreed terms when GR are accessed, assertion of sovereign rights over DSI held in databases, and rights of benefit-sharing based on further/persistent processes in line with article 5 (1) NP are examined. As the study shows, the disagreements concerning the issue are currently so profound and the outcomes of the parallel processes going on under different treaties and organizations are varying. In exploring the way forward a number of suggestions have been made which include the critical importance of developing a benefit-sharing system to avert the pending threat of provider countries

restricting generation of DSI. For this a bilateral benefit-sharing mechanism is unlikely to be practicable. Options can be the Global Multilateral Benefit-Sharing Mechanism envisaged under article 10 NP or a separate mechanism which supports other fora where the question of DSI is presently being discussed. However, this also invokes other questions that will need answers.

In Chapter "Lessons from Writing Binding and Enforceable ABS Contracts. A Contract Solution to Digital Sequence Data in ABS", Morten Walløe Tvedt focuses on the question, how ABS can be implemented in practice to become a functional legal tool for meeting the obligations of the fair and equitable benefit-sharing objective of the Convention on Biological Diversity (CBD) and its Nagoya Protocol (NP). The author is of the opinion that until there is a statutory system in place to promote the third objective of the CBD on benefit-sharing, contracts remain the functional legal tool for securing public benefits. Implementation of international law obligations occurs by tools of domestic legal instruments and a contract is a practical tool that can make access and benefit-sharing (ABS) work in practice thus providing legal certainty and sufficient flexibility to cater for each individual situation. A contract, for instance, is able to secure the rights of provider countries over findings of non-commercial research which are eventually used for commercial purposes. It will need in principle to have clear terms and conditions to become binding and enforceable on the user and have a format which is recognized in other countries to become binding in other jurisdictions. Besides, an access and benefit-sharing (ABS) contract must comprehensively regulate the relationship between parties and all aspects. Also, it will need to resolve fundamental challenges of ABS e.g. in regard to long value chains. In addition, it needs to anticipate the possible paths of value chain and establish clear legal consequences on non-monetary benefit-sharing. A contract likewise has the ability of dealing with the two scoping challenges (potential loopholes) of ABS based on biotrade (biological bulk) and digitalization of genetic information. As Lyal says in this volume, discussions on whether 'digital sequence data' fall under the scope of the CBD are still ongoing in different fora, however, the author believes that "there are practical solutions to regulate these subject matters under the current regime by a contractual approach". A contract does not rely on the outcome of the discussions on scope but depends on mutual acceptance from its parties and is able to set a global standard for this kind of data. Further, a contract is able to contemplate the fast growing and future technologies as well as ways of sharing data. For a contract to be effective what is referred to as "Golden rules for contract drafting" must be taken into consideration while drafting. Contract obligations must be clear, dynamic and not narrow. A contract should opt for positive regulation other than prohibition of some actions e.g. not to commercialize, seek intellectual property rights or access traditional knowledge, obligations which are hard to enforce in contracts, but rather clearly regulate actions by formulating enforceable consequences should these activities take place. These should be regulated in the original contract as comeback clauses are not effective or enforceable. Therefore, a core issue is how contract clauses can be formulated in order to embrace relevant scenarios and translate them into binding language. A change in the manner of drafting contracts is proposed with

need for improvement of the level of details and bridging of the language in both law and in research. This is deemed a critical step in making ABS work in practice even in the era of data technology in applied research and development.

In Chapter "Cases and Questions in Application of ABS Regimes", Gerd Winter and Evanson Chege Kamau endeavor to offer solutions for questions on ABS based on real life cases and hypothetical ones following existing legal documents. Stakeholders in the access and benefit-sharing (ABS) process have been confronted with many questions concerning the regulation of access to genetic resources and associated traditional knowledge (aTK), their utilization and sharing of benefits arising therefrom. Besides guidance provided by the EU Commission, ABS literature is mute on issues concerning practice. Until now, stakeholders faced with such inquiries have been forced to look for answers from national competent authorities and/or experts in the area. Looking at queries that have been asked by researchers, research institutions, commercial organizations and intermediary enterprises as well as inferred scenarios, the authors construct cases and suggest legal solutions. The answers proposed are not based on any judgement of courts but on the authors' opinion. Cases touch on varying matters on ABS and are clustered under two groups: issues concerning provider States and issues concerning user States. Most of the issues examined concern user States. We start with the former. The issues interrogated concern: (1) Cooperation between local and foreign research the question asked in essence being: In conditions requiring cooperation for access to be permitted, what kind of collaboration is acceptable? Should the local scientist accept an offer only to perform facilitating duties or should he/she insist on substantial participation in research? The authors conclude that the latter is what should be understood with such a condition and is what the local scientist (or, what the authors should have added, the relevant national competent authority) should insist on; (2) Multiple permits: If provider State's measures require an applicant for a permit for access to genetic resources (GR) to obtain several other permits and to establish mutually agreed terms (MAT) as a condition for grant of such a permit, can an authority facilitate the procedure for non-commercial research in accordance with article 8 (a) of the Nagoya Protocol (NP) by integrating all procedures of the relevant organs into one? It is concluded that the authority can, if it is mandated through executive powers to organize administrative procedures. If not, this can only be done if streamlined procedures are established by explicit legislative order; (3) Publication of research results. The main issue concerns the dilemma of allowing sequenced data by non-commercial research to be placed in public domain e.g. through publication in databases and their fate in regard to the possibility of their eventual use for commercial purposes. Should the competent authority hinder access by denying a permit? No, as this will have a negative impact on the provider State in regard to possible future benefit-sharing opportunities. However, the competent authority should insist that results be published with a conditional proviso that benefits from commercialization of products resulting from the utilization of the data are to be shared with the provider based on prior *bona fide* negotiation; and 4) Consent of indigenous communities. The authors want to know, what advice can a lawyer E give to a company C that plans to collect plant material for utilization from a territory

occupied by indigenous communities? Forgetting other conditions of the State, if C would like to use traditional knowledge of the communities, their PIC must be obtained. Also, their PIC must be obtained for access to GR if the communities have the established right to grant access to such resources. Besides, E must advice on the number of communities to be approached if that is necessary, their customary laws, community protocols and procedures and may offer his services concerning the issue. The case may change if no information is required from the communities or if the national law either does not regulate aTK, or if the provider country considers traditional knowledge a national heritage, or if communities have no established right to grant access to GR. In these cases the PIC of the communities will not be required, *albeit* this might be a violation by the host country of their CBD/NP access and benefit-sharing rights ensuing from the Indigenous and Tribal Peoples Convention, 1989 (No. 169). The issues concerning user States are discussed mainly based on the perspective of the ABS regime of the European Union (EU) which is built on the ABS Regulation (EU) 511/2014. Generally, issues dealt with involve the scope of application of the EU Regulation (concerning both GR/aTK and R&D); when use of GR can be considered as 'utilization' or not; when PIC should be obtained, MAT established or benefit-sharing agreement concluded etc. They are so broad and will hence be only mentioned without describing the cases or briefly explaining the relevant issue. These include the question on: (1) "Temporal scope" concerning GR and aTK accessed before the entering into force of the NP, from a country that is not party to the NP, or which has no ABS regime: the EU Regulation does not apply. Thus, a user who accessed GR/aTK before will not be under any obligation under EU law even for uses continued on the old GR. However, if the country from where the GR/aTK was accessed establishes retrospective measures, the user is advised to respect the law of the provider e.g. by entering into a benefit-sharing agreement, *albeit* the EU competent authority in the relevant user State cannot enforce this; (2) "Geographical scope" concerning GR collected from a CBD/NP party with an ABS regime without permission and utilized in a non-CBD/NP party by a researcher R from the latter in cooperation with a researcher A from an EU Member State. R is not under any obligation of his/her country, but nevertheless should comply with the measures of the provider country. A is expected to exercise due diligence according to EU law; (3) "Material scope" related to screening of a number of plants/herbs with the question: When does this qualify as utilization? If EU law is to be considered, screening is divided into three categories with two being considered as utilization. Concerning source countries, the rule can only be established following consultations with relevant authorities. In regard to data from screening which is published in databases the authors advice that it should be considered as utilization because it might be a subject of future research and development (R&D); (4) "Information stored at and taken from public databases or print media" looking at different scenarios relating to MAT conditions concerning published data and publication of R&D results; (5) "Contributions or not to product development" delving into questions if research is being carried on or with the GR and thus deciding when the obligation to share benefits is triggered, and "research without modification" and qualifications for PIC and MAT requirements; (6) Whether the uses made of the GR

are bulk or they comprise utilization examining the question of "change of intent from consumption to R&D", "known properties and new R&D" and "propagation and cultivation of GR"; (7) Technological application interrogating issues on "studying mechanisms of a lawfully acquired GR" and "purchase of derivatives" from an intermediary outside the EU and the EU Commission's criterion of continuum in R&D; (8) Regularization in regard to "*ex post* PIC and MAT" (i.e. rectification of unlawful situation), and "transfer to third parties of unlawfully obtained GR"; (9) Due diligence in ascertaining provider State requirements in case of a "unresponsive provider State" (i.e. when should the user be considered as having exercised due diligence in regard to a provider State that does not respond to inquiries concerning its ABS requirements?) and "ABS clearance declaration" (i.e. concerning a country that does not regulate ABS); (10) Benefit-sharing in relation to "ABS and patenting", "ABS and plant variety protection" and "sharing of benefits accruing to the buyer of a patent on accessed GR information"; and (11) Cut-off points in regard to "processing of raw materials for subsequent incorporation into a product". The questions dealt with and the solutions offered by the authors show that a stage of maturity has now been reached in ABS whereby practice can begin solving relevant issues.

5 New Legislation and Practice and Status of Implementation of the Nagoya Protocol. Synthesis, Observations, Recommendations and Conclusion

The book grapples mainly with the new environment of accessing and utilizing genetic resources and traditional knowledge in R&D as well as sharing benefits therefrom. The post Nagoya Protocol laws regulating this scenario can now be referred to as the second-generation ABS legislation since the adoption of the CBD in 1992. The architecture of the first-generation legislation was influenced by reactionary approach for what was perceived as past violations of the rights of (mainly developing) provider countries, great expectation of 'green gold' money, lack of binding obligations for compliance in (mainly developed) user countries, and a lack of detailed, concrete and obligatory measures on ABS in the CBD. The ensuing atmosphere was not conducive for R&D based on GR and aTK and the expected benefits remained a dream yet to come true.[23] The Nagoya Protocol was meant to heal this situation. Whilst implementation is being undertaken in order to comply with the obligations of the NP the underlying thought and intention of the negotiators of the instrument (NP) should not be lost/forgotten. That is, to deal with (or eliminate) the challenges faced in access and benefit-sharing caused by *inter alia* legal uncertainty, unclarity and intransparency of provider measures and lack of

[23] Ruiz Muller (2015) attributes the failure of achieving benefit-sharing to the bilateral system and advocates for "bounded openness".

compliance measures in user countries, and thus ensure the fair and equitable benefit-sharing. We therefore ask ourselves: Have the new laws and practice managed to be *de jure* and *de facto* compliant with the Nagoya Protocol? Besides complying with the Protocol, which other challenges are being faced in the implementation and how are they being surmounted, or which solutions are contemplated? How are arising/unresolved issues affecting the ABS landscape?

Our book has shown that compliance with the NP should not be one of "form" but "fact". Many provider legislations, for instance, have implemented the word of the instrument in order to conform, without having in mind how the measures taken will facilitate access, which is its spirit. Conformity only to the law does not necessarily ease access. A Nagoya Protocol compliance check depicts most measures as having conformed to the requirements of its provisions, but do not solve the question as to whether those who intend to access GR/aTK are able to navigate through the process with ease, without delay, with certainty etc. A juxtaposition of the Ethiopian and Kenyan regimes may serve as a good example. The former's regime is intentionally strict, but is clear and streamlined. The latter's regime does not intend to be restrictive but is fragmented and oblique. Comparing how many permits have been issued by the two it is evident that Ethiopia experiences and executes many times more requests for access than Kenya.[24] The standard of *de facto* compliance should hence be the effectiveness of the regime. In relation to this the role of procedures, predictability, timeliness etc. is critical. Below a number of observations and recommendations have been made.

Like the old situation, fragmentation of measures is still a problem with some new laws. The resulting complexity is still widely observed. This is in particular true in Federations (Argentina), and where ABS powers are delegated to provinces or counties (South Africa, Argentina, Kenya). Centralized regulation and/or standalone laws seem to put this situation under control and are recommended.

Although centralization eases access occasionally the consultation right of the indigenous and local communities is thereby sometimes ignored and thus violated. In trying to resolve access challenges it is advised not to lose sight of this right.

Where law complicates or aggravates the process, practice can still help. This is exhibited by the case of Kenya. This practice, however, is not without flaw. As noted, without a legal backing the uncertainty the practice aims to rout out returns. Besides, most persons who might be interested in accessing GR/aTK depend on published laws, regulations and guidelines and would not know about such temporal, not legally prescribed measures. Therefore we recommend that any well-functioning requirements and procedures which are not yet foreseen in law should be established by explicit legislative order.

[24] Since the adoption of the NP in 2010 Ethiopia has granted 983 permits for research purposes and 13 for commercial purposes (with 13 access agreements signed), *pers. comms* (15 November 2020) with Ashenafi Ayenew Hailu, NFP, EBI. Kenya on the other hand has granted 148 permits in the same period, all for non-commercial purposes, *pers. comms* (7 January 2021) with Joyce Imende, ABS Desk Officer, NEMA.

Following on the same example, it has been demonstrated that the timing of the measures applied in practice matters. The said measures of the Kenyan practice come at the end of the process, i.e. during the review of the access application. That means, it is important to locate points in the procedure where most challenges are encountered and offer the measures/solutions there. In this particular case, however, it could be an indication that the relevant agencies are still not ready to give up their mandates for the sake of explicit streamlining. This is also the case in South Korea. In such a case procedural streamlining could help but the most effective option which we recommend is one of the variants of material integration.[25] For the latter, some stakeholders will have to give up their ABS powers.

Lack of uniformity creates a big burden for researchers. A person interested in undertaking research activities in several countries will have a massive task of understanding the varying laws, requirements and procedures. Alternatively he/she would be subjected to consultancies by lawyers and experts, which can raise the research budget exponentially, at times to levels which e.g. basic biodiversity research cannot afford. Whereas the NP does not prescribe a stiff approach to implementation—leaving room for parties to implement it in light of their national circumstances—a certain level of harmonization e.g. of PICs and MATs would be a big asset for the success of the ABS regime. In the same vein, harmonization of terms is important. The use of terms across regimes is presently a calamity. At times the same term is given varying meanings in different ABS laws within the same domestic regime (e.g. Kenya).

Some providers extend the scope of application of their legislation to activities conducted abroad involving their GR/aTK (Ethiopia, Costa Rica, Cameroon, South Africa). This approach was initially influenced by lack of compliance measures in user countries. However, this is ineffective and also against the international law principle of territoriality. The model of user measures examined in this book and representing user States, i.e. the EU ABS Regulation, nonetheless depict weaknesses which do not encourage providers to give up their approach. The Regulation, for instance, establishes a temporal scope as the date of entry into force of the NP. This might be interpreted as undercutting provider States in terms of opportunities for benefit-sharing. But since the NP does not exclude GR and aTK accessed prior to its entry into force, the provider countries can still impose benefit-sharing obligations by establishing a temporal scope which covers the duration starting from the entry into force of the CBD and requiring users of such GR and/or aTK to conclude benefit-sharing agreements with the source country. At least the EU Regulation does good to caution Member States' users to respect MATs established with providers of GR and aTK. The same can be done concerning benefit-sharing from Digital Sequence Information (DSI) relating to previously accessed GR. For DSI relating to post NP genetic resources, conditions on use and benefit-sharing can be included in MAT. Many provider countries are asserting their rights over DSI and although

[25] See Kamau and Winter (2009), p. 371ff. For a summary of details see Kamau (Ch. on Kenya) in this volume.

discussions are still ongoing to establish whether DSI falls under the scope of the CBD/NP, it has been demonstrated that the will of parties can still be effectively expressed and protected under the law. Therefore, MAT can be concretized in contracts. For that well formulated contracts have been recommended.

But, of course, contracts cannot solve problems of formerly accessed GR/aTK and related DSI. Besides, retrospective approach without the intervention by user States pushes the provider back to the weak position as a result of the territoriality principle. Without enforcement by the user States, such rules are likely to remain largely ineffective, especially where users do not need to conduct supplementary access to the GR. Furthermore compliance checks, e.g. in Germany, have shown that it is difficult to establish when the GR were accessed if the user claims to have accessed them prior to the NP. In addition, the EU due diligence concept of compliance is also having its share of challenges probably due to its unique nature which is different from other concepts of due diligence in other sectors; or due to its novel approach of trying to enforce foreign law. It implies that even where GR and aTK are considered to fall under the scope of the user regime, compliance still relies much on good faith by users. Thus, putting more effort in developing cooperation between providers, users and user countries, intensifying communication between competent authorities of both sides under article 17 NP might be more productive.

Likewise, trust plays a big role in operationalizing ABS. This has been demonstrated by the case of a German researcher working in Ecuador and of RBG Kew. The possibility to have registered collections under the EU ABS system is also supposed to foster the same.

Most provider countries have implemented only access measures. This approach probably stems from the old attitude that traditional provider States are not users. The NP's approach is that every party is both a provider and a user. For example, whereas Argentina has in the past being referred to as a provider country, its exponential growth in biotechnology industries show that it is equally a user. In any case each party must establish measures to counteract violations of other parties' requirements in its jurisdiction. Partial implementation needs to be addressed.

At times provisions of the NP are implemented improperly, for example, in regard to functions of checkpoints under article 17.1 (a). Most provider States' laws have established checkpoints to monitor compliance with their own legislation/regulations. Of course each party has the prerogative to do that, but the functions on monitoring compliance with measures of other parties have to be included.

Capacity-building is required in provider countries in regard to the implementation of user measures and generally the proper implementation of the instrument. The role GEF and UNDP projects have played to develop legislation e.g. in Viet Nam, Argentina, Malaysia is evident and speaks for more international cooperation, resources and experts to build local skills.

New issues are challenging the ABS system e.g. on: (1) DSI (issue mentioned above); (2) Limit of the duration of provider rights as most provider States do not foresee any end to their rights. Users on the other hand feel that if provider rights are *ad infinitum* the burden on R&D will be so heavy and therefore they solicit for