

## Implementing the Nagoya Protocol

# Legal Studies on Access and Benefit-Sharing

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# Implementing the Nagoya Protocol

*Comparing Access and Benefit-Sharing  
Regimes in Europe*

*Edited by*

Brendan Coolsaet  
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John Pitseys  
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# Foreword

Biodiversity, the extraordinary variety of ecosystems, species and genes that surround us, is our planet's life insurance. We depend on it for clean air and fresh water, food and medicine, and many other ecosystem services that help sustain our economies. Today more than ever, this biodiversity is under pressure from many different sources and the world is losing species and habitats at unprecedented rates. This in turn is putting the livelihoods of millions of people around the world at risk. That is why when I took office as European Commissioner for Environment in 2009, I made the conservation of biodiversity, both in the EU and at international level, a major priority of my mandate.

It takes time, sometimes years, before we are able to see the positive results of efforts to protect biodiversity, and some measures also take a long time to agree and put in place. In 2010, after years of negotiations, the 194 States Parties to the Convention on Biological Diversity adopted a Protocol which provides an implementation framework for the third objective of the Convention, namely the fair and equitable sharing of benefits arising from the use of genetic resources. The so-called Nagoya Protocol, named after the Japanese city where the tenth conference of the Parties to the Convention was held, represents a major breakthrough in international efforts to step up biodiversity protection and making the "access and benefit-sharing" objective fully operational.

The European Union was one of the driving forces in the elaboration of this landmark treaty, and I was involved myself in the final stages of negotiations in Nagoya. I know first-hand how much effort went into finding agreement between so many countries on a text as complex, and in some aspects controversial, as this. I also know first-hand that the process of translating it into legislation can be almost as challenging.

The publication of this book coincides with the entry into force of a new EU regulation that fully implements the mandatory elements of the Nagoya Protocol in the Union. The EU and its 28 Member States are now well prepared to implement the Protocol, once it enters into force ninety days after the deposit of the fiftieth instrument of ratification. We are also prepared to advise and assist other countries in doing the same. In the coming months and years, our experience with its implementation and enforcement will grow exponentially.

Now that the rules are in place in the EU, the focus needs to shift towards raise awareness about them among all concerned stakeholders, including law-makers and enforcement authorities, business representatives and civil society. I therefore welcome this publication, which not only analyzes the

frameworks on access and benefit-sharing in several EU and other European countries, but also looks at the experiences of those who are concerned in practice, including an indigenous community, the private sector, and collections of genetic resources. It brings together an impressive number of experts, many of whom were directly involved in the process of negotiating and adopting the Nagoya Protocol.

Whatever your reason for having selected this book, whether you are a scholar, lawyer, practitioner, collector, researcher, customs officer, or simply a curious reader, I am confident that it will provide you with valuable insights into the Nagoya Protocol and make a major contribution to the understanding of this important yet complex new legal instrument.

*Janez Potočnik*

European Commissioner for the Environment (2009–2014)



# Acknowledgements

My particular gratitude goes to the contributing authors for their excellent work and for trusting me with the edition of this book. With the recent entry into force of the Nagoya Protocol, their work undoubtedly constitutes a major and valuable contribution to international understanding of the implementation of the Protocol in Europe and beyond.

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Responsibility for the content of this book remains with the individual authors.

*Brendan Coolsaet*

Brussels/Louvain-la-Neuve, October 2014

# Acronyms

ABS	Access and Benefit-sharing
ABNJ	Areas Beyond National Jurisdiction
BCCM	Belgian Coordinated Collection of Micro-organisms
BELSPO	Belgian Federal Science Policy Office
BfN	Federal Agency for Nature Conservation (Germany)
BIO	Biotechnology Industry Organisation
BGB	German Civil Code
BGM	Bank of Genetic Material (Greece)
BMBF	Federal Ministry of Research and Education (Germany)
BMEL	Federal Ministry for Food and Agriculture
BMJ	Federal Ministry of Justice (Germany)
BMU	Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (Germany)
BMZ	Federal Ministry for Economic Cooperation and Development (Germany)
BTC	Belgian Technical Cooperation
CABIN	Central African Biodiversity Information Network (Belgium)
CARNG	Center of Agricultural Research of Northern Greece
CBD	Convention on Biological Diversity
CETAF	Consortium of European Taxonomic Collections
CGIAR	Consultative Group on International Agricultural Research
CGN	Centre for Genetic Resources (the Netherlands)
CHM	Clearing-House Mechanism
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CJEU	Court of Justice of the European Union
CNA	Competent National Authority
CNAs	Competent National Authorities
COM	Overseas Collectivities (France)
COP	Conference of the Parties
COSHH	Control of Substances Hazardous to Health Regulations (UK)
CPVR	Community Plant Variety Right
DAAD	German Academic Exchange Service
DBL	Draft Biodiversity Law (France)
DEFRA	Department for Environment, Food and Rural Affairs
DFG	German Research Foundation
DFID	Department for International Development (UK)
DGD	Directorate General for Development Cooperation (Belgium)

DIB	German Association for Biotechnology
DPMA	German Patent and Trade Mark Office
DROM	French overseas departments and regions
DSMZ	German Collection of Micro-organisms and Cell Culture
ECJ	Court of Justice of the European Union
EEA	European Economic Area
EEZ	Exclusive Economic Zone
EFPIA	European Federation of Pharmaceutical Industries and Associations
EPO	European Patent Office
EU	European Union
EUTR	European Union Timber Regulation
FAO	Food and Agriculture Organization
FSC	Forest Stewardship Council
GATT	General Agreement on Tariffs and Trade
GBIF	Global Biodiversity Information Facility
GCDT	Global Crop Diversity Trust
GI	Geographical Indications
GENRE	National System of Information on Genetic Resources (Germany)
GMO	Genetically Modified Organisms
HSE	Health and Safety Executive (UK)
IBPGR	International Board for Plant Genetic Resources
IDA	International Depositary Authority
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
ILC	Indigenous and Local Community
ILCs	Indigenous and Local Communities
ILO	International Labor Organization
INPI	National Industrial Property Institute (France)
IPEN	International Plant Exchange Network
IPO	Industrial Property Organization (Greece)
IPR	Intellectual Property Rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for Conservation of Nature
JMD	Joint Ministerial Decision (Greece)
LNR	Local Nature Reserve
MARA	Ministry of Agriculture and Rural Affairs (Turkey)
MAT	Mutually Agreed Terms
MEDDE	Ministry of Ecology, Sustainable Development and Energy (France)
MHSWR	Management of Health and Safety at Work Regulations (UK)
MoA	Ministry of Agriculture (Greece)
MoEECC	Ministry of Environment, Energy and Climate Change (Greece)

MoRDF	Ministry of Rural Development and Food (Greece)
MOP	Meeting of the Parties
MOSAICC	Micro-organisms Sustainable Use and Access Regulation International Code of Conduct
MOU	Memorandum of Understanding
MTA	Material Transfer Agreement
NFP	National Focal Point
NGO	Non-Governmental Organization
NIEO	New International Economic Order
NMO	National Measurement Office (UK)
NNR	National Nature Reserve
NP	Nagoya Protocol
NRSC	Natural Resources Stewardship Circle
NVWA	National Food Safety Authority (the Netherlands)
OCT	Overseas countries and territories (France)
OECD	Organization of Economic Cooperation and Development
PCT	Patent Cooperation Treaty
PIC	Prior Informed Consent
PIL	Private International Law
PVR	Plant Variety Right
R&D	Research and Development
RIDDOR	Reporting of Incidents, Diseases and Dangerous Occurrences Regulations (UK)
SAC	Special Area of Conservation
SAN	Sustainable Agriculture Network
SEEDNet	South East European Development Network
SERR	Smarter Environmental Regulation Review (UK)
SMTA	Standard Material Transfer Agreement
SPA	Special Protected Areas
SSSI	Sites of Special Scientific Interest
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
TK	Traditional Knowledge
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UNCLOS	United Nations Convention on the Law of the Sea
UNCTAD	United Nations Conference on Trade and Development
UNEP	United Nations Environment Programme
UNGA	United Nations General Assembly
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples

UNFCCC	United Nations Framework Convention on Climate Change
UPOV	Union for the protection of plant variety rights
USSR	Union of Soviet Socialist Republic
VCI	Association of Chemical Industry (Germany)
WCA	Wildlife and Countryside Act (UK)
WIPO	World Intellectual Property Organization

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joined the Ministry of Foreign Affairs as a senior officer in the Special Programme Biotechnology and Development Cooperation, in particular responsible for capacity building. Since 1997 he is the director of the Centre for Genetic Resources, the Netherlands (CGN) which under its own mandate is part of Wageningen University and Research Centre. As the director of CGN he fulfils an advisory role for the Ministry of Economic Affairs on policies regarding (agro)biodiversity. In this capacity he has been a regular member of the delegations to FAO (International Treaty) and CBD. Furthermore he functions as the national focal point for the implementation of the Global Plan of Action on PGRFA, and has been appointed as the National Focal Point on Access and Benefit Sharing of the CBD. His interests and activities concern genetic resources management and policy development, international collaboration in the area of genetic resources management, on-farm conservation of genetic resources, and the interface of agrobiodiversity and biotechnology.



# Introduction. Access Benefit-Sharing and the Nagoya Protocol: The Confluence of Abiding Legal Doctrines

*Arianna Broggiato, Tom Dedeurwaerdere, Fulya Batur and  
Brendan Coolsaet*

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (hereafter, “the Nagoya Protocol”) to the Convention on Biological Diversity (CBD) was adopted in 2010. Its objective is the fair and equitable sharing of the benefits arising from the utilization of genetic resources and traditional knowledge, with the aim of contributing to the conservation of biological diversity and the sustainable use of its components. As an international agreement, the Nagoya Protocol complements the international legal regime related to the management of genetic resources and traditional knowledge. However, this introductory chapter illustrates an innovative perspective<sup>1</sup> aimed at demonstrating that the inception of this legal regime long predates the discussion on access and benefit-sharing (ABS) of the CBD and is the product of the interaction of different legal fields: the international laws on development, trade, environment and intellectual property protection. The negotiation history (see Section II of this chapter) of the different international documents related to these domains shows three core motives that have driven international policy makers and civil society in promoting the development of a specific regime for access and benefit-sharing as a protocol to the CBD. The first motive is the fight against misappropriation of natural resources, which is predominant in the global social movements focusing on the right to development and environmental justice. The specific misappropriation of genetic resources and traditional knowledge (TK) was particularly brought to light through the debate on the emergence of highly exclusive intellectual property rights’ legislations in various countries around the world. The second political motive is the ethical duty to conserve the Earth’s limited resources, which gained public attention through the emergence of the internationally prominent environmental movement in the 1970ies, and was

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<sup>1</sup> The hypothesis that the concept of benefit-sharing long predated the discussion on ABS of the CBD and it is the product of the interaction between three fields of international law is here presented for the first time by the authors of this chapter, therefore the argumentations lack in references to previous literature.

institutionalized through the 1972 Declaration of the United Nations Conference on the Human Environment<sup>2</sup> (hereafter, “Stockholm Declaration”) and the numerous subsequent international and regional conservation treaties.<sup>3</sup> The third motive is the promotion of international cooperation for scientific research in support of the two first motives.

Traces of these three political motives can be found in all of the main international documents related to genetic resources and traditional knowledge. They have however had different weights in the development of the different sectors of international law making. The core foundation of the first motive is the fundamental principle of sovereignty of a State over its natural (tangible) resources, which inspired the first claim to the right to development and which already included the basic principles of benefit-sharing within the early international documents.<sup>4</sup> This motive is still very important in the current debate, in particular because of its focus on people centred development which announced the current emphasis on the protection of traditional knowledge associated with genetic resources. The environmental motive emerged to balance the risk of the depletion of the resource. However, although biodiversity conservation is the official underlying principle of the CBD, it can be argued that the more utilitarian “sustainable use” objective focusing on a monetization of biodiversity got the upper hand.<sup>5</sup> Finally, the central role of research and the consequent necessity to support the development of scientific capabilities of developing countries was felt strongly in the 1970s. It nonetheless lost its weight at a later stage and disappeared from the international law making, to arguably regain momentum in the beginning of this century through

2 Declaration of the United Nations Conference on the Human Environment, U.N. Doc. A/Conf.48/14/Rev.1 (1973); 11 ILM 1416 (1972).

3 Among many others: the 1972 Convention concerning the Protection of the World Cultural and Natural Heritage (UNESCO); the 1973 Agreement on the Conservation of Polar Bears; the 1973 Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); the 1979 Convention on the Conservation of Migratory Species of Wild Animals (CMS).

4 UNGA Resolution 1803 (XVII) of 14 December 1962 “Permanent sovereignty over natural resources”; UNGA Resolution 523 of 12 January 1952 on “Integrated economic development and commercial agreements.”

5 In 1992, germplasm and associated traditional knowledge are increasingly considered as raw material for the biotechnology industry and, thus, as a tradable economic goods. See Alain Lipietz, “Enclosing the Global Commons: Global Environmental Negotiations in a North–south Conflictual Approach,” in *The North the South and the Environment*, eds. Bhaskar, V. and Glyn, A. (London: Earthscan, 1995): 118–142; Marc Hufty, “La gouvernance internationale de la biodiversité,” *Etudes internationales* 32 (2001): 5–29; Catherine Aubertin and Geoffroy Filoche, “The Nagoya Protocol on the use of genetic resources: one embodiment of an endless discussion,” *Sustentabilidade em Debate* 2 (2011).

the legal regimes governing agricultural plant genetic resources and within the Nagoya Protocol.

The chapter's hypothesis is that the adoption of the Nagoya Protocol to the Convention on Biological Diversity in 2010 is an attempt to strike a balance between these three political motives, and their underlying legal and political doctrines. The Protocol is expected to lay the ground for the long needed legal certainty for the many players involved in sustainable use, conservation and international exchange of genetic resources and traditional knowledge. The way that the three motives however will be translated into practices will depend on the concrete implementation in the national countries' legislations across the world. For this reason, it is important to build international experience with balanced implementation efforts that satisfy these three motives and to learn from best country practices. The authors of this collective volume aim to contribute to efforts in that direction, by gathering the most up to date knowledge on the on-going implementation efforts of the Nagoya Protocol in Europe.

This introductory chapter will therefore first describe the ABS legal framework by introducing the main ABS legal instruments and their characteristics (see Section I). It will then illustrate the reach and effects of the three aforementioned policy motives that can be identified in the international law of genetic resources and traditional knowledge management (Section II). To conclude the third Section of the chapter will describe the structure and the research questions behind this publication.

## I The ABS Legal Framework

### 1 *The Convention on Biological Diversity and the Nagoya Protocol*

The Nagoya Protocol, adopted in 2010 and entered into force on October 12 2014, was negotiated under the Convention on Biological Diversity. The Convention on Biological Diversity, signed in May 1992 and entered into force in December 1993, is the first international conservation agreement addressing biological diversity as a whole rather than through sectorial approaches focusing on specific species, ecosystems or sites. Its 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.<sup>6</sup> The broad objectives of the CBD are a consequence of the opposing interests of developing and developed countries:<sup>7</sup> the former ones were not

<sup>6</sup> CBD Article 1.

<sup>7</sup> Thomas Greiber, *et al.*, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing* (Gland: IUCN, 2012), 4.

willing to accept a commitment only focused on biodiversity conservation, so the “Rio package deal” conditioned their support for conservation obligation to socio-economic considerations and to the obligation of developed countries (more advanced in biotechnology) to share the benefits gained from the use of genetic material. The Convention is a framework treaty setting down the basic principles Parties have to follow in providing for the conservation and sustainable use of biological diversity and in granting access to their genetic resources, leaving to each Party to implement those principles in its own territory and according to its own policies and legislations.

The conservation and sustainable use clauses of the Convention impose to Contracting Parties obligations to develop national strategies, plans or programmes; to identify components of biological diversity, monitor them and to identify processes and activities which might have an adverse impact on the biological diversity; and to adopt measures for *in situ* conservation and *ex situ* conservation (see Section II.2). Research which contributes to the conservation and sustainable use of biological diversity shall be promoted by Contracting Parties, particularly in developing countries.

The Convention recognizes the states’ sovereign right to exploit their own biological resources and that the authority to determine access to genetic resources rests within the national government and is subject to national legislation. Access to genetic resources shall be subject to prior informed consent (PIC) of the country providing the resources, if this is required by its legislation, and should be granted on mutually agreed terms (MAT) between the provider and the user. Therefore the ABS concept is based on the bilateral relationship between a provider of a genetic resource and a user of this resource.

The Convention applies in relation to each Contracting Party to components of biological diversity in areas within the limits of its national jurisdiction and to processes and activities carried out under its jurisdiction or control. While the provisions on access apply only to genetic resources, the provisions on conservation and sustainable use cover all biological diversity, including genetic resources. The Convention covers access to genetic resources in countries of origin after the entering into force of the CBD in those countries. It is important to remember that most of the genetic resources collected in *ex situ* collections (see Section I.3) were collected prior to the CBD entering into force for the country holding the collection.

As far as the relationship with other international treaties on biological diversity is concerned, the CBD provides that its provisions shall not affect the rights and obligations of any Contracting Party deriving from any *existing* agreement, except where the exercise of those rights and obligations would

cause serious damage or threat to biological diversity.<sup>8</sup> The CBD Conference of the Parties recognized later on the importance of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)<sup>9</sup> (See Section I.2).

Article 15.7 of the CBD prescribes that each Contracting Party shall take legislative, administrative or policy measures with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing them.

Few CBD Parties had the legal capacity to translate the CBD provisions into national ABS legislations and most industrialized Parties were reluctant to adopt measures supporting effective benefit-sharing. As a consequence several megadiverse countries adopted restrictive legislation on access to genetic resources, in order to protect their resources from the risk of “biopiracy.” This led to a visible lack of implementation of the CBD’s third objective of sharing of the benefits arising from the utilization of genetic resources.<sup>10</sup> The first attempt to provide more detailed guidance on ABS was the adoption by the CBD Conference of the Parties of the non-legally binding Bonn Guidelines<sup>11</sup> in 2002. The Bonn Guidelines aimed at guiding governments in the establishment of legislative, administrative or policy measures on ABS, but still a few countries adopted domestic ABS legislations after their adoption.

In the same year, to further advance the third objective of the CBD, the 2002 World Summit on Sustainable Development in Johannesburg called for the negotiation of an international regime to promote and safeguard the fair

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8 CBD Article 22.

9 CBD Decision VI/6. For a complete analysis of the relationships between the CBD and the ITPGRFA see Study on the relationship between an international regime on ABS and other international instruments and fora which govern the use of genetic resources The International Treaty on Plant Genetic Resources for Food and Agriculture and the Food and Agriculture Organisation’s Commission on Genetic Resources for Food and Agriculture. Prepared by Jane Bulmer, IUCN Environmental Law Centre. UNEP/CBD/WG-ABS/7/INF/3/Part.1. 3 March 2009.

10 Elisa Morgera *et al.*, *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective. Implications for International Law and Implementation Challenges* (Leiden: Martinus Nijhoff, 2013), 5.

11 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (Bonn Guidelines), CBD Decision 6/24, “Access and Benefit-sharing as Related to Genetic Resources” (27 May 2002) UN Doc UNEP/CBD/COP/6/20.

and equitable sharing of the benefits arising from the utilization of genetic resources.<sup>12</sup> In 2004 the CBD Conference of the Parties mandated its Ad Hoc Open-ended Working Group on Access and Benefit-sharing to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing in order to effectively implement Article 15 and Article 8(j) of the Convention and its three objectives. The outcomes of these negotiations brought to the adoption of the Nagoya Protocol in October 2010. Its objective is the fair and equitable sharing of the benefits arising from the utilization of genetic resources and traditional knowledge, with the aim of contributing to the conservation of biological diversity and the sustainable use of its components.

The Protocol is aimed at operationalizing the third objective of the CBD by setting up rules and procedures on access, benefit-sharing, and compliance. Therefore it is further detailing the rights and obligations of the CBD in relation to genetic resources and traditional knowledge associated with such resources, thus developing further the concept of benefit-sharing. The Protocol clarifies key concepts of the ABS field, such as “utilization of genetic resources” and “derivatives”; it illustrates the key elements of national measures in provider and user countries; and it strengthens the link between ABS and traditional knowledge. It applies to access over genetic resources as well as traditional knowledge associated with them, and to the benefits arising from the “utilization” of such resources and knowledge, that is to say genetic resources over which States exercise sovereign rights. The reference to the utilization in the description of the scope expands the material scope of application to naturally occurring biochemical compounds, even if they do not contain functional units of heredity.<sup>13</sup> The Protocol includes innovative clauses on the possible future negotiation of a global multilateral benefit-sharing mechanism, that could be used for sharing the benefits arising out of the utilization of genetic resources coming from areas outside national jurisdiction; and the cooperation efforts for transboundary situations of genetic resources found *in situ* within the territory of more than one Party, or TK associated with genetic resources shared by one or more indigenous and local communities in several Parties. It also strengthens the CBD obligation to “promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries,” indicating the adoption of “simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research.”

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12 United Nations, “Report of the World Summit on Sustainable Development” (2002) UN Doc A/CONF.199/20, Resolution 2: Johannesburg Plan of Implementation, paragraph 44.o.

13 Thomas Greiber, *et al.*, *An Explanatory Guide*, 70.

The Protocol's system of compliance is based on a mixture of international and domestic measures, such as the obligation on users to respect national laws on access; the monitoring measures including the obligations to designate checkpoints, to issue internationally recognized certificate of compliance as proof of legal acquisition in provider countries; the establishment of an Access and Benefit-sharing Clearing House for sharing information related to access and benefit-sharing; and the future discussions on procedures and institutional mechanisms to promote compliance and to address cases of non-compliance in a cooperative way.

The Protocol is the result of six years of intergovernmental negotiations and of the consensus adoption by 193 CBD Parties at the tenth meeting of the Conference of the Parties (COP) to the CBD of the compromise text proposed by the Japanese delegation, in order to break through the deadlock of the negotiations. This politically very successful strategy prevented the rigorous legal consistency check that normally take place at the end of a treaty negotiation, therefore this created some room for interpretative questions.<sup>14</sup>

As far as relationship with other international treaties on genetic resources is concerned, the Protocol recognizes the specialized international ABS instruments that are consistent with and does not run counter to the objectives of the CBD and the Protocol and does not apply for the Parties to such specialized instruments in respect of the specific genetic resources covered by and for the purpose of the specialized instruments.<sup>15</sup> However the Protocol call for a mutually supportive manner of implementation with other international instruments relevant to the Protocol.<sup>16</sup>

## 2 *International Instruments for Plant Genetic Resources for Food and Agriculture*

The need to design an ad hoc instrument for the conservation, but also the sustainable and equitable use of plant genetic resources for food and agriculture (PGRFA) while ensuring the widest possible access to germplasm for research and development was espoused by the international community as early as the 1980's. Policy discussions on the international management and status of plant genetic resources started in the 1970's: they led to the adoption of the FAO Global System for the Conservation and Utilisation of PGRFA in 1983. This package addressed both *in situ* and *ex situ* agrobiodiversity management, and comprised of a non-binding yet promising international agreement,

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<sup>14</sup> Elisa Morgera *et al.*, *The 2010 Nagoya Protocol on Access and Benefit-sharing*.

<sup>15</sup> Nagoya Protocol Article 4.4.

<sup>16</sup> Nagoya Protocol Article 4.3.

the International Undertaking for Plant Genetic Resources<sup>17</sup>(IU). The International Network of *ex situ* Collections was established along with the Commission on Plant Genetic Resources for Food and Agriculture, the first permanent inter-governmental body specifically dedicated to PGRFA. The Undertaking, adopted at the twenty-second session of the FAO Conference held in Rome professed its goals to include the exploration, preservation, evaluation and availability of PGRFA for plant breeding and scientific purposes. The IU identified plant genetic resources as a heritage of mankind (HM). The Undertaking originated from the early practice within the Consultative Group on International Agricultural Research (CGIAR)<sup>18</sup> of granting free access and free exchange of plant genetic resources for food and agriculture, then however this practice was hampered by a shortage of funds for public research and so by the privatization of agricultural research in the 80s. The system was born and drafted as an open access system, and then it was characterized by contrasting interests: on one hand the developing countries wanted to keep control over the abundant PGRFA, while the developed ones wanted to maintain control over the refined products of breeding for engineering. So the battle was between sovereignty on one side and intellectual property on the other hand, as the two different tools chosen respectively by developing and developed states to protect their interests.

In the meantime, the CBD and its national sovereignty principle got adopted in 1992, followed by the international minimum intellectual property (IP) protection standards of the Agreement on Trade-Related Aspects of Intellectual Property Rights<sup>19</sup> (TRIPS Agreement) two years later, urging for an adaptation of the international agricultural community to the new legal landscape. The Commission on Genetic Resources for Food and Agriculture set out to re-negotiate the legal component of the FAO Global System, an effort that took “six and a half arduous years,” mostly because of the polarisation between developed and developing countries. The debates initiated before the UN Food and Agriculture Organisation came about as “heavily politicised, with concerns about intellectual property rights and national germplasm embargoes” that were set up through other international instruments. Adopted by the

17 Resolution 8/83 of the Twenty-second Session of the FAO Conference, Rome, 5–23 November 1983.

18 The CGIAR is an international organisation which funds and co-ordinates research into agricultural crop breeding with the goal of “reducing rural poverty, increasing food security, improving human health and nutrition, and ensuring more sustainable management of natural resources.” It was established on May 19, 1971.

19 Agreement on Trade-Related Aspects of Intellectual Property Rights, 1869 UNTS 299; 33 ILM 1197 (1994).



Conference in November 2001, the International Treaty on Plant Genetic Resources for Food and Agriculture came into force in June 2004. The objectives of the Treaty are “the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.” In its conservation angle, it advocates an “integrated approach to the exploration, conservation and sustainable use” of agrobiodiversity, where both *in situ* and *ex situ* efforts are equally acknowledged. The FAO Treaty re-affirms the sovereignty of States over their own plant genetic resources for food and agriculture. Through the exercise of this sovereignty Member States determine their own access policy. Moreover, they agreed to establish a Multilateral System (MLS)<sup>20</sup> to facilitate access to plant genetic resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilization of these resources. This facilitated access shall be pursuant to the standard material transfer agreement (SMTA).<sup>21</sup> Any benefits that arise from the use of these resources under the MLS shall be shared fairly and equitably.<sup>22</sup> Thus facilitated access is required for a closely defined set of circumstances: for the purpose of utilization and conservation for research, breeding and training for food and agriculture.<sup>23</sup> The scope of the ITPGR covers all plant genetic resources for food and agriculture,<sup>24</sup> however, the MLS was established to deal with a subset of those resources, which are listed in Annex I to the ITPGR. Let alone a comprehensive evaluation of the Multilateral System that goes beyond the scope of this chapter, there are many issues of efficiency that underpin the System and do not create enough incentives for the private sector to step into it.

As far as the relationship with other international instruments dealing with genetic resources the ITPGR is a subsequent agreement to the CBD and arguably a form of *lex specialis*,<sup>25</sup> therefore its MLS prevails on the

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20 The MLS facilitates access to 35 crop species and 29 forage species upon which the world is interdependent and which are critical to food security. These are held by governments and the International Agricultural Research Centres of the Consultative Group on International Agricultural Research.

21 See ITPGR Resolution 2/2006.

22 ITPGR Article 13.2.

23 ITPGR Article 12.

24 ITPGR Article 3.

25 Study on the relationship between an international regime on ABS and other international instruments and fora which govern the use of genetic resources The International Treaty on Plant Genetic Resources for Food and Agriculture and the Food and Agriculture Organisation's Commission on Genetic Resources for Food and Agriculture. Prepared by

CBD obligations.<sup>26</sup> The ITPGR should be implemented in harmony, and in mutual supportiveness, with the CBD and the Nagoya Protocol.

### 3 *Conservation in ex situ Collections*

*Ex situ* conservation is defined by Article 2 of the CBD as “the conservation of components of biological diversity outside of their natural habitats.” *Ex situ* collections are collections of genetic resources held for example in gene banks, botanical gardens, arboreta, zoos, in vitro storage and DNA storage. According to the CBD, contracting Parties shall use *ex situ* conservation methods, preferably in the country of origin of such components, to support *in situ* measures. Moreover, contracting Parties are required to adopt *ex situ* measures to facilitate the rehabilitation of threatened species and the reintroduction of them into their natural habitats. This confines their significance to that of returning species to their habitual *situ*. However, culture collections conserving microbial genetic diversity have acquired a growing importance within the ABS panorama, thanks to the inclusion of microbial genetic resources within the scope of the CBD and the growing scientific importance of microbial genetic resources in the last decades.

Most research undertaken at the level of *ex situ* collections, if not all, is of a non-commercial nature, aimed at improving understanding of genetic diversity and how to best conserve it.<sup>27</sup> Moreover, most of the genetic resources found *ex situ* were accessed before the entry into force of the CBD in biodiversity-rich countries. The Bonn Guidelines prescribes that for *ex situ* collections, prior informed consent should be obtained from the competent national authority(ies) and/or the body governing the *ex situ* collection concerned as appropriate. It is important to notice that some *ex situ* collections, such as botanical garden and herbaria consider the whole of their collection as falling under the obligations of the CBD, regardless of the date of the first collection of the resources, due to ethical and pragmatic reasons.

Most of *ex situ* collections networks have adopted non-binding ABS codes of conduct, best practices and /or guidelines, such as for example:

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Jane Bulmer, IUCN Environmental Law Centre. UNEP/CBD/WG-ABS/7/INF/3/Part.1. 3 March 2009, 9.

26 Where Parties to the CBD are Contracting Parties to the ITPGR, in accordance with Article 30 of the Vienna Convention on the Law of Treaties, on the application of successive treaties relating to the same matter, then the legal relationship of the ITPGR would prevail among them to the extent of the scope of the ITPGR.

27 Thomas Greiber, *et al.*, *An Explanatory Guide*, 15.

- The Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) developed within the framework of culture collections in 1999 and revised in 2009. It is currently under revision in light of the Nagoya Protocol and translated into the Transparent User Friendly System of Transfer for Science and Technology (TRUST);
- The International Plant Exchange Network (IPEN) Code of Conduct for botanic garden governing the acquisition, maintenance and supply of living plant material, developed in 2001;
- The Consortium of European Taxonomic Facilities (CETAF) Code of Conduct and Best Practice for Access and Benefit-sharing, developed in 2012.

The goal of an ABS codes of conduct is triple: first a political recognition and support of the international ABS framework by the institution drafting the code; second the raising awareness among the practitioners working within a group of researchers; and third the facilitation of exchanges of resources by the creation of a group where exchanges are governed by the same standardized rules that implies ABS compliance, thus minimising bureaucracy. The combination of dedication to the respect of the ABS principles and standardized and facilitated exchanges among the group creates a sort of voluntarily “network of compliance” with ABS international rules, on which users can rely.

The Nagoya Protocol encourages Parties to develop and use voluntarily codes of conduct, guidelines and best practices in relation to ABS, and the Open-ended Ad Hoc Intergovernmental Committee (ICNP) for the Nagoya Protocol on ABS, acting as an interim governing body for the Nagoya Protocol until the first meeting of the Parties to the Protocol takes place, has been gathering and discussing recent updates of such documents. Moreover, the EU Regulation has recognized the strong efforts towards ABS compliance of the culture collections, working on the MOSAICC code of conduct even before the adoption of the Bonn Guidelines, through the creation of a register of collections established and maintained by the European Commission. Only collections that fulfill certain criteria (linked to ABS requirements) can become part of the register, and users that obtain genetic resources from a collection in the register should be considered to have exercised due diligence as regards the seeking of all information necessary from the point of view of ABS.

The *ex situ* collections are therefore important actors in the field of ABS. Moreover, given their role in conserving biodiversity and ensuring access for scientific research purposes and their usually publicly funded origin, they provide to the society fundamental services. Their advanced raising awareness activities in the field of ABS is of paramount importance.

## II From the Right to Development to International Concern for Sustainable Use and Global Biodiversity Research

After the brief description of the main features of the international legal framework dealing with ABS, the central section of the chapter illustrates in depth the innovative hypothesis that the concept of benefit-sharing long predated the discussion on ABS of the CBD, and that it is the product of the interaction between three fields of international law is here presented for the first time by the authors of this chapter, therefore the argumentations lack in references to previous literature.

### 1 *Rationale and Origins of the “Right to Development Motive” in the ABS Regime*

The legal framework on ABS is based on the sovereignty of states over their natural resources. The root of the principle of sovereignty over natural resources (and genetic resources, see later) is the traditional principle of international law of sovereignty and territorial jurisdiction of a state. In 1962, through its Resolution on Permanent Sovereignty over Natural Resources, the United Nations General Assembly (UNGA) recognised “the inalienable right of all States freely to dispose of their natural wealth and resources in accordance with their national interests.”<sup>28</sup> This principle has firstly been encoded in the post-war era and it has been used as a tool by international economic law to support two main concerns of the United Nations: economic development and self-determination of colonial people.<sup>29</sup> In the 1950s, developing countries advocated this principle to secure the benefit arising from the exploitation of natural resources and to provide newly independent states with legal tools to defend their economic sovereignty against property and contractual rights

28 Resolution 1803 (XVII) of 14 December 1962 “Permanent sovereignty over natural resources”: the UNGA created in 1958 the Commission on Permanent Sovereignty over Natural Resources “to conduct a full survey of this basic constituent of the right to self-determination, with recommendations, where necessary, for its strengthening” and the work of the Commission resulted in the adoption of the Declaration on Permanent Sovereignty over Natural Resources in UNGA Resolution 1803. It is important to underline that Resolution 1803 of 1962 can be considered a binding Resolution, apart from the strong political force every General Assembly Resolution has, because principle 7 clarifies that the violation of the rights of peoples and nations to sovereignty over their natural wealth and resources is contrary to the spirit and principles of the Charter of the United Nations.

29 Nico J. Schrijver, “Natural Resources, Permanent Sovereignty over,” *Max Planck Encyclopedia of Public International Law* (New York, NY: Oxford University Press, 2010).

claimed by foreign states and companies. By 1952, the United Nations General Assembly had already underlined that the right of developing countries to determine access to their natural resources was a pre-requisite to foster their economic development “in accordance with their national interests.”<sup>30</sup>

Ever since the first mention by the United Nations General Assembly, the right to use national resources has been strongly linked to the right to development. Already in 1952, Resolution 523 on “Integrated economic development and commercial agreements” underlined the root of the problem of the upcoming globalised market where the contractual power of less developed/newly independent states in selling raw materials and resources was not proportionate to the buying states (the developed ones). The Resolution recalled that a necessary requisite for

economic development plans in under developed countries is the creation of conditions under which these countries could more readily acquire machinery, equipment and industrial raw materials for the goods and services exported by them.<sup>31</sup>

Therefore, commercial agreements should facilitate the movement of such machinery, equipment and industrial raw material for the development and improvement of standards of living in under-developed countries. Moreover such agreements “shall not contain economic or political conditions violating the sovereign rights of the under-developed countries, including their rights to determine their own plans for economic development.” This first very weak safeguard of the contractual powers of the countries providing natural resources can be seen as the root of the principles of transfer of technology and mutually agreed term for the achievement of fair and equitable benefit-sharing, later codified in the Convention on Biological Diversity.

By the end of 1952, the United Nations General Assembly went back to these principles in Resolution 626 on the Right of States to exploit freely natural wealth and resources. The Resolution referred to the good faith and balance within the economic exchange of natural resources: it encouraged member States “to have due regard, consistently with their sovereignty, to the need for *maintaining the flow of capital in conditions of security, mutual confidence and economic cooperation among nations*.” This passage is a very light obligation on states to keep a balance and avoid disproportionate flow of capital in economic

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30 Resolution 523 of 12 January 1952 on Integrated economic development and commercial agreements (Preamble, first paragraph).

31 United Nations General Assembly Resolution 523, preamble.

transactions with developing states, within the use and exploitation of natural resources. It can be argued that the principle of benefit-sharing echoed this UNGA call. The same Resolution also recognised the need to encourage under developed countries towards the proper use and exploitation of their natural wealth and resources, which anticipates the issue of sustainable use of resources that came to the foreground of international attention in the 1970ies. Going back to the economic exchange of natural resources another Resolution in 1952 (Resolution 523), expressly considers that “commercial agreements shall not contain economic or political conditions violating the sovereign rights of the under-developed countries, including the right to determine their own plans for economic development.”<sup>32</sup> Another step forward was taken ten years later, with Resolution 1803 of 1962, which underlines that “economic and financial agreements between the developed and the developing countries must be based on the principles of equality and of the right of peoples and nations to self-determination.”<sup>33</sup> International soft law is here interfering with national commercial practices in favour again of an economic balance in the exchange of natural resources. Resolution 1803 of 1962 goes even further by stating that in case where authorization for activities of exploration, development and disposition of national natural resources is granted by a state to a foreigner, the profits arising from such activity “must be shared in the portions *freely agreed upon*, in each case, between investors and the recipient state.” It also added that “due care being taken to ensure that there is no impairment, for any reason, of that State’s sovereignty over its natural wealth and resources.” This text is the origin of the modern principles of prior informed consent and benefit-sharing upon mutually agreed terms.

Another highly relevant factor is the fact that Resolution 1803 focused also on people and not only on the State. It specified that

the right of peoples and nations to permanent sovereignty over their natural wealth and resources must be exercised *in the interest of their national development and of the well-being of the people of the State concerned*.

This principle, even if not yet related to the awareness of the key role of indigenous and local communities in the conservation and sustainable use of biological diversity, laid the ground for the later work for the social movements in

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32 Resolution 523 of 12 January 1952 on Integrated economic development and commercial agreements paragraph. 1 (b).

33 United Nations General Assembly Resolution 1803 (XVII) on Permanent sovereignty over natural resources, Preamble.

defence of the specific rights of these communities in the context of the access and benefit-sharing regime.

In 1974, during the Sixth Special Session of the General Assembly exclusively devoted to the problems of raw materials and development, the UNGA adopted Resolution 3201 entitled Declaration on the Establishment of the New International Economic Order (NIEO Declaration), submitted by the Group of 77 made up of nearly all developing countries. The NIEO Declaration proclaimed “full permanent sovereignty of every State over its natural resources and all economic activities,”<sup>34</sup> including the right to nationalise resources or to transfer their ownership to nationals. The NIEO Declaration thus reinforced principle 10 of the Stockholm Declaration<sup>35</sup> (see Section II.2) by calling for a just and equitable relationship between the prices of raw materials, primary commodities, manufactured and semi-manufactured goods exported by developing countries and those imported by them. From that point onwards, the motive of the right to development easily lead international law-making and the reaffirmation of the claims of sovereignty over natural resources in the Convention on Biological Diversity.

From 1970ies onwards, the growing discussions on the looming global environmental crisis reinvigorated the right to development claim and the related sovereignty rights, as developing countries saw “the possibility of linkage between environmental concerns and reform of the international economic order.”<sup>36</sup> The 1971 Founex Report on Development and Environment<sup>37</sup> was the first authoritative study placing the environment-development nexus on the international agenda. As a consequence, Principle 11 of the Stockholm Declaration already called for “environmental policies of all States [to] enhance and not adversely affect the present of future development potential of developing countries”;<sup>38</sup> and “resources should be made available to preserve and improve the environment”<sup>39</sup> with a special attention to developing countries and the costs they have to face to incorporate environmental concerns in their development plans.

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34 NIEO Declaration Paragraph 4 (e).

35 Declaration of the United Nations Conference on the Human Environment, U.N. Doc. A/Conf.48/14/Rev. 1 (1973); 11 ILM 1416 (1972).

36 Marc Williams, “Re-Articulating the Third World Coalition: The Role of the Environmental Agenda,” *Third World Quarterly* 14 (1993): 15.

37 Founex Report on Development and Environment: a Report Submitted by a Panel of Experts Convened by the Secretary General of the United Nations Conference on the Human Environment, June 4–12, 1971, in 586 *International Conciliation* 7 (1972).

38 Stockholm Declaration Principle 11.

39 Stockholm Declaration Principle 12.

In the years following the Stockholm Conference, the call for the right to development further echoed in the global governance arena. The 1974 UNEP/UNCTAD Cocoyoc Conference, for instance, is a watershed moment for modern environmentalism<sup>40</sup> and paved the way for contemporary ABS principles. The Conference' Declaration explicitly supported "the setting up of strong international regimes for the exploitation of common property resources" and the idea of using the international commons "for the benefit of the poorest strata of the poor countries."<sup>41</sup>

Finally, the strengthening of sovereign rights over genetic resources and traditional knowledge should also be understood as a reaction to expanding enclosure of biological material through intellectual property rights. More particularly, the start of GATT's Uruguay Round in 1986 and the discussions on the Trade Related Aspects of Intellectual Property Rights (TRIPS), triggered by a booming biotechnology industry, expanded the use of patents to biotechnology. In this context, developing countries "abandoned the common heritage strategy and successfully demanded reconfirmation of national sovereign rights over genetic resources."<sup>42</sup> Paradoxically, the call for increased sovereign control over genetic resources was used by developed countries to justify the expansion of intellectual property rights over these resources. In order to reap the benefits from this increased sovereignty, profits had to be generated, which required the establishment of a market and a mechanism for intellectual property protection, so the argument went.<sup>43</sup> The idea of genetic resources and traditional knowledge as a new source of economic prosperity thus appealed to developed and developing countries alike. This is why, in addition to increased sovereignty, the Convention on Biological Diversity also recognizes the need for intellectual property rights.

The right to development, triggered by the unequal international political and economic order of the 20th century, thus can be said to have laid the

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40 The Cocoyoc Declaration *inter alia* coined the term "eco-development," i.e. "ecologically sound socioeconomic development," which paved the way for the concept of sustainable development.

41 Cocoyoc Declaration, adopted by the participants in the UNEP/UNCTAD symposium on "Patterns of Resource Use, Environment and Development Strategies," Cocoyoc, Mexico, 8–12 October, 1974.

42 Kristin Rosendal, "The Convention on Biological Diversity: Tensions with the WTO TRIPS Agreement over Access to Genetic Resources and the Sharing of Benefits," in *Institutional Interaction in Global Environmental Governance: Synergy and Conflict among International and EU Policies*, eds. Oberthür and Gehring (Cambridge: MIT Press, 2006): 86.

43 Kal Raustiala and David G. Victor, "The Regime Complex for Plant Genetic Resources," *International Organization* 58 (2004): 277–309; Hufty, "La gouvernance internationale de la biodiversité."



groundwork of the claim for “fair and equitable sharing of benefits,” the third objective of the CBD. In this regard, the strong claim for sovereignty was seen by developing countries as the only tool to exercise legal protection and acquire benefit-sharing, while developed countries relied on intellectual property rights to get benefits and to get back some of their investments in research. Benefit-sharing then emerged to counterbalance the strong IPRs assets built up by developed countries, and as compensation for the keepers of traditional knowledge.

## 2 *Rationale and Origins of the “Sustainable Use Motive” in the ABS Regime*

International standards and objectives for the prevention or mitigation of environmental harm have been established from the 1940’s onwards.<sup>44</sup> The regulation of biological diversity first grew into a global priority with the international environmental negotiations back in the 1970’s,<sup>45</sup> supported both by conservationist pleas and requests for financial compensations deriving from the use of genetic resources.

Before the initiation of global environmental governance in the 1970’s, the international regulation of genetic resources had long remained an untamed and singular creature. Indeed, most of the environmental regulations had formerly been concerned with “truly” global resources, such as air for example, where “joint international strategies for their use, conservation and development have to be agreed.”<sup>46</sup> As such and in their material form, biological resources are linked to land and thus domestic in nature, as public or private tangible goods, subject to the property regime set out in national laws. However, the information found within these resources’ genotypes possess global public goods qualities.<sup>47</sup> Genetic resources thus do not conform to the traditional

44 International environmental agreements include purpose-specific conventions such as the 1946 International Convention for the Regulation of Whaling (ICRW); regional agreements such as the 1976 Barcelona Convention for Protection against Pollution in the Mediterranean Sea; and also cross-cutting agreements such as the 1973 CITES Convention on International Trade in Endangered Species of Wild Fauna and Flora.

45 See Philippe Sands, *Principles of International Environmental Law* (second edition) (Cambridge University Press, 2003): 25–69.

46 As for instance the regulation of the ozone layer and its 1985 Vienna Convention and 1987 Montreal Protocol on Substances that Deplete the Ozone Layer; Timothy Swanson, “Why Is There a Biodiversity Convention? The International Interest in Centralized Development Planning,” *International Affairs* 75 (1997): 307–308.

47 Joseph Straus, “The Rio Biodiversity Convention and Intellectual Property,” *International Review of Industrial Property and Copyright Law* 24 (1993): 602–603.

definition of global resources in international environmental law making. It is important to note that in the first international environmental instruments, natural resources were only considered as tangible goods, raw materials. Therefore, the aspect that was the target of regulation was the quantitative transaction for the economic exploitation of the resources, as knowledge on genetic resources was scarce in the 1950s and 1960s.<sup>48</sup>

Biodiversity depletion concerns were however gradually recognised on account of a “confluence of international dialogues that have existed for several decades,” including but not limited to debates focusing on protected areas, the sustainable use of natural resources or environmental funding, and the international environmental law concerned with biological resources was developed as a “snapshot of environmental conservation movements.”<sup>49</sup> Its more progressive pleas also include the desire to overcome the existing patchwork of regulation covering selected species or areas, mainly through an ecosystems approach,<sup>50</sup> but also to address the issue of informational goods that are part of such ecosystems.

With the 1972 Stockholm Declaration of the United Nations Conference on the Human Environment, the duty that accompanied sovereign rights over resources shifted from a right to use resources to a “responsibility to protect and improve the environment for present and future generations.”<sup>51</sup> Although states have permanent sovereignty over their natural resources and the right to determine their own environmental policies, they are not free to disregard protection of the environment of common spaces or of other states. Nevertheless, developmental needs remain an obstacle to stronger environmental regulation for developing and developed economies alike.<sup>52</sup> The Declaration specified

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48 The 1949 United Nations Scientific Conference on the Conservation and Utilisation of Resources, made up of technical experts, focused on specific groups of natural resources such as land, water, forests, fuels, minerals, and wild life, included a session on land natural resources, which also included chemurgy, food yeasts, and microorganisms. The conference concentrated on shortage of resources due to increase of population and demand, rather than the importance of the still unknown research information contained within microorganisms. No or little consideration was given to resources as objects of research, neither to what was then identified as the information contained in genetic material.

49 Timothy Swanson, “Why Is There a Biodiversity Convention? The International Interest in Centralized Development Planning,” *International Affairs* 75 (1): 307–331.

50 International Law of relevance to Plant Genetic Resources: a practical review for scientists and other professionals working with PGR. (2004).

51 Stockholm Declaration Principle 1.

52 Patricia Birnie and Alan Boyle, *International Law and the Environment* (Oxford University Press, 2001).

that “environmental policies of all States should enhance and not adversely affect the present or future development potential of developing countries”;<sup>53</sup> and “resources should be made available to preserve and improve the environment”<sup>54</sup> with a special attention to developing countries and the costs they have to face to incorporate environmental concerns in their development plans. Therefore the Stockholm Declaration called for the mobilisation of monetary resources as an incentive for developing countries to adopt environmental legislations. The origin of benefit-sharing lays in this exchange of monetary resources as an incentive for under developed countries. Amongst other endeavours having followed the Stockholm Declaration, a soft-law instrument acknowledging mankind’s responsibility for all species inhabiting the Earth had seen the light of day through United Nations General Assembly Resolution 37/7 in 1982, commonly referred to as the “World Charter for Nature.” The Charter asserted that “the degradation of natural systems owing to excessive consumption and misuse of natural resources [...], leads to the breakdown of the economic, social and political framework of civilization.”

Owing to these steps, the official advent of biodiversity came about during the process leading to the 1992 United Nations Conference on Environment and Development,<sup>55</sup> otherwise known as the “Earth Summit” and the adoption of the Convention on Biological Diversity.<sup>56</sup> The Convention on Biological Diversity is the product of the philosophy of sustainable development, where the goal of environmental protection needs to be balanced with the need and right to development.

Despite the preservation objective, the CBD also embodies a shift towards a utilitarian economic exploitation of the resources, albeit in a sustainable way. The growing attention to environmental protection does not only derive from sudden awareness of the intrinsic value of natural wealth and/or from a better understanding of the functioning of ecosystems. Indeed, as early as the energy crises of the 1970ies, developing countries increasingly saw their natural resources as an important strategic and economic bargaining chip. This led to

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53 Stockholm Declaration Principle 11.

54 Stockholm Declaration Principle 12.

55 The first stages of the adoption of the CBD can be traced back to a 1981 Resolution adopted by the World Conservation Union’s General Assembly, requesting further analysis on a potential international agreement on the conservation, accessibility and use of biological resources; see Regine Andersen, *Governing Agrobiodiversity. Plant Genetics and Developing Countries* (Ashgate, 2008): pp. 117–119, citing C. De Klemm, “Conservation of species: The need for a new approach,” *Environmental Policy and Law* 9 (1982): 118–128.

56 Opened for signature on 5th June 1992, the CBD entered into force on 29th December 1993.

a growing understanding on the fact that the availability of genetic diversity and traditional knowledge as a raw material for the biotechnology industry can only be guaranteed through the protection of a strong variety of *in situ* ecosystems (including humans), which is to be found in developing countries.<sup>57</sup> Unlike in the 60s and 70s, developed countries started questioning the effectiveness of so-called “fortress conservation,” through which large areas of “virgin” nature were freed from human interaction, and increasingly promote *in situ* conservation and the concept of “sustainable use” of biodiversity.<sup>58</sup> As underlined in Section I.1 as an effect of negotiation bargain between developing countries and developed ones, the second and third objectives of the Convention thus became the “sustainable use of its components and the fair and equitable sharing of the benefits arising out of the *utilisation* of genetic resources.”<sup>59</sup>

The exchange of monetary resources as an incentive for the conservation of biological diversity in developing countries was further institutionalized in the CBD. Article 3 of the CBD reaffirms “the sovereign right (of States) *to exploit* their own resources pursuant their own environmental policies”: this indicates a balance between national environmental policies and, again, the right of States to their economic development.<sup>60</sup> The only limit put to such prerogative seems to be the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.<sup>61</sup> This focus on development echoed the approach of Rio Declaration on Environment and Development that had shifted from an environmental to a development one. The Rio Declaration in fact makes no reference to the conservation of flora, fauna, habitats and ecosystems.<sup>62</sup> However, the CBD focuses on *in situ* conservation and the protection of ecosystems, natural habitats (Article 8.d), re-appropriating the conservation angle of the Stockholm Declaration.

The focus on utilisation and exploitation goes along with a broader change in global environmental governance, which is the confluence of the neo-liberal economic order of the 80s and 90s and environmental protection (termed

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57 Lipietz, “Enclosing the Global Commons.”

58 Marian A.L. Miller, *The Third World in Global Environmental Politics* (London: Lynne Rienner, 1995).

59 CBD Article 1, emphasis added.

60 CBD Article 3, emphasis added.

61 *Ibid.*

62 Schrijver, “Natural Resources.”

“liberal environmentalism”).<sup>63</sup> With the Brundtland report,<sup>64</sup> more economic growth (mainly through liberalized market-mechanisms for environmental management) was pictured as *the* solution for the protection of the environment. This was partially made possible through the extended sovereignty over natural resources and the developing countries’ call for a compromise between development and environmental protection. In the ABS context, the sustainable use approach thus can be seen as a compromise position between developed countries (who need genetic resources for biotechnology), developing countries (who expect financial returns in exchange with granted access to their genetic resources) and global environmental groups (“newly enchanted by market mechanisms”).<sup>65</sup>

The liberal environmentalism approach of the CBD is further exemplified by the fact that the CBD originally did not contain language on the obligation to devote the benefits to conservation of biological diversity. The underlying view was that biological diversity served the purpose of utilization, which on its turn generated benefits and allowed for development in developing countries. In line with the right to self-determination and to development, provider countries could decide to use the monetary benefits acquired through a benefit-sharing arrangement as they saw fit. However, this was partially redressed in the 2002 Bonn Guidelines,<sup>66</sup> which recommended redirecting benefits towards measures for the conservation of biological diversity and the sustainable use of its components. The Nagoya Protocol further strengthened this encouragement.<sup>67</sup>

### 3 *Rationale and Origins of the “Scientific Research Motive” in the Global ABS Regime*

The research community is arguably the stakeholder group most affected by access and benefit-sharing under the CBD and the Nagoya Protocol: access to genetic resources in almost all cases is undertaken with no commercial intent at the time of access.<sup>68</sup> It has been demonstrated that at the time when the

63 Steven Bernstein, “Liberal Environmentalism and Global Environmental Governance,” *Global Environmental Politics* 2 (2002): 1–16.

64 Brundtland G.H. and World Commission on Environment and Development, *Our common future: report of the World Commission on Environment and Development* (Oxford University, 1987).

65 Raustiala and Victor, “The Regime Complex for Plant Genetic Resources.”

66 CBD, *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*, 2002.

67 Nagoya Protocol Article 9.

68 Matthias Buck and Claire Hamilton, “The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the

entry into force of the CBD was approaching (end of 1993), the amount of exchange of plant genetic resources in food and agriculture for public research purposes, within the Consultative Group on International Agricultural Research, dropped considerably as a result of the re-affirmation of national sovereignty over genetic resources under the CBD, in conjunction with the fear of legal uncertainty over intellectual property right.<sup>69</sup>

The importance of international cooperation for biodiversity research has been recognized early on in the broader context of the debates in international environmental soft law. The Stockholm Declaration underlines that the “free flow of up-to-date scientific information and transfer of experience must be supported and assisted, to facilitate the solution of environmental problems; environmental technologies should be made available to developing countries.”<sup>70</sup> This requirement has been reiterated by the Rio Declaration on Environment and Development that goes further in calling for states to “cooperate to *strengthen endogenous capacity-building* for sustainable development by improving scientific understanding through exchanges of scientific and technological knowledge, and by *enhancing the development*, adaptation, diffusion and transfer of technologies, including new and innovative technologies.”<sup>71</sup> In 1992 the Rio Declaration is putting forward the innovative idea that cooperation is aimed at strengthen endogenous capabilities rather than focusing only on the transfer of technologies, which is more passive and less effective in the view of developing countries.

The need for international scientific cooperation has been inspiring also the international law making of some international binding treaties: the United Nations Convention on the Law of the Sea,<sup>72</sup> the Antarctic Treaty<sup>73</sup> and the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture contain important obligations to this regards.

The whole Antarctic Treaty System (ATS),<sup>74</sup> whose origin dated in 1959 when the Antarctic Treaty was signed, is focused on scientific research and the

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Convention on Biological Diversity,” *Review of European Community & International Environmental Law* 20 (2011): 59.

69 Michael Halewood, “Governing the management and use of pooled microbial genetic resources: Lessons from the global crop commons,” *International Journal of the Commons* 4 (2010): 403.

70 Stockholm Declaration Principle 20.

71 Rio Declaration Principle 9.

72 United Nations Convention on the Law of the Sea, 1982, 21 ILM (1982), 1261.

73 1959 Antarctic Treaty, 19 ILM 860 (1980).

74 The Antarctic Treaty System is the whole complex of arrangements made for the purpose of regulating relations among states in the Antarctic. At its heart is the Antarctic Treaty

promotion of international scientific cooperation. The main objectives of the Antarctic Treaty are to demilitarize Antarctica and to ensure that it is used for peaceful purposes only; to promote international scientific cooperation and to set aside disputes over territorial sovereignty.<sup>75</sup> Contracting Parties are obliged to exchange scientific information, personnel and results “to the greatest extent feasible and practicable.”<sup>76</sup>

The 1982 United Convention on the Law of the Sea (UNCLOS) does not mention genetic resources for historical reasons, but prescribes important rules for the organization of marine scientific research (MSR), which can be considered to apply to genetic resources. The UNCLOS requires States and international organization (indeed stressing the aspect of international cooperation) to promote and facilitate the development and conduct of marine scientific research.<sup>77</sup> MSR, notwithstanding in which maritime area it is conducted, must have peaceful purpose, respect the whole system of the law of sea (protection of the marine environment included) and cannot be the legal basis for claim of appropriation of marine environment and resources.<sup>78</sup> International cooperation in MSR is to be promoted and to this end states and international organizations are required to make available information on proposed major programmes, their objectives and the knowledge resulting from MSR.<sup>79</sup> These obligations to share knowledge produced through marine scientific research constitute non-monetary benefit-sharing obligations of the UNCLOS<sup>80</sup> that are applicable both in areas within national jurisdiction and in areas beyond national jurisdiction. Moreover States “shall actively promote the flow of scientific

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itself. The Treaty is augmented by Recommendations adopted at Consultative Meetings, by the Protocol on Environmental Protection to the Antarctic Treaty (Madrid, 1991), and by two separate conventions dealing with the Conservation of Antarctic Seals (London 1972), and the Conservation of Antarctic Marine Living Resources (Canberra 1980).

75 Antarctic Treaty Article I–IV.

76 Antarctic Treaty Article III.

77 UNCLOS Article 241.

78 UNCLOS Article 240–241.

79 UNCLOS Article 244.1.

80 Greiber Thomas, “Common Pools for Marine Genetic Resources,” in *Common Pools of Genetic Resources. Equity and Innovation in International Biodiversity Law*, eds. Kamau and Winter (Earthscan, 2013), 407. Broggiato Arianna, *et al.*, “Fair and equitable sharing of benefits from the utilization of marine genetic resources in areas beyond national jurisdiction: Bridging the gaps between science and policy,” 49 *Marine Policy* (2014), 176. IUCN Information Papers for the Intersessional Workshop on Marine Genetic Resources 2–3 May 2013, available at <http://www.un.org/depts/los/biodiversityworkinggroup/documents/IUCN%20Information%20Papers%20for%20BBNJ%20Intersessional%20Workshop%20on%20MGR.pdf>.

data and information and the transfer of knowledge resulting from marine scientific research, especially to developing States, as well as the *strengthening of the autonomous marine scientific capabilities of developing States*.<sup>81</sup> This focus on the development of own scientific capabilities of developing countries was innovative at that time. It survived and inspired the 1992 Rio Declaration (as seen above) but it was lost in favor of the more passive technology transfer obligation emerged in the negotiation of the CBD, that same year (see below).

The 1984 International Undertaking on Plant Genetic Resources, as well as the ITPGRFA, adopted a research oriented approach: access to resources is to be facilitated for research purposes, plant breeding and conservation.<sup>82</sup> The International Undertaking is about collaboration on research and interdependency rather than direct commercial use. The ITPGRFA is also a research oriented treaty rather than an environmental one. It stresses the importance of international cooperation and transfer of technologies.

However, with the above-mentioned exceptions (the United Nations Convention on the Law of the Sea, the Antarctic Treaty and the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture), the international legal framework has been limited to the "commercial" end of the research chain and focused mainly on the issues surrounding technology transfer and intellectual property rights. As a result, outside the specific areas of application of these international agreements, there is not clear legal framework under public international law establishing the rights and duties of global research collaborations with basic knowledge assets for scientific research, in spite of evidence of increasing restrictions on access to basic research assets in areas such as scientific publishing;<sup>83</sup> access to research samples<sup>84</sup> and access to databases.<sup>85</sup>

As illustrated in Section I.1 the CBD requires the states to "promote and encourage research which contributes to the conservation and sustainable use of biological diversity." However, within the implementation of the CBD, growing protectionism by developing countries and issues related to intellectual

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81 UNCLOS Article 244.2.

82 International Undertaking Article 5; International Treaty on Plant Genetic Resources Article 12.3.

83 "Open sesame – When research is funded by the taxpayer or by charities, the results should be available to all without charge," *The Economist* (14 April 2012).

84 Sikina Jinnah and Stephan Jungcurt, "Could Access Requirements Stifle Your Research?" *Science* 323 (2009): 464–465.

85 Jerome Reichman and Ruth L. Okediji, *Empowering Digitally Integrated Scientific Research: The Pivotal Role of Copyright Law's Limitations and Exceptions*, 2009.



property rights in developed countries impacted the world of scientific research and its access to resources for research purposes. At the same time many parties were concerned that special treatment for research could create loopholes in the system of ABS compliance to the detriment of countries providing genetic resources.<sup>86</sup> Due to these emerging constraints the scientific community pushed for a facilitated access for research purposes within the negotiation of the Nagoya Protocol, but the colliding interests at stake generated a compromising article far from been clear.

The rationale of Article 8a of the Nagoya Protocol is to create legislative conditions to promote and encourage research which contributes to conservation and sustainable use of biological diversity *i.e.*, to the first and second objective of the CBD. To this end, Article 8a of the Nagoya Protocol singles out the adoption of simplified measures to access genetic resources for non-commercial purposes as a tool to promote and encourage this research. Other tools are possible as well, but legislation in provider countries, if adopted, “shall” provide for simplified measures to access genetic resources for non-commercial research that contribute to conservation and sustainable use of biological diversity. Moreover, when such simplified procedure is adopted in drafting national ABS legislation, it needs to take into account and define the issue of “change of intent.” Nevertheless, some crucial concepts in this provision still need to be clarified through practice or further legislative development:<sup>87</sup> where does the limit between commercial and non-commercial research lay? How to demonstrate that research is aimed at the conservation and sustainable development of biodiversity? And how to identify a change of intent?

The main contribution, in this context, of the Nagoya Protocol’s provision on simplified procedure to access materials for non-commercial purposes is that it offers new opportunities by explicitly including provisions that address

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86 Buck and Hamilton, “The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity,” 59; Evanson C. Kamau, Bevis Fedder and Gerd Winter, “The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?” *Law, Environment and Development Journal* 6 (2010): 256.

87 The precise manner in which these provisions of the Nagoya Protocol will have an impact on global research collaborations with basic knowledge assets for scientific research is still a question of intense debate: Tom Dedeurwaerdere *et al.*, “Governing Global Scientific Research Commons under the Nagoya Protocol,” in *The Nagoya Protocol in Perspective: Implications for International Law and Implementation Challenges*, eds. Elisa Morgera, Matthias Buck and Elsa Tsioumani (Leiden/Boston: Brill/Martinus Nijhoff, 2012).

the global organization of scientific collaboration at the non-commercial stages of the research cycle.<sup>88</sup>

The EU ABS Regulation recalls the Nagoya Protocol's obligation to promote and encourage research related to biological diversity, in particular research with non-commercial intent. It will be interesting to see what innovative solutions are proposed by the different national legislations implementing the Nagoya Protocol and the EU ABS Regulation.

### III Overview of the Book

The law-making on genetic resources culminated with the adoption of the Nagoya Protocol to the Convention on Biological Diversity. In order to evaluate if the Protocol offers an adequate balance between the three motives that characterized the law making on genetic resources – the right to development of the developing countries, the global environmental concerns and the need of the research community to have smooth and rapid access to biological materials – it is necessary to gather the most up to date knowledge on the ongoing implementation efforts of the Nagoya Protocol in Europe. The aim of this book is to comparatively analyse the heterogeneous legal and institutional state of the art of access and benefit-sharing instruments in Europe, and to identify cross-cutting issues for the forthcoming implementation of the Nagoya Protocol in the EU, within the framework of the EU Regulation on Access and Benefit-sharing.

The focus of this book is a comparative analysis of the heterogeneous legal and institutional state of the art of access and benefit-sharing instruments in Europe, in light of the forthcoming implementation of the Nagoya Protocol within the EU.

Through its recently adopted EU Regulation on Access and Benefit-sharing,<sup>89</sup> aiming at implementing the Nagoya Protocol in the European Union, the European Commission establishes an EU-harmonised approach on ABS, creating

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88 Jerome H. Reichman, Tom Dedeurwaerdere and Paul Uhler, *Global Intellectual Property Strategies for the Microbial Research Commons* (Cambridge: Cambridge University Press, forthcoming).

89 Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Official Journal of the European Union L 150/59, 20.05.2014.

a level playing field for European users. According to the Regulation, this harmonized approach only entails minimum features which are to be complemented with existing ABS systems and best practices left to the choice of users of genetic resources. However, current instruments strongly differ in terms of depth, scope and effectiveness as well as across different types of users. Furthermore, it is likely that the utilization of genetic material is already (directly or indirectly) regulated by private and public law provisions—if not by specific ABS laws—which will be impacted by a harmonization at EU level. This is further complexified by the plurality of political structures and the division of competences within member states, as well as by the different utilization profiles of member states (user, provider or both).

The implementation of the EU Regulation on ABS is offering a unique opportunity for the reassessment of the national legislative framework in European and non-EU countries, and this collective volume aims to shed light on this heterogeneity from an academic perspective.

The first part of the book, “Access and Benefit-sharing Regimes in Europe,” provides detailed case-studies of ABS frameworks in selected European countries (including non-EU countries, like Norway and Turkey). Drafted by national ABS experts, these country case-studies were conducted on the basis of the following common research questions:

- (1) *Legal status of genetic resources and traditional knowledge*: Under currently applicable law, what is the legal status of genetic resources and associated traditional knowledge in your country?
- (2) *Access to domestic genetic resources and traditional knowledge*: Is access to genetic resources and associated traditional knowledge regulated in your country? How?
- (3) *Benefit-sharing mechanisms*: Which benefit-sharing obligations can be found in currently applicable law in your country?
- (4) *Compliance mechanisms*: Can PIC and MAT currently be controlled/enforced in your country on the basis of specific legislation and/or general private international law principles?
- (5) *Distribution of competences*: How are ABS-related competences politically and administratively distributed in your country?

These chapters show that the economic, historical and social developments of each country, together with its geographical and environmental conditions, have deeply influenced the choices these countries have been making and are making in balancing the conservation of biodiversity, their efforts to acquire a better economic development and the support they are willing to give to

research in the field of biodiversity and to its necessity to have a smooth and easy access to natural resources.

The second part of the book, “Implementing the Nagoya Protocol in the European Union,” explores several cross-cutting issues related to the implementation of the Nagoya Protocol in the EU.

Chapter 11 by Philippe Karpe, Alexis Tiouka, Ivan Boev, Armelle Guignier and Florencine Edouard underlines the importance of protecting traditional knowledge of the Amerindians of French Guyana and the possibility to implement this protection through the use of indigenous customary law and their existing autonomy. It however stresses the limitation of this protection. The contribution looks into the opportunity given by the implementation of the EU Regulation on compliance measures for users from the Nagoya Protocol to improve effective protection of traditional knowledge.

Chapter 12 by María Julia Oliva introduces the development of private standards, as particular kinds of best practice or voluntary norms, and their benefits towards compliance with ABS requirements. These requirements are developed through multi-stakeholder consultation. In meeting the challenge of monitoring and evaluating utilization of genetic resources for compliance with ABS requirements, private standards bring to bear relevant traceability systems, reporting requirements and independent audits. They are likely to be helpful in implementing the due diligence principle of the EU ABS Regulation.

Chapter 13 by Christine Godt argues that the EU approach camouflages a simplistic understanding of how the uses of genetic resources are regulated in detail. The approach ignores the administrative set-up of various pre-existing procedures, which fine-tune in many ways, the quality control of research and production. It willfully downplays the difficulties of information flow, and gives broad leeway to circumvention. Thus, it shows that the EU ABS Regulation focusing on user measures is not ambitious enough to complement existing and future provider measures.

Chapter 14 by Lorenzo Maggioni, Isabel López Noriega, Isabel Lapeña, Vojtech Holubec and Johannes Engels presents and analyses current and potential difficulties for collecting plant germplasm *in situ* in Europe. These difficulties are the result of the combination of international rules on access and benefit-sharing with pre-existing national laws and administrative procedures that both add complexity and influence the way international conventions are implemented. This contribution offers some ideas about how the objective of providing facilitated access to plant genetic resources, which is embraced by the CBD, the Treaty and the Nagoya Protocol, can be effectively achieved in European countries.

The conclusion to the book by Brendan Coolsaet articulates a comparative analysis of the ABS regimes in Europe, based on the country case-studies, and outlines a comprehensive evaluation of the challenges related to the implementation of the Nagoya Protocol in the EU, taking into account the provisions of the EU Regulation on ABS and the input provided by the chapters of the second part of this book.<sup>90</sup>

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90 See contribution by Coolsaet to this volume (Conclusion).



**PART 1**

*Access and Benefit-Sharing Regimes in Europe*







# Genetic Resources in a Multi-Layered Institutional Cake: The Regulation of Access Benefit-Sharing in Belgium

*John Pitseys, Brendan Coolsaet, Fulya Batur, Tom Dedeurwaerdere and Arianna Broggiato*

On 30th October 2010, the final plenary of Convention on Biological Diversity (CBD) COP10 successfully adopted the Nagoya Protocol on “Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.” The Nagoya Protocol on ABS delineates the means of implementation of the third objective of the CBD, that is to say “the fair and equitable sharing of benefits arising from the utilization of genetic resources.”<sup>1</sup>

This chapter analyses how original the Belgian context is – and especially the federal nature of the regime – for the implementation of the Nagoya Protocol. To what extent must the Belgian legal order and environmental policies be adapted in order to comply with the Protocol? What are the political and institutional challenges the ratification process will have to face? These questions are not only interesting *per se*: the Belgian case is interesting as it allows us to broach some of the governance issues federal states are likely to present when implementing environmental treaties. In addition, Belgium is a key user of genetic resources. With 340 biotechnology companies, the country is among the world’s frontrunners in terms of biotechnology companies per capita.<sup>2</sup> The majority of these companies are active in the health-care sector, making the country the third largest importer and exporter of medicinal and pharmaceutical products and medicaments.<sup>3</sup> According to its own figures, the

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1 CBD Article 1.

2 Belgian Foreign Trade Agency, *Belgian Biotechnology* (Brussels, 2011).

3 Figures from UN Commodity Trade Statistics Database, *Medicinal and pharmaceutical products, other than medicament (SITC 541)* and *Medicaments (including veterinary medicaments) (SITC 542)* (New York, 2011); Brendan Coolsaet and Kristof Geeraerts, “Country Report: Belgium,” in *Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union*, IEEP, Ecologic and GHK (Brussels/London, 2012): annex 1.

biopharmaceutical sector employs over 30 000 people, while providing 40% of the total private R&D used in the country. The implementation of the Nagoya Protocol is thus an economic and ethical issue of paramount importance for the country.

In order to answer these questions, this paper will be structured in four parts. The first part will describe the peculiarities of the distribution of ABS-related competences in Belgium, be it the political distribution of ABS-related competences or the institutional role played by non-State actors. The second part will depict the different status of the genetic resources – both the bio-physical entity and the informational component – are susceptible to have in Belgian legal order and the currently existing liability rules which could be drawn upon in case of illicit acquisition. The third part will study the extent to which Belgian law already complies with the provisions of the Nagoya Protocol. To do so, the paper will take stock of the existing ABS-related measures in Belgium, be they related to measures resulting from the coordination between the three regions and the federal level, to federal or regional measures, or research institutions' and private initiatives and policies on ABS. On the other hand, it will assess the degree of conformity of the existing national legislation and measures to the obligations of the Nagoya Protocol. This latter part will also consider the obligations of the Nagoya Protocol that are currently not addressed by legal or non-legal instruments in Belgium. The last part concludes.

## **I Belgium: The Multi-Layered Institutional Reality of a Federal State**

### **1 *Three Regions, Three Communities and a Federal Government***

In Belgium, competences relating to ABS are divided between the federal level, the three Regions (Brussels-Capital, Walloon and Flemish Region) and the three Communities (the Flemish Community, the German speaking Community and the Wallonia-Brussels Federation). This distribution stems from successive transfers of competences from federal to federated entities through the six state reforms since 1970.<sup>4</sup> As a general principle, federated collectivities possess the full competence for matters that have been attributed to them, while the Federal State possesses those competences that have been reserved

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4 Belgian State reforms were performed in 1970, 1980, 1988, 1993, 2001 and 2013. The main provisions pertaining to these reforms are to be found in the "special law" dated 8th August 1980 related to the general institutional reforms, and the special law of 12th January 1989 pertaining to the institutions of the Brussels Region.

on its behalf by the Constitution or legislation enacted with special voting quorums, as well as those residual competences that have not been otherwise attributed to other entities.<sup>5</sup> The Federal State does not have any pre-eminence on the federated collectivities. The implementation of the Nagoya Protocol, as a “mixed treaty,”<sup>6</sup> will thus fall under the competences of both the federal and federated entities – that is to say both the Regions and Communities – and require extensive inter- and intra-departmental coordination.

Today it is the three Regions (Flemish Region, Walloon Region and Brussels Capital Region) that have a general competence on overall environmental policy, and thus have the greatest responsibility in biodiversity-related issues.<sup>7</sup> However, applicable legislation still reserves a number of competences to the Federal State, as an “exception” to the general competence on environmental policy and nature conservation of the Regions.<sup>8</sup> Besides, as the Belgian territorial sea is not considered a part of the territory of (one of the) Regions, the exercise of environmental and nature conservation competences within the Belgian territorial sea is considered to fall under the residual competence of the Federal Government.

The influence of this multi-layer institutional cake on the implementation of the Nagoya Protocol can be illustrated by the case of the existing legislation on physical access to and use of genetic material. The legislation is dependent on the relevant authority, which means that each Region and the

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5 This repartition principle could however be overturned if Article 35 of the Constitution is activated through a “special law,” as a result of which the residuary competences could fall within the hands of federated entities.

6 In Belgium, the conclusion of international agreements that fall under the competence of the federal and of federate entities is regulated by the coordination agreement for mixed treaties. This agreement considers three types of international treaties in Belgium: (1) treaties under the exclusive federal competence, (2) treaties under the exclusive competence of the Regions and/or Communities and which are concluded and ratified by the regional and/or community Governments and (3) “mixed” treaties (or “*traités mixtes*”) when the agreement covers both the competence of the federal and federate entities. The first two types of treaties do not necessarily require coordination between federal and regional authorities. The “mixed” treaty however, must be concluded by a special procedure, agreed on by all concerned Governments, and must also be approved by all competent parliaments. Considering the distribution of competences described previously, the CBD and the NP are obviously “mixed” treaties.

7 Special Law of institutional reform of 8/8/80 Article 6§1, II and III, which provides for the so-called “competence block” in accordance with Article 39 of the Constitution that dictates regional competences.

8 For instance, the establishment, for purposes of environmental protection, of product norms for market access (Special Law 8/8/80 Article 6§1, II indent 2) or the export, import and transit of non-indigenous plant varieties as well as non-indigenous animal species and their cadavers (Special Law 8/8/80 Article 6§1, III, 2°).

Federal level have their own rules. In the Flemish Region, as regulated by the 1997 Flemish Nature Conservation Decree, all acts that do not encompass the normal maintenance of vegetation require a permit, including for commonly accessible green areas such as parks and gardens.<sup>9</sup> In the Walloon Region, however, permit delivery is regulated by the regional Code for urban and land-use planning,<sup>10</sup> which regulates acts in zones previously prescribed by the government as being in need of protection, such as Natura 2000 sites. In the Brussels-Capital Region, different rules apply for protected and non-protected areas: while the collection of natural resources requires no permit for unprotected parks, gardens or squares, any acts implying the adaptation of the vegetation in protected areas is strictly regulated by the 2009 Nature Conservation Ordinance.<sup>11</sup> Finally, access to marine resources is regulated by federal laws on the protection of the marine environment and the exclusive economic zone, containing specific rules for accessing resources – including biological ones – for scientific research purposes.<sup>12</sup> All four power levels thus have appointed specific authorities for the handling of physical access requests and provide for different administrative sanctions in case of non-compliance. Even though the Nagoya Protocol has not been ratified yet and ABS is currently not regulated through these dispositions, it could be expected that the implementation of the Nagoya Protocol will lead to a similar situation, where the three regions and the Federal State each have their own access and compliance rules under the Nagoya Protocol.<sup>13</sup>

Moreover, ABS encompasses a large range of issues extending far beyond sole environmental matters, including market regulation and access, international trade, industrial policy, agriculture, health, development cooperation, research & development and innovation. Although the implementation of the

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- 9 Flemish Decree of 21 October 1997 on nature conservation and the natural environment (Decreet betreffende het natuurbehoud en het natuurlijk milieu), Belgian Official Journal 10 January 1998.
  - 10 Walloon Code for Land-use planning, Urbanism, Heritage and Energy of 14 May 1984 (Code wallon de l'Aménagement du Territoire, de l'Urbanisme, du Patrimoine et de l'Energie), Belgian Official Journal 19 May 1984.
  - 11 Ordinance of the Brussels Capital-Region concerning the conservation of nature of 1 March 2012 (Ordonnance de la Région Bruxelles-Capitale relative à la conservation de la nature), Belgian Official Journal 16/03/2012.
  - 12 Act of 20 January 1999 on the protection of the marine environment in sea areas under Belgian jurisdiction (Loi du 20 janvier 1999 visant la protection du milieu marin dans les espaces marins sous juridiction de la Belgique), Belgian Official Journal 12/03/1999.
  - 13 Brendan Coolsaet, Tom Dedeurwaerdere and John Pitseys, "The Challenges for Implementing the Nagoya Protocol in a Multi-Level Governance Context: Lessons from the Belgian Case," *Resources* 2 (2013): 555–580.

Protocol is likely to be conducted by environmental ministries and administrations, these competences are also scattered around in Belgium. Agricultural policy, including the application of common European measures is also mainly a regional competence, with the exception of the standardization and monitoring of the quality of raw and vegetal material which is a reserved federal competence. Regions are also the prime responsible authorities with regards to economic and industrial policy, even if the Federal government conserves full competence over competition law, trade practices and intellectual property, all of which will play a role in the implementation of the Nagoya Protocol.

The management of public and private research and development, arguably the most important aspect of the implementation of the Nagoya Protocol for a user country such as Belgium, is divided differently between different power levels. Fundamental research and higher education, as well as the regulation of researchers' funding and the management of research institutions were transferred to the French and the Flemish Communities.<sup>14</sup> In 1993, federated entities were made the prime responsible authorities in matters of R&D. Therefore in this context, the Flemish and French Communities are in first line, as they regulate fundamental research and higher education. However, the regions and the Federal government are competent as for the research matters coming under the exercise of their competences, including for instance economically oriented and industrial research (Regions) or the organization of data exchange networks between scientific institutions on the national and international level (Federal government).<sup>15</sup> Finally, foreign policy and development cooperation are divided between the different entities according to the principle "*in foro interno, in foro externo*": the Federal Government, the Communities and Regions are all responsible for foreign policy related to their respective material competences.<sup>16</sup>

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14 Belgian Constitution Article 127 and Special Law 8/8/80 Article 4.

15 Jacques Wautrequin, "Nouveaux Transferts de Compétences en Matière de Politique Scientifique? Critère D'appréciation" (paper presented at "Paroles de chercheurs. Etats des lieux et solutions," Namur, 4 March 2011); Catherine Goux, *La recherche scientifique dans la Belgique fédérale: examen de la répartition des compétences*, (Bruges: La Charte, 1996); Brendan Coolsaet et al., *Study for the implementation in Belgium of the Nagoya Protocol on Access and Benefit Sharing to the Convention on Biological Diversity* (Louvain-la-Neuve/Brussels: Université catholique de Louvain, 2013).

16 Manuel Duran, and David Crikemans, *Een vergelijkend onderzoek naar en bestedingsanalyse van het buitenlands beleid en de diplomatieke representatie van regio's met wetgevende bevoegdheid en kleine staten. Rapport* (Antwerpen: Steunpunt Buitenlands Beleid, 2009).

Consequently, several levels of competence – as well as the corresponding administrative departments – could be responsible for the future implementation of the NP, at federal, regional and community level. Even though Belgium will be a single Party to the Protocol (once ratified), it remains bound by political dynamics at sub-national level, which distribute ABS-related competences between and within the different power-levels. As underscored here above, the implementation of the Nagoya Protocol falls within the competence of both the federal and federated entities. The Nagoya Protocol is thus treated as a double “mixed treaty” by the Belgian Interministerial Conference on Foreign Policy, *i.e.* one which requires consent from the federal State on the one hand, and from *both* the Regions and the Communities on the other to be able to ratify. To this effect, the Regions and the Federal Government coordinate their actions in the framework of the 1995 Cooperation Agreement on international environmental matters,<sup>17</sup> which provides *inter alia* for an Intra-Belgian coordination framework (supplied by the Belgian Coordination Committee on International Environment Policy) for the implementation of multilateral environmental treaties.

## 2 The Role of Para-Public and Private Actors

One of the most challenging features of the ABS framework is that access and benefit-sharing is legally grounded in the national sovereign rights states have over genetic resources, while in practice it is mostly private actors that manage transnational transactions of genetic resources.<sup>18</sup> In practice, the implementation of ABS, with its multiple incidences on private economic, social and environmental interests, implies active participation of the civil society, research actors, *ex situ* collections and, in particular, private companies utilizing genetic resources situated both in the user and provider countries.

The research community, private or public, is arguably the stakeholder group most affected by ABS under the CBD and the Nagoya Protocol. This

17 Accord de coopération du 5 avril 1995 entre l'Etat fédéral, la Région flamande, la Région wallonne et la Région de Bruxelles-Capitale relatif à la politique internationale de l'environnement/Samenwerkingsakkoord van 5 April 1995 tussen de Federale Staat, het Vlaamse Gewest, het Waalse Gewest en het Brussels Hoofdstedelijk Gewest met betrekking tot het international milieubeleid.

18 Matthias Buck and Claire Hamilton, “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,” *Rev. Eur. Community Int. Environ. Law* (2011): 47–61.

explains why the sharing of benefits for the exchange or the utilization of genetic resources currently tends to be self-regulated by the sector, with many institutions already proposing their own rules and standard agreements. Some stakeholders have taken a leading role in formulating standard contractual clauses and procedures for establishing private law agreements that can be used by the research community, some of which are compliant with the provisions of the Protocol.

In Belgium, the major collections of genetic resources, the Belgian Coordinated Collection of Micro-organisms (BCCM) and the National Botanic Garden, each have their own codes of conduct aiming to foster conformity of the distributed genetic resources with the PIC requirements of the provider countries. The BCCM launched the international Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) initiative in 1997. MOSAICC is a voluntary code of conduct to facilitate access to microbial genetic resources in line with the CBD, the TRIPS Agreement and other applicable national and international laws. It ensures that the transfer of material takes place under appropriate agreements with the downstream users and is monitored to secure benefit-sharing. The BCCM uses a standard Material Transfer Agreement (MTA) for getting access to the genetic resources of its public collection, which is established according to the guidelines of the MOSAICC code of conduct. The MTA stipulates that anyone seeking to access genetic resources held by the BCCM has the responsibility to obtain any intellectual property licenses necessary for its use and agrees, in advance of such use, to negotiate in good faith with the intellectual property rights owner(s) to establish the terms of a commercial license; taking also into account specific national laws regarding Article 15.7 of the Convention on Biological Diversity as to conditions concerning benefit-sharing.<sup>19</sup>

The National Botanic Garden of Belgium joined the International Plant Exchange Network (IPEN), a network of botanic gardens that organizes the exchange of living plant specimens. IPEN's members have adopted a code of conduct regarding access to genetic resources and benefit-sharing. In line with the code, the Botanic Garden only accepts plant material that has been acquired in accordance with the provisions of the CBD. The Garden only supplies seed material to other IPEN-members, according to the same terms under which it was acquired, unless an "agreement on the supply of living plant material for non-commercial purposes leaving the International Plant Exchange Network" is signed by authorized staff.

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19 Belgian Coordinated Collection of Micro-organisms, Material Transfer Agreement Article 8.

## II The Status of Genetic Resources and Traditional Knowledge in Belgium

Access to genetic resources, as understood in the Nagoya Protocol, is not as such yet regulated by Belgian public law measures. Nevertheless, existing public and private law provisions already regulate related matters such as property rights, physical access to (genetic material in) protected areas and protected species, or modification and transformation of natural environments. Several of these existing provisions could be used as a basis for the implementation of the Nagoya Protocol in Belgium. In this context, one has to differentiate the legal ownership of genetic resources in their quality of material goods under national law on the one hand, and the sovereign rights the Belgian State holds over its genetic resources on the other. Given the latter, the State can decide to regulate the access and utilization of genetic resources through public law measures, in line with the provisions of the Nagoya Protocol. Moreover, it is important to remember that while genetic resources can be seen as biophysical entities (*e.g.* a plant specimen, a microbial strain, an animal, etc.), they also include an “informational component” (*i.e.* the genetic code, traditional knowledge, published data etc.). Access to genetic resources therefore relates to both the physical component and/or the informational component.

### 1 *Regulation of the Tangible Components of Genetic Resources: Liability Issues and Specific Legislation*

Currently available national provisions relevant for the legal status of genetic resources in Belgium mainly relate to the question of legal ownership over genetic material. The conditions and rules surrounding the legal ownership of the genetic material, as a biophysical entity, follow from those governing the ownership of the organism this material can be found in. Legislation relevant to physical access thus depends upon the type of ownership (private, public or *res nullius*), the existence of restrictions to the ownership, such as specific protection (protected species, protected areas, forests or marine environments) and the location, as noted above, of the genetic material.

In this context, physical access to and use of genetic material are already regulated – and thus possibly restricted – by property law and the liability and redress options made available under both civil and criminal procedures related to the enforcement of property rights. These rules might be important during the implementation of the Nagoya Protocol in cases where an illicit acquisition of genetic resources is established. When assessing which legal principles might address the illicit acquisitions of genetic resources as physical entities, it should also be noted that most conflicts will bear an international dimension. In a



context of globalized exchanges of genetic resources, where the contentious access or use of genetic resources might occur in a different country than the country of origin, it is thus useful to envisage extra-contractual liability through the lens of private international law, which would apply, “in default of particular rules” adopted by the legislator in this regard. A number of specific legal provisions of the Belgian Code of Private International Law<sup>20</sup> govern material goods and the case of their theft. These principles can contribute in particular to uphold the conditions specified in private law agreements, in situations where the procedures for mutually agreed terms, established by the country of origin include private law contracts.

Furthermore, the rules regulating physical access and use of genetic material also depend upon the existence of restrictions to the ownership linked to specific legislation, such as for instance legislation on protected species, protected areas, forests and marine environments. These are used to propose a general set of dispositions regulating, limiting and – in some cases – forbidding to deliberately capture, pick, collect, cut, uproot, destroy, transplant transport, sell, offer for sale or exchange specimens of protected animal species, of protected plant-species or other types of organisms.<sup>21</sup> These dispositions can be related of course to the protection of natural areas and species in general but can bear about specifically protected areas as well, like natural or forest reserves, underground cavity of scientific interest or Natura 2000 sites.<sup>22</sup> They could related also to the specific statute public authority might to state owned land outside protected areas – each public entity having its own public domain that it regulates in accordance with the competences attributed or granted by the Belgian legal order. These dispositions are dedicated to the conservation and protection of nature rather than regulating access for the utilization of biological resources. The prospecting of genetic resources is thus not included

20 Law of 16 July 2004 related to the Code of Private International Law (Loi du 16 Juillet 2004 portant le Code de droit international privé), Belgian Official Journal 27 July 2004, p. 57344.

21 Voy. Decision of the Flemish Government of 15 May 2009 on species protection and species management (Besluit van 15 mei 2009 van de Vlaamse Regering met betrekking tot soortenbescherming en soortenbeheer), Belgian Official Journal 13 August 2009; Nature Conservation Act of the Walloon Region of 12 July 1973 (Loi du 12 juillet 1973 sur la conservation de la nature: Région wallonne), Belgian Official Journal 11 Septembre 1973; 2009 Ordinance of the Brussels Capital-Region concerning the conservation of nature.

22 Beyond the legislations envisaged here above, see also Article 35 of the 1997 Flemish Decree on nature conservation and the natural environment; Article 136 of the 1984 Walloon code for urban and land-use planning; concerning the forest reserves, see the Flemish Forest Decree of 13 June 1990 (Bosdecreet).

in the actions requiring a permit. Nonetheless, they encompass various measures that could be potentially helpful and offer a legal basis for a future implementation of the Nagoya Protocol.

## 2 Regulation of the Informational Component of Genetic Resources

As opposed to its physical components, and unless they are protected by exclusive rights like intellectual property rights, the informational components regarding the genetic resources may constitute a *res communis* – that is to say a thing owned by no one and subject to use by all. Unauthorized access to the informational component of genetic resources is as such today neither sanctioned by legislation pertaining to property rights nor covered by subject-specific legislation. Theft of information is not a qualified infraction under Belgian law, and should most probably be fought through provisions related to breach of trust if the informational component is accessed by third parties without the transfer of actual material possession of the specimen. The use of informational components of genetic resources without PIC or MAT will most probably not be covered by those remedies addressing theft. Indeed, if the informational component of genetic resources is viewed as *res communis*, it may not be subject to theft since it cannot be appropriated.<sup>23</sup> Furthermore, theft provisions apply solely to corporeal objects. However, there exists prominent jurisprudence regarding the theft of computer programs, where these have been considered as corporeal because of their economic value and because of them constituting an element of the patrimony of the original software's proprietor.<sup>24</sup> Neither the doctrine nor the jurisprudence is nonetheless unanimous on this issue, as the fraudulent copying of software has been ruled not to constitute a theft or a breach of trust due to its incorporeal nature, precluding the possibility to cede its ownership.<sup>25</sup>

Of course, other possibilities of redress recognized in Belgian criminal law may be exploited. A first option that might be envisaged is the concealment offense, which normally only applies to corporeal objects. Concealment punishes the act of a third party to fraudulently conceal a contentious good, knowing that such good has been acquired through a crime or infraction.<sup>26</sup> It therefore implies the preliminary recognition of a crime and could only be

23 See Alain Lorant, "La notion de chose d'autrui en matière de vol," in *Liber Amicorum Jean du Jardin*, eds. Yves Poullet and Hendrik Vuye (Deurne: Kluwer, 2001), 79.

24 Anvers, 13 dec. 1984, Bruxelles, 5 dec. 1986, or also Corr. Bruxelles 24 juin 1993, *J.L.M.B.* 1994.

25 Liège, 25 avr. 1991, *Rev. dr. pén.*, 1991, p. 1013.

26 Criminal Code of the Kingdom of Belgium Article 505.

relevant for ABS if the criminal code is amended to constitute the use of the informational component of genetic resources in contradiction to PIC and MAT as a criminal offense.

Another possible – but non-exclusive – option would be the breach of trust: the diversion or dispel of goods of any kind from the initial usage or determined use that had been convened.<sup>27</sup> This provision could for instance be applied in an ABS context with regard to the exceptions that ought to be provided for research purposes,<sup>28</sup> but most importantly against utilization of genetic resources contrary to MAT or in absence of PIC or MAT in countries where the Protocol has been ratified and PIC and/or MAT has been requested in national legislation.

Finally, the exercise of some use rights could be regulated through intellectual property rights that have been recognized on portions, functions, or uses of biological material resulting from innovations on these materials. This discussion could be relevant since IPR indirectly give the informational component of genetic resources a legal status: if the information itself cannot lead to an intellectual property right, the treatment of this information can. Besides, this discussion could be particularly useful for evaluating the best available options for the monitoring process, *e.g.* a patent application might be an indication of commercial interest in the genetic resource and an upgraded patent application could potentially be used as a checkpoint. The competence pertaining to intellectual property rights in Belgium is reserved to the federal level.<sup>29</sup> However, protection tools which constitute designations of origin with a regional or local character fall under regional competence.<sup>30</sup> In this framework, three categories of IPR protection can be distinguished: patents, plant variety rights and geographical indications.

In Belgium, patents are regulated mainly by the patent law of 28 March 1984. In this context, the law states that “inventions are patentable even when they relate to biological material or contain a process that enables the production, treatment or use of the biological material.”<sup>31</sup> Furthermore, “a biological

27 Criminal Code of the Kingdom of Belgium Article 491.

28 Nagoya Protocol Article 8a.

29 It is a formal exception to the attributed competence of regions in terms of economic policy, see Special Law 8/8/80 Article 6§1 VI, indent 4, 7°.

30 Special Law 8/8/80 Article 6§1 VI, indent 4, 4°.

31 “Sont brevetables les inventions nouvelles, impliquant une activité inventive et susceptibles d’application industrielle, même lorsqu’elles portent sur un produit composé de matière biologique ou en contenant, ou sur un procédé permettant de produire, de traiter ou d’utiliser de la matière biologique” (Art XI.3 of the Code of Economic Law, inserted by the Law of 19 April 2014, Moniteur belge, 12 June 2014).

material isolated from its natural environment can be subject to patent protection, even when it pre-existed under its natural state”<sup>32</sup>; patents are for instance quite often granted for molecular markers that are developed to assist plant breeders in the identification of interesting genetic sequences. However, a general research exemption to the rights granted by patents is provided by the law. These rights do not extend to “acts accomplished in a private environment and for non-commercial purposes, nor to acts accomplished for scientific purposes on and with the object of the patented invention.”<sup>33</sup> Scientific purposes should in this regard be understood in a large sense.<sup>34</sup> Finally, and most importantly in the ABS context, following obligations stemming from the CBD (particularly its Articles 8(j), 15 and 16), the patent law has been amended to include a (qualified) origin indication requirement, if the origin of the material is known.<sup>35</sup> In order for the patent application to be admissible, the filing must contain a statement regarding the geographical origin of the biological material that has been used as a basis for the invention, if known.<sup>36</sup>

32 “Une matière biologique isolée de son environnement naturel ou produite à l’aide d’un procédé technique peut être l’objet d’une invention, même lorsqu’elle préexistait à l’état naturel” (Belgian Patent Law, Article 2§3).

33 “Les droits conférés par le brevet ne s’étendent pas: (a) aux actes accomplis dans un cadre privé et à des fins non commerciales; (b) (aux actes accomplis à des fins scientifiques sur et/ou avec l’objet de l’invention brevetée. Belgian Patent Law Article 28§1 (indents 1 and 2), as amended by the law of 28 May 2005.

34 Projet de loi modifiant la loi du 28 Mars 1984 sur les brevets d’invention, en ce qui concerne la brevetabilité des inventions biotechnologiques, Rapport fait au nom de la Commission des Finances et Affaires Economiques par Mme Zrihen, *Doc.Senat*, sess. 2004–2005, no.3-1088/3, p.3. See also Geertrui Van Overwalle, “Van groene muizen met rode oortjes: de EU-Biotechnologierichtlijn en het Belgisch wetsontwerp van 21 September 2004,” *Intellectuele Rechten – Droits Intellectuels (IRDI)* (2004): 378.

35 See Article 15§1(6) of the 1984 patent law. This clause is a transposition of European Directive 98/44/EC of 6th July 1998 on the legal protection of biotechnological inventions, which takes Articles 8(j) and 15 of the CBD into consideration. Its preamble notes that in case an invention is based on biological material of plant or animal origin or if such material is used, the patent application should, where appropriate, include information on the geographical origin of such material, if known. The Directive furthermore stresses that Member States must give particular weight to Article 8(j) of the CBD when bringing into force the laws, regulations and administrative provisions necessary to comply with this Directive.

36 This requirement is much narrower than the first proposed Bill, which stated that non-compliance with CBD provisions would be considered as contrary to the public order and morality, while the Council of State declared that such obligation would deviate from the initial objective of transposition measures and run counter to the objective of achieving

Plant variety rights were formerly regulated in Belgium by the law of 20th May 1975, which has been recently abrogated and replaced by the law of 10th January 2011. The latter has not yet entered into force, but gives nonetheless the necessary general framework so as to put Belgium in conformity with the provisions of the 1991 UPOV Convention (Union for the protection of plant variety rights). According to this law,<sup>37</sup> the production, reproduction, conditioning for the purpose of propagation, sale, marketing, import, export or stocking of this variety would need the authorization of the breeder<sup>38</sup> with, like the patent law, the exception of certain specific prerogatives granted for research on the material and breeding with the variety, as well as for certain flexibilities recognized towards small farmers.<sup>39</sup>

Finally, Geographical Indications (GI) used to describe a specific agricultural product or a foodstuff that is protected due to its regional and local nature, within general agricultural quality policies. GI's may relate to ABS since the product specification includes a description of the product, comprising the raw materials (and if appropriate the principal physical and microbiological characteristics of such material). They are protected in Belgium through different legislative texts, including the Federal law of 6th April 2010 on trade practices and consumer protection (Chapter 7 on geographical indications and protected designations of origin), the Decree of the Walloon Region of 7th September 1989 related to the local geographical indication and designated Walloon certificate and the Ministerial Decree of the Flemish Government of 19th October 2007 on the protection of geographical indications.

### 3 *Traditional Knowledge*

There are no contemporary legal provisions in Belgium explicitly governing the concepts of "traditional knowledge," "traditional knowledge associated with genetic resources" and "indigenous and local communities" (ILCs). One might argue that some types of knowledge could be qualified as "knowledge, innovations and practices" that "embody traditional lifestyles relevant for the conservation and sustainable use of biological diversity." One example

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effective harmonization throughout the European Union. See Geertrui Van Overwalle, "Implementation of the Biotechnology Directive in Belgium and its After-Effects," *International Review of IP and Competition Law* 37 (2006): 895–897.

37 See. Article 72 of the law for the conditions of its entry into force, which render the mandatory force of the text conditional to the adoption of a royal decree, which has to this day not yet been adopted. As long as the required Royal Decree has not been adopted, the relevant legal framework is still the law of 1975.

38 Article 12 of the law of 10th January 2011.

39 Article 14 and 15.

would be knowledge involved in the conservation and use of old seed varieties by farmers. However, this knowledge is not related to specified local communities and their traditional lifestyles as specified in the CBD's understanding of the concept. Nevertheless, concerns over traditional knowledge and the rights of indigenous and local communities have been addressed in some international instruments, especially in the area of development cooperation and sustainable development, to which Belgium is a Party.<sup>40</sup> Three international instruments broach the rights of indigenous and local communities and recognize the importance of traditional knowledge: the 1957 International Labor Organization (ILO) Convention No. 107 on Indigenous and Tribal Populations, the ILO Convention No. 169 on Indigenous and Tribal Peoples and the United Nations Declaration on the Rights of Indigenous Peoples.

### III Is Belgian Law Compliant with the Nagoya Protocol?

No existing national legislation or measures are in contradiction with the obligations under the Protocol. However, relevant existing legislation will need to evolve and be complemented by additional instruments in order to implement the obligations of the Protocol, and ensure Belgian users are complying with PIC and MAT of the providing countries.

#### 1 *The Grey Zone of Soft Law and Administrative Law*

Given the federal character of the Belgian State and the repartition of the biodiversity-related competences, most of the Belgian public policies take the form of multi-level platforms, strategic indicative guidelines or administrative initiatives. The existing set of measures first consists in coordinating the action of the three regions and the federal level. In 2006, Belgium adopted its National

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40 Partnership agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000 (ACP-EU Cotonou Agreement); Political Dialogue and Cooperation Agreement between the European Community and its Member States, of the one part, and the Andean Community and its member countries, the Republics of Bolivia, Colombia, Ecuador, Peru and the Bolivarian Republic of Venezuela, of the other part, Rome, 15 December 2003; International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), signed in Rome on 6 June 2002; United Nations Convention to Combat Desertification in Those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa (UNCCD), Paris 17 June 1994.

Biodiversity Strategy 2006–2016,<sup>41</sup> which established 15 strategic objectives and 78 operational objectives to reduce and prevent the causes of biodiversity loss. The 6th strategic objective aims to contribute to an equitable access to and sharing of benefits arising from the use of genetic resources. This objective is projected to be realized mainly through capacity building of national ABS stakeholders and further implementation of the Bonn Guidelines on ABS. In 2006, a study on the awareness of Belgian users of genetic resources concerning the CBD and the level of implementation of ABS dispositions and the Bonn Guidelines in their activities has revealed mixed knowledge within stakeholder groups.<sup>42</sup> The Convention seemed to be better known in upstream activities (*e.g.* fundamental research) than in downstream activities (*e.g.* commercial products). The strategy has been evaluated at the end of 2011 and is currently under review in order to bring it into line with the new multilateral and European biodiversity objectives (the Biodiversity Strategic Plan 2011–2020 and its Aichi Targets, the EU Biodiversity Strategy and other national and international commitments) and to extend subsequently the reviewed strategy until 2020.

As for the measures taken at the federal level, the National Biodiversity Strategy followed the Second Federal Plan for Sustainable Development 2004–2008<sup>43</sup> and calls for a coherent national position on access and benefit-sharing. These two plans contributed to lead to adoption the Federal Plan for the integration of biodiversity, adopted by the Federal Government in 2010, of which three of key policy sectors are particular relevant for ABS-implementation: the economy, the development cooperation and the scientific policy. For each of these sectors a separate and detailed action plan has

41 Belgian Coordination Committee for International Environment Policy, Directorate-General for the Environment, *Belgium's National Biodiversity Strategy 2006–2016* (Brussels, 2006). The process of drafting the National Biodiversity Strategy was initiated by the Interministerial Conference for the Environment in June 2000.

42 Christine Frison and Tom Dedeurwaerdere, *Infrastructures publiques et régulations sur l'accès aux ressources génétiques et le partage des avantages qui découlent de leur utilisation pour l'innovation de la recherche des sciences de la vie. Accès, conservation et utilisation de la diversité biologique dans l'intérêt général* (Louvain-la-Neuve: Centre de Philosophie du Droit, Université Catholique de Louvain, 2006).

43 CIDD/ICDO, *Federaal plan inzake duurzame ontwikkeling 2004–2008/Plan Fédéral de Développement Durable 2004–2008* (Brussels: Interdepartmental Commission for Sustainable Development, 2008); A third Federal Plan for Sustainable Development, calling for an “equitable distribution of the commercial exploitation of biological resources,” was drafted for the period 2009–2012 but never adopted. The Second Plan was instead extended until 2012.

been developed for integration of biodiversity, including several ABS-related measures. For the economic sector the plan mainly focuses on awareness-raising and capacity building of the private sector and call for a pro-active participation of the Federal Government in the establishment of an international ABS-regime. The plan also calls for an increased participation of the customs administration in biodiversity policy, albeit not directly linked to ABS. This stronger understanding of biodiversity-related issues inside the customs could however be beneficial for and facilitate the implementation of the Nagoya Protocol (*e.g.* as a potential checkpoint keeping track of genetic resources being imported in Belgium).

Several ABS-related actions were also planned in the context of development cooperation. In 2003, the Royal Belgian Institute of Natural Sciences started supporting ILCs in developing countries in their implementation efforts of the CBD, through a convention with the Federal Directorate General for Development Cooperation (DGD).<sup>44</sup> The first phase of this convention has been running from 2003 to 2007, but has been renewed from 2008 to 2012. In April 2008, the Royal Belgian Museum for Central Africa, together with the Belgian Technical Cooperation (BTC), has launched the Central African Biodiversity Information Network (CABIN) whose aim is to establish a network of databases on biodiversity information, in collaboration with several Central African research institutions.<sup>45</sup> Awareness-raising on ABS could easily be added to such programs. Also, the Federal Public Service Environment and the DGD have contributed to the creation of the TEMATEA project,<sup>46</sup> which is a web-based capacity-building utility to support the coherent implementation of international and regional biodiversity related conventions and provides an overview of national obligations regarding ABS.

In the science policy field, the first proposed action of the Federal Plan for the integration of biodiversity is also particularly relevant to ABS as it calls for an inventory of the national collection of plant germplasm, which will directly benefit from existing projects and initiatives. For instance, the BELSPO, together with Ghent University, developed straininfo.net,<sup>47</sup> a pilot project using bioinformatics tools (web crawlers and search engines) to access and make available data and information stored in 60 biological resource centres

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44 "Biodiversity: an essential partner in development," Belgian Development Cooperation, accessed 2012, <http://www.biodiv.be/info0405/activities>.

45 "Belgian Development Cooperation," Royal Museum for Central Africa, accessed 2012, [http://www.africamuseum.be/museum/about-us/cooperation/index\\_html](http://www.africamuseum.be/museum/about-us/cooperation/index_html).

46 "tematea," accessed 2012, <http://www.tematea.org>.

47 "StrainInfo," accessed 2012, <http://straininfo.net>.



worldwide. A standard format to allow for culture collection catalogue information to be exchanged easily has also been developed. PLANTCOL is another similar Belgian initiative, taken by the Association of Botanical Gardens and Arboreta.<sup>48</sup> It has developed a navigation system for sharing plant information from different databases in a common format. It is also worth noting that a Belgian Biodiversity Platform was created by the Belgian Federal Science Policy Office in 2003, which functions as an interface between providers and users of biodiversity information.<sup>49</sup>

Regions each have separate biodiversity policy-plans, mostly as part of a broader environmental strategy, in which ABS measures could be taken up. Although these plans all explicitly refer to the CBD as guidance for biodiversity policy, none of them contain ABS-related provisions. In its recently released Environmental Policy Plan 2011–2015 (MINA-4), as well as in the latest Flemish Strategy for Sustainable Development,<sup>50</sup> the Flemish Government also refers to the 10th COP of the CBD as an important watershed moment, but without identifying or emphasizing the need for ABS-related actions.

Finally, the Belgium institutional system also relies upon a strong interaction between public institutions and non-state actors: research institutions' and private initiatives could play an active role in the diffusion of an ABS framework. As illustrated in part I of this chapter, and among other examples, the Belgian Coordinated Collection of Micro-organisms (BCCM) established its own voluntary code of conduct for ABS exchanges and uses a standard BCCM Material Transfer Agreement (MTA) for getting access to the genetic resources of its public collection.

## 2 *Conformity of Existing Instruments in Belgium that Already Address ABS Obligations*

In 2010, in the context of its reporting obligations to the EU, Belgium qualitatively monitored the implementation of the EU Biodiversity Action Plan (BAP) actions and achievement of targets, including the implementation of the CBD Bonn Guidelines on ABS and other agreements relating to ABS such as the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). It was noted that over the period 2006–2009, Belgium did not provide funding for the ABS Working Group; did not pass any national legislation

48 "PLANTCOL: Belgian Living Plant Collections," accessed 2012, <http://www.plantcol.be>.

49 "Belgian Biodiversity Platform: give wings to your research," accessed 2012, <http://www.biodiversity.be>.

50 "Samen Grenzen Verleggen. Vlaamse strategie duurzame ontwikkeling," accessed 2012, <http://ebl.vlaanderen.be/publications/documents/23237>.

implementing the CBD Bonn Guidelines on Access and Benefit-sharing existed; did not vote any national legislation implementing the MTA Agreement of the ITPGRFA; and did not have implemented any national activities that raise awareness of the CBD Bonn Guidelines. The economic weight of biotechnology industry in Belgium, the distribution of political competences among the federated collectivities, the “mixed treaty” nature of the Nagoya Protocol, and the decentralized role of non-state institutions might explain the lack of proactive vertical implementation of the Bonn Guidelines.

Nevertheless, some implementation measures have been adopted in Belgium. The ABS national focal point for instance already exists: Belgium nominated a civil servant of the Federal Public Service Environment that currently ensures the function of national focal point on ABS. To be compliant with Article 13 of the Protocol, Belgium will still need to designate one or more competent national authorities.

The (qualified) origin indication requirement in patent applications discussed earlier can serve as a basis to comply with Article 17. This provision would need to be amended to allow its use as checkpoint under the Nagoya Protocol, specifying that patent application should contain relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources in the patent applications.

Other principles described above (on physical access, property law and private international law) might represent useful contributions to the implementation of the Protocol, but are clearly insufficient. First, utilization is often based on a derivative of genetic material,<sup>51</sup> with the original material being located in another country. In this context and with the current legal principles, the Belgian judiciary might be found incompetent to hear cases of misappropriation or misuse happening on Belgian soil.<sup>52</sup> As the Belgian Code for Private International Law does not explicitly refer to the utilization of genetic resources under the Nagoya Protocol (and thus does not cover derivatives of these resources), such cases are not covered by its legal dispositions.<sup>53</sup> Second,

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51 Kerry ten Kate and Sarah A. Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-sharing* (London: Earthscan, 1999).

52 Article 85 of the Code of Private International Law states that the Belgian judiciary is competent to rule on disputes involving a physical access to a material good “if the good is located in Belgium at the time the claim is made.”

53 Concerns can also be raised for the lack of reference in these legal dispositions of important issues of “access to justice” addressed in the Nagoya Protocol, such as the legal standing of ILCs before Belgium courts.

while legal principles of physical access and property law might be useful for Belgium to organize access to its domestic genetic resources, it should be noted that the biodiversity potential of the country is one of the lowest in the world.<sup>54</sup> In other words, as stated earlier, Belgium is primarily a user country. The implementation of the Protocol should thus mainly relate to the compliance of Belgian users with the PIC and MAT of provider countries. This will involve public law requirements, administrative acts and policy measures, all reaching beyond the scope of the legal principles described above. Therefore, additional measures will be needed to comply with the obligations under Articles 15, 16, 17 and 18.

Regarding the compliance with MAT, the issues covered by Article 18 are mostly provided for in the Belgian legal system.<sup>55</sup> Like most countries in the world, the Belgian legal system provides for an opportunity to seek recourse in cases of breach of contract, and has established international private law provisions regulating lawsuits involving an “external” law element, provisions that are called for in Articles 18.1 and 18.2 of the Protocol. Access to justice and the recognition and enforcement of foreign judgments, the third point of Article 18, is regulated by several international legal arbitration instruments. The recognition and enforcement of decisions on civil and commercial matters are ruled by the EC Regulation 44/2001 (Brussels 1) as well as by the 2007 Lugano Convention on Jurisdiction and the Recognition and Enforcement of Judgments in Civil and Commercial Matters, to which Belgium is a contracting Party. Finally, various conventions could act as “effective measures regarding access to justice” (Article 18.3.a). Even if Belgium did not ratify the 1970 Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters,<sup>56</sup> it ratified the 1965 Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters.<sup>57</sup>

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54 “GEF benefits index for biodiversity,” The World Bank, accessed on March 12, 2014, <http://data.worldbank.org/indicator/ER.BDV.TOTL.XQ>.

55 Which are, for reminder: (a) determining the jurisdiction that is internationally competent to deal with disputes raised within ABS agreements; (b) determining the applicable law which has to be applied in the case of ABS-related disputes; (c) recognizing and enforcing in another country, party to the NP, judgments rendered by a jurisdiction in the ABS context.

56 This convention is mainly referring to “*commissions rogatoires*,” through which a judge delegates his investigation powers through a limited mandate allowing another judge or judicial officer to execute an investigation act on his behalf in another jurisdiction.

57 And, more incidentally, the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters This convention, negotiated at the European Union level, requires user countries to take effective

Finally, other important axes of the Nagoya Protocol have not been settled yet. There is currently no Competent National Authorities, no access procedure to genetic resources as understood by the Nagoya Protocol, and no benefit-sharing regulation.

#### IV Conclusion and Suggestions

All of the potential approaches, instruments and (self-regulated) initiatives discussed in this chapter require an important stretch from currently applicable legislation to address the utilization of genetic resources as understood in the Nagoya Protocol. While some might be more adequate than others, it is important to note that relying only on these existing instruments will fail to be sufficient to implement the Nagoya Protocol.

As detailed elsewhere,<sup>58</sup> a minimal implementation relying on generally accepted principles of private international law and on the responsibility of self-regulated stakeholders is doomed to fall short of achieving the objectives of the Nagoya Protocol and the CBD. Transnational justice issues and inter- and intra-national conservation of biodiversity, which are at the core of the Protocol, are unlikely to be adequately addressed through existing instruments which did not result from an intended political will to implement the Nagoya Protocol. For the social and environmental objectives to be met, Parties to the Protocol should move from the current tendency of market-based meta-regulation of providers and users of genetic resources, towards more sustainable forms of regulation, which translate these normative goals of the Protocol and the CBD both into legal principles and public policy.

Both the institutional competition between levels of authority in the Belgian federal state and the consequences of the global financial crisis on the national economy generate strong pressure to adopt a minimal implementation of the Protocol. A combination of a set of light information-sharing and monitoring measures and the application of existing general clauses of international private law, referring back to provider country legislation in case of litigation, could be considered sufficient in such a self-regulatory approach. Easier to set

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measures to ensure that provider countries have recourse to their legal system to obtain redress. It includes an obligation to provide access to administrative or judicial procedures to challenge breaches of national law in a similar way as provided for by Article 18(2) of the Protocol.

58 Coolsaet, Dedeurwaerdere and Pitseys, "The Challenges for Implementing the Nagoya Protocol."

up, this approach might also be preferred to allow for timely ratification, making Belgium a Party to the Protocol and allowing it to join the negotiation table when the Protocol enters into force.

However, highly decentralized ABS-competences between the Regions and the Federal government and the importance of biotechnology for their economies might fuel a race to the bottom between the federated entities in a context of internal competition, hoping to attract private sector investment in key economic sectors and spur the market in genetic resources. This is especially relevant for the cooperation on the obligations related to user-compliance, as it is unlikely that private actors will promote effective monitoring measures on their own without clear guarantees that all players have to make similar efforts.

In addition to legal measures that will be needed to address the environmental justice and sustainability issues of the Protocol, additional non-legal measures to overcome some of the drawbacks of a minimal approach will be needed to foster a broad adoption of the Protocol. Examples include the establishment of standard agreements and procedures by both state and non-state actors; the inclusion and empowerment of civil society actors in the design of such agreements and procedures; capacity building initiatives in the context of international development cooperation; the creation of behavioural incentives such as quality labels for certain key sectors; and the effective monitoring of the utilization of genetic resources and traditional knowledge through full-fledged checkpoints along the development chain.

Finally, as indicated above, Belgium is an important political player in the access and benefit-sharing regime. A strong and timely signal, through the adoption of both legal and non-legal measures, could encourage countries faced with similar multi-governance challenges to step-up their efforts towards the implementation of the Nagoya Protocol. International instruments, which are mutually supportive of (or even reinforce) the social and environmental objectives of the Nagoya Protocol and to which Belgium is a Party (the ILO conventions, Agenda 21, the ITPGRFA and the CBD itself), already provide a solid legal basis for going beyond a minimal implementation of the Nagoya Protocol.

## The ABS Framework in Denmark

*Veit Koester*

The Kingdom of Denmark (the (Danish) Realm) consists of Denmark, the Faroe Islands and Greenland.<sup>1</sup> The Faroe Islands and Greenland have legislative and executive competences covering almost all fields of civil and public law,<sup>2</sup> and none of them are included in the Danish membership of the EU. This is, at least partly, the reason why there is, in respect of the ABS framework in the Danish Realm, a need to differentiate between the frameworks in Denmark, the Faroe Islands and Greenland, although all parts of Denmark are included in the Danish ratification of the 1992 Convention on Biological Diversity (CBD).<sup>3</sup>

The present paper, focusing on the ABS framework in Denmark, however, starts by providing an overview of the frameworks in all parts of the Realm. Part II is dealing with Danish property and intellectual property law and Part III and Part IV with respectively Denmark as a provider and user country, while Part V contains some preliminary conclusions.

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- 1 The Danish Constitutional Act (the Constitution) applies pursuant to its Section 1 to all parts of the Kingdom.
  - 2 The relevant acts are lov nr. 137 af 23. Marts 1948 om Færøernes hjemmestyre (Act on Home Rule of the Faroe Islands) and lov nr. 473 af 12. juni 2009 om Grønlands Selvstyre (Act on Greenland Self-Government).
  - 3 Denmark ratified the CBD on 31 December 1993. Since the CBD also applies to the Faroe Islands and Greenland they are being informed by the Danish Nature Agency under the Ministry of Environment about important negotiations in the framework of the Convention (*e.g.* the ABS negotiations). The Faroe Islands and Greenland may, if they so wish, provide comments or observations to meeting documents or be represented in Danish delegations to such negotiations. If relevant, the Faroe Islands and Greenland are being involved in the preparation and drafting of Danish bills. This, however, was not relevant in the context of the Danish ABS Act (see Part I below), because ABS belong to the legislative and executive competences of those parts of the Realm, and the Act, accordingly, excludes the Faroe Islands and Greenland from its territorial application (Section 17). Such provision is obligatory when an act does not apply to the Faroe Islands and/or to Greenland. On the exclusion of those parts of Danish Realm from the Danish ratification of the Nagoya Protocol on ABS, see Part I below at notes 11–13. Of the 183 members of the Danish Parliament two members are elected by the Faroe Islands and two by Greenland.

## I Main Traits of the ABS Frameworks in the Danish Realm

The main traits of the current situation regarding specific ABS frameworks in the various parts of the Realm may be outlined broadly as follows.

The ABS framework in Denmark is partly governed by Act No. 1375 of 23 December 2012 on Sharing of Benefits Arising from the Utilization<sup>4</sup> of Genetic Resources (the Danish ABS Act). The Act provides for some basic user requirements, *i.e.* compliance with Articles 6 and 7 of the Nagoya Protocol, and confirms that Denmark does not require prior informed consent (PIC) for access to genetic resources in Denmark.<sup>5</sup>

The Faroese Parliament (*Lagting*) has not adopted any special ABS-legislation, nor has it taken any specific position as to whether to demand PIC regarding access to genetic resources in the Faroe Islands.

The Greenland Parliament (*Inatsisartut*) has promulgated Act No. 20 of 20 November 2006 on Commercial and Research-Related Use of Biological Resources.<sup>6</sup> Under Section 6, subsection 1 of Part 3 on survey licenses:

[a]ny acquisition, collection or survey of biological resources in connection with research or with a view to possible subsequent commercial utilization shall be subject to prior issue of a survey license [by the Greenland Government].<sup>7</sup>

Hence, access to genetic resources in Greenland is governed by PIC. There are no provisions on access to traditional knowledge associated with genetic resources held by indigenous and local communities which is probably due to the nature of the Greenland society being *per se* an indigenous community. And no legislation regarding user requirements exists in Greenland.

4 An official translation of the Act into English would probably replace the “z” by a “s.” Due to the spelling of this word and similar words in the Protocol and in order to be consistent the word is in the present paper generally being spelt with a “z.”

5 The Danish ABS entered into force on 12 October 2014. On the entry into force, see Part IV.2 below.

6 Landstingslov nr. 20 af 20. November 2006 om kommerciel og forskningsmæssig anvendelse af biologiske ressourcer.

7 Biological resources are in Section 3 (1) of the Act defined as “all kinds of genetic resources, organisms or parts thereof, or any other biotic component of ecosystems with actual or potential use of value for humanity.” Part 4 of the Act contains provisions on the publication of survey results *etc.*, Part 5 on patenting results *etc.*, Part 6 on commercial utilization, Part 8 on withdrawal of survey license and/or commercial license, while actions being subject to a fine are outlined in Part 10.

The basic legal features of personal and real property rights are more or less the same in all parts of the Danish Realm.<sup>8</sup> As far as intellectual property rights are concerned, the legal situation, however, differs to some extent. Almost all provisions of the Danish Patent Law are, by virtue of a special decree,<sup>9</sup> applicable to Greenland, including provisions relating to “biological material,” while the Faroe Islands have a law on patents dating from 1967, which does not include provisions relating to “biological material.”<sup>10</sup> The Danish Act on Plant Varieties is not applicable to the other parts of the Realm, and none of these parts has adopted legislation in that regard.

Accordingly, the current situation with regard to the three parts of the Danish Realm may be summarized in the following manner:

- Denmark: No PIC-requirements, but user legislation;
- Faroe Islands: No legislation regarding PIC or user requirements;
- Greenland: PIC, but no user legislation;
- All parts of the Realm: More or less the same rules governing personal and real property, but to some extent different rules concerning intellectual property rights.

Since there are no plans to legislate on user measures in accordance with the Nagoya Protocol in Greenland, or to consider such measures or PIC in the Faroe Islands, the Danish ratification of the Protocol excludes those parts of the Realm from the ratification. This is why the above Danish ABS Act, which, according to the explanatory notes to the Bill<sup>11</sup> (“the Explanatory Notes”)<sup>12</sup>

8 In reality, however, the situation in respect of real property differs very much. *E.g.* almost the whole land area of Greenland is the property of the Greenland society and accessible to everybody, and specimens of organisms (if the species is not subject to special protection), fruits *etc.* may be considered as *res nullius*, because they can be appropriated by anybody.

9 Anordning (Decree) nr. 658 af 11. juni 2010 om ikrafttræden for Grønland af en række love om ændring af patentloven.

10 Lov (Act) nr. 479 of 20 December 1967 with subsequent amendments, the latest dating from 1989.

11 Lovforslag nr. L 70, Folketinget 2012–13.

12 Explanatory notes to bills play an important role in the Danish legal system. They govern to some extent, *inter alia*, the legality of the scope and contents of ministerial regulations (orders) rooted in mandates provided by an act, and may, according to the practice of the Danish courts, play a decisive role for determining the exact scope and application of such mandates, *e.g.* Section 5 of the Danish ABS Act (see Part IV.5 below). Equally, they are according to the jurisprudence of Danish courts and administrative tribunals, which frequently refer to explanatory notes, important in respect of the interpretation of the objectives of an act or of terms of an act, *e.g.* when the notes support a specific meaning



shall ensure that Denmark may ratify the Nagoya Protocol, does not apply to the Faroe Islands and Greenland.<sup>13</sup> Only Denmark is going to be affected by the EU Regulation on ABS, as indicated above.

The present analysis is focusing on Denmark. Hence, it is not being discussed, for example, whether or to what extent the Greenland provisions on PIC fulfil provider requirements of the Nagoya Protocol.<sup>14</sup>

## II Danish Property Law and Intellectual Property Law Regarding Genetic Resources

### 1 *General Material Subject to Real or Personal Property Law*

General provisions regulating the status of and access to genetic resources relate to the regulation of physical access to the genetic material itself. Such

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of a term the ordinary meaning of which is dubious. Due to their important role in the Danish legal system the explanatory notes to the Danish ABS Act are widely referred to in the present paper, underscored by the fact that the Act is to a large extent a framework act and that the meaning of some of its terms are not clear (see *e.g.* Part 5.3 below). On the role of explanatory notes and the jurisprudence in this regard, see generally Jens Garde, "Kapitel 4. Saglige krav," in *Forvaltningsret. Almindelige emner*, Jens Garde et alia eds. (Jurist- og Økonomforbundets Forlag, København 2009) 161–164.

<sup>13</sup> On the same grounds the act paving the way for a Danish ratification (on 27 August 2002) of the 2000 Cartagena Protocol on Biosafety did not apply the Faroe Islands and Greenland. According to Section 19, subparagraph 1 of the Constitution, the King (*i.e.* the Government) acts on behalf of the Realm in international affairs. However, the approval of the Folketing (the parliament) is needed, if fulfillment of obligations requires the concurrence of the Folketing or which is otherwise of major importance. In this respect it should be noted that Denmark is a dualist state. Hence, treaties have to be incorporated into domestic law, and the parliamentary approval is not only formal when implementing legislation is needed. Breach of an international obligation entails state responsibility, and according to Art. 27 of the 1969 Vienna Convention on the Law of Treaties a part "may not invoke the provisions of its internal law as justification for its failure to perform a treaty." Accordingly, if the subject matter of a treaty relates also to the competences of the parliaments of the Faroe Islands and Greenland, ratification of the treaty needs for internal reasons approval from those parts of the Realm. Otherwise, those parts of the Realm must be excluded by a declaration on signature or ratification. Such declaration may, according to a firmly established practice by the UN Secretary-General as depositary of multilateral treaties, be made also in respect of treaties, which, like Article 34 of the Nagoya Protocol, exclude reservations, because the purpose of such declaration is not to exclude certain provisions of the treaty, but, in accordance with Article 29 of the 1969 Vienna Convention on the Law of Treaties, to establish a different intention in respect of the territorial application of the treaty. See, Anthony Aust, *Modern Treaty Law and Practice*, Second Edition (Cambridge: Cambridge University Press 2007): 205–206.

<sup>14</sup> Especially Article 6 of the Protocol.

access is regulated by property law and legislation, both civil and criminal, governing violation of property law. There is no general act on property rights, but rooted, *inter alia* in the Danish Constitution,<sup>15</sup> the right to property constitutes a right to use the property in all respects where the application is not limited by legislation, general principles of law or a private declaration of intention.<sup>16</sup> Hence, the legal ownership of genetic material belongs to the owner of the organism as a whole. This ownership, however, does not constitute an exclusion from using it. The same applies to the informational components of genetic material. Thus, it may be argued that informational components of genetic resources are encompassed by property rights, to the extent that the use of informational components is not limited by intellectual property rights belonging to somebody else.

## 2 Genetic Resources Subject to Intellectual Property Rights

Leaving aside specific ABS provisions it is unlikely that Danish intellectual property law differs much from that of most other EU Member States.<sup>17</sup> Such law has to be in accordance with relevant EU legislation, and, furthermore, part of this legislation is issued in the form of an EU regulation being directly applicable and enforceable in Member States.<sup>18</sup> In addition, Denmark is, like

15 Section 73, subpara. 1 states that “[t]he right to property shall be inviolable. No person shall be ordered to surrender his property except where required in the public interest. It shall be done only as provided by statute and against full compensation.”

16 Orla Friis-Jensen, “Ejendomsret og Miljøret,” in *Miljøretten 1, Almindelige Emner*, ed. Ellen Margrethe Basse, (Copenhagen: Jurist- og Økonomforbundets Forlag, 2006), 49.

17 It should be observed, however, that according to Tine Sommer, *Can Law Make Life (too) Simple? From Gene Patents to the Patenting of Environmentally Sound Technologies* (Copenhagen: DJØF Publishing, 2013) 172 (at note 172) “e.g. Germany, France and Italy have [implemented Directive 98/44, see *infra* note 18] in ways that differs substantially from other Member States.”

18 Communication of 23 December 2003 from the Commission to the European Parliament and the Council on the Bonn Guidelines (COM (2003) 821 final) refers in Part 3 to Directive 98/44 EC on Legal Protection of Biotechnological Inventions and Council Regulation 2100/94 on Community Plant Variety Rights, mentioning, however, that EC regulations on the conservation and characterization of plant genetic resources for food and agriculture “are also relevant.” Directive 98/44 is transposed mainly by Section 1, subparas. 4, 5 and 6, Section 1b, Section 3a, subpara. 1, and Section 3b of the Danish Patent Law, Consolidated Act No. 108 of 24 January 2012, and Section 20, subparas. 2 and 3 on the Danish Law on New Plant Varieties, Consolidated Act No. 190 of 12 March 2009. Interestingly enough, however, the Commission stated by the end of part 1 of the explanatory memorandum to the initial Proposal for a regulation of the European Parliament and of the Council on ABS in the Union of 4 October 2012 (COM (2012) 576 final) (hereafter, the “*Commission Proposal*”) that “[n]either the implementation of the access nor of user-compliance

most other EU Member States, a party to some international instruments that are or might be relevant in the above context.<sup>19</sup> Hence, Danish legislation corresponds generally by and large to *e.g.* Belgian legislation on genetic resources subject to intellectual property as outlined in Pitseys *et al.* in this volume. This includes the recognition of patentable inventions, relevant in the present context, research exemption to the rights granted by patents, and the protection of plant variety rights (including exemptions relating to “farmers privilege” and research).<sup>20</sup>

### 3 *Limitations to Personal and Real Property Rights*

General limitations of property rights relating to genetic resources (in the sense that the limitation also pertains to those who may be perceived as owners of the specimens by virtue of their property rights) includes legislation on both protected areas and protected species. Danish legislation on protected areas and protected species is, however, not limited to fulfilling the requirements of

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pillars of the Protocol is currently addressed in Union-law.” Accordingly, there is no reference to the above EU-law in the considerations of the proposed regulation which was not questioned by the European Parliament in Draft Report of 8 April 2013 (2012/0278 (COD)), (hereafter, the “*European Parliament Draft Report*”), nor is there any such reference in the EU Regulation on ABS. Thus, it may be argued that intellectual property rights as such do not *stricto sensu* belong to the ABS framework. The Commission Proposal supported the observation of the present author in Veit Koester, “The Nagoya Protocol on ABS: Ratification and Implementation Challenges for the EU and its Member States,” *IDDDRI Studies* 3 (2012), part 7.8 that the claim of the Commission (in a note of 6 October 2011) that unilateral ratifications by Member States of the Nagoya Protocol would be in conflict with the EU Treaty represents a rather doubtful statement. At the end, however, only Denmark, the EU, Hungary and Spain adhered to the Protocol more or less at the same time and timely enough to be Parties when the Protocol entered into force on 12 October 2014. Seen in the perspective of the Commission legal considerations apparently had to yield to pragmatism and the benefits of being in the full power when the Protocol entered into force!

19 *E.g.* the 1973 Convention for the European Patent and a number of other patent-related conventions, the 1991 International Convention for the Protection of New Varieties of Plants (UPOV Convention), and the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Potential implications of the 2013 Agreement on a Unified Patent Court and Statute in respect of the Nagoya Protocol are not addressed by the present paper. Danish acceptance of these instruments was confirmed by the positive outcome of a referendum held in 2014. On the instruments, see Sommer, “*Can Law Make Life (too) Simple*,” *supra* note 17, at p. 166.

20 On the Danish Patent and Plant Variety Law, see Thomas Riis, *Intellectual Property Law in Denmark* (Copenhagen: DJØF Publishing and the Netherlands: Kluwer Law International, 2012), Chapters 2 and 7.

relevant EU directives.<sup>21</sup> Hence, there are other areas and species being protected under Danish legislation than those being protected by virtue of the legislation implementing the directives. Pursuant to the Danish Nature Protection Act,<sup>22</sup> protected areas may be established by individual conservation orders, and many such protected areas do exist in addition to protected areas due to relevant EU legislation. It depends, however, on the content of a specific conservation order whether collection of (certain) genetic resources is prohibited. This applies equally to protected areas established on the sea, including the Danish exclusive economic zone (EEZ). Collection of genetic resources from species of wild fauna and flora is regulated by a ministerial order rooted in a provision of the Danish Nature Protection Act.<sup>23</sup> The Game Management Act<sup>24</sup> provides a protection of all species of wild birds and mammals in respect of which no explicit hunting season is established.

No restrictions of the above nature exist regarding domesticated or cultivated species, but utilization of genetic resources of such species, *e.g.* for breeding or propagation, may be subject to intellectual property rights.

#### 4 *Public Access to Genetic Resources?*

The actual or *de facto* control of biological resources of the owner of a property may be limited by “*Danske Lov*” (*i.e.* The Danish Law of King Christian V) Article 6-17-31.<sup>25</sup> This provision grants a right for everybody to collect as many nuts “as he can consume at once and no more.” “Nuts” are interpreted also to include flowers, leaves, berries, fruits, fungi *etc.*, and consumption should not be understood literally or as immediate consumption. This provision does not in itself provide a right to access properties, but the Danish Nature Protection Act grants public access to nature in the countryside, *i.e.* to publicly owned land as well as privately owned forests, uncultivated fields, beaches, pathways, *etc.* “*Danske Lov*”

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21 In particular Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (codified version), O.J.L. 20/07 (Bird Conservation Directive), and Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, O.J.L. 206/07 (Habitat Directive).

22 Section 30, subpara. 1 of Consolidated Act No. 951 of 3 July 2013.

23 Ministerial Order No. 330 of 19 March 2013 providing also a prohibition of collecting some species of wild fauna (not birds and mammals) which are not protected by the Habitat Directive (*supra* note 21).

24 Consolidated Act No. 735 of 14 June 2013 (with later amendments) on Hunting and Game Management the scope of which in some respect exceeds the scope of relevant EU legislation.

25 “*Danske Lov*” was issued in 1683 by the Danish King Christian V, and several provisions are still valid, *e.g.* the provision contained in “*Danske Lov*” 6-17-31, which stands for Book 6, Chapter 17, Article 31.

6-17-31 and specific regulations based on it are applicable in all these respects.<sup>26</sup> One may argue that the utilization of the biological resources is usually harmless, since it neither damages the property nor it depletes the resources. If genetic resources, however, are utilized in the sense of the Protocol and this leads to a patentable invention, the landowner's property is damaged by being cut off from a similar utilization. However, this kind of argumentation is hardly tenable.

### III Denmark as a Provider Country

#### 1 *No PIC-Requirements regarding Danish Genetic Resources*

CBD Article 15 demands PIC in order to obtain access to genetic resources that are found in other Parties, unless the concerned Party decides otherwise. The Danish ratification of the CBD was based on a governmental motion that was ratified by the Danish Parliament. The section of the motion on Denmark's fulfilment of its obligations under the Convention includes a statement in respect of Article 15(5) of the Convention which requires that access to genetic resources is subject to prior informed consent, unless otherwise determined by the Party. According to the statement, implicitly adopted by the ratification of the Parliament of the motion, the decision not to apply the principle of "prior informed consent" to the exportation of genetic resources from Denmark, and – for the time being – not to adopt rules in that respect, was adequate for meeting the requirements of Article 15(5).<sup>27</sup>

The Explanatory Notes to the Bill of the Danish ABS Act (the Danish ABS Act)<sup>28</sup> confirm this statement as follows:

In its ratification of the Convention on Biological Diversity, [Denmark] declared that it would not request prior consent for collecting genetic resources in Denmark.<sup>29</sup> There is no plan to change this, and there is therefore no reason to implement the provisions of the Protocol aimed at requiring prior consent. This concerns, among others Articles 6–8.<sup>30</sup>

26 Veit Koester, *Kommenteret Naturbeskyttelseslov* (Commentary to the Danish Nature Protection Act), (Copenhagen: Jurist- og Økonomforbundets Forlag, 2009): 569.

27 Motion no. B, Folketingstidende (the Danish Parliament Herald) 1992–93, 2. Session, Addendum A 8600, B 1243 and FF 6581, 7806 and 7945.

28 *Supra* Part 2 at note 11.

29 This statement is not accurate. Leaving aside the above statement included in the governmental motion, *supra* note 27, no such declaration was made.

30 Unofficial translation provided by the Danish Nature Agency. Unless otherwise indicated all subsequent translations of the Explanatory Notes to the Bill or of provisions of the Act are equally unofficial translations provided by the Agency, quite often, however, amended by the present author.

This statement, however, is not reflected directly in the provisions of the Danish ABS Act, although it would have been better to include a provision on the non-requirement of PIC for access to genetic resources in order to provide legal clarity, predictability and transparency. The inclusion of such provision would, however, not have changed the legal situation, since PIC, due to the above statement accepted by the Parliament, cannot be introduced in the future without a specific legal provision to such effect.

The statement was not questioned in the course of the public hearing on the Draft Bill which included, *inter alia*, relevant authorities, universities, industry and NGOs, nor was it questioned during the debate of the *Folketing* (Parliament) on the Bill. The Bill was positively received by all political parties represented in the *Folketing*,<sup>31</sup> and the debate did not raise any major controversies,<sup>32</sup> nor did it result in any amendments.<sup>33</sup>

## 2 *Reporting Requirements in Respect of Danish Genetic Resources*

In Section 6, the Danish ABS Act includes the following provision:

The Danish Minister for the Environment may make regulations on reporting the collection of genetic resources from wild organisms in Denmark, including information on the intended utilization. The Danish Minister for the Environment may specify that this is done electronically.<sup>34</sup>

The Act empowers the minister to decide its entry into force, which, according to the Explanatory Notes, is intended to coincide with the entry into force of

<sup>31</sup> The debate, however, reveals some misunderstandings which is not unusual in parliamentary debates. *E.g.* one of the political parties was under the impression that the proposed user measures are also applicable to States not being parties to the Protocol which is certainly not the case. See Part IV below.

<sup>32</sup> Controversies related mostly to Section 8 of the Act providing for the right of the Minister for the Environment (and persons authorized by the Minister) of access to, *inter alia*, private properties without a court order to exercise the powers provided by the Act or in regulations issued in accordance with the Act. Such provisions are, however, quite common in Danish environmental legislation.

<sup>33</sup> The Bill was submitted to the Parliament on 15 November 2012, *i.e.* shortly after the date of the initial *Commission Proposal*. The Bill was debated by the *Folketing* on 21 November 2012, and thereafter discussed at three meetings of the Environment Committee of the *Folketing*. After a presentation of the report of 12 December 2012 of the Committee the Bill was finally adopted by the Parliament without any further debate on 19 December 2012.

<sup>34</sup> On the definitions of the Act of genetic resources and of utilization, see Part IV.4 below.

the Protocol. Such decision was made by Regulation No. 1101 of 6 October 2014 determining the entry into force to be 12 October 2014 coinciding with the entry into force of the Protocol, including in respect of Denmark.<sup>35</sup> The Regulation designates the Nature Agency as the competent authority with the responsibility to monitoring compliance with the provisions of the Act. As of yet no regulations on reporting have been issued. The minister is empowered, however not obliged, to issue such regulations, but the Explanatory Notes seem to indicate that the power is actually going to be exercised.

According to the Explanatory Notes the rationale of reporting requirements is that

[t]his will provide the information on these resources which can identify them in further stages and will allow them to be tracked in the same way as genetic resources originating from countries requiring prior consent, and their legal status to be reported to the global “clearing house” set up under the Nagoya Protocol.<sup>36</sup>

While species of wild animals and plants are rather well defined concepts in existing Danish legislation, the concept of “wild organisms” seems to be new.<sup>37</sup> The Act does not include any definition, and the Explanatory Notes only indicate that since reporting requirements will only apply to genetic resources from wild organisms, such requirements will not affect commercial breeding and cultivation using genetic resources.<sup>38</sup> Presumably, however, the concept of wild organisms includes, in addition to species of wild animals and plants, also

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35 The Explanatory Notes to the Bill indicate that a collective adherence to the Protocol across the EU would be appropriate, but that a Danish ratification before such adherence is possible, if the Protocol enters into force before the EU is ready for a collective adherence.

36 It is somewhat doubtful whether a renunciation of the right to require PIC entails an obligation under Article 14 of the Protocol to inform the Access and Benefit-sharing House accordingly. This issue should be addressed and clarified as quickly as possible by a decision of the COP-MOP, since Parties shall under Article 14 (2) also make available to the Clearing-House information required pursuant to such decision. A regulation on reporting requirements may, however, be seen as “a measure on access” in the sense of Article 14 (2) (a) with ensuing obligations to inform the Clearing-House thereon.

37 The concept of “species of wild animals and plants” is normally being understood to include also fungi.

38 It might have been relevant to point to the fact that Denmark, in the sense of the Protocol, is not the country of origin of a number, if not the majority, of these species. As far as wild organisms are concerned the Explanatory Notes include information to the effect that in the knowledge of the Danish Nature Agency genetic resources of wild organisms are in Denmark not collected by industry, but only for educational reasons or with a view of non-commercial research.

microorganisms which probably are not included in the concept of species of wild animals and plants as applied hitherto by Danish legislation.

A regulation on reporting must address a number of issues, *e.g.* when and what kind of information has to be provided, whether or to what extent collection for non-commercial research is excepted, the geographical coverage, acknowledgement of receipt of information, and the legal effect of non-compliance with information requirements. While the Act empowers the minister to specify that violations of the provisions of a regulation shall be sanctioned by a fine, it is not likely that genetic resources collected without the prescribed information may be seized or benefits achieved may be confiscated. Also the question of whether non-compliance may be remedied by providing information at a later stage should be addressed.

### 3 *“Foreign” Genetic Resources*

The issue of access to “foreign” genetic resources in Denmark is not addressed by the Act nor by the Explanatory Notes, but it is clear that there are no PIC requirements regarding such resources, and that this fact does not entail a claim of Danish sovereignty over these resources. Nor does the above provision in Section 6 of the Act on reporting apply to such resources. Hence, it does not seem to be in conflict with the Act to access such resources provided that they are not being utilized in Denmark (see Part IV.3 below). The problematic might be relevant not only in respect of a particular genetic resource acquired by a potential user in Denmark before the entry into force of the Protocol (see Part IV.2 below), but also regarding a particular genetic resource acquired by a potential user after the entry into force of the Protocol in conflict with the domestic requirements of the Party from which the genetic resource was coming. This, however, would not diminish the right of that Party to seek to enforce the user measures prescribed in Article 15 of the Protocol.<sup>39</sup>

## IV Denmark as a User Country

### 1 *Patent Applications*

Denmark is one of the rather few industrialized countries – maybe the first ever – that (in 2000) implemented disclosure of origin requirements. In other words,

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39 For a discussion of the above problematic, see Claudio Chiarolla, “The Role of Private International Law under the Nagoya Protocol,” in *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective: Implications for International Law and Implementation Challenges*, eds. Elisa Morgera, Matthias Buck and Elsa Tsioumani (Leiden: Martinus Nijhoff Publishers, 2013): 444.



patent applications concerning an invention, which is based on or utilizes biological materials of plant or animal origin, shall contain information on the materials' geographic origin. Besides, if the applicant does not know the origin of material, this must be stated in the application. However, the lack of information concerning the geographic origin or the material neither affects the processing of the application nor the granting and enforcements of patents rights.<sup>40</sup>

The Explanatory Notes presuppose that the above rule is going to be expanded with a view of fulfilling the requirements of the provisions of Article 17 of the Protocol regarding checkpoints, although additional checkpoints are foreseen. However, after having submitted the Bill on the ABS Act to the *Folketing*, the Minister for the Environment informed the Environment Committee of the *Folketing* that it would not necessarily be appropriate to use the Danish rule on patent applications as a means of monitoring the utilization of genetic resources,<sup>41</sup> and that the *Folketing*, accordingly, will be informed on the choice of checkpoints when considering the EU Regulation on ABS. Hence, so far there are no Danish rules or checkpoints and monitoring in order to implement Article 17 of the Protocol.

It should also be observed that the above rule on patent applications does not include an obligation to disclose information on TK.

## 2 Core Provisions of the Danish ABS Act

The Danish ABS Act,<sup>42</sup> titled "Act on Sharing of Benefits arising from the Utilization of Genetic Resources," is basically an act on utilization in Denmark

40 The rule, which is now found in Section 3, subpara. 4 of ministerial order No. 93 of 29 January 2009 on patents and supplementing protection certificates is based on recital 27 of European Parliament and Council Directive 98/44 on Legal Protection of Biotechnological Inventions (*supra* note 18), but it differs from this, because the "should" in the recital has become a requirement in the Danish order. Provision of false or deliberately wrong information may be sanctioned under the General Civil Penal Code. The idea of "disclosure of origin" in patent applications as a means to control that the PIC demand of CBD is met was likely launched for the first time in F. Hendrickx, V. Koester and Chr. Prip, "Convention on Biological Diversity – Access to Genetic Resources: A Legal Analysis," in *Environmental Policy and Law* 23 (1993), 254, cf. the same authors in *Biodiplomacy. Genetic Resources and International Relations*, eds. Vicente Sánchez and Caletous Juma, (Nairobi: AC TS Press 1994), 148. The authors also suggest (at pp. 147) the enactment of a legal obligation of corporations *etc.* to keep a register of genetic resources which they hold for research and development purposes, to be open for inspection by the competent authority. Without claiming that these ideas has been a source of inspiration, it may be observed the Articles 4 and 5 of the EU Regulation on ABS contain elements corresponding to the above ideas.

41 Nagoya Protocol Article 17.

42 See introduction above. The Act enters into force upon Danish ratification of the Protocol, subject to the entry into force of the Protocol (Part 4.2 above at note 35).

of non-Danish genetic resources and TK associated with such resources. The title of the Act is somewhat misleading, since there are no provisions on benefit-sharing other than Section 1 according to which “[t]he objective of the Act is to ensure the sharing of benefits from the utilization of genetic resources.”

The following observations or suggested interpretation of the Act are based on the Explanatory Notes only if specifically indicated.

Section 3 (1) of the Act states “[t]hat the utilization of genetic resources in Denmark is prohibited when genetic resources have been acquired in contravention of the legislation on access to genetic resources of the country from which they originate.”

Section 4 (1) lays down an equal prohibition in respect of TK associated with genetic resources, if the TK has been acquired in contravention of the legislation of the country “from which the utilized TK originates” (see below).

Benefit-sharing arising from the utilization of TK associated with genetic resources is formally speaking not reflected by the objective of the Act, because the definitions of the Act relating to “utilization” and “genetic resources” do not include any reference to TK. The reason is probably that an inclusion of a reference to TK in the objective of the Act would have made the appropriateness of a definition of TK more obvious, which might have caused problems.<sup>43</sup> In this context it may be observed that the concept of TK does not appear elsewhere in Danish legislation related to intellectual property rights. Protection of TK was prior to the ABS Act never raised as an internal legislative issue, but the Danish Government has, of course, been following the international discussions and negotiations on the protection of TK, *inter alia* in WIPO, and is probably going to continue to do so.

The application of Sections 3 (1) and 4 (1) of the Act is restricted to genetic resources and TK from countries which, in their capacity as Parties to the Protocol, have “established legislation”<sup>44</sup> in these respects “in accordance with,” respectively, Articles 6 and 7 of the Protocol.<sup>45</sup> Accordingly, there are no

43 The Act does not define TK, but with a reference to the content of CBD Article 8 (j) the Explanatory Notes state that the concept of TK as referred to by the Act should be understood in accordance with the content of CBD Article 8 (j). See, equally, along the same lines, Amendment 2 and 29 of the *European Parliament Draft Report* as well as Recital 5 and Article 3 (7) of the EU Regulation on ABS.

44 In spite of the reference to “legislation” there is due to explicit references to the relevant articles of the Protocol probably no doubt that “legislation” should not be understood literally. Hence, “legislation” also includes other measures by provider countries fulfilling the requirements of the Protocol.

45 Articles 6 and 7 of the Protocol are explicitly referred to in the above provisions of the Danish ABS Act, respectively Sections 3 (2) and 4 (2). The Explanatory Notes, however, include references to relevant provisions of the Protocol on the measures to be taken by

user measures *vis-à-vis* non-Parties to the Protocol. Nor does the Act probably apply to genetic resources or TK acquired before the entry into force of the Protocol. Arguably, these two legal dimensions are still governed by the provisions of the CBD, at least as far as access to genetic resources is concerned.<sup>46</sup>

Section 1 of the Act is the only provision in Danish legislation referring to benefit-sharing, and Article 4, equally, the only one referring to TK.

### 3 *Some Interpretative Issues relating to the Core Provisions*

Sections 3 and 4 of the Act are raising some interpretative questions. The Act applies in Sections 3 and 4 the Danish words "*kommer fra*" which may be translated into "coming from," but could also be understood to mean "originating from." The Explanatory Notes do not offer any explanation on the exact meaning of "*kommer fra*." There is, however, probably no doubt that Section 4, due to the in principle immovable nature of TK, refers to TK which is "coming from" in the sense of "originating from." Furthermore, Section 4 contains an explicit reference to Article 7 of the Protocol dealing with measures to be taken by Parties in respect of their TK.

Arguably, "coming from" in Section 3 on genetic resources should be understood in the same manner. If not, "coming from" in the two provisions would have two different meanings. Section 3 of the Act on genetic resources includes, however, an explicit reference to Article 6 of the Protocol which not only refers to "the Party providing such resources that is the country of origin of such resources," but also to "a Party that has acquired the genetic resources in accordance with the Convention." Hence, the notion of "coming from" in Section 3 has to be interpreted with a view of covering the two situations outlined in Article 6 of the Protocol.<sup>47</sup>

Another issue is that the delict enshrined in Section 3 is not illegal access *per se*, but utilization of genetic resources which have been illegally accessed (acquired), and that in order for a utilization to be illegal, it is required that the utilization takes place in Denmark. Therefore, the fact that a subsidiary of a Danish company, based in another country, does not violate Section 3 of the Act

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user countries to control compliance with domestic legislation on PIC and TK, respectively Articles 15 and 16 of the Protocol.

46 On the relationship between the provisions of CBD on access to genetic resources and the Protocol, see Koester, "The Nagoya Protocol on ABS," 17–18.

47 The author, in general, refrains from suggesting amendments of the unofficial translation of the Danish ABS Act provided by the Danish Nature Agency. Nevertheless, it is suggested that "*kommer fra*" in section 3 of the Act is translated into "coming from" while the translation of the same notion in section 4 to "originates" may be kept.

by utilizing a particular genetic resource having been misappropriated by that company, seems to follow from the way in which the provision is drafted. To what extent Article 16 might be, in such circumstances, enforceable in that other country would apparently depend on, in the first instance, whether the country is a Party to the Protocol. Even a utilization taking place in the Faroe Islands or Greenland would not constitute a breach of the Act. Accordingly, the question on whether the scope of the provision is too narrowly drafted may be raised. Probably, it might have been more appropriate for the provision to have been drafted along the following lines: "Possession of genetic resources for utilization or utilization of genetic resources is prohibited when these resources have been acquired..."

Leaving aside the above interpretative issues, it seems that the Danish ABS Act has circumvented or provided its own stand in respect of some of the problems related to the way in which some of the crucial provisions of the Protocol are drafted. Thus, it clearly follows from Sections 3 and 4 of the Act:

that the courts of the forum [*i.e.* Danish courts] [shall] give extraterritorial application to the domestic law of a foreign country (*e.g.*, the alleged country of origin) in order to determine the conditions under which a responsibility for non-contractual ABS obligations [arises] – *i.e.*, by qualifying the disputed facts in the merit.<sup>48</sup>

Non-contractual ABS obligations include obligations that require users of genetic resources and TK to obtain PIC and establish MAT. There is no explicit provision in the Danish ABS Act on the obligation to establish MAT. The Explanatory Notes, however, state that a complete failure to establish MAT may constitute non-compliance with Section 3 of the Act (see Part IV.7 below). Whether this statement is sufficient to entail penalties if no MAT has been established may, however, be questioned.

The Explanatory Notes do not contain any guidance in respect of whether Danish courts in establishing eventual breaches of domestic measures taken under the Protocol should give particular consideration to any legal and factual findings by competent administrative or judicial bodies of the relevant country.<sup>49</sup> It is, however, difficult to imagine how a public prosecutor would be capable of preparing a solid case without having to rely, at least to some extent, on findings by such bodies.

<sup>48</sup> Chiarolla, "The Role of Private International Law," 440, arguing that "in this limited sense, the Protocol appears to provide grounds for the extraterritorial application of the "domestic ABS legislation [...] of the other Party" as the law applicable to non-contractual ABS obligations."

<sup>49</sup> *Ibid.*, 440.

Although the Explanatory Notes, in the explanation of the content of Sections 3 and 4 of the Act, refer to respectively Article 15 and Article 16 of the Protocol, the provisions themselves avoid the contentious issue related to the reference in Article 15 (1) to the “domestic access and benefit-sharing legislation or regulatory requirements of *the other Party*” (emph. ad.). The Explanatory Notes simply state that

[t]he provision implements the Nagoya Protocol’s requirements for the parties to ensure compliance with the requirements in place in the countries from which the resources originate (emph. ad.), which is essentially stated in Article 15 of the Protocol.

This means that the Act has adopted, at least indirectly, “an expansive interpretation of Article 15” in the sense that Section 3 of the Act refers to Article 6, *i.e.* the domestic requirements of the country of origin (or a Party having acquired the genetic resources in accordance with the Convention) and not simply to “the other Party,” *i.e.* the providing Party.<sup>50</sup> It is questionable, however, to what extent this entails that Section 3 of the Act is also applicable when a particular genetic resource utilized in Denmark has been accessed in accordance with PIC requirements of the providing Party, but in conflict with Article 6 of the Protocol, because the resource was illegally acquired in the first instance. In any event, in such circumstances it is unlikely that a Danish court would impose a penalty for infringement of Section 3 on a user having exercised due diligence, and also in other respects the implications would be very doubtful,<sup>51</sup> *e.g.* in respect of seizure of the resource or confiscation of benefits. It is, after all, a rather delicate issue to “set aside” a permit issued by another Party.

#### 4 *Definitions of “Genetic Resources” and “Utilization” as Provided by the Act*

“Genetic resources” are defined by Section 2, subparagraph 1 of the Act as “... the functional inherited properties of organisms and naturally occurring biochemical compounds<sup>52</sup> resulting from the genetic expression or metabolism of the organisms.”

<sup>50</sup> *Ibid.*, 443.

<sup>51</sup> For a full discussion of the interpretation of “the other Party” in Article 15 (1), and the reason why the same issue is not relevant in respect of TK, see *ibid.*, 440–445.

<sup>52</sup> The unofficial translation provided by the Danish Nature Agency refers to “substances” instead of compounds.

Section 2, subparagraph 3 of the Danish Act read in conjunction with Section 2, subparagraph 1 indicates that utilization of genetic resources includes utilization of derivatives, as defined by the Protocol Article 2 (e). The last part of this definition (“even if it does not contain functional units of heredity”) is not included in the definition of the Act. This, however, does not seem to be important, because compounds containing functional units of heredity are already covered by the first part of the definition (“functional inherited properties”). This corresponds to the explanation provided by the Explanatory Notes to the effect that the definition of genetic resources corresponds to that of the Protocol, but in addition also includes derivatives.

By virtue of Section 2, subparagraph 2 of the Act, “utilization” “mean[s] to conduct research and development of genetic and/or biochemical composition of genetic resources, including through application of biotechnology.” The fact that the provision, unlike Article 2(c) of the Protocol, refers to “the application of biotechnology as defined in Article 2 of the Convention,” and does not, like Article 2(d) of the Protocol, include the definition of “biotechnology” as defined by CBD, is hardly of any importance.

The extent to which utilization of derivatives is included in the provisions of the Protocol might be debated.<sup>53</sup> There probably is no doubt, however, that provider countries may regulate such utilization if they so wish. Nor is there probably any doubt that user countries may control compliance with such rules if they so wish. The EU Regulation on ABS does not include the use of derivatives without functional units of heredity,<sup>54</sup> which may cause some problems.

The above definition of utilization of the Danish ABS Act contains a supplementary provision to the effect that “[u]tilization is also understood to mean development and marketing of products based on genetic resources.”

The Explanatory Notes state that the definition of utilization of the Act corresponds to the definition of the Protocol. Formally speaking this is not true, *inter alia*, due to the above supplementary provision. This provision, however, is not in direct conflict with the provisions of the Protocol,<sup>55</sup>

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53 See, Koester, “The Nagoya Protocol on ABS,” 10. See also, Morten Walløe Tvedt and Peter Johan Schei, “The Term ‘Genetic Resources’. Flexible and Dynamic while Providing Legal Certainty?” in *Global Governance of Genetic Resources. Access and Benefit Sharing After the Nagoya Protocol*, eds. Sebastian Oberthür and G. Kristin Rosendal (Routledge: New York and London, 2014), 18–32.

54 Article 3 (4) in conjunction with Article 3 (1).

55 Such supplementary provision was also included in one of the latest drafts of the definition of utilization of genetic resources, see Morten Walløe Tvedt and Olivier Rukundo,

although the “Explanatory Guide”<sup>56</sup> to the Protocol provides the following explanation:

Utilization of genetic resources finishes when the research and development process ends. Any subsequent application or commercialization may then be covered by the benefit-sharing provisions found in Article 5 (1) [of the Protocol]

## 5 *Relationship with EU Law*

Sections 3 and 4 of the Danish ABS Act are supplemented by Section 5 of the Act which reads:

The Danish Minister for the Environment may make regulations on procedures and standards that must be followed to ensure compliance with the prohibitions in Sections 3 and 4, including regulation on digitization of these.

According to the Explanatory Notes this provision empowers the Minister to establish rules requiring institutions and enterprises using genetic resources to apply fixed procedures, routines and standards ensuring that resources are acquired in conformity with the legislation of countries of origin. The Explanatory Notes, furthermore, state:

A duty of due diligence can thus be stipulated, including the requirements that transactions of genetic resources shall be accompanied by a statement on the legal status of the resources. This type of regulation may become an object of control in itself, regardless of whether or not access legislation of providing countries may be infringed.<sup>57</sup>

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“Functionality of an ABS Protocol,” *FNI Report* 9 (2010) 14. The supplementary provision underscores to some extent that derivatives (including those without functional units of heredity) are included in the coverage of Section 3 of the Act. See, Riccardo Pavoni, “The Nagoya Protocol and WTO Law,” in *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective: Implications for International Law and Implementation Challenges*, eds. Elisa Morgera, Matthias Buck and Elsa Tsioumani (Leiden: Martinus Nijhoff Publishers 2013) 187–188.

56 Thomas Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing* (Gland, Switzerland: IUCN, 2012), 64.

57 Unofficial translation by the Nature Agency, *supra* note 30, however, with some modifications inserted by the author.

The rationale of Section 5 of the ABS Act is in the language of the Explanatory Notes “to comply with anticipated EU legal requirements on “due diligence” schemes.” The statement should be seen in light of the general remarks of the Explanatory Notes on the relationship of the Act with EU law. While referring to the EU Regulation on ABS, the Explanatory Notes indicate that the Act does not foreclose considerations on potential EU legal regulation, because the Act contains only provisions that are needed in order to comply with the provisions of the Protocol, and these provisions can only be implemented by national legislation. In order to make sense this statement should most likely be understood to mean that since the EU Regulation on ABS does not include provisions like Sections 3 and 4 of the Act such provisions have to be stipulated by means of national legislation. By virtue of Section 5 of the Act the Minister is empowered to set rules realizing future EU legislation. Hence, the Act has, according to the general remarks of the Explanatory Notes, very limited aspects relating to EU law.

## 6 *Supplementary Provisions*

The Act also includes other provisions supplementing the above core provisions laid down in Sections 3 and 4 of the Act, namely

- Section 7 on the obligation of the Minister to monitor compliance with the Act and regulations issued pursuant to the Act;<sup>58</sup>
- Section 8 on the right of access without a court order to public and private properties referred to above;<sup>59</sup>
- Section 9, subparagraph 1 mandating the Minister for the Environment to delegate the powers conferred on the Minister by the Act to an agency established as part of the Ministry or, of negotiation with the relevant ministers, other state authorities;<sup>60</sup>
- Section 10, subparagraph 1 authorizing the Government to conclude agreements with other states on common measures to implement the objective of the Act;<sup>61</sup>

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58 This obligation is according the Explanatory Notes going to be transferred to the Nature Agency.

59 Part III.1 at note 32.

60 In accordance with what is indicated in the Explanatory Notes, the administration of the Act has been delegated to the Nature Agency, which is part of the ministry of environment (see Section III.2 above). Hence, the Nature Agency is the national focal point addressed by Article 13 of the Protocol.

61 The precise nature of such agreement does not appear from the Explanatory Notes, but since the power is conferred to the Government it is likely that the power refers to



- Section 10, subparagraph 2 stipulating an obligation of the Minister to make regulations in order to implement the international agreements referred to in Section 10, subparagraph 1;
- Section 10, subparagraph 3 authorizing the Minister to make regulations which are necessary for the application in Denmark of regulations of the EU concerning matters covered by the Act; and
- Section 11, subparagraphs 1, 2 and 5<sup>62</sup> on penalties for infringements of Sections 3 and 4, the main rule being a fine (unless a higher penalty is applicable in accordance with other legislation) with due consideration of the size of the benefit achieved or strived towards if the benefit is not confiscated, and a possibility that the penalty in certain circumstances may increase to imprisonment of up to two years;<sup>63</sup> and
- Section 11, subparagraph 3 authorizing the Minister to include in regulations issued pursuant to the Act provisions on penalties in the form of fines for infringement of provisions of regulatory provisions.

Section 10, subparagraph 3 of the Act, cited above, is the only provision of the Act referring to EU legislation, but also Section 5 should be seen in the light of future EU legislation, as it appears from the observations above in connection with that section. This may seem to exceed what would be needed, taking into consideration that the EU instrument is a regulation that does not require, nor allows for, a transposition to domestic legislation.<sup>64</sup> The Government, however,

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international agreements, *i.e.* treaties, since it is the Government which is acting on behalf of the Realm in international affairs (*supra* note 13). The power conferred to the Government is limited to agreements on “common measures to comply with the objective of the Act,” *i.e.* to ensure benefit-sharing from the utilization of generic resources (thus, limiting the regulating power of the Minister according to Section 10, subpara. 2 to the same extent). Hence, presumably, Section 10, subpara. 1 is not referring to international agreements in the sense of Article 4 (2) of the Protocol, nor to ongoing work or practices under international instruments and relevant international organizations addressed by Article 4 (3) of the Protocol. The Explanatory Notes provide as an example of the substance matter of an agreement under Section 10, subpara. 1 of the Act shared data collection and exchange of data for use in the implementation of the Nagoya Protocol.

62 Companies *etc.* (legal entities) may be penalized in accordance with rules in accordance with rules of the General Civil Penal Code (Section 11, subpara. 4). The statute of limitation for criminal liability is five years (Section 11, subpara. 6).

63 When the infringement has been committed intentionally or due to gross negligence and, as a result of the infringement, an economic benefit has been obtained or is intended for the one who committed the infringement or others.

64 Generally speaking, only domestic provisions on penalties are required.

was facing a kind of dilemma when submitting the Bill to the *Folketing*, namely to arrive at an act that would enable the Government to become part of a collective EU adherence to the Protocol, entailing, *inter alia*, implementation of the EU Regulation, but, alternatively, would enable the Government to ratify the Protocol on its own and to implement the Protocol on basis of the Act only.<sup>65</sup>

#### 7 *Provisions Relating to Mutually Agreed Terms (MAT)?*

There are no provisions relating to MAT in the Danish ABS Act itself, but a few remarks in that respect can be found in the Explanatory Notes. Accordingly, the general approach of the Act in that respect is that non-compliance with MAT is not a concern of the Act. Enforcement of MAT has to be pursued under private law. However, a complete failure to agree on terms for PIC or for the utilization of TK could, depending on the legislation of the provider country, constitute an infringement of the prohibitions in Sections 3 and 4 which is stated in the Explanatory Notes (also) in the following way:

While an infringement of the provisions of the Act reflects an infringement of the provisions of the legislation of the providing country on prior consent for collecting genetic resources and for the utilization of traditional knowledge associated with these resources, an infringement of the mutually agreed terms for utilization of the genetic resources or the traditional knowledge shall be prosecuted via civil legal proceedings. Formal infringement of the providing country's legislation on entering into mutual agreement on utilization, including sharing of benefits, will represent an infringement of the prohibitions in sections 3 and 4.

Hence, there are no specific provisions to implement the commitments of Article 18 on compliance with MAT. To what extent already existing opportunities to seek recourse under the Danish legal system can be taken to court are sufficient "to ensure" that disputes arising from MAT can be taken to court (Article 18(2)) has apparently not been examined. This also applies to the requirement of "effective measures," as appropriate in accordance with Article 18(3)(b) regarding "[t]he utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards."

As far as arbitral awards are concerned the above observations may be remedied to some extent by the fact that Denmark is a Party to the 1958 New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards

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65 See Part III.2 above.

which has gained a considerable recognition.<sup>66</sup> However, it cannot be excluded that additional legislation in the longer perspective might be needed<sup>67</sup> in order to fulfil the requirements of Article 18, *inter alia*, because Denmark according to a Danish analysis of private international law is, outside the scope of what is regulated by treaties, “hostile to the recognition” of foreign court decisions.<sup>68</sup>

No specific Danish measures have been taken regarding “access to justice” as required (as appropriate) by Article 18(3)(a) of the Protocol. The scope of this provision, however, is not clear, *inter alia*, because it is not specified whether access to justice also includes access to legal aid, which is relevant since most often the provider country will be a developing country and thereby also the weaker party.<sup>69</sup> Apart from this, Denmark is not a Party to the 1980 Hague Convention on International Access to Justice, although being a Party to the 1954 Hague Convention on Civil Procedure which includes some provisions on legal aid. As it has rightly been observed by an author, “one of the most important constraints that limits the utilization of the tools, provided for by [these] conventions, is their small number of state Parties.”<sup>70</sup> Furthermore, almost all Parties to both conventions are not developing countries.<sup>71</sup>

It may serve as a kind of excuse for non-inclusion, in the Danish ABS Act, of provisions with a view of implementing the commitments of Article 18 of the Protocol, that the implications of Article 18 (the effectiveness of which is subject to a specific clause on review) are not clear and are raising a number of complex issues.<sup>72</sup> Thus, some guidance by means of COP-MOP decisions may be needed.

An analysis of the present Danish legislation relating to fulfilment of the commitments under Article 18 of the Protocol exceeds the scope of the present

66 The Convention has currently 146 Parties.

67 The various powers conferred on the Minister for the Environment by the Act do not provide any mandate to make regulations in the area of private law.

68 Joseph Lookofsky and Ketilbjørn Hertz, *International privatret på formuerettens område* (Copenhagen: Jurist- og Økonomforbundets Forlag, 2008), 51.

69 Koester, “The Nagoya Protocol on ABS,” 15 and Chiarolla, “The Role of Private International Law,” 432.

70 *Ibid.*, Chiarolla, “The Role of Private International Law,” 433.

71 Of the 24 Parties to the 1980 Convention only one Party may (however, with some difficulties) be categorized as a developing country (Brazil). The same applies to the 45 Parties to the 1954 Convention (Suriname).

72 See *e.g.* Morten W. Tvedt and Ole K. Fauchald, “Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit Sharing in Norway,” *The Journal of World Intellectual Property* 14 (2011): 383.

paper.<sup>73</sup> Furthermore, it may be assumed that various potential problems in respect of Danish legislation vis-à-vis the commitments under Article 18 do not substantially differ very much from the same kind of problems encountered by the present legislation of other EU Member States indicating the need for common efforts to identify potential problems and to seek adequate solutions by means of appropriate COP-MOP decisions.<sup>74</sup>

## V Some Preliminary Conclusions

It is quite obvious that the Nagoya Protocol is a very difficult instrument to implement both as a user Party and as a provider Party. Although Denmark has chosen the most easy legislative way in respect of its potential role as a provider Party by refraining from PIC requirements (Part III.1 above), problems in respect of how to implement the foreseen reporting requirements (Part III.2 above) are visible in the horizon. Denmark deserves admiration for its courage of being the first EU Member State drafting a relatively simple act addressing the country's user obligations, and leaving room for either a unilateral ratification of the Protocol, or ratification as part of a collective ratification by the EU and its Member States. The Danish ABS Act, however, is raising a number of interpretative issues (Part IV above). Some of these may be clarified by means of the regulations that the Act empowers the Minister to issue. Thus, over and above, the Act represents the beginning of a process paved with a number of difficulties, rather than the end of a process.

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73 For a general explanation of the commitments, see Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol*, 183–189, and for a theoretical discussion of various issues related to Article 18, Chiarolla, “The Role of Private International Law,” 423–449.

74 Although, in part 1 of the Explanatory Memorandum of its initial proposal, the Commission stated “Parties must also ensure that disputes arising from specific benefit-sharing contracts can be taken to court [but that] different than in the case of access, *the user-compliance provisions leave Parties quite some discretion on the type and mix of implementing measures chosen* (emph. add.).”

# Commentary on the ABS Provisions of the Draft Biodiversity Law of France

*Claudio Chiarolla*

France not only provides a wealth of genetic resources, including from its metropolitan regions and overseas territories, its territorial sea and exclusive economic zone, for research and development (R&D) activities worldwide. It is also a user country with advanced biotechnology capacity, several economic and industrial sectors actively participating to the bioeconomy, and a multitude of public and private research institutes directly concerned by the application of access and benefit-sharing (ABS) requirements to their activities.<sup>1</sup>

Although in some overseas territories access to genetic resource and benefit-sharing issues are already regulated by local mechanisms,<sup>2</sup> such as in the South Province of New Caledonia,<sup>3</sup> in the Amazonian Park of Guiana<sup>4</sup> and in

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\* The author would like to express his most sincere gratitude to Sarah Aubertie for her thorough comments and suggestions on an earlier version of this chapter. Any remaining mistakes and inaccuracies are the sole responsibility of the author. This commentary discusses the draft text of the Biodiversity Law that was presented to the French National Assembly on 26 March 2014, which is available at: <http://www.assemblee-nationale.fr/14/projets/pl1847.asp>. Throughout the chapter, the English summaries of relevant provisions are based on an unofficial translation of the French text made by the author. Excerpts from the original French text are included in Annex I at the end of this chapter.

1 République Française, Ministère de l'écologie, du développement durable, des transports et du logement, *Accès aux ressources génétiques et partage des avantages issus de leur utilisation (APA). Comprendre le fonctionnement du mécanisme d'APA et les dispositions clés du Protocole de Nagoya*. June 2011, <http://www.developpement-durable.gouv.fr/IMG/pdf/1-MEDDTL-Synthese-Protocole-Nagoya.pdf>.

2 In accordance with the French Constitution, some overseas collectivities have the competence to regulate ABS on their territory.

3 See the *Délibération 06–2009 du 18 février 2009 relative à la récolte et à l'exploitation des ressources biochimiques et génétiques*, which is now included into the provincial Environmental Code. *Code de l'environnement de la province sud de Nouvelle Calédonie*, Articles 311-1 to 315-4, available at: [http://www.fondationbiodiversite.fr/images/stories/telechargement/ed\\_48\\_apa\\_outre\\_mer.pdf](http://www.fondationbiodiversite.fr/images/stories/telechargement/ed_48_apa_outre_mer.pdf), pp. 162–166.

4 Currently, applications for access to genetic resources are to be submitted to the Regional Council of Guiana, in accordance with the procedures set out in the Charter of the Park, which is about to be adopted. The Charter also establishes modalities for benefit-sharing.

French Polynesia,<sup>5</sup> in France there is no overarching ABS framework that is currently applicable to the entire territory. At present, notwithstanding this legislative gap, the *ad hoc* treatment of requests for access to genetic resources and associated traditional knowledge (TK) is the responsibility of the National Focal Point on ABS, namely the French Ministry of Ecology, Sustainable Development and Energy (MEDDE). In particular, since November 2012, a voluntary access procedure has allowed applicants to transmit their access requests to the National ABS Focal Point and establish specific conditions for access to genetic resources and the sharing of benefits on a voluntary basis.<sup>6</sup> In addition to this voluntary access procedure, the Focal Point also

inform[s] applicants of the related regulations concerning access and the exportation of biological material, which apply within the existing legal framework (*e.g.* regulations on protected species and protected areas, health rules, CITES, law of the sea, etc.), and which applicants may have failed to identify on their own.<sup>7</sup>

However, this situation is expected to radically change with the upcoming adoption of the so-called draft Biodiversity Law (DBL) – or “*Projet de Loi relatif à la biodiversité*” in French – which will introduce, *inter alia*, compulsory procedures for access to genetic resources and associated TK. In particular, in order to clarify and harmonise the regulatory framework applicable to biodiscovery and to the utilization of genetic resources in France, and in light of the forthcoming ratification of the Nagoya Protocol, the Ministry of Ecology, Sustainable Development and Energy started consultations in 2011 with the view to proposing a new legislative framework on ABS. On 17 December 2013, after a long and impervious consultative process, the draft Biodiversity Law was eventually considered and approved by a consultative body, called National

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See: <http://www.parc-guyane.gf/site.php?id=76> See also: Article L. 331-15-6 of the Environmental Code and Law no. 2006–436 of 14 April 2006, [http://www.fondationbiodiversite.fr/images/stories/telechargement/ed\\_48\\_apa\\_outre\\_mer.pdf](http://www.fondationbiodiversite.fr/images/stories/telechargement/ed_48_apa_outre_mer.pdf), pp. 189–193. Interestingly, the entry into effect of the draft Biodiversity Law (DBL) will automatically repeal the specific ABS provisions of the Amazonian Park of Guiana in favour of the direct application of national ABS provisions. DBL, Title IV, Article 25.

5 Law no. 2012–5 of 23 January 2012.

6 “Le Protocole de Nagoya sur l'accès et le partage des avantages,” French Biodiversity Clearing House Mechanism, <http://biodiv.mnhn.fr/convention/le-protocole-de-nagoya-sur-l-acces-et-le-partage-des-avantages>.

7 *Ibid.*

Council for Ecological Transition,<sup>8</sup> with a majority of 28 votes in favour, nine against and one abstention.<sup>9</sup> The Ministry of Ecology, Sustainable Development and Energy also announced that the draft Biodiversity Law will be transmitted to the Council of State<sup>10</sup> in early 2014 with the view to its inclusion in the agenda of the Council of Ministers for its adoption in March 2014.<sup>11</sup> On 26 March 2014, the Minister of Ecology presented the draft Biodiversity Law to the Council of Ministers with the view to submitting the text for consideration by the National Assembly possibly in October 2014.<sup>12</sup> However, at the time of writing, the calendar of the National Assembly does not provide yet a date for the discussion of the draft law.

Once adopted by the French Parliament, the norms of the Biodiversity Law will be included into the Environmental Code and they will become an integral part of it.<sup>13</sup> In particular, Title IV of the draft Biodiversity Law focuses on ABS and it provides for the inclusion of a new section of the Environmental Code titled “Access to genetic resources and associated traditional knowledge, and the fair and equitable sharing of the benefits arising from their utilization.”<sup>14</sup>

This chapter will present, analyse and discuss key aspects the ABS provisions of the draft Biodiversity Law of France. At the outset, it is worth emphasising that French legislators have primarily focused on issues of access to genetic resources and associated TK, since other key obligations under the Nagoya Protocol will be implemented also through the Regulation of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and

8 The *Conseil national de la transition écologique* (CNTE) is a French administrative commission with consultative functions.

9 “Le projet de loi biodiversité sera transmis au Conseil d’État début janvier,” Agri85, <http://www.agri85.fr/V3/Le-projet-de-loi-biodiversite-sera-transmis-au-Conseil-dtat-debut-janvier-actualite-numero-5295.php>

10 The Council of State (*Conseil d’État*) is a body that acts, *inter alia*, as legal adviser of the French Government.

11 “Conseil national de la transition écologique: avis sur le projet de loi Biodiversité adopté à une large majorité,” Ministère de l’écologie, du développement durable, des transports et du logement, [http://www.developpement-durable.gouv.fr/spip.php?page=article&id\\_article=36324](http://www.developpement-durable.gouv.fr/spip.php?page=article&id_article=36324).

12 The text of the draft Biodiversity Law (NOR: DEVL1400720L/Bleue-1) is available at: [http://www.developpement-durable.gouv.fr/IMG/pdf/Texte\\_du\\_projet\\_de\\_loi\\_relatif\\_a\\_la\\_biodiversite.pdf](http://www.developpement-durable.gouv.fr/IMG/pdf/Texte_du_projet_de_loi_relatif_a_la_biodiversite.pdf).

13 The French Environmental Code is available at <http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074220&dateTexte=20030805>.

14 These norms will be included in Chapter 2, Title I, Book IV of the Environmental Code. DBL, Title IV, Articles 18.

Equitable Sharing of Benefits Arising from their Utilisation in the Union (hereafter “the EU Regulation on ABS”).<sup>15</sup> Therefore, the latter and the relevant provisions of the draft Biodiversity Law will jointly concur to regulate ABS obligations in France.<sup>16</sup>

The next section provides an overview of the legal status of genetic resources and associated traditional knowledge in France by describing how the relevant legal landscape will be changed with the eventual adoption and entry into effect of the Biodiversity Law. Section II explains the scope of application of the ABS provisions of the draft Biodiversity Law with a particular focus on their material scope and subject matter exclusions, as well as on temporal and territorial scope. Section III describes the procedures for accessing genetic resources and associated TK in France. Then, Section IV analyses the key benefit-sharing obligations provided for by the Law. Section V considers the provisions and mechanisms envisaged by the draft Biodiversity Law in order to promote compliance by users with domestic ABS legislation or regulatory requirements of other Parties to the Nagoya Protocol. Section VI examines relevant institutional arrangements, including the establishment of ABS Competent National Authorities. The following section limits this chapter’s scope by excluding the examination of aspects that concern compliance by France with the Nagoya Protocol. Finally, Section VIII provides some concluding remarks.

## I Legal Status of Genetic Resources and Associated Traditional Knowledge in France: A Changing Landscape

The draft Biodiversity Law confirms that genetic resources are part of the “common heritage of the nation” alongside with “natural areas, resources and habitats, sites and landscapes, air quality, animal and plant species, and the biological diversity and balance to which they contribute.”<sup>17</sup> As this chapter will illustrate in the ensuing sections, the new ABS provisions of the Biodiversity

<sup>15</sup> The EU Regulation on ABS was approved by the EU Council on 14 April 2014.

<sup>16</sup> See below the section on *territorial scope* for further details.

<sup>17</sup> See Article 110-1 of the Environmental Code. Act no. 2002–276 of 27 February 2002, Article 132, Official Journal of 28 February 2002. This Article further specifies that “their protection, enhancement, restoration, rehabilitation and management are of general interest and contribute to the objective of sustainable development, which aims to satisfy the development needs and protect the health of current generations without compromising the ability of future generations to meet their own needs.” (Official translation, [www.legifrance.gouv.fr/content/download/1963/13739/.../Code\\_40.pdf](http://www.legifrance.gouv.fr/content/download/1963/13739/.../Code_40.pdf)).



Law will make important improvements to the Environmental Code in terms of defining, *inter alia*, the modalities of access and use of genetic resources and associated TK in France.<sup>18</sup>

Apart from the protection which may be possibly granted to traditional knowledge (TK) under the Intellectual Property Code – if such knowledge meets standard protection requirements (for instance, as a trade secret) – TK associated with genetic resources did not enjoy yet a particular legal status under French law. However, as a result of the forthcoming adoption of the draft Biodiversity Law, its legal status will be improved – at least in some respects – since the former also applies to the utilization of TK associated with genetic resources.<sup>19</sup>

The draft law provides a specific definition of “TK associated with genetic resources,” which shall be understood as knowledge and practices concerning the genetic or biochemical properties of genetic resources, their utilization or characteristics, and that are held in a traditional and continued manner by one or more communities of inhabitants (“*communautés d’habitants*”), as well as the evolution of such knowledge and practices within such communities.<sup>20</sup>

The concept of “communities of inhabitants” is defined by the draft law as communities that traditionally derive their means of subsistence from the natural environment and whose lifestyles are relevant for the conservation and the sustainable use of biodiversity.<sup>21</sup> This concept shall be interpreted also in light of the opinion of the National Council for Ecological Transition, which called for transcribing the expression “indigenous and local communities” (used in the Nagoya Protocol) in the least restrictive possible manner into French law,

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18 However, the draft Biodiversity Law will not define the concept of “access to genetic resources” *as such*. This is because although the act of accessing a particular genetic resource or associated TK may trigger *de facto* the relevant administrative procedures, benefits-sharing obligations will arise as a consequence of their utilization, in accordance with the Nagoya Protocol. Annelaure Wittmann, Chargée de mission “instruments économiques et biodiversité,” MEDDE, *Personal communication*, 11 March 2014, on file with the author. Therefore, the draft Biodiversity Law defines “utilization of genetic resources” as comprising all activities that involve the conduct research and development on the genetic or biochemical composition of plant, animal, microbial or other biological material, or parts thereof, containing functional units of heredity, as well as subsequent applications and commercialization. It also defines “utilization of TK associated with genetic resources” as their study and the further enhancement of such knowledge. DBL, Title IV, Article 412-3.

19 However, there are important exceptions. See below the section *Subject matter exclusions*.

20 DBL, Title IV, Article 412-3.

21 *Ibid.*

with the view to covering the whole range of possible holders of TK who must benefit from ABS mechanisms and procedures, within the limit imposed by the French Constitution.<sup>22</sup>

## II Scope of Application

### 1 *Subject Matter*

As anticipated in the previous section, the scope of application of the draft ABS provisions covers both accesses to genetic resources for their utilization as well as the utilization of associated TK.<sup>23</sup> However, the law provides several subject matter categories that are excluded, namely:<sup>24</sup>

- human genetic resources;
- genetic resources in areas beyond national jurisdiction (ABNJ);
- genetic resources covered by specialized ABS instruments that are consistent with, and do not run counter to the objectives of, the Convention on Biological Diversity;
- genetic resources of cultivated or domesticated species that are used as models in R&D activities (*i.e.* model species);<sup>25</sup>
- traditional knowledge associated with genetic resources that may not be attributed to one or more communities of inhabitants;
- traditional knowledge associated with genetic resources, whose properties are well known, and that has been used repeatedly and for a long period of time outside the communities of inhabitants that have initially developed such knowledge;
- traditional knowledge covered by the value enhancement measures that are defined by Article 640-2 of the *Code rural et de la pêche maritime*.<sup>26</sup>

22 See *supra* note 8 and accompanying text. See also the opinion of the National Council for Ecological Transition, available at: <http://www.arnaudgossement.com/media/01/00/1984099581.doc>

23 DBL, Title IV, Article 412-4, II.

24 DBL, Title IV, Article 412-4, III.

25 The definition of what constitutes a “model species” is to be specified by decree at a later time.

26 The latter applies to agriculture and food, forestry and seafood products, whose value can be enhanced and captured through: (1) quality and origin identification labels (*i.e.* the red label – Official Quality Guarantee, Protected Geographical Indications, and the mention “Organic Agriculture” in their sale denomination); (2) value-adding statements (*e.g.* mountain or farm produced); and (3) certification schemes. Available at: <http://www.legifrance>

In addition, the ABS provisions of the draft Biodiversity Law are not applicable to personal or non-commercial uses of genetic resources and associated TK within and between “communities of inhabitants.” However, other personal or non-commercial uses of such resources and knowledge outside such communities are subject to regular declaration or authorization procedures.<sup>27</sup>

Aside from the above exclusions, the Biodiversity Law singles out five categories of genetic resources, whose ABS conditions will be set out by specific regulatory measures.<sup>28</sup> These categories are:

- (1) genetic resources of domesticated or cultivated species;<sup>29</sup>
- (2) genetic resources of wild relatives of cultivated crop and domesticated animal species;<sup>30</sup>
- (3) genetic resources used in forestry;<sup>31</sup>
- (4) genetic resources collected by laboratories for the prevention, surveillance and eradication of health risks that threaten plant and animal health as well as the food safety of animals;<sup>32</sup>
- (5) genetic resources collected by laboratories for the prevention, surveillance and eradication of serious health risks that threaten human health.<sup>33</sup>

With regard to the above categories of genetic resources (ranging from domesticated and cultivated species to microbial pathogenic species), the following repartition of competences is established:<sup>34</sup>

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.gouv.fr/affichCodeArticle.do?sessionId=AD1FD4F7AA51DEBFCB2B3A49ABF5C332.tpdj  
oo8v\_2?idArticle=LEGIARTI000022657487&cidTexte=LEGITEXT000006071367&dateText  
e=20140210&categorieLien=id&oldAction.

27 DBL, Title IV, Article 412-4, III. See below also the section on “Access to genetic resources and associated traditional knowledge.”

28 DBL, Title IV, Article 412-4, IV.

29 Domesticated or cultivated species are defined as all species in which the evolutionary process has been influenced by humans to meet their needs. DBL, Title IV, Article 412-3.

30 Wild relatives' species are defined as all animal species capable of sexual reproduction with domesticated species, as well as all crop species capable of crossing with cultivated species within the framework of varietal selection. DBL, Title IV, Article 412-3.

31 These forest genetic resources will be regulated by a Decree of the Council of State in accordance with Article 153-1-3 of the Forestry Code.

32 *Code rural et de la pêche maritime* Article 201-1, Paragraphs 1° and 2°.

33 *Code de la santé publique* Article 1413-5.

34 Annelaure Wittmann, Chargée de mission “instruments économiques et biodiversité,” MEDDE, *Personal communication*, 11 March 2014, on file with the author.

- (1) the Ministry of Agriculture, Agrifood and Forestry is responsible for the access procedures that concern genetic resources of domesticated or cultivated species;
- (2) the Ministry of Ecology, Sustainable Development and Energy is responsible for the access procedures that concern genetic resources of wild species;
- (3) the Ministry of Social Services and Health is responsible for the access procedures that concern pathogenic and microbial genetic resources that entail health risks which may threaten human health.

It also is worth emphasising the opinion of the National Council for Ecological Transition, which has questioned the opportunity to establish three distinct sets of ABS rules and procedures. In particular, the Council requested that the ABS rules and procedures that apply to the above genetic resources, which are not excluded *as such* from the scope of application of the Nagoya Protocol, be harmonised for the benefits of users seeking access to them.<sup>35</sup> However, regardless of the above repartition of competences between three different competent administrative authorities,<sup>36</sup> these concerns are—at least partially—reduced by the fact that, once delivered, all access permits (or their equivalent) will be identical in nature and will be posted on-line through the ABS Clearing-House Mechanism of the CBD.<sup>37</sup>

## 2 *Temporal Scope*

In the case of collections of genetic resources or associated TK that have been assembled before the Biodiversity Law comes into force, Article 412-4 V provides that the ABS procedures are applicable to all new uses.<sup>38</sup> Another provision is also specifically dedicated to *ex situ* collections.<sup>39</sup> It prescribes that if a collection was constituted before the date of the entry into effect of the CBD,

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<sup>35</sup> See *supra* note 22.

<sup>36</sup> See below the section on *Competent national authorities and relevant institutional arrangements*.

<sup>37</sup> However, some information may be classified as commercially sensitive or confidential and it will not be disclosed to the public. See DBL, Title IV, Article 412-14 and *supra* note 34.

<sup>38</sup> While a definition of “new uses” has not yet been adopted, a proposal has been put forward that this concept may comprise all new research and development activities, whose objectives and contents are distinct from those previously pursued by the same users. The characteristics of a “new use” will be defined by a Council of State’s decree.

<sup>39</sup> DBL, Title IV, Article 412-13.

then the benefits arising from new uses of genetic resources shall accrue to the holder of the collection.<sup>40</sup>

### 3 *Territorial Scope*

This chapter has already mentioned the EU Regulation on ABS and the relevant provisions of the draft Biodiversity Law will jointly regulate ABS obligations in France. However, while this is certainly the case for “continental” France, the repartition of (sometimes overlapping) competences between the central government, the French overseas departments (*départements et régions d’outre-mer* – DROM), the French overseas countries and territories (OCTs),<sup>41</sup> and the European Union, makes the legislative landscape on ABS far more complex than it could appear at first sight.

The DROM include Martinique, Guadeloupe, French Guiana, Réunion and Mayotte. These departments are an integral part of the EU and are qualified as EU outermost regions (ORs). With the exception of express derogations, the same legislative framework applicable to continental France, including both the EU Regulation on ABS and the draft Biodiversity Law, will be applicable to them.<sup>42</sup> Although Clipperton does not belong to the DROM as such,<sup>43</sup> this island is also subject to the principle of “legislative identity” with the consequence that it can be assimilated to the DROM with regard to the law applicable to ABS issues. A similar case is Saint-Martin, which is also subject to the regime applicable to the EU outermost regions – regardless of its recently upgraded status amongst the COM in July 2007.

As regards the territorial scope of national (and regional) ABS measures, however, an important distinction shall be drawn between outermost regions that belong to France (such as the DROM), on the one hand, and the French overseas countries and territories,<sup>44</sup> which are associated to the EU, without being part of it, on the other. As a consequence, neither the draft EU Regulation

40 For more details, see below the section on key benefit-sharing obligations concerning *Genetic resources accessed in accordance with declaratory procedures*.

41 The French overseas countries and territories include the *collectivités d’outre-mer* (COM) as well as other territories, namely the French Southern and Antarctic Territories, and New Caledonia and its dependencies. The COM include Saint-Barthélemy, Wallis and Futuna Islands, French Polynesia, and Saint Pierre and Miquelon. See: [http://ec.europa.eu/regional\\_policy/sources/docconf/epa/doc/ruptom\\_en.pdf](http://ec.europa.eu/regional_policy/sources/docconf/epa/doc/ruptom_en.pdf)

42 This follows from the application of the principle of “legislative identity” which is enshrined in Article 73 of the French Constitution.

43 From February 2007, Clipperton island is subject to title II of the *loi no 55–1052 du 6 août 1955 portant statut des Terres australes et antarctiques françaises et de l’île de Clipperton*.

44 *Supra* note 41.

on ABS nor the French Biodiversity Law *as such* will apply to the *collectivités d'outre-mer* (COM).<sup>45</sup> The same can be said for the French Southern and Antarctic Territories, and New Caledonia and its dependencies.<sup>46</sup> However, selected national ABS provisions of the Biodiversity Law can be made expressly applicable to:<sup>47</sup>

- New Caledonia and French Polynesia;<sup>48</sup> and
- Wallis and Futuna, and the French Southern and Antarctic Territories.<sup>49</sup>

Finally, the COM that are defined in Article 73 of the French Constitution may request, at their own option, to exercise the functions of the competent Administrative Authority concerning declarative and authorisation procedures.<sup>50</sup> According to its drafters, this provision will allow to reconcile the uniform application of national law with the needs and prerogatives of certain COM to play a proactive role in these procedures.<sup>51</sup>

This section has synthetically described the most important features of the repartition of legislative and administrative competences between the central Government of France and its overseas territories for the scope of application of the ABS provisions of draft Biodiversity Law. While the present chapter does not consider these issues in any depth, it refers to the 2011 study by *Fondation pour la Recherche sur la Biodiversité* for background information on this topic.<sup>52</sup>

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45 With the exception of the Saint Pierre and Miquelon, to which French laws and regulations are reported to be directly applicable. See: [http://www.fondationbiodiversite.fr/images/stories/telechargement/ed\\_48\\_apa\\_outre\\_mer.pdf](http://www.fondationbiodiversite.fr/images/stories/telechargement/ed_48_apa_outre_mer.pdf), p. 39.

46 *Ibid.*

47 DBL, Title IV, Article 24. However, note that the EU Regulation on ABS will not be applicable to the territories listed below.

48 In New Caledonia and French Polynesia, the draft Biodiversity Law provides for the direct application of: the definitions of “*communauté d'habitants*” and “traditional knowledge associated with genetic resources”; as well as a provision concerning the modalities for the sharing of the benefits that arise from the use of TK associated with genetic resources, which shall be affected towards the conservation of biodiversity and associated TK at the local and community levels.

49 The draft Biodiversity law provides for the direct application of the entire ABS chapter to Wallis and Futuna, and to the French Southern and Antarctic Territories (with the exception of an article on sanctions and other final provisions).

50 DBL, Title IV, Article 412-15. See below the section on *Access to genetic resources and associated traditional knowledge*.

51 *Ibid.*

52 [http://www.fondationbiodiversite.fr/images/stories/telechargement/ed\\_48\\_apa\\_outre\\_mer.pdf](http://www.fondationbiodiversite.fr/images/stories/telechargement/ed_48_apa_outre_mer.pdf)

### III Access to Genetic Resources and Associated Traditional Knowledge

This section will consider the following key questions: how is access to genetic resources and associated traditional knowledge regulated in France under the draft Biodiversity Law? Does it rely on administrative permits or rather establish licensing mechanisms, which are autonomously administered by individual providers and other relevant entities?

A crucial distinction that needs to be drawn in order to answer the above questions is the one that lies between the access permit that concerns genetic resources and associated TK (*i.e.* an important step of the ABS procedure which authorizes their legal utilization), on the one hand, and the authorization to collect samples of biological materials, which may be required by legislation on protected areas or protected species, on the other. As regards the first type of permit, it was highlighted in the introduction that currently a voluntary access procedure allows applicants to submit their access applications to the National ABS Focal Point. In these cases, applicants may voluntarily choose to comply with specific ABS conditions and establish a contract for the sharing of the benefits.<sup>53</sup>

However, as regards the specific authorization to collect samples of biological materials, which are found *in situ*, the National Focal Point “informs applicants of the related regulations concerning access and the exportation of biological material, which apply within the existing legal framework (*e.g.* regulations on protected species and protected areas, health rules, CITES, law of the sea, etc.), and which applicants may have failed to identify on their own.”<sup>54</sup> In these cases, the kind of procedures to be followed may vary depending on the level of protection that is accorded to the concerned species or the areas from which the collection takes place.

While this chapter will not consider in any depth specific national legislation or other regulatory measures, which may have *per se* an impact on the sampling of biological materials, relevant documentation may be found through the portal of the “*Inventaire National du Patrimoine Naturel*.”<sup>55</sup> In conclusion, a specific authorization to collect samples of biological materials of protected species or for bioprospecting activities that occur in protected areas may need to be obtained by users in addition to the declaration or the access

53 See *supra* note 6.

54 *Ibid.*

55 In particular, the National Inventory for Natural Heritage is managed by the French National Museum of Natural History. See: <http://inpn.mnhn.fr/synthese/sommaire-syntheses-indicateurs>

permit to be delivered by the Competent National Authority (in accordance with the access procedures of draft Biodiversity Law).

Under the draft Biodiversity Law, access measures can be divided into three categories:

- Declarative procedures;<sup>56</sup>
- Authorization procedures concerning access to genetic resources;<sup>57</sup> and
- Authorization procedures concerning access to traditional knowledge associated with genetic resources.<sup>58</sup>

#### 1 *Declarative Procedures*<sup>59</sup>

Declarative procedures are simplified access procedures that have been envisaged for two main situations in accordance with Article 8 (a) and (b) of the Nagoya Protocol. Such procedures do not require that users of genetic resources obtain prior informed consent (in the form of an authorization from the competent administrative authority) for access-related activities.<sup>60</sup>

First, a simple declaration to the competent administrative authority is required when genetic resources are accessed with the view to increasing knowledge on biodiversity, promoting *ex situ* conservation or value enhancement for non-commercial research purposes. Second, declarative procedures will also apply in the case of emergency situations concerning human, animal or plant health, which are not already covered by specialised measures and procedures in accordance with the articles that define the scope of application of the draft Biodiversity Law (in terms of subject matter exclusions).<sup>61</sup> Finally, if the user considers that the standard modalities for benefit-sharing (that are applicable to his or her activity in accordance with the declarative procedure)<sup>62</sup> are not suitable for the envisaged activity in a specific case, the user may request to negotiate *ad hoc* benefit-sharing conditions in accordance with the authorization procedures.<sup>63</sup>

Finally, specific provisions are dedicated to *ex situ* collections of genetic resources.<sup>64</sup> In particular, holders of such collections may request the inclusion

<sup>56</sup> DBL, Title IV, Article 412-5.

<sup>57</sup> DBL, Title IV, Article 412-6.

<sup>58</sup> DBL, Title IV, Articles 412-7 to 412-12.

<sup>59</sup> DBL, Title IV, Article 412-5.

<sup>60</sup> See the following sections on *Authorization procedures*.

<sup>61</sup> See above notes 32 and 33 and the accompanying text.

<sup>62</sup> See below the section on *Key benefit-sharing obligations*.

<sup>63</sup> See below the section on *Authorization procedures concerning access to genetic resources*.

<sup>64</sup> DBL, Title IV, Article 412-13.



of the latter, in whole or in part, in the register of collections within the European Union.<sup>65</sup> When the holder of a registered collection provides access to genetic resources for utilizations that are subject to the declaration (*i.e.* in the two cases described above), the collection holder shall make the relevant declaration to the competent administrative authority on behalf of the user. The practical consequence of this provision is that users, which have accessed genetic materials from a registered collection, are *de facto* exempted from the compliance-related due diligence obligations set out in Article 412-17 of the draft Biodiversity Law.<sup>66</sup>

This is indeed a good thing for users. At the same time, it also entails a huge responsibility for the holders of collections. It will require some time and means for this responsibility to be duly taken charge of. One of the potential consequences, according to some holders, is that small collections will stop transferring their samples. The status of these holders and their position in the benefit-sharing arrangement is not clear. Therefore, it can be argued that they have many duties and responsibilities, because their role as providers is crucial, but they are unlikely to receive any direct benefits from the ABS system as it is currently envisaged.<sup>67</sup>

## 2 *Authorization Procedures Concerning Access to Genetic Resources*<sup>68</sup>

Access to genetic resources for utilizations that are not subject to *declarative procedures* requires a specific authorization, which is delivered by the competent administrative authority. Such authorization specifies the terms of use of the genetic resource for which it is granted as well as the applicable benefit-sharing conditions.<sup>69</sup>

The draft Biodiversity Law also specifies that an access authorisation may be denied when:

- the applicant and the competent authority do not reach an agreement on the applicable benefit-sharing conditions. In this case, prior to the issuance of the final decision, a conciliation procedure is made available to the applicant with the view to promoting agreement on the such conditions;

65 See article 5 of the EU Regulation on ABS.

66 See below the section on *Provisions and mechanisms to promote compliance with domestic legislation and regulatory requirements on ABS*.

67 Sarah Aubertie, Fondation pour la Recherche sur la Biodiversité, *Personal communication*, 20 June 2014 (on file with the author).

68 DBL, Title IV, Article 412-6.

69 See below the section on *Key benefit-sharing obligations* concerning genetic resources accessed in accordance with authorization procedures.

- the technical and financial capacity of the applicant is insufficient *vis-à-vis* the objectives of the proposed activity; and
- the proposed activity or its potential applications pose a significant risk for biodiversity.

Finally, any decision that denies access to a genetic resource shall be motivated.

### 3 *Authorization Procedures Concerning Access to Traditional Knowledge Associated with Genetic Resources*<sup>70</sup>

The draft Biodiversity Law envisages specific authorization procedures for the utilization of TK associated with genetic resources and the required authorization can be delivered only in accordance with such procedures.<sup>71</sup>

The text of the draft Biodiversity Law includes the following key elements. Upon its designation by the Council of State, the competent administrative authority is responsible for granting authorizations.<sup>72</sup> In each local government area, the Council of State also designates a legal person (with juridical personality under public law) with the view to organising necessary consultations with communities of inhabitants that hold traditional knowledge. Such legal person is responsible for negotiating and signing benefit-sharing agreements with users, in accordance with the outcome of such consultations.<sup>73</sup>

Upon request of the competent administrative authority, the designated legal person examines each application concerning access to traditional knowledge associated with genetic resources, defines the maximum length of the access procedure, notifies this information to the applicant, and undertakes the following specific tasks:<sup>74</sup>

- identifies the relevant community or communities of inhabitants that are concerned by the application;
- determines, as appropriate, the existence of relevant representative bodies within such communities, which may be called upon to make a decision on the utilization of traditional knowledge;

<sup>70</sup> DBL, Title IV, Articles 412-7 to 412-12.

<sup>71</sup> DBL, Title IV, Article 412-7.

<sup>72</sup> *Ibid.*

<sup>73</sup> DBL, Title IV, Article 412-8. See also the section on *Key benefit-sharing obligations* concerning TK associated with genetic resources.

<sup>74</sup> DBL, Title IV, Article 412-9.

- establishes appropriate arrangements for informing relevant communities of inhabitants and disseminates such information;
- undertakes all necessary consultations with competent institutions or bodies that are relevant to the content of the application or the concerned communities;
- ensures the participation of all concerned communities with the view to seeking their consensus; and
- prepares a report on the consultation process and its outcome, including both on whether to allow the utilization of TK and, if the parties have reached an agreement, on the sharing of the benefits arising from such utilization.

In light of the above report, the competent administrative authority may either authorize or reject, in whole or in part, the application for the utilization of traditional knowledge.<sup>75</sup> This decision is notified to the application and it is made public in accordance with conditions to be further established. The utilization of TK for purposes other than those expressly authorized in the above decision is forbidden.<sup>76</sup>

#### IV Key Benefit-Sharing Obligations

This section provides an overview of key benefit-sharing obligations in the ABS provisions of the draft Biodiversity Law. In particular, in the definition section, the latter includes a specific characterisation of benefit-sharing, which is describes as the fair and equitable sharing of the benefits that arise from the utilization of genetic resources and associated traditional knowledge – understood as to comprise the results of research and other value enhancement activities, as well as the advantages resulting from their commercial and other uses – with the State that exercise sovereignty over such resources or with the communities of inhabitants that are the holders of associated traditional knowledge.<sup>77</sup> In addition, benefit-sharing may comprise the sharing of both monetary as well as non-monetary advantages.<sup>78</sup> In considering such provisions, the opinion of the National Council for Ecological Transition particularly emphasised that it is desirable that all non-monetary benefits that arise

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<sup>75</sup> DBL, Title IV, Article 412-10.

<sup>76</sup> *Ibid.*

<sup>77</sup> DBL, Title IV, Article 412-3, 3°.

<sup>78</sup> *Ibid.*, (a) to (e).

from the use of genetic resources and associated TK are directed towards conserving and enhancing biodiversity in a broad sense, including the promotion of economic and social activities associated to it.<sup>79</sup>

### 1 *Genetic Resources Accessed in accordance with Declaratory Procedures*

Under the draft Biodiversity Law, the Council of State is mandated to establish general (model) conditions for the sharing of the benefits that arise from the utilization of genetic resources to which *declarative procedures* apply.<sup>80</sup> In addition, the benefits that arise from new uses of genetic resources, which were acquired by collections prior to the entry into effect of the CBD, are to be shared directly with the collection's holder.<sup>81</sup> In the case of post-CBD collections, the sharing of the benefits that arise from the utilization of *ex situ* materials, which were initially collected in other countries, is subject to the applicable legislation of State Parties to the CBD that have ratified the Nagoya Protocol.<sup>82</sup>

### 2 *Genetic Resources Accessed in accordance with Authorization Procedures*

When access to genetic resources is subject to the authorization of the competent administrative authority, the applicable benefit-sharing conditions are to be mutually agreed between the applicant and the authority.<sup>83</sup> An initial proposal to mandate by law that the benefit-sharing agreement shall include a clause attributing jurisdictional competence to the French administrative courts as well as a clause providing French law as the applicable law was eventually deleted from the draft.

The draft Biodiversity Law also provides that maximum thresholds for the sharing of monetary benefits that arise from activities subject to the authorization will be established by the Council of State.<sup>84</sup> These maximum thresholds are to be fixed for each relevant sectors of activity.<sup>85</sup> Finally, all monetary benefits are to be allocated to the French Agency for Biodiversity<sup>86</sup> and they

<sup>79</sup> See *supra* notes 22 and 87.

<sup>80</sup> DBL, Title IV, Article 412-5. *Emphasis added.* See above note 611 and accompanying text.

<sup>81</sup> See DBL, Title IV, Article 412-13 IV and the above section on *Temporal scope*.

<sup>82</sup> *Ibid.*

<sup>83</sup> DBL, Title IV, Article 412-6 II.

<sup>84</sup> DBL, Title IV, Article 412-6 IV.

<sup>85</sup> *Ibid.*

<sup>86</sup> The French Agency for Biodiversity is established under Title III of the draft Biodiversity Law.

will be disbursed to finance projects that fulfil the following benefit-sharing objectives:<sup>87</sup>

- (1) to enhance or preserve biodiversity *in situ* or *ex situ*;
- (2) to preserve traditional knowledge associated with genetic resources;
- (3) to contribute to local development of value chains that make sustainable use of genetic resources and associated TK, in connection with the territories that contribute to their conservation; and
- (4) to collaborate, cooperate or contribute to research, education and training activities, and to the transfer of relevant skills and technologies.

### 3 *Traditional Knowledge Associated with Genetic Resources*

This chapter has previously explained that a legal person (designated by the Council of State in accordance with relevant provisions on authorization procedures) is responsible for negotiating and signing benefit-sharing agreements with users, in accordance with the outcome of consultations with the communities of inhabitants that hold traditional knowledge associated with genetic resources.<sup>88</sup> In particular, the concerned communities can be designated as third party beneficiaries under the contract, whereas it is not expressly envisaged that they be parties to the contract as such.<sup>89</sup>

Additional clauses may be added to the contract after its conclusion by following the same procedures prescribed for the main benefit-sharing agreement.<sup>90</sup> Any clauses of a benefit-sharing contract that *exclusively* assign the right to access or use traditional knowledge shall be deemed not to have been written.<sup>91</sup> Besides, a model contract will be developed and made available through a Council of State's decree.<sup>92</sup>

The legal person referred to above may temporarily or permanently manage, as it may be required, vested property and other assets that arise from the execution of the benefit-sharing agreement on behalf of its beneficiaries.<sup>93</sup> In the event of the disappearance of a designated beneficiary under the contract, the benefit-sharing agreement may provide that the legal person referred to

87 DBL, Title IV, Articles 412-6 V and 312-3, 3° (a) to (d).

88 See DBL, Title IV, Articles 412-8 and 412-11, and the above section on *Authorization procedures concerning access to traditional knowledge associated with genetic resources*.

89 *Ibid.*

90 *Ibid.*

91 DBL, Title IV, Article 412-11 II.

92 DBL, Title IV, Article 412-11 III.

93 DBL, Title IV, Article 412-8.

above will succeed to the rights of that beneficiary.<sup>94</sup> When vested property and other assets arising from the benefit-sharing agreement are not assigned to a third party beneficial owner under the contract, they shall be assigned by the user to the legal person that signs contract.<sup>95</sup> Such legal person shall ensure that the management and the assignment of property and other assets benefit the concerned communities of inhabitants.<sup>96</sup> Such benefits may only be used for projects that directly further such communities.<sup>97</sup> The above legal person has also the right to bring civil law suits against users for any violations of the ABS provisions of the Biodiversity Law.<sup>98</sup>

However, the concept of “communities of inhabitants,” which is employed in the draft Biodiversity Law to translate the reference to “indigenous and local communities” (*i.e.* the expression used in the Nagoya Protocol), *prima facie* falls short of recognising the full range of rights that shall be attributed to such communities. As previously explained, the draft Biodiversity Law does envisage a consultative procedure with the aim of ensuring the approval and involvement of relevant communities of inhabitants for access to TK associated with genetic resources. However, on the one hand, the plain meaning of the articles described above may eventually allow by-passing traditional authorities when consensus cannot be reached on a benefit-sharing agreement between them and the users. If this was the case, such procedures would clearly violate international human rights minimum standards, namely those concerning the rights of indigenous peoples to express their “free prior and informed consent” for access to their cultural, intellectual, religious and spiritual property, in accordance with the UN Declaration on the Rights of Indigenous Peoples (UNDRIP).<sup>99</sup> On the other, the draft Biodiversity Law does

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94 DBL, Title IV, Article 412-12 III.

95 DBL, Title IV, Article 412-12 II.

96 DBL, Title IV, Article 412-12 I.

97 *Ibid.*

98 DBL, Title IV, Article 412-12 II.

99 UNDRIP, which was adopted in 2007 with support by France, sets out international minimum standards for the protection of the rights and well-being of indigenous peoples. In particular, UNDRIP, Article 11 states that: “Indigenous peoples have the right to practise and revitalize their cultural traditions and customs. This includes the right to maintain, protect and develop the past, present and future manifestations of their cultures, such as archaeological and historical sites, artefacts, designs, ceremonies, technologies and visual and performing arts and literature. States shall provide redress through effective mechanisms, which may include restitution, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their *free, prior and informed consent* or in violation of their laws, traditions and customs.” *Emphasis added.*

not make any reference to communities' customary laws, and to community protocols and procedures, while – at least in principle – it is required to take them into account in accordance with Article 12.1 of the Nagoya Protocol. Finally, under the current draft procedures, neither the prior informed consent nor the approval and involvement of relevant communities is required for accessing genetic resources “where [such communities] have established rights to grant access to [them].”<sup>100</sup> In particular, the Special Rapporteur on the Rights of indigenous peoples expressly highlighted that:<sup>101</sup>

Concern has been expressed that the reference to established rights in accordance with domestic legislation in these articles could be interpreted to suggest that the rights of indigenous peoples to genetic resources can only be established by domestic law, not international law. [...] Current discussions are focused on [...] ensuring indigenous participation and the incorporation of customary procedures within the “access and benefit-sharing clearing house” established under Article 14, which will serve as the place for sharing information related to access and benefit-sharing by parties to the Protocol [, and on] develop[ing] measures to establish and strengthen mechanisms to address non-compliance at the domestic level.

## V Provisions and Mechanisms to Promote Compliance with Domestic Legislation and Regulatory Requirements on ABS

This section provides an overview of available mechanisms and procedures that will enable compliance with domestic ABS provisions and regulatory requirements. In particular, it focuses on how compliance with foreign prior informed consent (PIC) and mutually agreed terms (MAT) can be monitored and enforced in France based on the compliance provisions of the draft Biodiversity Law.

100 Nagoya Protocol, Articles 5.2 and 6.2. See, in particular, the section on “Established rights” under Article 5 of the Nagoya Protocol, in Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unraveling the Nagoya Protocol. A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity* (Brill/Martinus Nijhoff: 2014, forthcoming).

101 James Anaya, Report of the Special Rapporteur on the rights of indigenous peoples (2012) UN Doc. A/67/301, para. 60–61, available at: <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N12/460/87/PDF/N1246087.pdf?OpenElement>.

At the outset, it must be highlighted that the drafters have explicitly excluded from the scope of application of the compliance provisions activities that involve the utilization of genetic resources and associated TK for the purpose of animal breeding and selection, as well as the utilization of plant varieties legally commercialised on the market.<sup>102</sup>

As regards the obligations to monitor the utilization of genetic resources and associated TK, the competent administrative authority makes available to the Clearing-House mechanism of the CBD<sup>103</sup> relevant authorizations and official records of declarations, in accordance with Article 14 of the Nagoya Protocol.<sup>104</sup> Upon their registration in the Clearing-House, these documents will acquire the status of internationally recognised certificates of compliance in accordance with Article 17.2 of the Nagoya Protocol.<sup>105</sup> However, the applicant may expressly request the administrative authority to keep specific pieces of information that are included in the dossier confidential, if their disclosure would otherwise encroach on the protection of trade or industrial secrets of the applicant.<sup>106</sup>

In the case of transfer of genetic resources or associated TK to a third party for their utilization, the first user must transfer to any subsequent user the authorization or the official record of the declaration, as well as the relevant benefit-sharing obligations.<sup>107</sup> A change of use which is not initially foreseen in the relevant authorization or in the official record of the declaration will require a new authorization or declaration.<sup>108</sup>

Users of genetic resources and associated TK are responsible for conserving and making available certain information to ensure compliance with domestic legislation and regulatory requirements on ABS of the party to the Nagoya Protocol providing the genetic resource or associated TK, as well as the fair and equitable sharing of the benefits that arise from their utilization in accordance with MAT, where applicable. In particular, users shall make available the information prescribed in Article 4 of EU Regulation on ABS in the following occasions:<sup>109</sup>

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102 DBL, Title IV, Article 412-16 I.

103 CBD Article 18(3).

104 DBL, Title IV, Article 412-14 II.

105 *Ibid.*

106 DBL, Title IV, Article 412-14 I.

107 DBL, Title IV, Article 412-14 III.

108 *Ibid.*

109 DBL, Title IV, Article 412-16 II (1) and (2). In accordance with Article 4(3) of the EU Regulation on ABS, "[...] users shall seek, keep and transfer to subsequent users: (a) the internationally recognised certificate of compliance, as well as information on applicable



- a) when they have received public research funding that involves the use of genetic resources or associated traditional knowledge; or
- b) at the time of commercialisation of a product or process developed on the basis of genetic resources or associated TK.

Under the above letter (a), in case of non-compliance with the obligation to provide the required information at relevant checkpoints, the administrative act, which assigns a public grant in support of research activities that involve the use of genetic resources or associated traditional knowledge, shall include a contractual clause that requires the recipient of funds to reimburse the grant.<sup>110</sup>

Under letter (b) concerning products or processes subject to market approval, relevant information is collected by the authority competent for the market approval process without examination.<sup>111</sup> Such information is then transmitted to the competent administrative authority that is responsible for the application of the EU Regulation on ABS.<sup>112</sup> In addition, when a patent application arises from the utilization of genetic resources and associated traditional knowledge, the applicant shall transmit, on his or her own initiative, the above information to the National Industrial Property Institute (INPI). In this case, the INPI makes this information available to the competent administrative authority

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benefit-sharing obligations; or (b) where no [such] certificate is available, information and relevant documents on:

- i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;
- ii) the description of the genetic resources or of [associated] traditional knowledge [...];
- iii) the source from which genetic resources or [associated] traditional knowledge were directly obtained as well as subsequent users of genetic resources or [associated TK];
- iv) the presence or absence of rights and obligations related to access and benefit sharing including rights and obligations regarding subsequent applications and commercialisation;
- v) access permits, where applicable;
- vi) mutually agreed terms, including benefit sharing agreements, where applicable.”

Besides, “[u]sers acquiring PGRFA in a country that is a Party to the Nagoya Protocol and which has determined, that PGRFA under its management and control and in the public domain, not contained in Annex I of the ITPGRA, will also be subject to the terms and conditions of the Standard Material Transfer Agreement for the purposes set out under the ITPGRFA shall be considered to have exercised the due diligence requirements set out in paragraph 3 [...]” of Article 4 of the EU Regulation on ABS.” EU Regulation on ABS Article 4(3)(b).

<sup>110</sup> DBL, Title IV, Article 412-16 II (1).

<sup>111</sup> DBL, Title IV, Article 412-16 II (2).

<sup>112</sup> *Ibid.*

that is responsible for the application of the EU Regulation on ABS, without examining it.<sup>113</sup>

A draft proposal to include in the draft Biodiversity Law the legal presumption that users, which have accessed genetic resources from a registered collection within the European Union, shall be considered to have complied with their due diligence obligations was eventually deleted from the currently text. However, such legal presumption will be still an integral element of the French legal framework and it is going to be directly enforceable in France by virtue of Article 4(4) of the EU Regulation on ABS. Similarly, in light of the fact that such obligation is already included in Article 4(3)(a) of the EU Regulation on ABS, a draft article providing that users shall discontinue the utilization of genetic resources and associated TK if the legality of their access is uncertain or insufficiently established, was eventually deleted from the draft Biodiversity Law. In addition, a draft article, which provided that information that is collected or received under the above provisions must be made available not only to the ABS Clearing-House mechanisms of the CBD (in accordance with Article 14 of the Protocol), but also to the competent national authorities of other State Parties to the Protocol, was not retained.

Finally, the draft Biodiversity Law includes specific provisions on civil law remedies as well as criminal sanctions for the violation of the obligations enshrined in its ABS provisions. In particular, a user can be liable to a term of imprisonment of one year and a fine of 150 000 Euros if he or she utilises genetic resources or associated TK without having at his or her disposal the documents referred to in Article 4(3) of the EU Regulation on ABS, when such documents are required by law.<sup>114</sup> The same sanctions can apply to users, which have failed to exercise due diligence by not seeking, keeping and transferring to subsequent users relevant ABS-related information in accordance with Article 4 of the EU Regulation on ABS.<sup>115</sup> The fine can be augmented up to 1 000 000 Euros when the illegal utilization of genetic resources and associated TK is undertaken for commercial purposes.<sup>116</sup> Additional complementary penalties may be also ordered by the competent court with the view to prohibiting the infringing user to apply for access to genetic resources and associated TK – or to a specific subcategory of genetic resources – for their commercial utilization during a maximum period of five years.<sup>117</sup>

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<sup>113</sup> *Ibid.*

<sup>114</sup> DBL, Title IV, Article 20(1).

<sup>115</sup> DBL, Title IV, Article 20(2).

<sup>116</sup> DBL, Title IV, Article 20(3).

<sup>117</sup> DBL, Title IV, Article 20(4).

## VI Competent National Authorities and Relevant Institutional Arrangements

This section considers relevant institutional arrangements and the distribution of ABS-related competences in France. It also provides an overview of how different departments may be coordinated with the view to regulating ABS issues both in France and its overseas territories.

The draft Biodiversity Law provides that the Council of State will designate the competent administrative authority/ies by decree.<sup>118</sup> An anonymous informant explained that the French Environmental Authority will likely be designated competent administrative authority.<sup>119</sup> However, the wording used in the draft Biodiversity Law reflects the fact that there is a possibility that this Authority might further delegate its competences, as appropriate, to: (1) the French Biodiversity Agency<sup>120</sup>; (2) (probably public) owners of registered collections; and (3) local authorities of overseas territories.<sup>121</sup> Therefore, upon express request, the local authorities of Martinique, Guadeloupe, French Guiana, Réunion and Mayotte will be provided the opportunity to exercise the functions of the competent administrative authority with regard to the three access procedures envisaged by the law.<sup>122</sup> On the contrary, the French overseas countries and territories of New Caledonia, Saint-Barthélemy, Wallis and Futuna, and French Polynesia may independently exercise relevant administrative functions and establish appropriate institutional arrangements (with the exclusion of criminal law sanctions).

In addition to the competent administrative authority (or authorities), the legal person designated by the Council of State (within the framework of the

<sup>118</sup> DBL, Title IV, Articles 412-5 I and 412-6 I.

<sup>119</sup> In French, *Autorité environnementale* (AE) or *autorité de l'Etat compétente en matière d'environnement*. Anonymous informant, personal communication, 12 February 2014.

<sup>120</sup> *L'Agence Française de la Biodiversité* is established under Title 3 of draft the Biodiversity Law.

<sup>121</sup> Gilles Kleitz, Technical Adviser on Biodiversity to Jean-Louis BORLOO, then State Minister for Environment, Transport, Energy, Seas and Sustainable Development, *personal communication*, 12 February 2014 (on file with the author).

<sup>122</sup> This is in line with the opinion of the National Council for Ecological Transition, which has emphasised that several of its members supported the possible decentralization, upon voluntary request, of the authorization procedures described above in favour of relevant administrative bodies of overseas departments (DROM), without reaching full consensus. See above also the sections on *Authorization procedures concerning access to genetic resources* and *Authorization procedures concerning access to traditional knowledge associated with genetic resources*.

authorization procedures that concern access to TK associated with genetic resources) also plays a critical role.<sup>123</sup> It plays such important role particularly during the consultations for the effective participation of relevant communities of inhabitants during the negotiation of benefit-sharing arrangements with potential users. In sum, while the competent administrative authority is responsible for the final decision to grant or deny the authorization to use genetic resources and associated TK, in the latter case, the above legal person negotiates and signs the benefit-sharing agreement, and it performs a range of other critical duties both prior to the conclusion, and during the execution, of the agreement.<sup>124</sup>

## VII Compliance with the Nagoya Protocol

Since this analysis is based on draft legislation, which was not yet adopted by the Parliament (and that may be subject to further amendments), this chapter will abstain from commenting on whether its provisions comply with international obligations that arise from the forthcoming ratification of the Nagoya Protocol by France.<sup>125</sup>

## VIII Conclusions

This chapter has provided a critical overview of the changing landscape concerning the legal status of genetic resources and associated traditional knowledge in France. In particular, it has focused on: the scope of application of the ABS provisions of the Biodiversity Law; the three procedures available to those seeking access to genetic resources and associated TK, as well as the related benefit-sharing obligations; the provisions and mechanisms to promote compliance with domestic legislation and regulatory requirements on ABS of

<sup>123</sup> DBL, Title IV, Article 412-8.

<sup>124</sup> See above relevant sections on *Access to TK associated with genetic resources and benefit sharing* from its utilization.

<sup>125</sup> Interestingly, a draft provision of the Biodiversity Law, which initially foresaw a review process that could have been potentially useful to promote compliance with the Protocol, was not retained in the final text presented to the Council of Ministers. In particular, such proposal had envisaged that the ABS provisions of the draft Biodiversity Law be subject to an evaluation after the period of five years after their implementation and that a report be submitted to the French Parliament, which might subsequently consider adopting the necessary amendments. Such revision is no longer expressly envisaged by the DBL.

another state Party to the Nagoya Protocol; and the competent administrative authorities in France.

This concluding section finally highlights three crucial regulatory aspects of the draft Biodiversity Law that are particularly important in light of its possible interactions with international standards and obligations arising respectively from human rights law and intellectual property law, on the one hand, and for the overall consistency and effectiveness of the international regime on ABS, on the other.

First, the concept of “communities of inhabitants,” which is employed in the draft Biodiversity Law to translate references to “indigenous and local communities” in the Nagoya Protocol, *prima facie* falls short of recognising the full range of rights that shall be attributed to such communities. Therefore, there is scope to make critical improvements to the ABS provisions of draft Biodiversity Law with regard to the further establishment and protection of the rights of indigenous and local communities, in accordance with international human right standards under international law.<sup>126</sup>

Second, as regards the relationship between the Biodiversity Law and the French intellectual property system, the draft ABS provisions are an important step forward towards promoting their synergies and improving transparency on the utilization of genetic resources and associated TK. It was explained earlier that such provisions provide for disclosure of origin of genetic resources and associated TK in patent applications. In particular, amongst other relevant checkpoints, when a patent application arises from the utilization of genetic resources and associated TK, the applicant shall transmit, on his or her own initiative, the required information to the National Industrial Property Institute (INPI). The INPI will make this information available to the French competent administrative authority and – through the latter – to the ABS Clearing-House mechanisms of the CBD. It is worth emphasising that the identification of the INPI as a checkpoint to monitor compliance with domestic legislation or regulatory requirements on ABS goes beyond what is legally required under the Nagoya Protocol<sup>127</sup> and the standards implemented by the EU Regulation on ABS.<sup>128</sup> Therefore, this development should be welcomed as an important indication of the willingness of the French Government to implement the compliance provisions of the Nagoya Protocol in an effective manner.

However, the potential impact of these norms shall not be overemphasised – at least in terms of their intellectual property-related implications. In France, as

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<sup>126</sup> See *supra* note 99 and accompanying text.

<sup>127</sup> Nagoya Protocol Article 17.

<sup>128</sup> See, in particular, EU Regulation on ABS, Article 7 on “Monitoring user compliance.”

well as in most other countries in the European region, there are three different types of patents, which will both coexist and be enforceable within its borders. They are:

- (1) national patents filed through the INPI;
- (2) European “classical” bundle patents filed through the European Patent Office and validated in each of the designated states; and
- (3) European patents with unitary effect.<sup>129</sup>

While the text of the draft Biodiversity Law – in particular, its disclosure provision – certainly applies to the filing of national patents at the INPI, such patents are quite marginal in terms of their numbers and relative importance for the life sciences *vis-à-vis* the other two patent types. Therefore, if such disclosure measures are to be designed in such a way as to have any teeth, the interpretation of relevant ABS provisions shall be sufficiently broad to imply that users seeking the enforcement of *any* patents in France will have to communicate relevant information to the INPI – independently of whether such patents were initially filed through the INPI or elsewhere.

This would have also a positive “virus” effect that could enable the discovery of biopiracy cases, which may occur within the jurisdiction of other countries – even if the latter do not provide for patent disclosure – by mapping all patents within the same “family” of the patent for which an initial disclosure is required by France.<sup>130</sup> In conclusion, despite the remarkable improvements introduced by the draft Biodiversity Law over and above exiting regional and international instruments, the potential gains arising from a functional and

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<sup>129</sup> In particular, with regard to the last two types of patents, Article 2 of the Agreement on a Unified Patent Court (UPC) distinguishes between the patents that can exist under the UPC scheme as follows:

- “European patent” means a patent granted under the provisions of the EPC, which does not benefit from unitary effect by virtue of Regulation (EU) No 1257/2012.
- “European patent with unitary effect” means a patent granted under the provisions of the EPC which benefits from unitary effect by virtue of Regulation (EU) No 1257/2012.

Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013;175:0001:0040:EN:PDF>

For more details see also: <http://ipkitten.blogspot.fr/2014/02/the-problem-of-mixed-european-patents.html>.

<sup>130</sup> “A patent family is a set of either patent applications or publications taken in multiple countries to protect a single invention by a common inventor(s) and then patented in more than one country. A first application is made in one country – the priority – and is then extended to other offices.” See: [http://www.epo.org/searching/essentials/patent-families\\_fr.html](http://www.epo.org/searching/essentials/patent-families_fr.html).

effective system to monitor user compliance are not a low hanging fruit that may be easily reaped without strong cooperation at the European regional level.

Finally, with regard to the overall consistency of the draft Biodiversity Law not only with the Nagoya Protocol, but also with the international regime on ABS and its different articulations,<sup>131</sup> the following considerations may be advanced. The broad set of subject matter exclusions provide by the Biodiversity Law for genetic resources and associate TK that are not (yet) covered by any specialised ABS instruments, in conjunction with legal presumptions concerning user compliance (in cases of resources and knowledge accessed from registered collections within the European Union), may be a cause for concern of our trading partners in the South as well as of French researches.<sup>132</sup> Serious endeavours remain to be done both in the final steps towards designing and adopting the Biodiversity law, as well as in its national implementation to show a constructive commitment to international equity, transparency in the use of genetic resources and associated TK, and towards promoting full respect for human rights both domestically and abroad.

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<sup>131</sup> CBD COP Decision X/1, through which the Nagoya Protocol was adopted in 2010, recognizes “that the International Regime is constituted of the Convention on Biological Diversity, 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, as well as complementary instruments, including the International Treaty on Plant Genetic Resources for Food and Agriculture and the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.”

<sup>132</sup> See, for instance, Brendan Tobin, “Biopiracy by Law: European Union Draft Law Threatens Indigenous Peoples’ Rights over their Traditional Knowledge and Genetic Resources,” *European Intellectual Property Review* 2 (2014): 124–136.

*IX Annex I*

N° 1847

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# ASSEMBLÉE NATIONALE

CONSTITUTION DU 4 OCTOBRE 1958  
QUATORZIÈME LÉGISLATURE

Enregistré à la Présidence de l'Assemblée nationale le 26 mars 2014.

## PROJET DE LOI

*relatif à la biodiversité,*

(Renvoyé à la commission du développement durable et de l'aménagement du territoire, à défaut de constitution d'une commission spéciale dans les délais prévus par les articles 30 et 31 du Règlement.)

### PRÉSENTÉ

au nom de M. Jean-Marc AYRAULT,

Premier ministre,

par M. Philippe MARTIN,  
ministre de l'écologie, du développement durable et de l'énergie.

[...]



#### TITRE IV. – Accès aux ressources génétiques et partage des avantages

Le titre IV du projet de loi relative à la biodiversité vise à introduire une nouvelle section au code de l'environnement intitulée « Accès aux ressources génétiques et aux connaissances traditionnelles associées, et partage juste et équitable des avantages découlant de leur utilisation ». Son objet est la mise en œuvre du protocole de Nagoya signé par la France le 20 septembre 2011 dans le cadre de la convention sur la diversité biologique, du 22 mai 1992, publiée par le décret n° 95-140 du 6 février 1995.

La convention sur la diversité biologique (CDB), négociée sous l'égide des Nations unies lors du Sommet de la Terre à Rio en 1992, a mis en place un cadre pour remédier à l'érosion mondiale de la biodiversité et des écosystèmes. Elle définit trois objectifs: la conservation *in situ* (dans le milieu naturel) et *ex situ* (dans des collections) de la diversité biologique, l'utilisation durable de ses éléments, et le partage juste et équitable des avantages issus de l'utilisation des ressources génétiques. Ce troisième objectif fait l'objet d'un instrument international spécifique et juridiquement contraignant, le protocole de Nagoya.

Le protocole de Nagoya a été signé par la France le 20 septembre 2011 et devrait entrer en vigueur fin 2014, ou fin 2015 conformément aux engagements internationaux dits « Objectifs d'Aïchi »<sup>(1)</sup> adoptés par les Parties à la Convention sur la diversité biologique (CDB) dont la France en octobre 2010.

Il impose aux États parties de s'assurer d'une part d'un « partage juste et équitable des avantages » découlant de l'utilisation des ressources génétiques et des connaissances traditionnelles associées à ces ressources génétiques, selon des « conditions convenues d'un commun accord » (article 5 du protocole de Nagoya), et d'autre part du respect sur leur territoire des législations prises au titre du protocole de Nagoya, par les États Parties à ce protocole. Le règlement européen en cours d'adoption fixera des règles s'appliquant sur tout le territoire de l'Union européenne pour garantir cette conformité au protocole.

Le protocole n'impose pas en lui-même de réglementer l'accès aux ressources génétiques et aux connaissances traditionnelles, chaque État partie étant libre de conditionner ou non cet accès au « consentement préalable en connaissance de cause » (article 6 du protocole de Nagoya).

À l'instar de la plupart des États européens, la France aurait donc pu faire le choix de ne pas réglementer l'accès à ses ressources génétiques et connaissances traditionnelles associées. Mais contrairement à ces pays, la France héberge une extraordinaire biodiversité à la fois *in situ* (dans des milieux naturels ultra-marins et méditerranéens notamment) et *ex situ* (dans des collections scientifiques qui comprennent plusieurs millions d'échantillons). Cette biodiversité fait partie des atouts de la France. Sa pérennité doit être préservée.

Ainsi, le Gouvernement s'est engagé lors de la conférence environnementale de septembre 2012 à mettre en place un régime d'accès et de partage des avantages (APA) en France en vue de la ratification du protocole de Nagoya. Cet engagement a été transcrit dans la feuille de route pour la transition écologique (volet biodiversité, points 2 et 13). Il s'inscrit dans la volonté de reconquête de biodiversité exprimée lors de la conférence environnementale. Il s'agit également de garantir la sécurité juridique des utilisateurs français de ressources génétiques et de connaissances traditionnelles.

Le principe de souveraineté de l'État sur les ressources génétiques relève de l'article L. 110-1 du code de l'environnement qui dispose dans son I modifié par le titre I<sup>er</sup> de cette loi que « Les espaces, ressources et milieux naturels terrestres et marins, les sites, les paysages, la qualité de l'air, les êtres vivants, la biodiversité font partie du patrimoine commun de la nation ». Cette souveraineté implique une responsabilité par rapport à la protection et à la gestion durable de ce patrimoine.

En effet, la France abrite une importante biodiversité, tout d'abord *in situ*: la métropole compte environ 4 900 plantes supérieures indigènes, ce qui la classe au quatrième rang européen. La zone méditerranéenne fait partie des trente-quatre points chauds mondiaux de la biodiversité caractérisés par une biodiversité riche mais fragilisée et un très fort taux d'endémisme (75% des plantes supérieures et entre 55 et 90% des vertébrés de France métropolitaine selon l'institut de recherche pour le développement – IRD). La France abrite en outre-mer un patrimoine biologique exceptionnel, sur plusieurs continents et zones bioclimatiques: la Guyane par exemple se situe dans l'un des plus grands massifs forestiers mondiaux, l'Amazonie. Enfin, le milieu marin français couvre 3% des mers et océans de la planète, dans les trois océans, représente le deuxième domaine maritime au monde, 10% des récifs coralliens et des lagons de la planète et héberge 13 000 espèces endémiques. La Polynésie française possède près de 20% des atolls coralliens de la planète.

En France, d'importants efforts de conservation *ex situ* sont déployés par des établissements de recherche publique qui jouent un rôle majeur au niveau mondial: le Muséum national d'histoire naturelle (MNHN) gère une centaine de collections comprenant plus de 60 millions de spécimens de matériel génétique ou minéral et dont certaines ont été initiées dès la fin du XVIII<sup>e</sup> siècle. L'Institut national de recherche agronomique (INRA) a constitué depuis plus de cinquante ans des collections de ressources génétiques végétales, microbiennes et animales. Le Centre de coopération internationale en recherche agronomique pour le développement (CIRAD) conserve dans plus de cent collections des ressources génétiques issues d'environ cinq cents espèces utiles pour les pays tropicaux. Les collections de l'Institut Pasteur

contiennent environ 15 000 souches de microorganismes pathogènes (virus, bactéries, champignons microscopiques).

Cette richesse génétique d'importance environnementale et sociétale majeure, est à la base de l'innovation scientifique et d'une multitude d'applications commerciales.

Les ressources génétiques ont une importante valeur d'option car les sociétés humaines doivent pouvoir puiser dans un large capital de ressources génétiques pour assurer leur adaptabilité et leur sécurité alimentaire, par exemple pour la conception de nouveaux médicaments, l'amélioration génétique des races d'animaux domestiques ou la sélection de plantes adaptées aux conditions locales.

Ainsi, pays riche en biodiversité et doté de secteurs pharmaceutique, cosmétique et agroalimentaire majeurs, la France est à la fois un pays fournisseur et utilisateur de ressources génétiques et de connaissances traditionnelles associées. Il convient donc à ce titre, qu'elle se dote d'un dispositif équilibré, qui préserve à la fois la diversité biologique et la compétitivité économique.

La « biopiraterie » ou le « pillage » des ressources génétiques sont des termes employés notamment par la société civile pour désigner les pratiques d'accès ou d'utilisation de certains acteurs utilisant la biodiversité en particulier dans des pays en développement, qui ne rétribuent pas ceux qui ont contribué à la préservation des ressources génétiques et connaissances traditionnelles associées. Dans ce contexte, le titre IV vise à faciliter l'accès aux ressources génétiques et connaissances traditionnelles associées pour les « utilisateurs » (chercheurs, entreprises), en clarifiant les attentes des « fournisseurs » (Nation en ce qui concerne les ressources génétiques, communautés d'habitants en ce qui concerne les connaissances traditionnelles associées). Cette sécurité juridique accrue contribuera au maintien d'un dynamisme d'innovation et de partenariats pérennes bénéficiant à l'ensemble des acteurs.

Actuellement, l'accès aux ressources génétiques et aux connaissances traditionnelles associées en vue de leur utilisation se fait sans encadrement réglementaire et sous différentes formes: prélèvement de matériel biologique dans des conditions *in situ* (en milieu naturel) et *ex situ* (dans des collections), consultation de séquences génétiques éventuellement dématérialisées; et dans le cas des connaissances traditionnelles associées, par l'acquisition d'informations via des entretiens ou des publications.

Le dispositif d'accès et de partage des avantages découlant de l'utilisation des ressources génétiques et des connaissances traditionnelles associées (APA) proposé est constitué de trois volets: *i*) l'accès pour une utilisation en recherche et développement (R&D), c'est à dire les procédures à respecter au moment de l'accès à une ressource génétique ou à une connaissance traditionnelle associée

en vue de son utilisation en R&D; *ii*) le partage des avantages, à mettre en place selon la nature de l'utilisation prévue (commerciale ou non-commerciale); et *iii*) la conformité, c'est à dire le fait pour un utilisateur, d'être à tout moment en mesure de prouver le respect du protocole de Nagoya et des législations prises à ce titre *via* la « diligence nécessaire » en France et à l'international.

Les volets *i*) et *ii*) correspondent à la sous-section 2 du titre IV, et le volet *iii*) à sa sous-section 3.

La structuration en 3 sous-sections du titre IV correspond à la logique séquentielle d'un projet de R&D.

La sous-section 1 composée d'un article unique L. 412-3, présente plusieurs définitions reprenant pour l'essentiel celles de la convention sur la diversité biologique et du protocole de Nagoya. Ces définitions sont utiles à la lisibilité du dispositif pour en préciser le champ d'application. La notion de communauté autochtone et locale présente dans le Règlement européen (considérant 5) est traduite en droit français, comme étant la communauté d'habitants englobant des modes de vie traditionnels qui présentent un intérêt pour la conservation et l'utilisation durable de la diversité biologique.

La sous-section 2 présente les règles relatives à l'accès aux ressources génétiques et aux connaissances traditionnelles associées sur le territoire national et au partage des avantages découlant de leur utilisation. Le dispositif prévu s'inspire repose sur un régime dual adapté aux pratiques des secteurs concernés: déclaration, dans la plupart des cas, et demande d'autorisation lorsqu'il y a commercialisation de ressources génétiques et de connaissances traditionnelles associées.

Une grande latitude sera possible pour définir l'échelle de la déclaration ou de la demande (ex: pour plusieurs ressources génétiques en même temps).

Tant que la R&D ne débouche pas sur un produit ou un procédé commercialisable, l'acteur concerné pourra dans un premier temps procéder à une déclaration, puis dès que la perspective de commercialisation se précisera et en tout état de cause, avant la mise sur le marché, procéder à une demande d'autorisation.

La sous-section 3 présente certaines des règles relatives à l'utilisation des ressources génétiques et connaissances traditionnelles associées, rendues nécessaires pour l'application du Règlement du Parlement européen et du Conseil relatif aux mesures concernant le respect par les utilisateurs dans l'Union du protocole de Nagoya sur l'accès aux ressources génétiques et le partage juste et équitable des avantages découlant de leur utilisation, qui devrait être adopté définitivement en avril 2014.

Enfin des dispositions prévoient le régime de contrôles et de sanctions applicables en cas de non-respect de la législation nationale et des législations

étrangères, que la France est tenue de définir au titre des articles 7, 9, 10 et 11 du projet de règlement européen.

Dans la sous-section 1, il est précisé que les définitions présentées à l'article L. 412-3 ne s'appliquent qu'à la section 3 relative à l'APA dans le code de l'environnement. Elles sont sans préjudice de définitions éventuellement différentes du même code ou d'autres codes. Les exemples de partage des avantages cités à titre indicatif sont issus de l'annexe du protocole de Nagoya.

Dans la sous-section 2, au sein du paragraphe 1, l'article L. 412-4 rappelle dans son premier alinéa les objectifs du dispositif en concordance avec ceux affichés dans les articles 1 et 5 du protocole de Nagoya. Il vise à faciliter des pratiques de recherche et développement respectueuses dans un cadre partenarial et avec un retour positif sur la biodiversité.

Il précise dans son II les activités déclenchant l'application du dispositif. Il s'agit des activités de recherche et développement (R&D), menée par des acteurs français ou étrangers, personne morale ou privée, travaillant pour le secteur public ou privé, sur les ressources génétiques (ex: métabolisme d'un insecte pouvant déboucher sur la découverte de molécules intéressantes) et les connaissances traditionnelles associées (ex: connaissances d'une population sur les propriétés médicinales d'une plante). Le fait générateur de l'application de l'APA est l'utilisation dans le cadre d'une activité de recherche et développement et non l'accès à la ressource ou à la connaissance en tant que telle.

Son alinéa III liste les activités et les situations n'entrant pas dans le champ d'application (par référence aux articles 3 et 12.4 du protocole de Nagoya, et aux articles 4 et 15 de la Convention sur la diversité biologique).

L'alinéa IV liste les ressources génétiques et situations qui seront concernées par des dispositions spécifiques, dans le cadre du code rural et de la pêche maritime pour les ressources génétiques issues des espèces végétales cultivées et animales domestiquées et du code de la santé publique pour les microorganismes pathogènes pour tenir compte des procédures administratives spécifiques existantes et de la structuration particulière des acteurs concernés.

Enfin, le V précise le cas des collections de ressources génétiques et de connaissances traditionnelles associées déjà constituées avant l'entrée en vigueur de la loi. Cet article permet d'explicitier que les accès visés sont à la fois *in situ* (exemple: prélèvement d'une plante dans son milieu naturel) et *ex situ* (exemple: acquisition d'un échantillon d'une plante en collection auprès d'un conservatoire botanique). Exclure totalement les collections *ex situ* du dispositif aurait conduit à le vider de son sens, étant donné qu'une partie importante des ressources utilisées par la recherche sont issues de collections dont certaines très anciennes. Conformément au principe de non-rétroactivité de la loi, et puisque le fait générateur de l'application de l'APA est l'utilisation, seules les

nouvelles utilisations de ressources génétiques ou connaissances traditionnelles associées déjà présentes en collection, et non les utilisations passées et en cours, seront soumises au dispositif. De même, seuls les avantages nés de la nouvelle utilisation feront l'objet d'un partage.

Au sein du paragraphe 2, l'article L. 412-5 présente les procédures déclaratives, les situations dans lesquelles elles sont applicables et leurs modalités, ainsi que les modalités du partage des avantages dans ce cadre. Par référence à l'article 8 du protocole de Nagoya, l'État permettra par une procédure très simplifiée l'accès aux ressources génétiques relevant de sa souveraineté pour les utilisations sans intention de développement commercial, notamment les recherches académiques, et dans les situations d'urgence menaçant la santé humaine, végétale et animale.

L'accès est simplifié dans la mesure où l'utilisateur devra simplement informer l'autorité administrative par le biais d'une déclaration informatisée, et souscrira à des modalités standard de partage des avantages définies spécialement pour ces cas d'utilisations sans intention de développement commercial. Les avantages seront alors essentiellement non-maténiels (exemple: dépôt de doubles d'échantillons dans une institution locale). Les modalités générales de partage des avantages seront définies dans le cadre d'une large concertation en fonction de critères géographiques et sectoriels, de manière à définir les avantages à partager les plus pertinents. Cette concertation, au-delà des collectivités ciblées par la loi pourra s'appuyer sur les instances chargées du débat sociétal sur la biodiversité et permettra la prise en compte des intérêts de tous les acteurs. Si ces modalités générales de partages ne conviennent pas à un utilisateur, il peut choisir de les négocier en passant par le régime d'autorisation.

Au sein du paragraphe 3, l'article L. 412-6 présente les procédures d'autorisation pour l'accès aux ressources génétiques, les situations dans lesquelles elles sont applicables et leurs modalités, ainsi que les modalités du partage des avantages dans ce cadre. Le principe est celui de pouvoir définir des conditions communes d'un commun accord entre le demandeur et l'autorité administrative. Pour autant, des limites supérieures d'avantages matériels seront fixées par décret, établi dans un cadre concerté avec les mêmes acteurs que pour les modalités générales du système déclaratif. Les avantages matériels seront affectés à l'Agence française pour la biodiversité créée au titre III qui sera chargée de les affecter à des projets. À cette fin, une gouvernance sera mise en place au sein de l'agence pour sélectionner les projets. Enfin, une procédure de conciliation est prévue si les négociations entre le demandeur et l'autorité administrative pour éviter les cas de blocage.

Au sein du paragraphe 4, les articles L. 412-7 à L. 412-12 présentent les procédures d'autorisation pour l'utilisation des connaissances traditionnelles associées

à des ressources génétiques, inspirées des articles 7 et 12 du protocole de Nagoya qui prévoient que « Conformément à son droit interne, chaque Partie prend, selon qu'il convient, les mesures appropriées pour faire en sorte que l'accès aux connaissances traditionnelles associées aux ressources génétiques détenues par les communautés autochtones et locales soit soumis au consentement préalable donné en connaissance de cause ou à l'accord et à la participation de ces communautés autochtones et locales, et que des conditions convenues d'un commun accord soient établies ».

Ces articles décrivent les modalités de consultation des communautés d'habitants détentrices de connaissances traditionnelles associées aux ressources génétiques (exemple: propriétés des plantes médicinales), et les modalités du partage des avantages dans ce cadre.

La personne morale de droit public chargée des missions visées aux articles L. 412-8 à L. 412-12 s'assurera du respect de l'esprit et des dispositions du protocole de Nagoya, en particulier de celles relatives au « consentement préalable donné en connaissance de cause » par les communautés d'habitants. La procédure prévue qui se veut adaptée et souple, s'inspire des principes guidant la conduite des enquêtes publiques telles que pratiquées par les commissaires enquêteurs, ainsi que de ceux relatifs aux débats publics tels qu'organisés par la Commission nationale du débat public. Sa position d'intermédiaire entre les communautés d'habitants détentrices de connaissances traditionnelles, l'autorité administrative et l'utilisateur (exemple: une entreprise) permettra d'assurer un niveau d'information aussi équilibré que possible entre les différentes parties prenantes, en particulier dans l'intérêt des acteurs les plus faiblement organisés et outillés pour ce type de situations.

Au sein du paragraphe 5, l'article L. 412-13 présente les conditions auxquelles une collection de ressources génétiques ou de connaissances traditionnelles associées peut être labellisée par l'État (article 5 du projet de règlement européen), ainsi que les modalités du partage des avantages dans ce cadre.

La labellisation des collections par l'État français permettra leur inscription dans un registre européen et aura pour effet pratique de dispenser les utilisateurs du travail de recherche des informations relatives aux ressources génétiques et aux connaissances traditionnelles telles que visées à l'article L. 412-17.

Cette labellisation renforcera l'attractivité des collections françaises, notamment vis-à-vis des utilisateurs d'autres pays européens dont on peut supposer que les détenteurs de collection, en l'absence de législations nationales sur l'APA, auront été peu sensibilisés aux implications du protocole de Nagoya et pourraient ne pas être inscrits à ce registre.

Au sein du paragraphe 6, l'article L. 412-14 présente une série de dispositions communes à la procédure déclarative, aux procédures d'autorisation et aux

dispositions spécifiques pour certaines ressources génétiques. Ces dispositions sont relatives à la confidentialité des données, à l'articulation avec le dispositif international d'enregistrement des permis d'accès nationaux (délivrance du « certificat de conformité internationalement reconnu », véritable passeport APA, pièce majeure de la sécurité juridique des utilisateurs), aux modalités de transfert des ressources génétiques et des connaissances traditionnelles associées à des tiers.

Son dernier alinéa précise le principe général d'affectation des avantages (monétaires et non-monétaires) à la conservation, à la valorisation locale et à l'utilisation durable des ressources génétiques et des connaissances traditionnelles associées. Le protocole de Nagoya, dans son article 9, encourage les États dans cette voie sans les y contraindre. La France a choisi de privilégier le retour des avantages vers la biodiversité.

Enfin, l'article L. 412-15 prévoit la possibilité pour les collectivités d'outremer relevant de l'article 73 de la Constitution, d'exercer à leur demande les fonctions de l'autorité administrative compétente concernant les procédures déclaratives et d'autorisation. Cet article permettra ainsi de concilier l'application uniforme de la loi nationale (les procédures déjà cadrées par les articles de loi, seront complétées par des décrets pris en Conseil d'État) et les demandes de certaines collectivités d'outre-mer, très impliquées dans la préservation de la biodiversité de jouer un rôle important dans ces procédures.

La sous-section 3 vise à rendre pleinement effectives les dispositions du règlement européen qui le nécessitent.

En particulier, l'article L. 412-16 détermine le dispositif de « points de contrôle » en application de l'article 4 du projet de règlement européen qui contraint les États membres à établir de tels points de contrôle.

Dans le cas de la France, il s'agira de moments clés dans une chaîne d'utilisation de ressources génétiques et de connaissances traditionnelles associées (réception d'un financement public, dépôt d'une demande de brevet, mise sur le marché) auxquels l'utilisateur devra prouver son respect des réglementations applicables, française ou étrangères le cas échéant.

L'article 19 ajoute les agents de la concurrence, de la consommation et de la répression des fraudes, et les agents assermentés des ministères de la défense et de la recherche à la liste des agents habilités à rechercher et à constater des infractions aux procédures décrites aux sous-sections 2 et 3.

Pour respecter l'effort d'harmonisation et de simplification initié par l'ordonnance n° 2012-34 du 11 janvier 2012 portant simplification, réforme et harmonisation des dispositions de police administrative et de police judiciaire du code de l'environnement, et en application de l'article 11 du projet de règlement européen qui demande aux États membres d'établir des sanctions



« effectives, proportionnées et dissuasives », le projet de texte prévoit dans son **article 20** des sanctions pénales. La proportionnalité des sanctions sera assurée par le fait que les « points de contrôle » joueront en premier lieu un rôle préventif des risques d'infraction » puisque l'utilisateur sera tenu d'y présenter les informations de nature à démontrer sa conformité au protocole de Nagoya.

Dans le cas le moins grave, si un utilisateur sans intention commerciale réalise une recherche et développement sur une ressource génétique sans disposer du récépissé de déclaration, il pourra faire l'objet d'une mise en demeure par l'autorité administrative qui aura détecté cette infraction et aura ainsi la possibilité de régulariser sa situation, sans poursuites.

Mais en cas de récidive, ou dans le cas d'une entreprise qui commercialise un produit ou un procédé ayant été mis au point à partir d'une ressource génétique sans disposer de l'autorisation nécessaire, les sanctions pourront être plus élevées. C'est dans ce deuxième cas, et au vu des revenus des ventes habituellement observés qu'il est prévu une sanction pécuniaire plus dissuasive.

Ces sanctions s'alignent sur celles prévues au code de l'environnement pour des actes illégaux sans conséquence grave sur la santé humaine ou le milieu naturel: un an d'emprisonnement et 150 000 € d'amende. Une amende de 1 000 000 € est prévue pour les cas d'utilisation commerciale frauduleuse permettant un niveau d'appréciation de la peine au regard des avantages tirés. Ces niveaux de sanctions constituent des plafonds.

Le projet de loi prévoit une sanction complémentaire, consistant en une interdiction de solliciter une autorisation d'accès aux ressources génétiques et connaissances traditionnelles ou à certaines d'entre elles auprès des autorités françaises pendant maximum cinq ans.

L'**article 21** insère le dispositif d'APA dans les activités listées au code de l'environnement comme faisant l'objet de sanctions pénales à hauteur de deux ans d'emprisonnement et 100 000 € d'amende avec la circonstance aggravante du refus de se mettre en conformité malgré une mise en demeure par l'autorité administrative compétente. La peine privative de liberté sera donc significativement plus importante dans ce cas.

L'**article 22** ajoute à la liste des structures pouvant se porter partie civile dans le cadre des procédures d'APA les différentes personnes morales chargées de recueillir le consentement préalable en connaissance de cause des communautés d'habitants, et les associations régulièrement déclarées et exerçant leurs activités depuis au moins trois ans et exerçant leurs activités statutaires dans le domaine de la conservation des connaissances traditionnelles. Cette disposition est issue de l'article 18 du protocole de Nagoya.

L'**article 23** insère un dispositif d'APA dans le code de la santé publique pour les ressources microbiologiques (pathogènes).

L'article 24 étend aux îles Wallis et Futuna et aux Terres australes et antarctiques françaises, collectivités régies par le principe de spécialité législative, les dispositions relatives à l'accès et à l'utilisation des ressources génétiques et des connaissances traditionnelles qui leur sont associées. Il rend également applicables à la Nouvelle-Calédonie et la Polynésie française les définitions des communautés d'habitants, des connaissances traditionnelles associées et le principe du partage des avantages découlant de l'utilisation des connaissances traditionnelles avec les communautés qui les détiennent.

L'article 25 abroge, au profit de l'application du dispositif national lorsqu'il sera opérationnel, le dispositif d'APA existant pour le territoire du Parc amazonien de Guyane créé par la loi en 2006, qui régit actuellement l'accès aux ressources génétiques des espèces prélevées dans le parc national ainsi que leur utilisation.

L'article 26 prévoit la prise d'ordonnances par le Gouvernement pour les dispositions spécifiques relatives aux ressources génétiques des espèces domestiques et cultivées et relevant du ministère chargé de l'agriculture.

## Access and Benefit-Sharing in Germany

*Lily O. Rodríguez, Miriam Dross and Karin Holm-Müller*

Germany has been actively involved in the development of the international regime for access and benefit-sharing (ABS) since its earliest stages. It signed the Convention of Biological Diversity (CBD) on 12 June 1992 and ratified it on 21 December 1993, just before the CBD entered into force.<sup>1</sup> In October 2001, Germany hosted the meeting in Bonn at which the *Ad Hoc* Open-Ended Working Group on Access and Benefit-sharing adopted the draft of the Bonn Guidelines, which were subsequently approved by the Sixth Conference of the Parties (COP 6) in 2002. In 2008, Germany also hosted COP 9 in Bonn.

Along with other European countries, it signed the Nagoya Protocol in 2011,<sup>2</sup> the legally binding framework adopted at the 10th COP to promote the implementation of ABS; while already being also a signatory of the CBD International Treaty on Plant Genetic Resources (ITPGRFA), which entered into force in 2004; that treaty is considered to be a specialised ABS instrument, under Article 4.2 of the Nagoya Protocol.

As a country with little natural resources, Germany clearly identifies itself not as a provider, but as a user of genetic resources originating from other countries. Germany's public and private institutions invest largely in both basic and applied research<sup>3</sup> and experimental development. Worldwide, Germany is ranked fifth in granting intellectual property rights over all inventions, especially patents.<sup>4</sup> Consequently, Germany's research-related industry is highly competitive. Some of these industries are related to the use of genetic resources in one way or the other. Industries related to such resources include

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1 The CBD went into force on 29 December 1993, 90 days after the 30th country ratified it. According to the CBD webpage (<http://www.cbd.int/convention/parties/list/>), Germany ratified the CBD after the 30th country; according to article 36 of the CBD, the CBD went into force in Germany on 22 March 1994.

2 Germany signed the Nagoya Protocol along with other 11 European countries on 23 June 2011.

3 Approximately 2.84% of its GDP, making it 4th after the United States, Japan and China. <http://data.worldbank.org/indicator/GB.XPD.RSDV.GD.ZS>.

4 German Patent and Trade Mark Office, *Annual Report*, 2012.

sectors such as pharmacy, horticulture, plant breeding (for food, agriculture and ornamentals), nutraceuticals, cosmetics and biotechnology industries, which either use natural compounds or synthesise their own material.

In what follows, we will first give an overview of the specific legal provisions on ABS in Germany and a brief overview (in Section II) at how access to biological material is regulated. In Section III, we focus on the different activities and the diversity of actors concerned with access and use of genetic resources from foreign countries, in compliance with the CBD, followed by our conclusions (in Section IV).

## I Legal Provisions on Access and Benefit-Sharing in Germany

The Nagoya Protocol will be implemented EU-wide through the new EU Regulation No 511/2014 of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (hereinafter referred to as the "EU Regulation on ABS").<sup>5</sup> This regulation entered into force on 9 June 2014 and applies as of 12 October 2014, when the Nagoya Protocol itself enters into force worldwide and for the European Union. However, the most relevant Articles 4, 7 and 9 of the EU Regulation on ABS will apply only one year after that,<sup>6</sup> because additional measures need to be put in place before they can be applied. The EU Regulation on ABS implements all relevant international obligations uniformly on EU level that concern the use of genetic resources, especially Articles 15, 16 and 17 of the Nagoya Protocol. The regulation of access remains with the member states.<sup>7</sup>

Germany is currently in the process of adopting a law to complement the implementation of the Nagoya Protocol on the national level and to implement the parts of the EU Regulation on ABS that need to be substantiated.<sup>8</sup> Germany is a federal state, the competency to legislate is split between the

5 Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, OJ L 150/59, 20.5.2014.

6 EU Regulation on ABS Article 17 para. 3.

7 Bundestags-Drucksache 17/14245, 27.06.2013, p. 2.

8 Draft law of 7 February 2014, Law for the implementation of the obligations stemming from the Nagoya Protocol and the EU Regulation (Gesetz zur Umsetzung der Verpflichtung aus dem Nagoya-Protokoll und aus der Verordnung EU (xxx/xxx), Gesetz über die Nutzung genetischer Ressourcen – NgRG) (translation by the authors). This draft law has not yet been agreed on between the different ministries that are responsible for ABS. Therefore, it is

state and the federal *Länder* depending on the subject matter. Article 74 para. 1 no. 29 of the Constitution (*Grundgesetz*)<sup>9</sup> contains a concurrent competence of the federal state and the *Länder* to regulate nature conservation issues and the draft federal law on ABS is based on this competency.

The draft federal law provides that access to genetic resources in Germany is not restricted, unless legal exceptions apply,<sup>10</sup> confirming current practice.

While Article 17.1 lit (a) of the Nagoya Protocol calls for the Parties to support compliance with the Protocol by designing “checkpoints” that collect or receive information on ABS, no mention of this term is made in the EU Regulation on ABS (apart from the recitals) and the German draft law. In the EU Regulation on ABS, reporting is foreseen at two points of the user chain. Firstly, when users receive research funding<sup>11</sup> and, secondly, at the stage of final development of a product via the utilisation of genetic resources.<sup>12</sup> These provisions will be further detailed by the implementing acts that the European Commission will adopt in this regard, under Article 7.6.

According to Section 3 of the draft law, recipients of research funding that is related to the use of genetic resources and to traditional knowledge that relates to genetic resources, are obliged when they apply for such funding to declare that they will proceed with due diligence as required by Article 4 of the EU Regulation on ABS. The explanatory memorandum of the drafted German law points out that this provision is only relevant until the European Commission has adopted implementing acts under Article 7.6 of the EU Regulation on ABS, which would then take precedence over the national rule.

The German Patent Act has already covered genetic resources in the past.<sup>13</sup> Section 34a first sentence of the Patent Act requires that, should an invention be based on biological material of plant or animal origin or if such material is used therefore, the patent application is to include information on the geographical origin of such material, if known. This shall not prejudice the examination of applications or the validity of rights arising from granted patents.<sup>14</sup> This wording (which is identical in the EU patent regulation) implies that the

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possible that some aspects will be regulated differently in the law once it is adopted than it is described here.

9 Constitution of 23 May 1949 (*Grundgesetz*), Federal Law Gazette 2012 I S. 1478.

10 German ABS draft law Section 2.

11 EU Regulation on ABS Article 7 para. 1.

12 EU Regulation on ABS Article 7 para. 2.

13 Patent Act of 5 May 1936 in the version of 16 December 1980, (*Patentgesetz*), Federal Law Gazette 1981 I page 1.

14 Translation by the WIPO, [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=238776](http://www.wipo.int/wipolex/en/text.jsp?file_id=238776) (last accessed 18 August 2014).

omission of a statement of origin does not affect the patent-granting process.<sup>15</sup> This disclosure of origin procedure is therefore a voluntary measure of transparency with no legal consequences, as there are no sanctions if it is not provided. In the draft German law for the implementation of the Nagoya Protocol it is foreseen to add a paragraph to Section 34a of the Patent Act that will state that in the case described above, notice shall be given to the competent authority, which so far in the draft law is foreseen to be the BfN. While the German patent office thus already asks for information about the origin of material, the Patent Act does not require a benefit-sharing agreement, and a failure to disclose the origin of the material does not lead to the rejection of the patent. In the same line, micro-organisms are implicitly excluded from the disclosure requirement, as they are not mentioned in the Patent Act, but are patentable.

Section 4 of the draft law details the tasks and the competencies of the competent authority which is assigned all the monitoring tasks described in Article 7 and 9 of the EU Regulation on ABS. The draft law allows to fine violations of the obligations of the law with up to 50.000 €.<sup>16</sup> An offence in the sense of Section 7 is given, when the reporting obligations under Article 7.1 and 7.2 of EU Regulation on ABS, the due diligence obligations under Article 4.1 and 4.2 of the EU Regulation on ABS and the obligations concerning the certificate of compliance under Article 4.3 of the EU Regulation on ABS, are violated. Furthermore, an infringement of Section 1 of the draft law can also be fined. In Section 9 of the draft law it is currently foreseen that the Federal Agency for Nature Conservation (BfN) will be the competent authority. However, this competency is currently still under discussion within the government. The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, the BMUB will remain the national focal point according to Article 13.1 of the Nagoya Protocol. While in general, according to Article 87 Section 3 sentence 1 of the Constitution, the execution of laws are in the hands of the *Länder*, the EU Regulation will be applied by a federal institution. In Section 6, the draft law also foresees the possibility of the BMUB, to issue an ordinance to further regulate the “monitoring” as far as it is necessary, according to the EU Regulation on ABS. This pertains to investigations, including the taking of samples, and methods of analysis, and related details.

15 IEEP, Ecologic and GHK, *Study to analyze legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union* (Brussels/London, 2012), annexes, 39; Thomas Henninger, “Disclosure Requirements in Patent Law and Related Measures: A Comparative Overview of Existing National and Regional Legislation on IP and Biodiversity,” in *Triggering the Synergies between Intellectual Property Rights and Biodiversity* (Eschborn, Germany: Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), 2010); See also WIPO Doc. WIPO/GRTKF/IC/16/INF/15.

16 German ABS draft law Section 7.

Covered are also the reporting obligations under Article 7.1 and 7.2 of the EU Regulation on ABS.

### 1 *Due Diligence*

According to the Nagoya Protocol, transparency in the use of genetic resources under the CBD should be achieved through the clearinghouse mechanism for information about both use and access. According to the EU, the competent authority will have to report to it on its monitoring duties, as stated in Article 7.3 of the EU Regulation on ABS.

A study conducted by Dross and Wolf<sup>17</sup> for the BfN, examined the compatibility of a disclosure of origin requirement with the German legal system. The study concluded that such a requirement would not violate the freedom of science and research guaranteed by Article 5 of the Constitution because restrictions caused by compliance with legal access to genetic resources can be justified for the purpose of environmental protection. According to the authors, a similar argument holds when considering the free exercise of a profession, protected by Article 12 of the Constitution. In this case researchers, importers and merchants, as restrictions may be seen to be in the public interest. Furthermore, it appears that no less-restrictive alternative is available. The authors also saw no conflict with Article 14 of the Constitution, which protects private property. Additionally, concerning a possible conflict with Article 3 of the Constitution, which forbids an unequal treatment of equal actors, the authors concluded that this possibility should not pose a problem, because the certificate requirements would apply equally to all who engage in research, export and commercialisation with genetic materials. To summarise, the only study that to our knowledge examined the possible conflicts between requiring a certificate of legal compliance and the German Constitution did not find any problems there.

Generally, the German government has expressed the opinion that, according to the principle of freedom of contract, the government might be obligated to make sure that a MAT exists, but could not evaluate or enforce its content.<sup>18</sup> Germany supports the “due diligence” principle for compliance, as included in the EU Regulation on ABS. This requires three elements of a due diligence system (as considered in the EU regulation on timber products):<sup>19</sup> information,

17 Miriam Dross, and Franziska Wolff, *New Elements of the International Regime on Access and Benefit Sharing of Genetic Resources – The Role of Certificates of Origin* (Bonn: BfN Skripten, 2005).

18 Bundestags-Drucksache 17/14245, 27.06.2013, p. 8.

19 Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market, OJ L 295/23, 12.11.2010.

risk assessment and risk mitigation,<sup>20</sup> where information means allowing for the traceability of resources used. This implies checking for more information about legal access, mainly when there are suspected risks; for example, when provider countries point to possible cases of non-compliance.<sup>21</sup> However, the due diligence approach of the EU Regulation on ABS seems to be more reactive than proactive and relies on the capability of provider countries to effectively perform their own monitoring tasks.<sup>22</sup>

## 2 *Temporal Scope and Applicability of the Nagoya Protocol*

Concerning the temporal scope of the Nagoya Protocol, the German federal government is of the view that the Nagoya Protocol only pertains to genetic resources accessed after its adoption, which is in accordance with Article 2 of the EU Regulation on ABS. We must recall here that the Nagoya Protocol does not specifically address this controversial subject, as no consensus was reached on this subject during the international negotiations of the Nagoya Protocol. A group of countries, mainly the so-called biodiversity-rich and provider countries, were more of the opinion that the obligation of the Nagoya Protocol should apply as of the adoption of the CBD in December 1993, whereas the EU sought to enforce the Nagoya Protocol only after its entering into force. Nevertheless, since 1994 some *ex situ* collections have started to document at least permits, PIC or MAT for new collections whenever possible, as in the case of the DSMZ. This will be of relevance, as other countries, outside the EU, may adopt different time scopes for the application of the Nagoya Protocol.

## 3 *Utilisation of Genetic Resources*

As important as they are, the definitions of use and utilisation are probably among the more unclear parts of the EU Regulation on ABS, leaving room for interpretation. For instance, when referring to “*ex situ* collections” the German government considered that simply collecting and storing genetic information does not represent “use,” thus questioning the applicability of the term “research and development” in these cases.<sup>23</sup> At the time of the drafting of the EU Regulation on ABS, the Leibniz Association<sup>24</sup> released a document suggesting that there

20 IEEP, Ecologic and GHK, *Study to analyze legal and economic aspects of implementing the Nagoya Protocol*, Annex 1, p. 36.

21 Bundestags-Drucksache 17/14245, 27.06.2013, p. 7.

22 [For a more detailed analysis of the due diligence approach of the EU regulation, please refer to contributions to this volume by Oliva (Chapter 12) and Godt (Chapter 13).]

23 Bundestags-Drucksache 17/14245, 27.06.2013.

24 Leibniz Association, Position paper by the Section C Life Sciences of the Leibniz Association As well as the Leibniz Research Network on Biodiversity (LVB) on the



should be a clear definition of “research and development” in the EU Regulation on ABS to mean “specifically and only any research on biological or genetic material (or its genetic and biochemical composition) that intends to or actually does lead to commercial applications or market-based products.” However, the EU Regulation on ABS did not provide further definition of “utilisation of genetic resources” than the one provided by the Nagoya Protocol itself. Article 8a of the Protocol asks parties to create conditions that promote and encourage research.... “including through simplified access measures for non-commercial research.” Thus, by including this Article in the Protocol, it is understood that both commercially and non-commercially intended research ought to be covered by the Protocol. Any interpretation excluding basic research as part of the Protocol or the EU Regulation on ABS may not be viewed accurately or favourably by the international community, because it would mean that the EU legislation did not assume responsibility for the compliance of non-commercial research.

## II Germany as a Provider Country

Germany, like most members of the European Union, has no intention of demanding a share of benefits derived from the use of its own genetic resources. Therefore, it has no intention to put in place procedures for prior informed consent (PIC) or mutually agreed terms (MAT) to access German genetic resources. This is in accordance with the Nagoya Protocol, under which all countries are required to implement user measures, but it is left to each country’s discretion to implement access regulations.

Though the CBD has conferred ownership of its genetic resources upon the countries, Germany has no law defining the ownership of biological or genetic resources.

Therefore, for *in situ* resources, the owner of the land is generally also the owner of the biological and genetic resources that occur on private lands (or waters) as property protected by Article 14 of the Constitution, which guarantees property and the right of inheritance and is governed by the German Civil Code (BGB).<sup>25</sup>

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“Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union” 2012/0278 (COD), [http://www.leibniz-verbund-biodiversitaet.de/fileadmin/user\\_upload/downloads/Biodiversitaet/2012\\_0278\\_COD\\_\\_position\\_Leibniz.pdf](http://www.leibniz-verbund-biodiversitaet.de/fileadmin/user_upload/downloads/Biodiversitaet/2012_0278_COD__position_Leibniz.pdf).

25 Civil Code of 18.08.1896 (Bürgerliches Gesetzbuch), Federal Law Gazette 2002 I page 42, 2909; 2003 I page 738.

Provided that the species on the land are not protected by the Federal Nature Conservation Act (BNatSchG)<sup>26</sup> – for example, because of their endangered status<sup>27</sup> or because they are located in a protected area<sup>28</sup> – owners of the land can dispose of genetic resources found on it. For example, if a genetic resource is exchanged through a purchase contract, it is subject to civil law. In contrast, decisions about natural resources in public lands or protected areas remain in the hands of the government (federal or the *Länder*) and are regulated by the Federal Nature Conservation Act or the respective acts in the *Länder*.

While access to genetic resources is not restricted in general, it is prohibited to take from the wild wild plants of specially protected species, or their developmental stages, or to damage or destroy them or their sites according to Section 4 para. 1 no. 4 BNatSchG.<sup>29</sup> Section 44 para. 2 lit. (b) specifies that it is also prohibited to acquire, display to the public or use in some other manner for commercial purposes, such animals and plants (prohibitions on marketing). The competent authorities for nature conservation and landscape management, pursuant to the legislation of the *Länder*, and, in the case of introduction from other countries, the BfN, may, in individual cases for purposes of research, teaching, education, or reintroduction, or for the breeding operations or artificial propagation measures necessary for these purpose grant further exceptions from the prohibitions of Section 44. The implementation of this lies with the *Länder*.

Also, when the genetic resources are located in a part of the territory area that is protected under Chapter 4 of the Federal Nature Conservation Act (Protection of certain parts of nature and landscape), restrictions apply. According to Section 22 BNatSchG, parts of nature and landscape are placed under protection by means of declaration. Such declarations shall among other things define the area to be protected, the purpose of its protection, and the orders and prohibitions required to fulfil this purpose.

In the case of *ex situ* collections, ownership varies from public collections that are in the hands of private societies (such as the Senckenberg society in Frankfurt), public law foundations (such as the Museum Koenig in Bonn) or

26 Federal Nature Conservation Act of 19.7.2009 (Bundesnaturschutzgesetz), Federal Law Gazette 2009, I S. 2542.

27 BNatSchG Sections 13 and 14.

28 BNatSchG Section 44.

29 Unofficial translation of the Federal Nature Conservation Act by the German Ministry of the Environment, [www.bmu.de](http://www.bmu.de); [http://www.bmub.bund.de/en/service/publications/downloads/details/artikel/act-on-nature-conservation-and-landscape-management-entry-into-force-1st-march-2010/?tx\\_ttnews%5BbackPid%5D=864&cHash=416dc8b06daf491f720a64e58foed5fc](http://www.bmub.bund.de/en/service/publications/downloads/details/artikel/act-on-nature-conservation-and-landscape-management-entry-into-force-1st-march-2010/?tx_ttnews%5BbackPid%5D=864&cHash=416dc8b06daf491f720a64e58foed5fc) (accessed 10 October 2013).

universities (such as in Hamburg or Munich). There is no restriction against using genetic resources from public collections as long as no violation of any ABS regulations occurs; however, the decision to grant access is up to those responsible for the collections.

The German National Biodiversity Strategy covers wild and cultivated genetic resources, including plants, animals, fungi and microorganisms. It provides some directions for specific inventory measures, for protecting genetic resources and for developing a national system of information on genetic resources. The inventory mentioned above is currently in place and is called the “Information System of Genetic Resources” (GENRES). It is hosted by the Federal Office for Agriculture and Food (Bundesanstalt für Landwirtschaft und Ernährung, BLE) which is a subordinate authority of the Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft, BMEL).<sup>30</sup> It comprises the XGRDEU specialist databases of the national inventories, listing *in situ* and *ex situ* stocks of plant, animal, forest, aquatic and microbial genetic resources in Germany. At present, it includes forest, aquatic, cultivated and wild plants. At the time of writing, the section on microorganisms and invertebrates was under construction (along with the definition of a program for their conservation).

### III Germany as a User Country

Because Germany sees itself as a user country, the attitude of German actors towards the sharing of benefits is of major importance. We will first give a brief overview about the main actors and their positions concerning ABS and then address the main ways of access of German users as well as what is known about their benefit-sharing approaches.

#### 1 Actors

To describe the situation in Germany, we will distinguish between four groups of actors: government authorities, funding agencies, *ex situ* collections<sup>31</sup> and users. The last group includes researchers with non-commercial interests as well as those with commercial intentions (including industry). We do not concentrate on

<sup>30</sup> “GENRES – Informationssystem Genetische Ressourcen,” accessed 3 February 2014, <http://www.genres.de/>.

<sup>31</sup> We are well aware that *ex situ* collections belong to the wider realm of users, but because they are more dedicated to conservation and reference activities to which codes of conduct (voluntary measures) apply, we will treat them separately here.

the users of plant genetic resources for food and agriculture, as they are governed by the ITPGRFA. In this section, we will also mention some concepts regarding the characterisation of types of research and will mention the main guidelines, voluntary measures and benefit-sharing practices currently in place in Germany.

#### a Government Authorities

The BMUB is the ABS focal point at the international level, and it could be considered the authority driving the construction of a national policy for implementing ABS and the Nagoya Protocol in Germany. The BfN is the subordinate authority of the the BMUB, which is responsible for coordinating the implementation of the National Biodiversity Strategy. The BfN also hosts the German ABS Information Platform.<sup>32</sup>

In November 2007, the federal government adopted the National Biodiversity Strategy, which was prepared by the BMUB. This (not legally binding) strategy expresses the federal government's intention to ensure fair and equitable benefit-sharing and compliance with international (including CBD and those from the ITPGRFA) and national ABS regulations regarding genetic resources and traditional knowledge from other countries.<sup>33</sup> It also demands that the users and providers of genetic resources (collections, industry, science, trade, growers and private individuals) in Germany should know and comply with the ABS provisions of the CBD and related regulations.

Also in September 2007, the BMUB and the BfN published an "Information Brochure for Users,"<sup>34</sup> which was prepared for them by IUCN. This brochure provides an overview of the ABS concept and the CBD framework, the evolution of the negotiations, and basic elements of the future international regime for the implementation of ABS, including PIC and MAT, benefit-sharing and the obligations of those who use genetic resources.

Another important actor is the Federal Ministry for Food and Agriculture (BMEL), which has been actively involved in shaping the European position regarding genetic resources. At the international level, it is the German focal point for the ITPGRFA Treaty. At the national level, the BMEL is responsible for the conservation of genetic resources for food and agriculture (including crops and animal husbandry), forestry and aquatic resources. As such, it has developed a national strategy for the conservation and use of German biodiversity

32 [http://www.BfN.de/index\\_abs+M52087573abo.html](http://www.BfN.de/index_abs+M52087573abo.html).

33 BfN, *German National Strategy on Biodiversity*, 2007, [http://www.bfn.de/0304\\_biodivstrategie-nationale+M52087573abo.html](http://www.bfn.de/0304_biodivstrategie-nationale+M52087573abo.html).

34 Available at [http://www.BfN.de/fileadmin/ABS/documents/iucn\\_infobrosch\\_301007.pdf](http://www.BfN.de/fileadmin/ABS/documents/iucn_infobrosch_301007.pdf).

in food, agriculture, forestry and fisheries<sup>35</sup> complementary to the national biodiversity strategy. Additionally, because the BMEL is also responsible for the fisheries sector, it has developed a German Technical Program for the Conservation of Aquatic Genetic Resources, including fishing in the sea, lakes and rivers and aquaculture.<sup>36</sup> For forest genetic resources, the federal government has established a Forest Genetic Resources and Legislation on Forest Reproductive Material Working Group and has developed a program for the conservation and sustainable use of forest genetic resources.<sup>37</sup>

The Scientific Advisory Board on Biodiversity and Genetic Resources of the BMEL proposed a series of recommendations regarding the agricultural sector in April 2012,<sup>38</sup> before the release of the proposal for an EU Regulation on ABS in October 2012. In that document, they expressed their view that with respect to agricultural resources, a system for facilitated access and benefit-sharing should be developed in accordance with the Nagoya Protocol similar to the one currently in place for the ITPGRFA. Moreover, they recommended expanding this system to species used for food, energy and renewable resources, only excluding those used for pharmaceutical uses.<sup>39</sup> Finally, the report also recommended the disclosure of origin in patent applications. Though their view has not been taken up by any official authority, it may be a sign that there is a need for greater coherence between environmental, agricultural and trade policies.<sup>40</sup>

For at least a decade now,<sup>41</sup> the Ministry of Economic Cooperation and Development (BMZ) has been focusing mainly on strengthening the possibilities

35 See the Federal Conservation Strategy for food, agriculture, forestry and Fisheries [http://www.bmelv.de/SharedDocs/Downloads/EN/Publications/AgriculturalBiodiversity.pdf?\\_\\_blob=publicationFile](http://www.bmelv.de/SharedDocs/Downloads/EN/Publications/AgriculturalBiodiversity.pdf?__blob=publicationFile).

36 See German Ministry of Food, Agriculture and Consumer Protection, *Aquatic Genetic Resources. German National Technical Programme on the Conservation and Sustainable Use of Aquatic Genetic Resources*, 2010, [http://www.bmelv.de/SharedDocs/Downloads/EN/Publications/AquaticGeneticResources.pdf?\\_\\_blob=publicationFile](http://www.bmelv.de/SharedDocs/Downloads/EN/Publications/AquaticGeneticResources.pdf?__blob=publicationFile).

37 <http://www.genres.de/en/forest-plants/regulatory-framework/> (accessed 5 January 2014).

38 F. Begemann F.M. Herdegen, L. Dempfle, J. Engels, P.H. Feindt, B. Gerowitt, U. Hamm, A. Janßen, H. Schulte-Coerne, H. Wedekind, Scientific Advisory Council on Biodiversity and Genetic Resources at the BMELV, *Recommendations of the Implementation of the Nagoya Protocol with Respect to Genetic Resources in Agriculture, Forestry, Fisheries and Food Industries. Position Paper by the Scientific Advisory Board on Biodiversity and Genetic Resources at the Federal Ministry of Food, Agriculture and Consumer Protection*, 2012, (translation of German original paper).

39 Ibid p. 28.

40 German Agrobiodiversity Strategy, p. 19 (<http://www.genres.de/?L=3>).

41 Christine Schaeffer, "German Technical Development Cooperation: Measures to Promote Implementation of Article 8(j) of the Convention on Biological Diversity," in *Protecting*

for biodiversity-rich countries to combat poverty via ABS, such as by supporting biotrade and, in alliance with other European countries, an ABS capacity-building initiative.<sup>42</sup> By promoting capacity building to implement ABS and helping to develop guidelines to regulate access, the initiative is meant to enable African, Caribbean and Pacific states and stakeholders to use benefits generated by the use of genetic resources to conserve biodiversity and alleviate poverty.

The German Patent and Trade Mark Office (DPMA), attached to the Federal Ministry of Justice (BMJ), is the central authority for granting patents and registering other intellectual property rights. It is also in charge of managing information related to those property rights. A network of 23 information centres provides assistance to innovators across the country.<sup>43</sup>

The Federal Customs Administration is currently the competent authority with respect to the exchange of information aimed at combating crime in the field of species protection under CITES convention according to Section 48 para. 1 no. 4 BNatSchG, and it could in the future also be authorised to serve as a checkpoint. Section 49 BNatSchG entitles the Federal Ministry of Finance (BMF) and the customs authorities to supervise and monitor compliance regarding the import and export of fauna and flora subject to European regulations in goods' traffic with third countries. At present, these functions concern safety and health matters related to the exchange and trade of genetic resources and the implementation of CITES. If further "checkpoints" are introduced by the implementing acts of the European Commission or national ordinances in the future, the Federal Customs Administration might be considered.

#### b Funding Agencies

A key governmental actor is the Federal Ministry of Research and Education (BMBF), one of the main public funding agencies for research in Germany. BMBF largely funds and supports basic and applied scientific research and technical development. It has also funded biological research in biodiversity-rich countries, such as the BIOTA projects in Africa,<sup>44</sup> and continues to do, for example, in the case of the GlobE-Project, which conducts research for the global food supply.<sup>45</sup>

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*and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions*, eds. Sophia Twarog and Promila Kapoor (New York and Geneva: United Nations Conference on Trade and Development, 2004).

42 "ABS Capacity Development Initiative," <http://www.abs-initiative.info/index.html?&L=>.

43 "Arbeitsgemeinschaft Deutscher Patentinformationszentren e.V.," [www.piznet.de](http://www.piznet.de).

44 "Biodiversity Monitoring Transect Analysis in Africa," <http://www.biota-africa.org/>.

45 "GlobE – Research for the global food supply," <http://www.bmbf.de/en/16742.php>.

The other important funding organisation in Germany, the German Research Foundation (DFG), is dedicated to basic academic research. The DFG is a self-governing organisation of German science and research that is registered as an association under private law and funded by the federal government and by the states. The DFG funds basic research, and when funding is related to genetic resources, it also educates its applicants on the primary importance of ABS obligations. In 2008, the DFG developed and disseminated guidelines to ensure that necessary provisions were taken to comply with countries' regulations, in line with the Bonn Guidelines.<sup>46</sup> Every applicant has to declare whether he or she is going to be working with biological material and that the researcher knows how to comply with ABS rules of the country where the project is going to take place (where such rules exist) and how to contact the focal point for ABS. To our knowledge, no other public funding organisation in Germany puts that much weight on whether users fulfil the ABS obligations.

The German Academic Exchange Service (DAAD) plays an important role in funding the development of academic exchange and cooperation. Like most of the funding organisations, it does not explicitly consider ABS provisions in its funding guidelines.

#### c *ex situ* Collections

The third group of actors consists of the *ex situ* collections or "holders," which includes collections of preserved and living materials. Besides, all of these institutions also conduct their own research activities, mainly related to the classification of organisms. The group of preserved collections includes natural history museums and herbaria, such as the Senckenberg Museum of Natural History and the Herbarium in Frankfurt, the Botanical Museum of Berlin, the Herbarium of the University of Munich, the Museum Koenig of Natural History in Bonn. These institutions hold preserved collections of high value for the identification of species (taxonomy) and are of international importance.<sup>47</sup>

There are also *ex situ* collections of living material. These include botanical gardens (approximately 50 in Germany) and collections of micro-organisms

46 Deutsche Forschungsgemeinschaft, *Supplementary Instructions for Funding Proposals Concerning Research Projects within the Scope of the Convention on Biological Diversity (CBD)*, [http://www.dfg.de/formulare/1\\_021e/1\\_021e.pdf](http://www.dfg.de/formulare/1_021e/1_021e.pdf).

47 "ZEFOD – Zentralregister biologischer Forschungssammlungen in Deutschland," accessed 19 January 2014, <http://zefod.genres.de/index.php?> Please note that a number of the herbaria are also botanical gardens that also hold living collections. (accessed 19 January 2014).

(such as the DSMZ, the German collection of micro-organisms). For instance, botanical gardens in Germany acquire their material more often from exchange (58%), than from the wild (12%), purchases (18%) or other minor sources, such as private individuals (5%) and other sources (1%).<sup>48</sup>

#### d Codes of Conduct and Guidelines

Despite the lack of national regulation until now, many of the bigger collections are implementing measures to comply with the CBD. These measures, however, vary depending on the type of collection. For the time being, for zoological collections there is no specific code of conduct or other standard (such as a material transfer agreement model) for the transfer of materials such as it exists for botanical gardens or other living collections. Nevertheless, the Consortium of European Taxonomic Collections (CETAF), is currently developing a code of conduct<sup>49</sup> that will then also apply to some of the largest German zoological and herbaria collections.

In contrast to this, the International Plant Exchange Network (IPEN) developed a registration system to facilitate the exchange of living plant material among botanical gardens. It was initiated in 1999 by the association of gardens in German-speaking countries (*Verband Botanischer Gaerten*) and was adopted by the European Botanic Gardens Consortium in 2003.<sup>50</sup>

The German Collection of Micro-organisms and Cell Cultures (DSMZ) was one of the fourteen participants in the Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC), an EU-financed project. The code of conduct developed by MOSAICC aimed to facilitate access to microbial resources and to help in developing practical agreements when transferring microbial resources. Thus, MOSAICC established a system to identify the provenance of microbial resources via PIC and MAT to help monitor the transfer of resources via MTA defined by the provider and user (BCCM 2000, 2011).<sup>51</sup> The European Culture Collection Organisation (ECCO) has also developed an MTA for supplying samples of biological material from the public

48 B. Krebs, Marliese von Den Driesch, Frank Klingenstein, and Wolfram Lobin, Samentausch von Botanischen Gaerten in Deutschland, Oesterreich der deutschsprachigen Schweiz und Luxemburg, *Gaertnerisch Botanischer Brief* 151 (2002).

49 Cornelia Loehne, personal communication (6 November 2013).

50 Carmen Richerzhagen, Sabine Taeuber and Karin Holm-Mueller 2005 Users of genetic resources in Germany: Awareness, Participation and Positions regarding the Convention on Biological Diversity, in eds. Utte Feit, Marliese. von den Driesch und Wolfram. Lobin. Access and Benefit Sharing of Genetic Resources. Skript 163. BfN, Bonn. p. 34.

51 See "MOSAICC Micro-Organisms Sustainable use and Access regulation International Code of Conduct," BCCM, <http://bccm.belspo.be/projects/mosaicc/>.



collections. The MTA addresses traceability, benefit-sharing and IPR, among other aspects. This MTA allows, for instance, the use of material by researchers in the same laboratory or partners in a project for non-commercial purposes.<sup>52</sup>

The DSMZ also informs their users and depositors in the open collection of their responsibility to ensure compliance in the framework of the Biodiversity Convention. It accepts deposits only with disclosure of provenance and information about the rights and obligations of benefit-sharing, according to the PIC and MAT from the provider country.<sup>53</sup> At the same time, the DSMZ informs its recipients about “end-user obligations, especially with regard to the traceability of their samples, and precludes the transfer of cultures to third parties.” For the purpose of patenting, as an International Depositary Authority (IDA) for the deposit of biological material under the Budapest Treaty, it follows the procedures established there for when providing the source of the microorganism is optional.

*Ex situ* collections need to compare biological material, especially for identification purposes; thus, their regular and traditional way of working requires the extensive exchange of material. At present, molecular techniques are used for the comparison and differentiation of species; under specific arrangements, the extraction of DNA samples from preserved material may be allowed by the collections.<sup>54</sup> It would be very difficult to inform any checkpoint or competent authority about each of these transfers. Furthermore, most of these institutions’ guidelines, model material transfer agreements, and codes of conduct already contain provisions regarding the possibility of a change towards commercial utilisation. In such cases, they ask their users to follow CBD regulations or, as in IPEN, they commit themselves to procuring a new PIC for commercial uses.<sup>55</sup> The EU Regulation on ABS accordingly contains specific rules on *ex situ* collections. A collection that fulfils specific criteria spelled out in Article 5 para. 3 can be included in a register of collections that the European

52 Dagmar Fritze, “A Common Basis for Facilitated Legitimate Exchange of Biological Materials, Proposed by the European Culture Collections Organization (ECCO),” *International Journal of the Commons* 4 (2010).

53 “Convention on Biological Diversity, Its implications for culture collection users and depositors,” DSMZ, <http://www.dsmz.de/bacterial-diversity/convention-on-biological-diversity.html>.

54 Example: see Senckenberg Collections: [http://www.senckenberg.de/files/evaluation/collection\\_rules\\_final.pdf](http://www.senckenberg.de/files/evaluation/collection_rules_final.pdf).

55 “The International Plant Exchange Network (IPEN): An instrument of botanic gardens to fulfil the ABS provisions,” Botanischen Gärten der Universität Bonn, <http://www.botgart.uni-bonn.de/ipen/criteria.html#box3>.

Commission establishes. For a collection to be included in the register, it has to follow strict rules when exchanging genetic resources. Users acquiring genetic resources from a collection included in the register shall be considered under Article 4 para. 7 of the EU Regulation on ABS to have exercised due diligence.

The register of collections (initially called “trusted collections” in the proposal of the ABS EU Regulation on ABS)<sup>56</sup> was hotly debated in Germany. The approximately 300 *ex situ* public collections, including natural history museums, herbaria, but also other *ex situ* collections containing living material and genetic resources (botanical gardens, micro-organisms collections and gene banks) are dispersed across the 16 *Länder* and administered in a variety of ways. Not all of them, especially small collections in universities, will be able to apply for registered collections status, and they may experience the negative consequences of this segregation of collections.

#### e Users

The fourth group, the users, also contains sub-groups. In 2005, the BfN published the results of a research project<sup>57</sup> describing German users of genetic resources in terms of their positions, experience and level of information and offering recommendations for the implementation of ABS in Germany and Europe from a users’ perspective. The study covered mainly the biotechnology and plant breeding sectors. This study identified six different types of users: Biotechnology (food, energy, material biocatalysis), agriculture (plant breeding, pest control, livestock breeding), horticulture (ornamental), research institutions (universities: biology, chemistry, medicine, others) and *ex situ* collections (gene banks, natural history museums, herbaria, botanical gardens, micro-organism collections). Because only a few countries had ABS-specific procedures in place at the time, very few cases of PIC or MAT were reported then.<sup>58</sup> The same study pointed out the poor knowledge about ABS and the prospective obligations among many of the user groups.

<sup>56</sup> P7\_TC1-COD(2012)0278.

<sup>57</sup> Carmen Richerzhagen, Sabine Taeuber and Karin Holm-Mueller, Users of Genetic Resources in Germany: Awareness, Participation and Positions Regarding the Convention on Biological Diversity, in *Access and Benefit Sharing of Genetic Resources*, eds. Ute Feit, Marliese von den Driesch, and Wolfram Lobin (Bonn: BfN Skript 126, 2005).; Karin Holm-Mueller, Carmen Richerzhagen and Sabine Taeuber, *Users of Genetic Resources in Germany, Awareness, Participation and Positions Regarding the Convention on Biological Diversity* (Bonn: BfN-Skript 126, 2005).

<sup>58</sup> Sabine Taeuber, Karin Holm-Mueller, Therese Jacob & Ute Feit, *An Economic Analysis of New Instruments for Access and Benefit-sharing and the CBD – Standardization Options for ABS Transactions*. Final Report. BfN-Skripten 286. Bonn, (2011); According to the CBD

Although it is mentioned in Article 8a of the Nagoya Protocol, there exists no definition of “non-commercial research.” Therefore, we refer to the definition of “basic research” given in the Frascati Manual,<sup>59</sup> which defines it as “experimental, observational or theoretical work undertaken to formulate and test hypotheses, theories or laws, which results are published in scientific journals, and it is usually performed in the higher education sector.” The same document also defines “experimental development” as “systematic work drawing on knowledge gained from research and practical experience, directed toward producing new materials, products and devices. It usually involves the development of “scaling-up processes.” We shall, however, point out that the definitions of basic and applied research that are most frequently used in Germany,<sup>60</sup> follow closely the OECD definitions, and cannot immediately be translated into non-commercial and commercial research, as non-commercial research may entail “applied research” (for example, with applications in environmental management or nature conservation) leading then to social or public benefits, but entailing no intellectual property rights or any commercial value for the researcher. However, experimental development (in general) may more frequently result in inventions that are susceptible to IPR and private benefits.

As this definition makes clear, genetic resources first used for non-commercial research might in some cases contribute to R&D leading to commercial research, meaning that there might be a change of intent if a certain genetic resource that was originally collected for non-commercial research exhibits characteristics that could, through experimental development, convert it into a possible candidate for commercial development. Any distinction between the two user groups within the academic sector thus seems somewhat arbitrary. Researchers (and even more so, their institutions) may be involved in both commercial and non-commercial research. Therefore, it is much easier to group users according to the institutions they belong to. Therefore, for practical reasons and for the purpose of this document, we will group the users into academic and non-academic users.

Traditionally, universities in Germany have conducted basic, non-commercial research. But in the last decades (as in many other countries), they have been

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<http://www.cbd.int/abs/measures/default.shtml>, 57 out of 193 parties have some regulation related to ABS (14.02.2014).

59 OECD, *Frascati Manual 2002: Proposed Standard Practice for Surveys on Research and Experimental Development, The Measurement of Scientific and Technological Activities* (Paris: OECD Publishing, 2002).

60 “Research at Universities of Applied Sciences,” Federal Ministry of Education and Research, <http://www.bmbf.de/en/864.php>.

incentivised to acquire property rights, and they encourage their researchers to look for IPR and patent inventions and to work with the industry sector, so that material is frequently exchanged between private and public entities.<sup>61</sup> Nevertheless, in 2012, the German patent office received 46,586 applications for all types of inventions, of which only 640 (less than 1.5%) came from universities.<sup>62</sup> The data shows that requests for IPR still primarily come from the private-industry sector.

In the same line, universities encourage international research, and some departments specialise in biodiversity-rich countries through long-term collaborations. An important percentage of these researchers are relatively unaware of ABS principles and regulations.<sup>63</sup> Moreover, it can be assumed that the legal departments in universities are even less aware of it, as they may never have been involved in the process of procuring genetic or biological material.

Non-academic users comprise such industry sectors as *inter alia* pharmacy, care and cosmetics, industrial biotechnology, botanical medicine, nutraceuticals, horticulture and biocontrol agents.<sup>64</sup> Most industries working on biotechnology are part of the German Association for Biotechnology (*Deutsche Industrievereinigung Biotechnologie*, DIB),<sup>65</sup> which is part of the Association of Chemical Industry (VCI). The biggest companies also belong to the Biotechnology Industry Organisation (BIO), a worldwide organisation which since 2005 has published general guidelines with practical advice to help its members cope with ABS requirements and compliance.

## 2 Access to Genetic Resources by German Users

Users have two main ways to access genetic materials, directly from the field or through an intermediate provider.

### a Directly from the Field

One way to access genetic resources is by collecting samples in the field within a basic research project, mainly with a non-commercial end. This is the

61 Sabine Taeuber, Karin Holm-Mueller, Therese Jacob & Ute Feit, *An Economic Analysis of New Instruments for Access and Benefit-Sharing and the CBD – Standardization Options for ABS Transactions*. Final Report. BfN-Skripten 286. Bonn, (2011) p. 75.

62 German Patent and Trade Mark Office, *Annual Report*, 2012.

63 Karin Holm-Mueller, Carmen Richerzhagen and Sabine Taeuber, *Users of Genetic Resources in Germany*.

64 Sabine Taeuber, Karin Holm-Mueller, Therese Jacob & Ute Feit, *An Economic Analysis of New Instruments for Access and Benefit-Sharing and the CBD – Standardization Options for ABS Transactions*. Final Report. BfN-Skripten 286. Bonn, (2011), 120.

65 Deutsche Industrievereinigung Biotechnologie, <https://www.vci.de/dib/Seiten/Startseite.aspx>.

principal way in which researchers from universities and those from *ex situ* collection institutions (collecting preserved or living material)<sup>66</sup> obtain their material, usually in collaboration with researchers from the providing country.

One example of basic research activities and collections in the field is a project that has been taking place in Southern Ecuador since 1997.<sup>67</sup> The project has raised a significant amount of benefits for the providing country,<sup>68</sup> such as capacity-building (12 PhDs and at least 26 master degrees obtained by Ecuadorians in Ecuador and Germany), research facilities (new facilities, collections and equipment for research, or the establishment of a collaborative graduate program), or societal benefits, such as the improvement of roads and the electric system of the nearest town. Moreover, the results of this research have been applied to the restoration of soils and forests in the area of Loja, thus also helping to improve the ecosystem services of the area and accomplishing national goals related to the conservation of biodiversity.

The other way to access material in the field is commercially oriented, through bioprospecting activities (*i.e.* collections of biological material with the aim of finding new marketable compounds for personal care, pharmaceuticals or functional food products). An attempt to implement bioprospecting properly by fulfilling all possible ABS requirements was also made in Ecuador. The project was funded by BMBF (Pro-Benefit 2003–2008), which invested largely in developing the framework activities, such as PIC and documents for possible agreements. Nevertheless, mainly because of the lack of a complete set of procedures for these types of activities in Ecuador, no agreement to develop the prospected activities was obtained at the end.<sup>69</sup>

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66 Sabine Taeuber, Karin Holm-Mueller, Therese Jacob & Ute Feit, *An Economic Analysis of New Instruments for Access and Benefit-Sharing and the CBD – Standardization Options for ABS Transactions*. Final Report. BfN-Skripten 286. Bonn, (2011).

67 Started by individual researchers and followed by groups or Research Units from 2001 to 2012. Since 2012, they have been followed by a platform on biodiversity monitoring, see <http://www.tropicalmountainforest.org/>.

68 Jorg Bendix, Bruno Paladines, Mónica Ribadeneira-Sarmiento, Luis Miguel Romero, Carlos Antonio Valarezo and Erwin Beck “Benefit Sharing by Research, Education and Knowledge Transfer – A Success Story of Biodiversity Research in Southern Ecuador,” in *Tracking Key Trends in Biodiversity Science and Policy*, eds. L. Anathe Brooks and Salvatore Arico. Based on the proceedings of a UNESCO International Conference on Biodiversity Science and Policy (Paris: UNESCO, 2013).

69 Christiane Ploetz, “ProBenefit: Process-Oriented Development for a Fair-Benefit Sharing Model for the Use of Biological Resources in the Amazon Lowland of Ecuador,” in *Access and Benefit-Sharing of Genetic Resources. Ways and Means for Facilitating Biodiversity*

## b Intermediate Providers

The second and more common way to obtain genetic material in Germany, especially in the biotechnology sector, is from trade partners. The main providers for biotechnology are situated either in countries of origin or other countries outside of Germany, within and outside the EU. Biotechnology companies prefer easy access, quality material and unrestricted use. Additionally, for non-commercial research purposes, there is also a high rate of material exchange among *ex situ* preserved and living collections, many of which are already regulated by voluntary codes of conduct (see above).

Other users, such as plant breeders, animal breeders or researchers working on micro-organisms, use either culture collections or material from CGIAR centres, as regulated by the ITPGRFA. We also know of researchers who obtained their material from ornamental horticulture or pet shops importing living organisms. This perhaps demonstrates the difficulty of distinguishing between exporting biological and genetic resources.

## 3 *Benefit-Sharing by German Users*

Benefit-sharing has been decided on a case-by-case basis, as it was not prescribed by the law so far. From the industrial sector in Germany, there is apparently more openness towards technology transfer or know-how than towards sharing monetary benefits, as it also enhances productivity. However, this openness will depend on the size of the company and the sector.<sup>70</sup> One very common form of know-how transfer consists of hiring local employees who are participating in the project.<sup>71</sup> The association of biotechnology industries<sup>72</sup> has suggested the possibility of negotiating agreements for benefit-sharing during the latest steps of the industrial value creation process, when the resources are certain to be used for commercial purposes.

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*Research and Conservation While Safeguarding ABS Provisions*, eds. Ute Feit, Marliese von den Driesch, and Wolfram Lobin (Bonn: Bfn Skripten, 2005).

70 Sabine Taeuber, Karin Holm-Mueller, Therese Jacob & Ute Feit, *An Economic Analysis of New Instruments for Access and Benefit-Sharing and the CBD – Standardization Options for ABS Transactions*. Final Report. BfN-Skripten 286. Bonn, (2011) Chapter 4.

71 Ann Kathrin Buchs and Jörg Jasper, *For Whose Benefits? Benefit Sharing within Contractual ABS-Agreements from an Economic Perspective – The Example of Pharmaceutical Bioprospection*, Diskussionbeitrag 0701, Institut für Agrarökonomie, Georg August Universität Göttingen (2007).

72 Sabine Taeuber, Karin Holm-Mueller, Therese Jacob & Ute Feit, *An Economic Analysis of New Instruments for Access and Benefit-Sharing and the CBD – Standardization Options for ABS Transactions*. Final Report. BfN-Skripten 286. Bonn, (2011), Figure 6.

Although the Nagoya Protocol refers to technology transfer, collaboration and cooperation, this part of the benefit-sharing has not been addressed by the EU Regulation on ABS, nor by the German draft law. Nevertheless, within the academic sector, the sharing of non-monetary benefits is a current practice, promoted by funding agencies such as DFG<sup>73</sup> and as a traditional way of working more cooperatively in science, joining capacities with peer institutions (see the web pages of Helmholtz, Leibniz, Max Planck, and all universities in Germany). Other than familiarising researchers from biodiversity-rich countries with the latest research methods, it seems challenging for universities to engage in *technology transfer*, one of the important benefits derived from ABS according to Article 23 of the Nagoya Protocol (also discussed in Articles 16 and 19 of the CBD), as it takes money to invest in new technologies abroad. Unless funding agencies consider covering these expenses in the projects they fund, there will be no opportunities for this kind of technology transfer.

#### IV Conclusions

Germany is granting unrestricted access to its genetic resources as long as no specific legal exceptions apply. Though it sees itself as a user country, until now, regulation ensuring compliance with ABS has been weak in Germany, as it is in many other user countries. There is, however, already some familiarity with the CBD concepts, ABS requirements, the Bonn guidelines, and the Nagoya Protocol provisions within the academic sector, mainly because of the DFG guidelines. Living *ex situ* collections, such as botanical gardens, microorganism collections and other *ex situ* collections, also have systems in place that are meant to ensure compliance with ABS. These guidelines and codes of conduct may have to be slightly modified and updated to introduce the Nagoya Protocol and EU framework. They could then be a model for other funding organisations and collections to follow.

For the time being, there is no law on ABS in Germany, but there is a draft German law on ABS, implementing the EU Regulation on ABS. It designates the national Nature Conservation Agency (BfN) as the competent authority, but this is still under debate. According to the draft law all monitoring tasks are assigned to the competent authority, but the draft law provides the BMUB with the possibility to further regulate monitoring as far as necessary to comply with EU ABS. Furthermore, according to this draft law, recipients of

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73 "International Cooperation," Deutsche Forschungsgemeinschaft, [http://www.dfg.de/en/dfg\\_profile/international\\_cooperation/index.html](http://www.dfg.de/en/dfg_profile/international_cooperation/index.html), accessed November 2013.

research funds are obliged to declare to the competent authority that they will proceed with due diligence. Germany has included the disclosure of the origin of biological material used for innovations and inventions in the patenting process. The draft German law complements Section 34a of the Patent Act and obliges the DPMA to inform the competent authority in case an invention is based on biological material and the patent application includes information on its geographical origin. But this does not apply to microorganisms and it does not alter the fact that a patent will be awarded even when no disclosure took place.

The German research foundation DFG has already introduced guidelines for ABS for the recipients of their funds, but otherwise codes of conduct and guidelines are rarely to be found in Germany. Some public *ex situ* collections adhere to international standards and codes of conduct. A study showed that industrial users are more open to technology transfer than to sharing monetary benefits. Academic researchers generally seem very willing to do non-monetary benefit-sharing, but are restricted in their research budgets.

As it stands, benefit-sharing does not yet seem to be a standard praxis in Germany, though there are some initiatives from funding organisations and *ex situ* collections and a general openness of industry towards benefit-sharing. The German draft law so far restricts itself to complement the EU Regulation on ABS in a rather minimalistic way, which may follow the Nagoya Protocol to the letter, but not to the spirit. There is still a need for additional legislation regarding enforcement, arbitration and penalties,<sup>74</sup> which will depend mainly on further provisions made by the Commission according to Article 7 para. 6 of the EU Regulation on ABS.

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74 IEEP, Ecologic and GHK, *Study to Analyze Legal and Economic Aspects of Implementing the Nagoya Protocol*, Annex 1, p. 36 (2011).



## Legal Framework in Greece Regarding the ABS Regime, Implementation Gaps and Issues Requiring National and International Attention

*Efpraxia-Aithra Maria and Georgia-Panagiota Limniou*

Greece is situated on the southern end of the Balkan Peninsula, is part of the European eastern Mediterranean Sea and it has a total surface of 132,000km<sup>2</sup>, islands included. It is extremely rich in biodiversity with a wide variety of plants, animals, ecosystems and landscapes.<sup>1</sup>

Greece is a “biodiversity hot-spot” area for Europe since it is an important region for the European fauna and flora because of its high endemism,<sup>2</sup> but it is also a land of the many rare species refugees.<sup>3</sup> The *flora* of Greece is one of the richest in Europe consisting of 6,437 native plant taxa (species and subspecies), which correspond to approximately 50% of the plants of Europe, while 1,442 species and subspecies are endemic in the country.<sup>4</sup>

With regard to the *fauna* of Greece, according to official inventory<sup>5</sup> 23,130 species of land and freshwater have been recorded, in which 3,500 species of sea are not included. If a number of more species that has been recorded but not included in lists is added, the total number could reach about 30,000 species.<sup>6</sup>

The main objective of this study is to detect and record through a critical lens, and to evaluate the Greek legislation in terms of both public and private law, with regard to ABS. With regard to public law, this approach is performed under the light of the relevant ratified international conventions on biodiversity,

1 S. Dafis *et al.*, (eds.), *The Greek Habitat Project: NATURA 2000, an Overview* (Thessaloniki: Commission of the European Communities. Goulandris Natural History Museum-Greek Biotope Wetland Centre, 1996): 1–2.

2 First National Report on the Convention on Biological Diversity, Greece, January 1998, p. 10.

3 M. Arianoutsou-Faraggitaki, A. Giannitsaros, and L. Koumpli-Sovantzi, *Terrestrial Ecosystems of Greece* (Athens: National and Kapodistrian University of Athens, Faculty of Biology, Department of Ecology and Taxonomy, 2003): 1–3. (in Greek).

4 K. Georgiou and P. Delipetrou, “Patterns and Traits of the Endemic Plants of Greece,” *Botanical Journal of the Linnean Society* 162 (2010): 134.

5 Fauna Europaea 2004, Fauna Europaea. <http://www.faunaeur.org>.

6 A. Legakis, and P. Marangou, *The Red Data Book of Endangered Animals of Greece* (Athens: Greek Zoological Society, 2009): 14. (in Greek).

the Nagoya Protocol<sup>7</sup> and the Regulation of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (hereafter, “EU Regulation on ABS”).

The (public and private) law statutes are juxtaposed on the basis of the meaning that the EU Regulation on ABS attributes to the term “access,” *i.e.* acquisition of genetic resources in accordance with the applicable legislation or regulatory requirements of the Party to the Nagoya Protocol.<sup>8</sup> Moreover, we do not examine the issue of the legislative regulation of traditional knowledge held by indigenous and local communities, since according to the 3rd National Report on Convention on Biological Diversity (CBD), there are no such communities in Greece within the meaning of CBD.<sup>9</sup>

The statutes, the majority of which have been and still are in force simultaneously, are presented in two parts, distinguishing public and private law instruments. In each part, the statutes are examined in chronological order, divided into thematic units, so that the content and the differentiations of the regulations will be distinguished. The applicable statutes are presented through a critical analysis in both parts.

In the third part of the study, we formulate critical comments, we express considerations and we submit proposals for the elaboration of the necessary national regulatory framework.

## I Access According to Public Law – The Current Legislative Framework

The applicable legislation is presented on the basis of the 1975 Constitution, a special provision of which renders the protection of the environment and biodiversity an obligation of the state.<sup>10</sup> This provision forms the foundation for every future statute, and, therefore, the regulatory framework regarding access constantly expands and evolves. By contrast, the statutes that have been issued prior to the Constitution's entry into force exhibit a different approach to these issues, as is demonstrated below.

7 E. Morgera, M. Buck, and E. Tsioumani 2012. (eds), *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective: Implications for International Law and Implementation Challenges* (Martinus Nijhoff Publishers, 2012).

8 Nagoya Protocol Article 3.

9 Third National Report on CBD, Greece, 8-4-2008, pp. 76, 79.

10 Greek Constitution Article 24.

1 *First period: The Legislative Framework Before the 1975 Constitution – The Sources of Access Law*

The issue of access to genetic resources did not always have the same content within the Greek legal order. A first approach to regulate access attempted to manage forests and their products. This was achieved either within the context of logging management in private forests on the part of the State, for the purpose of covering public needs,<sup>11</sup> or within the context of monitoring logging and forest products, such as resin harvesting *etc.*,<sup>12</sup> with the simultaneous introduction of the right to suspend all logging activities in cases of damage to the forest.<sup>13</sup> During this period (1836–1923), the statutes were limited to species of *flora*, which are exclusively classified under a special category (forest), for the main purpose of securing their management.

The need for legislative protection of certain species of flora (*apiarian plants*) was later expanded, for the purpose of securing safe access or prohibition of access to them.<sup>14</sup> For the first time, regulations were introduced regarding species of *flora*, growing not only inside, but also out of forest areas. Public authorities granted the first permits, where felling or eradication of the species of heather and blackcurrant was allowed under certain conditions.

The legislative framework was later expanded to cover forest areas, together with their *flora* and *fauna*, as a result of the Forestry Code which was introduced at the time.<sup>15</sup> For the first time, the case of scientific research in protected forest areas was regulated, and, thus, exceptions to the general rule prohibiting access were introduced. The difference regarding the aforementioned permit system (Royal Decree 657/1963) is that the latter was related exclusively to felling or eradication and not to scientific research.

With the issuance of the Forestry Code, first, National Forests<sup>16</sup> and then, Protected Natural Monuments were declared as protected areas. Within their core, the collection, felling, logging, eradication, destruction and transfer of plant species and forest products that are found there, as well as hunting and

11 Royal Decree of 17(29) November/1 December 1836 “On private forests.”

12 Presidential Decree of 19/30 November 1928, “On forest management, resin collection and resin cultivation *etc.*”

13 E-A Maria, *Legal Protection of Forests* (Athens: Ant. Sakkoulas, 1998): 16–19. (in Greek).

14 Law 6238/1934 “On the improvement of bee-keeping” and Royal Decree 657/1963 “On the prohibition of felling and eradication of apiarian plants.”

15 Forest Code-Legislative Decree 86/1969. It should be noted that the Legislative Decree and the Royal Decree are legal tools with obligatory force throughout the territory, which reflect different polities before the Constitution of 1975.

16 Forestry Code Article 78.

fishing, are expressly prohibited.<sup>17</sup> Moreover, the Forest Inspector was granted the authority to issue an order, which had the capacity to regulate or restrict and even fully prohibit, with respect to space, time and manner, any unpermitted logging, collection or construction of forest products, as well as any logging, pruning or eradication of trees, scrub, brush and grass growing within agricultural or arboricultural cultivated areas, grasslands, partly woodland, and public or private forests.<sup>18</sup> Furthermore, the Forestry Code allowed the collection or eradication and transfer of plant species, as well as the capture and transfer of wild animals, under the condition that it is intended for scientific purposes, and pursuant to the approval of the administration.

The same protective spirit is demonstrated in the regulation of access to aquatic *flora* and *fauna*, yet without any provision for the exception of scientific research.<sup>19</sup> This gap was later filled, with the ratification of the Ramsar Convention,<sup>20</sup> and the express obligation on the part of states to encourage scientific research on wetlands, flora and fauna.<sup>21</sup>

In conclusion, the statutes issued during this first period (from 1836 until 1974) pertain to issues of access, not to genetic resources, in the modern sense of the term, but initially to species of *flora*, and then to species of *fauna*, which mainly exist in forests. Thus, the relevant legislation lied within and under the shade of forest law, while the relevant provisions are still valid today.

## 2 *Second Period: The Legislative Framework After the 1975 Constitution – The Developments in Access Law*

The real change in Greek environmental law took place in 1975, when the Constitution declared the protection of the natural and cultural environment as an obligation of the State and obliged the State to take special preventive or repressive measures for its preservation. It made particular reference to the protection of forests and forest expanses, and it expressly provided for the issuance of a relevant law.<sup>22</sup> This provision was later on complemented with the 2001 revision of the Constitution, where the protection of the environment has now been defined not only as an obligation of the State, but also as the right of

17 Legislative Decree 86/1969 Article 80. 2f, as applicable.

18 Forestry Code Article 66.

19 Royal Decree 142/1971 "On fishing of aquatic organisms of lakes and rivers and their protection" sets express prohibitions of fishing, trading and selling certain species of aquatic animals, during certain time periods, for the protection of their reproduction (Article 1).

20 Legislative Decree 191/1974 "International Treaty on the protection of wetlands."

21 Article 4 par. 3.

22 Greek Constitution Article 24.1.

every person, thus solemnly acquiring the status of a constitutional right.<sup>23</sup> In this last revision, the constitutional legislator makes explicit reference to the principle of sustainability, stating that the State is bound to adopt measures in the context of the sustainability principle; in the same article, (interpretative clause) the legislator provides the definitions of “forest,” “forest ecosystem” and “forest expanse,” making reference to the flora and fauna co-existing there, thus, comprising a particular biocommunity.

With these provisions, the protection of biodiversity is established as a constitutional right;<sup>24</sup> as a result, the legislator’s philosophy regarding access is gradually affected: from access within the frame of protected species of flora and fauna, and then within the frame of the protection of nature and landscape, to access to plant genetic material and genetic resources.

a            Access within the Frame of Protected Species of Flora and Fauna  
The issue of researches on wild *fauna* and native *flora*, which now also pertains to non-forest species, concerns the legislator within the frame of a discrete statute: The Presidential Decree 67/1981 “On the protection of native *flora* and wild *fauna* and the determination of the coordination and control procedure of related research.”<sup>25</sup>

The Presidential Decree 67/1981 is the first statute which addresses all issues pertaining to the cycle of access to native *flora* (collection, transplantation, eradication, felling, transfer, purchase, sale and export from the country) and wild *fauna*, as well as its parts or products (killing, attempt to kill, abuse, causing of injury, causing of harm, possession, capture, taxidermy, purchase, sale, transfer and export). For the first time, certain species of native flora are characterized as protected and, at the same time, they are distinguished into endemic and non-endemic rare species, which are expressly enumerated (Table A in the Presidential Decree). Similarly, for the first time, some species of wild fauna are characterized as protected and they are distinguished into invertebrates and vertebrates, also expressly enumerated (Table B in the Presidential Decree). Subsequently, a general and absolute (in terms of space

23    Gl. Siouti, *Handbook of Environmental Law* (Athens-Thessaloniki: Sakkoulas, 2011): 16. (in Greek) as well as Gl. Siouti and G. Gerapetritis, “Access to Justice in Environmental Matters in the EU. Chapter 9. Greece,” in *Access to Justice in Environmental Matters in the EU*, ed. Jonas Ebbesson (Hague: Kluwer Law International, 2002): 261–262.

24    M. Dekleris, *The Law of Sustainable Development. General Principles* (Belgium: European Communities, 2000): 94–95.

25    It should be noted that the Presidential Decree is issued by the President of the Republic pursuant to a preventive control of constitutionality from the Council of State. It has obligatory force throughout the territory.

and time) prohibition of any kind of access to them is introduced (in the sense of collection, transplantation, eradication, felling, transfer, sale, purchase and export) for vegetal species together with their flowers and fruits listed in Table A. A similar spatiotemporal prohibition is provided for the species of wild fauna listed in Table B (killing, abuse, causing of injury, capture, transfer, sale, purchase and export).<sup>26</sup> However, these prohibitions may be lifted for reasons listed exclusively.<sup>27</sup>

Moreover, according to the Presidential Decree, the forest laws (Forestry Code)<sup>28</sup> apply to the species of native flora and to the species of mammalian and feathered game which are not included in Table A and Table B, thus recalling its provisions and restoring its association with access to native flora and wild fauna.

Examining the issue of access for research purposes, the legislator adopts a different philosophy. In Article 6.1 of the Presidential Decree 67/1981, the legislator sets a general, non-prohibitive provision “research pertaining to any species of wild fauna and native flora is free” – in the sense that it is not subjected to the absolute, prohibitive rules of that period. However, this freedom, exceptionally restricted, applies on the condition that the researcher makes a simple announcement to the competent authorities about the nature of the research, the area in which the research will be conducted and the results of the research. The results are also announced to the Scientific Research and Technology Service and to at least one scientific establishment of the country, with a similar objective. The competent authority may ban research if it determines that it can cause serious harm to the balance of the ecosystem under research.<sup>29</sup>

An exception to the aforementioned rule is introduced with Article 8, which requires the issuance of a permit for the development of any activity aiming at the collection of protected or non-protected species of native flora and wild fauna, for research purposes, when the material collected is destined for export. The permit testifies to the manner of collection and the quantity of species, taking the areas’ ecological balance into consideration. The issuance of a permit is also required when the access for research purposes concerns the protected species listed in Tables A and B; in this case, a permit issued by the Ministry of Agriculture (MoA) is required. There is an express exclusion from this provision for Greek establishments of higher education, which only have the obligation to announce the research conducted to the local competent

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<sup>26</sup> Presidential Decree 67/1981 Articles 2–3.

<sup>27</sup> *Ibid.*, Article 7.

<sup>28</sup> *Ibid.*, Article 80.

<sup>29</sup> *Ibid.*, Article 6.1(b).

authorities.<sup>30</sup> Throughout the statute, the MoA is the surveillance authority which regulates the issues of permit granting, research coordination, effective protection of wild fauna and native flora and communication with the relevant authorities abroad.<sup>31</sup>

It thus arises that during this time period (1975–1981), the legislator continues to treat the issues of access mainly through forest laws. Thus, apart for the exceptions set forth in Tables A and B of the aforementioned Presidential Decree, all other cases of native flora and wild fauna are governed by the same legislative provisions as forest species. However, the appearance of a new category, *i.e.* the protected species of the Presidential Decree 67/1981 is conducive to an initial autonomization of access from forest laws.

#### b The Special CITES Permit and the Berne Convention in Association with the Applicable Law on Access

The applicable measures regarding access to protected species of wild fauna and native flora are supplemented in the EU level by Regulation 3626/1982/EEC on the implementation in the Community of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)<sup>32</sup> and the Berne Convention.<sup>33</sup> These two statutes introduce two innovations:

- (1) CITES adds protected species,<sup>34</sup> classifying them according to the degree of risk they run for their lives. For the issuance of the special CITES permit, for the export of a specimen of a species listed in Appendices I, II and III, the Management Authority of the export state<sup>35</sup> must have proof that the specimen (every animal or plant, alive or dead) was not obtained in violation of the laws on preservation of flora and fauna, which are applicable in this country;
- (2) With the Berne Convention, apart from wild species of fauna and flora, the habitats of wild species of flora and fauna are also protected, regardless of the area in which they live or grow. The protected species are listed

<sup>30</sup> *Ibid.*, Article 6.2.

<sup>31</sup> *Ibid.*, Article 10.

<sup>32</sup> In Greece the International Treaty CITES was ratified with Law 2055/1992, although its application had already been enforced a decade before, with Regulation 3626/1982.

<sup>33</sup> Ratified with Law 1335/1983.

<sup>34</sup> 33,500 species, subspecies or individual populations.

<sup>35</sup> The current CITES Central Management Authority is the Directorate of Aesthetic Forests, National Parks and Hunting of the Ministry of Environment, Energy and Climate Change, Article 13 Joint Ministerial Decision 125188/246/2013 “*Trading of Species of Wild Fauna and native flora.*”

and classified into three Appendices, and, therefore, access is regulated according to the Appendix in which they are included.<sup>36</sup>

c Access through the Protection of Nature and Landscape

Under the influence of the Berne Convention, and especially the 1975 Constitution, the framework-law 1650/1986 "On the protection of the environment" has been enacted. This law introduced a profound change in the protection of nature and biodiversity, setting it as one of its main pillars. Within this framework, it treats species of flora and fauna from an integrated, rather than fragmented perspective, and it broadens the scope of access to also cover the species that grow and live outside the forest ecosystems. The general protection starts from nature and landscape,<sup>37</sup> and it includes the species of native flora and wild fauna without exceptions and limitations.<sup>38</sup> At the same time, one can perceive the legislator's necessity to regulate the species of native flora and wild fauna as an organic whole, together with their biocommunity and their habitat as biogenetic reserves and constituent elements of ecosystems, which are in direct interaction and dependence.<sup>39</sup>

The scope of protection and the protected areas are broadened.<sup>40</sup> Protected species of flora and fauna are classified into categories (rare species, endangered species, species showing a decreasing tendency without being in danger of becoming extinct, and species with a particular ecological, scientific, genetic, traditional and economic value),<sup>41</sup> and the respective activities (agriculture, forestry, hunting, fishing) are harmonized with the native flora and wild fauna protection needs.<sup>42</sup> It is also stipulated that with a Joint Ministerial Decision lists of the particularly protected species will be compiled according to protection category. Additionally, restrictions, prohibitions, conditions and measures for their protection, as well as the conditions for the conduct of scientific researches on these species will be established.<sup>43</sup> However, this Joint Ministerial Decision has not been issued yet. It should be mentioned that the influence of Law 1650/1986 on genetic resources' regulation is scanty, since the aforementioned provisions focus on the enlargement of protected areas and the

36 G. Samiotis, *International Law of Wild Life. The International Provisions on the Protection of Biological Diversity* (Athens: Ant. Sakkoulas, 1996): 768 (in Greek).

37 Framework-law 1650/1986 Article 18.1.

38 *Ibid.*, Article 18.6.

39 *Ibid.*, Article 20.1.

40 *Ibid.*, Article 18.3.

41 *Ibid.*, Article 20.1b.

42 *Ibid.*, Article 20.3.

43 *Ibid.*, Article 20.2, 3b.



classification of protected species of flora and fauna. An explicit provision is omitted due to the absence of the notion of genetic resources.

An important deficiency of the law is that it does not include cultivated plants in the term native *flora*, and it does not perceive the plant genetic material as integrated.

Pursuant to Article 20.2, and in harmonization with Directive 92/43/EEC, the Joint Ministerial Decision 33318/3028/1998 "Preservation of natural habitats, wild fauna and flora," was issued, as applicable, regulating access to these areas. It sets express prohibitions to species of flora and fauna which are specified in an annex to the statute. It also establishes two important and innovative duties of the state, which will be fulfilled by means of a Joint Ministerial Decision:

- (a) the compilation of a national list of the particularly protected species of native flora and wild fauna of the country; and
- (b) the specification of access to them (restrictions, prohibitions, conditions and measures for their protection, and conditions for the conduct of scientific researches on these species). Nevertheless, until the issuance of this decision, which is still pending, the law expressly refers to the application of the Presidential Decree 67/1981.

Finally, chapter G of Law 1650/1986 introduces the regulative framework for the civil, administrative and criminal liability of anyone who acts against the environment and, thus, against biodiversity and genetic resources. With regard to civil liability, the "polluter pays" principle is applied, as, according to Article 29, whoever, natural or legal person,

causes pollution or any other degradation of the environment is liable to pay compensation, unless they prove that the damage is caused by force majeure or by the wrongful conduct of a third party acting fraudulently.<sup>44</sup>

It is a general explicit clause which introduces vicarious liability for the environmental damages and due to its generalized nature and broadness of the notion "environment,"<sup>45</sup> it is applicable in the case of genetic resources', especially

44 Translated by the authors. In Greek: «Άρθρο 29. Αστική ευθύνη. Οποιοσδήποτε, φυσικό ή νομικό πρόσωπο, προκαλεί ρύπανση ή άλλη υποβάθμιση του περιβάλλοντος ευθύνεται σε αποζημίωση εκτός εάν αποδείξει ότι η ζημία οφείλεται σε ανώτερη βία ή ότι προήλθε από υπαίτια ενέργεια τρίτου που ενήργησε δολίως.

45 Article 2.1: "Environment": the total of the natural and anthropogenic factors and elements which are in interaction and affect the ecological balance, the quality of life, the

when they become subject to pollution or degradation. It is worth noting that so far there is no relevant case law, and the clause appears to be inactive. At the level of criminal liability, the most interesting provision is the provision on the degradation of the environment with an act or omission,<sup>46</sup> which violates the provisions of the law or its regulatory acts; this provision pertains to the protected species of native flora and wild fauna, considering their biocommunity and their habitat as biogenetic reserves and constituent elements of the ecosystems. There are two more provisions that render this statute particularly noteworthy:

- (a) the broadening of the cycle of natural and legal persons who have the right to enter an appearance for the purpose of supporting the accusation, regardless of whether they have suffered any material damage, requesting the restoration of the earlier situation to the extent possible; and
- (b) the stipulation of the follow-up measures of seizure and confiscation of the captured, killed, injured or collected species of wild fauna and flora, which are in the possession of the violator or in the possession of a third party. Moreover, the relevant tools or means used are confiscated.<sup>47</sup>

In the field of administrative liability,<sup>48</sup> heavy administrative penalties (fine up to 2,000,000 Euros) are imposed on persons (natural or legal) who cause any pollution or other degradation of the environment or violate the provisions of the law, regardless of any additional civil or criminal liability. The application field of this provision is expanded to the illicit acquisition, pollution or degradation of genetic resources. In addition, the Environmental Liability<sup>49</sup> for damage or imminent threat of damage to biodiversity, soil and water (surface and underground) is implemented alongside.

Even though the provisions of articles 28–30 of Law 1650/1986 may be the main statute regulating criminal and civil liability, other statutes are also valid, *e.g.* Law 4042/2012, issued in line with the provisions of Directive 2008/99/EC

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health of residents, the historical and cultural tradition and the aesthetic values (translated by the authors). In Greek: «Περιβάλλον: το σύνολο των φυσικών και ανθρωπογενών παραγόντων και στοιχείων που βρίσκονται σε αλληλεπίδραση και επηρεάζουν την οικολογική ισορροπία, την ποιότητα της ζωής, την υγεία των κατοίκων, την ιστορική και πολιτιστική παράδοση και τις αισθητικές αξίες».

46 Framework-law 1650/1986 Article 28.2.

47 *Ibid.*, Article 28.9.

48 *Ibid.*, Article 30.

49 Directive 2004/35/EC and its harmonization via Presidential Decree 124/2009.

on the protection of the environment through criminal law. Moreover, the criminal provisions of the ratification laws and the acts of harmonization with international treaties (*e.g.* CITES) or with Directive 92/43 apply in parallel.

#### d Access to Plant Genetic Material

The gap left by Law 1650/1986, regarding the regulation of access to non-native flora is covered by the Presidential Decree 80/1990 "Protection of the plant genetic material of the country," which was issued in execution of Law 1564/1985 "Organization, production and trade of the propagating material of plant species."<sup>50</sup> This Presidential Decree makes reference to plant genetic material for the first time, setting the protection and preservation of the landrace genetic material of the cultivated plant species and their wild ancestors or relative species, as its pillar. Furthermore, for the first time, the legislator protects the plant genetic material, which is either in its natural habitat (*in situ*), or out of it (*ex situ*), making direct reference to the Bank of Genetic Material (BGM), botanical gardens, collections and rural plantations.<sup>51</sup> It distinguishes the plant genetic material under protection into groups:

- (a) indigenous varieties-populations of traditional cultivation;
- (b) wild and other plant species, close relatives or direct ancestors of the cultivated plants;
- (c) wild plant species which are directly utilized for the nutrition of humans and animals, the manufacture of industrial products, and decoration;
- (d) modern and older varieties, creations of plant breeders, which have survived, but are not extensively cultivated today, and have ceased to be protected by "plant breeder's rights"; and
- (e) inbred lines, which are very important for agriculture,<sup>52</sup> and then, it regulates the manner of access to it.

Although this Presidential Decree only concerns plant genetic material, its field of application is quite broad, as it expands to wild plant species.

With regard to the permit-granting scheme, it regulates it in a different manner compared to the Presidential Decree 67/1981, since this law requires a permit for all protected plant material, without exceptions and discriminations, depending on the purpose and the user concerned. In particular, it expressly introduces a permit-granting scheme for the species, varieties or

<sup>50</sup> Article 14.2.

<sup>51</sup> Presidential Decree 80/1990 Article 2.

<sup>52</sup> *Ibid.*, Article 3.

clones of Article 3 for collection and movement within the country and abroad. The permit is issued by the MoA, pursuant to an opinion of the competent scientific bodies in each case (BGM, Center of Agricultural Research of Northern Greece-CARNG, Universities, Research Establishments of the MoA and other establishments), as well as the prefectural services of the MoA, at the site where the collection will take place.<sup>53</sup> The purpose of the collection and movement (scientific, collective, commercial or other), the rarity of the plant, its particular significance for the country and its uniqueness constitute new criteria which are introduced and must be taken into consideration in granting the above permit.<sup>54</sup> However, foreign research missions collecting plant genetic material in Greece must be equipped with the above permit and accompanied and superintended by an agronomist from the BGM of the CARNG or a Scientific Expert from the country's establishment which is responsible for cultivation. The foreign research missions also undertake the duty to submit to the BGM representative samples of the collected plant genetic material and copies of the collection forms, for their long conservation and documentation.<sup>55</sup> These provisions are the nearest first approach to the concepts of bio-prospecting and Prior Informed Consent (PIC) and their regulation from a permit-granting scheme point of view.

#### e Access to Genetic Resources

Another important change is realized in the Greek legal order, when the CBD is ratified in Greece via Law 2204/1994 "Ratification of the Convention on Biological Diversity," State's sovereign rights over its genetic resources<sup>56</sup> and its relevant authority to determine access to its resources is acknowledged solemnly. However, it is investigated whether the obligations of Greece as a Party to the CBD, on the facilitation of access to its genetic resources and the fair and equitable sharing of the results of research and development (R&D) and the benefits arising from the commercial and other utilization of genetic resources among the Parties, finally influenced the subsequent legislation and were adopted by it in whole or in part and whether they changed its philosophy.

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53 *Ibid.*, Article 10. 1.

54 *Ibid.*, Article 10. 2.

55 *Ibid.*, Article 10. 3.

56 For CBD's sovereignty rights see M. Petit, C. Fowler, W. Collins, C. Correa, and C-G. Thornström, *Why Governments Can't Make Policy – The Case of Plant Genetic Resources in the International Arena* (Lima: International Potato Center, CIP-CGIAR, 2000): 11, as well as R. Rana, "Accessing Plant Genetic Resources and Sharing the Benefits: Experiences in India," *Indian Journal of Plant Genetic Resources*. 25 (2012): 39.

The first attempt to treat genetic material as a whole and to regulate the issues pertaining to it in a comprehensive manner is performed with the issuance of the relatively recent Law 3937/2011 “Preservation of Biodiversity and other provisions.” Its aim is the sustainable management and the effective protection of biodiversity, as a valuable and irreplaceable national capital of the country. In particular, Article 15.6 stipulates that the total of the genetic resources of the country is characterized as protected national capital and its use is subject to the terms and restrictions on ABS. For their definition, direct reference is made to the International Treaties (CBD, Nagoya Protocol, International Treaty of the Food and Agriculture Organization on Plant Genetic Resources for Food and Agriculture-ITPGRFA). Nevertheless, the utilization of genetic resources is not regulated, but it is provided that provisions will be issued, on the basis of which national catalogues, action plans and biodiversity inventories of private or public collections in Greece will be prepared, they will be inserted in a data-base, and within this framework, their use will be regulated.<sup>57</sup>

Law 3937/2011 attempts to treat genetic material from an integrated perspective, but at the same time it appears to fragment the regulation of access to it.<sup>58</sup> In particular, it distinguishes between two large categories, which it wishes to regulate:

- (a) important species; and
- (b) endemic species.

Its initial pursuit is to compile a national catalogue of important species and a national catalogue of endemic species of flora, fauna and other groups of organisms and types of natural habitats. These species are further distinguished into subcategories, whose protection is prioritized,<sup>59</sup> and they involve:

- (a) species whose protection and management is enforced by international and EU commitments;
- (b) species included in the risk categories of the national and international red data books,
- (c) endemic species;

<sup>57</sup> Law 3937/2011 Articles 10, 11 and 17. 4, 5.

<sup>58</sup> E-A Maria, Ch. Fournaraki, and K. Thanos, “Ex situ conservation of plant diversity – Considerations and recommendations for an efficient system of administrative organization of a Greek Seed Bank Network,” *Environment and Law* 4 (2012): 632, 646. (in Greek).

<sup>59</sup> Law 3937/2011 Article 10.

- (d) species exhibiting a particularly fragmented distribution;
- (e) species which are important for local communities (food, raw material, traditional medicine) even if they are not included in the red data books;
- (f) indigenous breeds of livestock and local varieties of plant species.<sup>60</sup>

For all important species, the legislator provides that the Ministry of Environment, Energy and Climate Change (MoEECC) in cooperation with the competent Ministries and other competent bodies, constructs and implements action plans.<sup>61</sup>

Similarly, for endemic species it is provided that the MoEECC will compile a national catalogue,<sup>62</sup> which will amend Tables A and B of the Presidential Decree 67/1981, by broadening them. The species of this catalogue will be respectively subdivided into protection categories, with a direct reference to the risk categories of the red data books. However, the legislator introduces express prohibitions on access to endemic species in particular, stating that their removal, collection, felling, eradication, possession, transfer of all kinds of specimens, trade, damage, destruction and direct or indirect killing is prohibited, at each stage of their biologic cycle. Species of flora, local varieties of plant species and indigenous breeds of livestock which are important for local production and consumption are excluded, unless the applicable national and EU legislation and the action plans for these species have different provisions.

The law also provides the regulative framework for permit-granting in cases of execution of researches or studies on these species.<sup>63</sup> The competent Department of the MoEECC, in cooperation with the competent services of the Ministry of Rural Development and Food (MoRDF-former MoA) is assigned with the task of approving applications. The methodology to be used and the expected results are described in the applications in detail. Two necessary preconditions for the issuance of the permit are that the endemic species or other protected species and the protected habitats of the area are not harmed and that the researcher

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60 The Presidential Decree 434/1995 "Preservation, protection of indigenous breeds of livestock" establishes a framework of rules and activities for the protection and preservation of the genetic diversity of indigenous breeds of livestock.

61 Action plans are constructed with a Joint Ministerial Decision. A decision of MoRDF establishes measures for the on-the-spot protection of endangered indigenous breeds of livestock and native wild plant species, related cultivated, while it sets restrictions on the collection and felling of these plants and on grazing, and it sets measures for fire protection, reduction of soil degradation, their *ex situ* preservation in botanical gardens and/or banks of genetic material and any other necessary detail (Article 20. 2a and b).

62 Law 3937/2011 Article 11.

63 Law 3937/2011 Article 11.3.

waives the franchise rights that may arise, for the benefit of the State. The results of the research or the study on endemic biodiversity are announced to the MoEECC. This is a first, tentative reference to the concept of sharing the benefits of the state, but it is incomplete, since it is very different from the content assigned to it by the Nagoya Protocol and the EU Regulation on ABS.

The same approach is adopted in the introduction of the permit-granting scheme on access to genetic resources for the purpose of conducting scientific research. Article 17.3,4 of Law 3937/2011 introduces the regulative framework for the applicable permit-granting scheme. It is in essence a horizontal provision, which concerns genetic resources, stating that research on the condition and utilization of the constituent elements of biodiversity, in which genetic resources are included, is licensed, controlled and encouraged by the state, but the permit-granting authority is different depending on the subject of the research. In particular, it provides that:

- (a) permits for the executions of scientific research programs and plans for species and habitats are issued by the competent services of the MoEECC;
- (b) permits for the conduct of researches on rural species, which are included in the ITPGRFA, as it was ratified by Law 3165/2003, for breeds and varieties are approved by the competent services of the MoRDF,
- (c) permits for wild species and related cultivated species are issued by the Department of Urban and Regional Planning and Environmental Protection with the assent of the BGM; and
- (d) permits for endemic species are issued by the MoEECC, in cooperation with the competent services of the MoRDF, following the aforementioned process.

These provisions indicate that despite the legislator's intention to regulate the total of the genetic resources from an integrated perspective, he, in essence, does not succeed in placing them under a common surveillance authority, competent to grant permits for access. The apparent fragmentation of responsibilities among the administrative authorities on the basis of the category to which the subject of the research belongs is highly likely to enhance the bureaucratic problems. Moreover, the fact that a species of flora (usually) belongs to more than one category of species, and, thus, it is required that a permit is issued by more than one service, is dissuasive for the user concerned.

### 3 *Evaluation of the Recently Issued Public Law Statutes*

From the above critical evaluation of Law 3937/2011, it arises that the national legislator expresses his intention to regulate access to the total of the genetic

resources and provides the administration with guidelines for the issuance of the relevant authorizing provisions, which will lead to a complete legislative framework, pertaining to their utilization. However, the intended aim of benefit-sharing is not fulfilled, at least within the scope of public law.

This deficiency is found to be even greater, since, even though the issuance of permits by the competent national authorities (MoRDF, MoEECC) is required for the acquisition of the right to access for the purpose of movement or research, there is no provision whatsoever for fair and equitable sharing of the results of the R&D and the benefits arising from the use, utilization and trade of genetic resources. The national legislator confines himself to the announcement of the results or to the researcher's waiver of the franchise rights on endemic species of flora and fauna, without reserving the right to participate in any manner in the benefits that will arise at a later point in time after the use of the genetic resources. However, it is encouraging that recently granted permits for scientific research contain the provision that if the results are commercially utilized at a later stage, there must be an agreement with Mutually Agreed Terms (MAT) within the frame of the Nagoya Protocol.<sup>64</sup> This provision is also included in permits granted by the Commission for the Issuance of Permits for Sea Researches, with regard to sea genetic resources, for which there is no special framework. In both cases, although they do not involve a regulation of the ABS, it is indicated that the conditions are now ripe for its drafting.

Similarly, with regard to the movement of the collected material, the provider cannot exert the claim for MAT against the user, which, according to the EU Regulation on ABS, must be exhibited by the user in accordance with the applicable legislative provisions. There is a provision on the submission of the results of a research/study to the MoEECC<sup>65</sup> and on the submission of representative samples of the collected genetic material and copies of the collection forms to the BGM.<sup>66</sup> This provision is not adequate and thus a more coordinated effort is required for the creation of the necessary legal background, so that all providers will be able to exert their claims against users.

Another remarkable deficiency of Law 3937/2011 is located in the postponement of important acts, such as the issuance of the Joint Ministerial Decision which will lay down the content of the action plans for important endangered species of flora and fauna. Moreover, the issuance of a Ministerial Decision which will lay down the measures for the on-the-spot protection of endangered indigenous breeds of livestock and native wild plant species, related cultivated,

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64 See sampling permit, dated 26-9-2013, granted by the MoEECC.

65 Law 3937/2011 Article 11.3.

66 Presidential Decree 80/1990 Article 10.3.



is pending. The fact that two years have passed and the above Ministerial Decision has yet to be issued is indicative of omissions, which undoubtedly raise considerations.

## II Private Law

Within the frame of private law, the issue of access to genetic resources moves around two poles, on which the system of civil law revolves, *i.e.* the property and the person.<sup>67</sup> Thus, rights *in rem* and rights *in personam* in conjunction with the patents and intellectual property rights (IPR) on genetic resources are examined. In addition, the aspect of private international law is approached.

### 1 *The Law of the Property*

Ownership on an immovable property extends above and below the ground, unless otherwise stipulated by law;<sup>68</sup> it thus extends to microorganisms and bacteria of the ground, while ownership also extends to the essential components of *rem*. In particular, the essential components of an immovable property include among others, expressly referred to, the products of the immovable property, as long as they are connected with the land, the seeds once they are sown and the plants once they are planted, without having to grow roots. The rights *in rem* that had existed in the component, before it connected with the main thing, are permanently erased with its connection, and they have the same legal treatment as the thing, *i.e.* an essential component of a communal thing (*e.g.* public grove or forest) is also rendered communal. Thus, prior to their collection, fruits do not entail any particular right *in rem*, but trees or nurseries that have been planted only for a temporary purpose, *e.g.* to be sold as nurseries, do not constitute essential components of the ground,<sup>69</sup> but they are considered as stand-alone movable things, entailing particular rights *in rem*, which do not share the fate of the immovable property. An exception to this rule is also provided for trees which are located at boundaries of immovable properties and are the object of separate ownership.<sup>70</sup>

67 *Person* is the subject of legal relations, especially rights and obligations, while *property* is the total of rights and obligations which can be monetarily evaluated, A. Georgiadis, in *Civil Code, vol. V*, eds. A. Georgiadis and M. Stathopoulos (Athens: P. Sakkoulas, 2004): 5. (in Greek).

68 Civil Code Article 1001.

69 Civil Code Article 955.

70 Civil Code Article 1023.

The ownership right may extend to the fruits<sup>71</sup> even after their separation from the main thing.<sup>72</sup> The State maintains a broader ownership right over *bona vacantia*,<sup>73</sup> communal things, and *res extra commercio*.<sup>74</sup> Communal things include, but are not limited to beaches, spring waters, antiquities, rivers, paleontological findings *etc.* However, it is provided that a municipality or a community, and natural or legal persons established under public or private law may have ownership rights over communal things, as long as it is stipulated by law<sup>75</sup>. Additionally, it should be noted that Civil Code provides for the introduction of restrictions on property rights, the majority of which is derived from public law *i.e.* protection of public health, protection of the environment, *etc.*<sup>76</sup>

## 2 *The Law of the Person*

Article 24.1 of the Constitution, as an individual right to the environment, extends to private law and has an indirect horizontal effect on private legal relations through the provision that establishes the absolute protection of personality.<sup>77</sup> The requirement of the spherical protection of the environment for the benefit of human beings is assessed at the delimitation of the right to personality, allowing the lodging of the claim for the protection of every element of the vital space, which is necessary for the free and spherical development of the personality of human beings. Moreover, as a result of the generalized protection of the environment<sup>78</sup> for the benefit of humans, as it arises from the constitutional right to the development of the human personality<sup>79</sup> and the primary obligation of the State to respect and protect the values comprising the human being,<sup>80</sup> goods that are not included among common or communal things are included in the right to personality. Such goods are wild flora and

71 According to the Civil Code, fruits of the thing are the natural or organic products of the thing, *i.e.* those produced according to natural laws, periodically and organically, without destroying or damaging the fruitful thing.

72 Civil Code Article 1064.

73 Civil Code Article 972.

74 Civil Code Articles 966, 967, 968.

75 Civil Code Article 968.

76 See Civil Code Article 1000 and A. Georgiadis, *Property Law* (Athens: Nomiki Bibliothiki, 2004): 317, 319–320. (in Greek).

77 According to the provision of Civil Code Article 57.1a, A person who has suffered an unlawful infringement on his personality has the right to claim the cessation of such infringement and the non-recurrence thereof in the future.

78 Article 24 of the Greek Constitution.

79 Article 5 of the Greek Constitution.

80 Article 2 of the Greek Constitution.

fauna, the preservation of biodiversity,<sup>81</sup> landscape aesthetics<sup>82</sup> *etc.* This direction is also followed by Greek case-law of civil courts,<sup>83</sup> according to which the meaning of the right to personality includes the right to use communal things,<sup>84</sup> such as the air, and non-communal things (*e.g.* waters without free and infinite flow, private forests), which fall under the broader sense of the environment and coincide to a great extent with the most important environmental goods, constituting both a precondition for life and elements for securing quality of life. Therefore, access to genetic resources is also dependent on the right to personality and it is proportionately protected.

### 3 *Intellectual Property Rights (IPR) over Genetic Resources*

The national framework for the protection of IPR over varieties of plants was established via Law 1564/1985, the scope of which is limited to the propagating material of all cultivated plant species except for forest species.<sup>85</sup> This national statute was issued before the Regulation 2100/1994/EC on Community plant variety rights and is currently in force, as it has been amended. According to Article 8 of this statute every natural or legal person who discovers or creates any variety of plant species of natural or technical origin, which is new, original, stable and uniform, is considered to be a “creator” (in the sense of “breeder”) of a variety of plant species. He holds the right to produce and trade the propagating material of his variety, and has the authority to exploit or transfer these rights. For the execution of these rights, the law requires the “creator” or any successor to have obtained a certificate of plant protection, issued by the MoA, now MoRDF.<sup>86</sup> The MoRDF keeps a registry of rights of “creators” of plant varieties, where it records the varieties for which a certificate of plant creation was granted, their names, and relevant data regarding the legal status of the “creator’s” rights. The registry of rights establishes a presumption of knowledge for any third person.<sup>87</sup> For the implementation of important issues concerning the aforementioned art. 8, a Presidential Decree is required. This Presidential

81 I. Karakostas, *Environment and Law* (Athens: Nomiki Bibliothiki, 2011): 293. (in Greek).

82 E-A. Maria, *The Legal Protection of Landscape, in International, EU and National Law* (Athens: Ant. Sakkoulas, 2009): 378–381. (in Greek).

83 Single-Judge Court of First Instance of Chalkida 1158/2010, Single-Judge Court of First Instance of Volos 1531/2002, *Elliniki Dikaiosyni* (2002): 1497 & Single-Judge Court of First Instance of Korinthos 2536/2001.

84 Civil Code Articles 967, 968–970.

85 Law 1564/1985 Article 1. 2.

86 *Ibid.*, Article 8 par. 1, 2, 3.

87 *Ibid.*, Article 8 par. 6b.

Decree has not been issued yet.<sup>88</sup> Thus, the EU plant variety protection constitutes the main current framework, according to which the Community Plant Variety Right is granted, and consequently, its owner also enjoys the protection of the community system in Greece.

Finally, the production and trade of a variety of plant species is only allowed if the variety to be produced/traded has been registered in the Greek national catalogue of varieties of cultivated plant species or in the common catalogues of varieties of the EU according to the regime of the Community Plant Variety Protection at the EU level<sup>89</sup> or in the national catalogue of a third state.<sup>90</sup>

Given that the IPR over plant varieties could not be equated with those over patents,<sup>91</sup> patents, as an issue that lies between law, technique and economy, were introduced in national law via Law 1733/1987 and the Presidential Decree 321/2001, on the basis of which the Greek legislation was harmonized with Directive 98/44/EC on the legal protection of biotechnological inventions. The former statute sets the formal requirements for patenting, *i.e.* first, it is assessed whether there is an invention, and then the remaining features of the invention are investigated (novelty, inventive activity, industrial application). These legal filters—requirements “distil” information accessible to all from information that can constitute the object of an exclusive and absolute right. They distinguish public interest from interest to be privatized.<sup>92</sup> In this statute, it is expressly stated<sup>93</sup> that patents are not granted for varieties of plants or species of animals or biological methods for the production of plants or animals, except for microbiological methods and products produced with these methods.

In addition, the Presidential Decree 321/2001<sup>94</sup> states that inventions concerning the above products, which consist of or contain biological material and the above methods, which apply to the production, processing or utilization

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88 See M-D. Papadopoulou, “Another aspect of intellectual property – protection and enforcement of plant variety rights in Greece,” *Review of Commercial Law* (2012):226. (in Greek).

89 We do not refer to this regime, since it constitutes common legislative field with the other EU countries.

90 Article 4 par. 1.

91 See European Court of Justice C- 431/2005 Merck Genericos – Produtos Farmaceuticos Lda and I Merck & Go. Inc. Merck Sharp & Dohme Lda, as well as 3830/2011 Athens’s Court of First Instance.

92 M-Th. Marinos, “Inventive activity. Some observations on the basic vague legal concept of patent law,” *Elliniki Dikaïosyni* 53 (2012): 913.

93 Law 1733/1987 Article 5 par. 8b.

94 Presidential Decree 321/2001 Article 3 par. 1.

of the biological material, can be patented. In particular, with regard to plants or animals, it is provided that inventions can be patented, as long as the technical applicability of the invention is not limited to a particular plant variety or breed of animals.<sup>95</sup> This statute also stipulates that any biological material which has been isolated from its natural environment, or has been produced with the aid of a technical method, can constitute the object of an invention, even if it pre-existed in nature.<sup>96</sup> However, this statute does not consider the information pertaining to the geographical origin of the biological material (plant or animal) as a necessary content of the patent application, despite the fact that it has been established in other EU member states, and it is mentioned as a possibility at the preamble of Directive 98/44/EC recital 27. The patent, which is granted by the Industrial Property Organization (IPO), provides its holder with the exclusive right to productively exploit the invention for twenty years,<sup>97</sup> through his individual rights, including but not limited to the production, marketing, possession and utilization of the protected products or methods. The patent holder has also the right to prohibit any third party to productively exploit his invention and to import the protected products without his consent. However, this prohibition is susceptible to exceptions involving the use of the invention for professional or research purposes, and the preparation of the medicine at a pharmacy for a specific person with a medical prescription and the distribution and use of this medicine.<sup>98</sup>

It is worthwhile to mention that the relevant EU legislation for the protection of Geographical Indications (GI) and designations of origin for agricultural products and foodstuffs,<sup>99</sup> is an additional aspect of benefit-sharing since benefits to a wider cycle of recipients (groups and natural or legal persons) arise.<sup>100</sup>

#### 4 *Private International Law*

Private International Law means the set of rules of law that designate which of the laws of the various states, which are simultaneously in force, is competent to regulate a relationship involving foreign elements or relationships which

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95 *Ibid.*, Article 3 par. 3.

96 *Ibid.*, Article 3 par. 2.

97 Law 1733/1987 Article 11.

98 Law 1733/1987 Article 10.

99 Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs.

100 See also and Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed.

exceed the boundaries of a country, and due to their various elements, are associated with more countries. In addition to conflict of laws, private international law also includes international jurisdiction, recognition and enforcement of foreign decisions.<sup>101</sup>

As regards the international compliance dimensions of PIC and MAT, especially in the field of private international law, there are not any provisions that explicitly address to the issue of compliance of PIC and MAT obtained in another country. Concerning PIC as a public law issue, the commitments are derived from the Public International Law, EU law and national law, which are applicable. Concerning MAT, if it is considered as a private law issue, the provisions of articles 25 and 26 of Greek Code of Private International Law,<sup>102</sup> as they are in force after the issuance of Rome I<sup>103</sup> and Rome II<sup>104</sup> Regulations, could be applicable as appropriate law to contractual and non-contractual obligations, respectively. More specific, obligations arising from contracts are regulated by the law chosen by the parties. In the absence of such choice, the applicable law is the law that has the closest connection with the contract, considering the total of the special conditions.<sup>105</sup>

For obligations arising from tort,<sup>106</sup> the law applicable is the law of the country where the tort was committed (*lex loci delicti*). However, for environmental damage, which includes adverse change of natural resources, impairment of a function performed by a natural resource for the benefit of another natural resource or the public, and impairment of the diversity among living organisms,<sup>107</sup> the Rome II Regulation applies. The law applicable to a non-contractual obligation arising from environmental damage or damage sustained by persons or property as a consequence of the environmental damage, is the law of the Country in which the (direct) damage occurs, regardless of the country in which the event that caused the damage occurred, unless the person seeking compensation chooses to base his or her claims on the law of the country in which the event giving rise to the damage occurred.<sup>108</sup>

101 A. Grammatikaki-Alexiou, Z. Papasiopi-Passia and E. Vasilakakis, *Private International Law*, 5th edition (Athens-Thessaloniki: Sakkoula, 2012): 21 (in Greek).

102 Civil Code Article 4–33.

103 Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I).

104 Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II).

105 *Ibid.*, Article 25 and Rome I, Art. 4 para. 1a.

106 Civil Code Article 26.

107 Rome II Regulation, recital 24.

108 Rome II Regulation Articles 7 and 4 para. 1 in combination. See S. Vrellis, *International Private Law* (Athens: Nomiki Bibliothiki, 2008): 263–287 (in Greek).

Moreover, rights in rem<sup>109</sup> are governed by the law of the country in which the property is situated (*lex situs rei*). When the movable property is transferred into the territory of another country, it is governed by the new *lex rei sitae*. If, for as long as the property is situated in a certain country, all requirements of the law of this country for the creation of a right in rem have been met, this right in rem will still be valid if the movable property is transferred into another country, provided that the new country has an institution with the same or similar content; otherwise, the right in rem is destroyed, and it is automatically reconstituted when it returns to the first country.<sup>110</sup>

In patents, the principle of territoriality entails that the recognition of rights in inventions on the territory of the Greek state is dependent on and exclusively governed by the provisions of the Greek law.<sup>111</sup>

### 5 *Evaluation of the Provisions of Private Law*

The issue of access to the total of the genetic resources of the country is regulated by the private law legislator, but in a more indirect way compared to the way it is regulated by the public law legislator. This is due to the fact that public environmental law sets specifications and requirements for the purpose of the protection of the environment, which is not acknowledged to the same extent by patent law for example, which emphasizes the technique, rewarding inventions that enrich the level of technique, without examining whether an invention involves risks for the environment.<sup>112</sup> The provisions concerning personality, with the horizontal effect of the constitutionally protected right of Article 24 of the Greek Constitution seem to be more palatable. Also, the connection of Article 24 of the Greek Constitution with Article 57 of Civil Code is accepted by the case-law of the Council of State, according to which, the social right to use the natural environment is a manifestation of the right to personality<sup>113</sup> and concerns every element of humans' vital space. As regards the compliance from the private international law perspective, the issue involves complex legal aspects which have to be further investigated. Prima facie, concerning MAT, if it is considered as a private law issue, the provisions of articles 25 and 26 of Greek Code of Private International Law,<sup>114</sup> as they are in force after the issuance of Rome I and Rome II Regulations, could be applicable as appropriate law to contractual and non-contractual obligations, respectively.

<sup>109</sup> Civil Code Article 27.

<sup>110</sup> S. Vrellis, *International Private Law*.

<sup>111</sup> *Ibid.*,

<sup>112</sup> M-Th. Marinos, "Inventive activity," 930.

<sup>113</sup> Plenary Session 3521/1992.

<sup>114</sup> Civil Code Article 4–33.

### III Conclusions – Suggestions

In public law, the national legislator has run a long course with regard to issues of access, and now shows explicit tendencies to make its regulation autonomous and to include it in an integrated legislated system for ABS, for the elaboration of which the conditions seem to be ripe. The acceleration of the processes is required, on the one hand due to the benefit-sharing gap in public law and on the other hand because, although the applicable statutes on access are undoubtedly numerous, they are in force in parallel, since none of them has been abolished, but they apply different criteria of distinction, which leads to frequent confusion with regard to the applicable statutes. Especially in flora, a species may be included in more than one category (endemic or non-endemic, native, aromatic *etc.*), and as a result, its treatment may be judged different, it may be supervised by more than one administrative service, and its permit-granting may be similarly dependent on more than one authority, operating under a different scheme. In the field of liability, especially criminal liability, it is underlined that it is not restricted only to the protection and criminal prosecution for the perpetrators of offences pertaining to species of wild flora and fauna, but it demonstrates a catholicity in criminal trial, as it allows third parties to participate in it. It is, therefore, demonstrated that the issues of the environment, and, hence, access to genetic resources (even under the restriction of the protected species), constitute an issue that concerns all humans, since they are part of it.

In private law, IPR as third parties' rights constitute intersections to the access to genetic resources with equitable benefit-sharing. It appears that there is a form of benefit-sharing, especially through CPVR, GI and patents, since their possessors have the right to produce, distribute and even trade their products at their own will, and thus, to recover their costs and make profits. Although the protection of the patent right is limited in terms of time, it seems to operate towards a system of benefit-sharing since the relevant legal framework provides for the transfer of patent rights and/or grant of license of qualification to others, broadening the scope of beneficiaries. The requirements that need to be fulfilled for a patent to exist in the sense of law as they exclusively are enumerated, delimit "public" from "private" information (information privatization process) and give effect to the right of intellectual property.

With regard to the suggestions, particular attention should be paid to the structure of the applicable regulatory framework. Particularly important issues such as protection, access for research purposes or not, and benefit-sharing of the genetic resources require a common and integrated regulation, which will be described in a single, clear and concise statute, which will exhibit a horizontal



character and will treat all genetic material of the country in an integrated manner. Among the necessary conditions are both the adoption of basic principles, which will govern the integrated legislative attempt and the codification of the existing statutes, so that, after the gaps, the overlaps and the discrepancies are disclosed, a new setting for the ABS regulation will arise.

Furthermore, given that the granting of permits falls under the exclusive competence of state authorities, which are found to operate either as permit granting or surveillance authorities, or as collections of genetic material, the State must retain its permit-granting authority. Thus the constitutional order on the State's duty to protect the environment and biodiversity is fulfilled. However, for the optimal fulfilment of the legislator's aims, we suggest the establishment and operation of a single permit-granting authority, which will have expert knowledge and experience, in order to manage the issue of access to the genetic resources of the country, through any activity. In particular, with regard to the issue of permit-granting, which exhibits significant complexity, it is essential that the process is simplified and that the concerned party addresses only one service, regardless of the type of permit required and the object which is to be granted a permit.

Nevertheless, this will not suffice; the State, complying with its constitutional duty, must broaden the field, so that the benefits arising from the use of genetic resources will be also directed towards it. To this end, a clear legislative foundation and clear provisions are required.

In conclusion, it is highlighted that, in the light of the EU Regulation on ABS, a unique opportunity for the reassessment of the national legislative framework is provided, so that it can be viewed from a more comprehensive perspective, and so that the foundations for the ABS law can be established. The core of the imminent amendments consists of the incorporation of PIC and MAT as horizontal legal concepts into national legislation and the provision of one single competent Authority for the ABS, which will be coincident with the predicted National Authority of the EU Regulation on ABS. In addition, the establishment of a licensing regime for *ex situ* collections which is lacking as well as the establishment of a monitoring system will be achieved in order for the Greek State to comply with international and EU commitments. The realization on the part of the State of the principles stemming from the Nagoya Protocol is a first basic step and to that end, there must be a general commitment (laws – state – administration), so that they will be integrated in each activity (pertaining to ABS), even by mere citizens. However, it is required that the value of genetic resources as a national capital is realized and that actions are planned, so that not only the rich biodiversity of the country, but also national wealth can be effectively protected.

# An Analysis of the ABS Regime in the Netherlands

*Bert Visser, Bernd van der Meulen and Hanna Schebesta*

## I An Underlying Government Policy Promoting Self-Regulation

For many years now, government coalitions in the Netherlands have opted for a policy of self-regulation<sup>1</sup> across society, whenever and wherever this is feasible and appropriate.<sup>2</sup> This generalised policy has also permeated the more specific policy regarding the conservation and utilization of genetic resources, from a conviction that administrative burdens need to be contained for the benefit of a healthy industrial sector and a lean government sector. Responsibility for providing access and practicing utilization of genetic resources has been delegated to the relevant stakeholders.

This chapter explains how domestic access and benefit-sharing (ABS) policies follow from a more generic national self-regulatory approach, and describes how the specific Dutch interests in international ABS arrangements relate to its strong plant and animal breeding sector. In that context, it provides more details on the Dutch policies regarding access to public genetic resources collections and on other national legislation that is pertinent for the management of genetic resources.

## II National Policy Regarding ABS

Given its major activities in the plant and animal breeding, food and beverage and pharmaceutical industries, in combination with the relatively small size of the country and its economy, the Netherlands has a major economic interest in ensuring the continued availability and accessibility of genetic material, across

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<sup>1</sup> In 1992, the Prime Minister published a guidance document for legislation and regulation (Aanwijzingen voor de regelgeving, Circulaire van de Minister-President van 18 November 1992). Section 2.1 addresses the use of regulation. Item 6(1) indicates that new rules should only be given if the necessity of such action has been established. Item 7 requires certain steps to be taken prior to deciding to make new rules. Among these the step described in 7(c) is to investigate whether the objectives can be achieved through self-regulation or if government intervention is really necessary.

<sup>2</sup> Zayenne D. Van Heesen-Laclé and Anne C.M. Meuwese, "The Legal Framework for Self-regulation in the Netherlands," *Utrecht Law Review* 3 (2007): 116–139.

borders and within the Netherlands, in order to maintain in the long term its capacity for the production, processing and export of agricultural products, ornamental plants, seeds and livestock,<sup>3</sup> as well as food products.

In the Netherlands, coordinating responsibility for the implementation of the Convention on Biological Diversity, the Nagoya Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture lies with the Ministry of Economic Affairs. This Ministry is also responsible for agriculture. To this end, the Ministry of Economic Affairs closely collaborates with the ministries responsible for environment, international cooperation and science. Policy development involves each of these ministries, whereas the Ministry of Economic Affairs is the leading ministry.

The Ministry has appointed one of its staff members to represent the Minister as Competent National Authority (CNA) on Access and Benefit-sharing, and notified this to the Secretariat of the Convention on Biological Diversity (CBD). The same staff member shares the role of National Focal Point (NFP) on Access and Benefit-sharing with the director of the Centre for Genetic Resources, the Netherlands (CGN).

In 2002 the Dutch government adopted the policy document *Sources of Existence*<sup>4</sup> on the conservation and sustainable use of genetic resources, which encompasses a policy of free access to genetic resources occurring in Dutch territories, regardless whether these regard agricultural, marine or forest genetic resources.

Some genetic resources occur *in situ*, including in protected areas. However, information on such genetic resources is scarce. Where these occur they are not specifically managed, and their maintenance will depend on general management policies of the land holder. For example, it is known that wild relatives of carrot, lettuce, caraway, black salsify, grasses and fodder crops occur in nature, including in nature reserves, and part of this material has been collected and incorporated in *ex situ* collections.<sup>5</sup>

As the Netherlands is considered to be the country of origin to only a limited set of species relevant for the life sector, its government has so far not deemed

3 Niels Louwaars *et al.*, "Breeding Business, the Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeders Rights," *CGN Report 14* (2009). Wageningen, the Netherlands.

4 "Sources of Existence: Conservation and the Sustainable Use of Genetic Diversity," [http://www.dienstlandelijkgebied.nl/txmpub/files/?p\\_file\\_id=41182](http://www.dienstlandelijkgebied.nl/txmpub/files/?p_file_id=41182).

5 R. van Treuren *et al.*, "Genetic Diversity in Perennial Ryegrass and White Clover among Old Dutch Grasslands as Compared to Cultivars and Nature Reserves," *Molecular Ecology* 14(2005): 39–52.

it necessary to consolidate its national sovereignty regarding access and use of resources under its jurisdiction through legislation. The CNA (see below) is not involved in providing access to such materials. No benefit-sharing arrangements in a strict sense have been concluded for access to genetic resources in the Netherlands. However, contracts that CGN has entered into with land owners guarantee future access of land owners to the collected materials, including for the purpose of reintroduction.

Local communities and in particular non-governmental organizations, herd book organizations and hobby breeders maintain traditional crop and farm animal varieties. Government authorities and the public at large increasingly appreciate the efforts to maintain this bio-cultural heritage.

Existing policy and practice do not explicitly consider traditional knowledge in particular.<sup>6</sup> Whereas it could be argued that knowledge regarding properties of some traditional genetic resources or their processing (land races, local varieties) is to be regarded traditional knowledge, this knowledge has already been largely incorporated in existing documentation systems, original holders of such knowledge can no longer be traced, and hence the use of such knowledge is not supposed to result in any ABS agreements.

Until now, the Dutch government has opted for a self-regulatory approach regarding the implementation of international agreements on ABS. In *Sources of Existence*, the government calls on businesses, research institutions and individuals to deal carefully with regulations, legislation and policy convened internationally or instituted in other countries.

In addition, the policy states that there are good opportunities to base the application (of ABS principles) on existing legislation, provided that:

1. The use and management of genetic resources in the Netherlands is conducted as openly as possible;
2. Transactions and trade in genetic resources are conducted with care;
3. Each person assumes responsibility for managing genetic resources.<sup>7</sup>

6 See also see the fourth national country report CBD, p. 37 <http://www.cbd.int/doc/world/nl/nl-nr-04-en.pdf>.

7 *Er zijn goede mogelijkheden om de uitvoering te baseren op bestaande wetgeving, op voorwaarde dat:*

1. *er een zo groot mogelijke openheid van zaken is over de genetische bronnen die we in ons land beheren en gebruiken;*
2. *transacties en handel in genetische bronnen zorgvuldig plaatsvinden; en*
3. *een ieder zijn/haar verantwoordelijkheid neemt voor het beheer van genetische bronnen.*

In the subsequent policy document “Biodiversity works, for nature, for people, forever”<sup>8</sup> of 2008 the Dutch government again underlined the importance of ABS at international level. At the same time, in its national legislation for the implementation of the Nagoya Protocol, the Dutch regime will remain one of free access to its national genetic resources.

### III Other National Legislation Pertinent for the Management of Genetic Resources

Although there is no specific Dutch legislation dealing with ABS, a number of national laws are pertinent for the use of and access to genetic resources. The free access to resources is thus embedded in a framework of public legislation, notably on nature conservation, animal and plant health, and nature and landscape protection.

The Netherlands is a member of the International Union for Conservation of Nature (IUCN), and as such is bound to protect the species occurring on the so-called IUCN Red List of Threatened Species. Species on the Red List are not automatically protected, but the authorities have committed themselves to endeavor such protection. In the Netherlands this has been effectuated through the Flora and Fauna Act<sup>9</sup> under which 1317 species have been identified as protected, the Nature Conservation Act (Natuurbeschermingswet) and the Forest Act (Boswet). Activities with a damaging effect on protected species, including forms of collecting are prohibited, although the responsible Ministry can provide for exemptions.

A proposal for a Nature Conservation Act (Wetsvoorstel Natuurbescherming) is currently in the legislative process with a view to consolidate the current Nature Conservation Act of 1998, the Flora and Fauna Act and the Forest Act, as well as an implementation of duties under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and the corresponding EU regulation and the EU Timber Regulation.<sup>10</sup>

As a consequence of government policy CGN relies on a simple contract with land owners which specifies that CGN obtains a permission for collecting specific species in a specific site and within a specific time frame, that the land

8 [www.dienstlandelijkgebied.nl/txmpub/files/?p\\_file\\_id=40923](http://www.dienstlandelijkgebied.nl/txmpub/files/?p_file_id=40923).

9 Flora and Fauna Act (Flora en Fauna Wet), 2002.

10 Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market.

owner retains the right on access to the collected material, that CGN will respect local conditions in nature areas, and will inform the land holder on the nature, size and timing of any planned collecting operation. In such contracts, no reference is made to international obligations regarding access and benefit-sharing.

Whereas the policy document Sources of Existence does address the efforts to maintain national bio-cultural heritage (traditional crops varieties and animal breeds) and CGN at the instruction of the government supports the organizations involved through technical and logistic assistance, no further legal or practical measures to maintain this heritage have so far been undertaken.

Equally, legislation on animal and plant health<sup>11</sup> has to be observed with respect to genetic resources, as well as laws for the protection of nature and landscape.<sup>12</sup>

#### IV Property Law in Relation to Access to Genetic Materials

The Dutch free access policy is characterized by the absence of specific legislation on the ownership of genetic resources. Therefore, within the confines of the public law framework, regular property law is applicable. In the system of the Dutch Civil Code (DCC),<sup>13</sup> the owner of a good owns all aspects of this good including all elements attached to it.<sup>14</sup> In the case of land, this includes all plants growing on the land and the fruits of these plants.<sup>15</sup> Ownership therefore generally comprises ownership of genetic resources on the land or the animal. Any interference with that right must be permitted (usually through contract) by the owner.

Animal genetic resources are often exchanged as a consequence of the transfer of a live animal or in the form of semen. Absent pertinent legislation, the rights and scope of the transfer are usually defined by agreement between the provider and the user of the genetic resources (the breeding animal or breeding material) under general contract law. For example rights to the offspring of an animal can be reserved by a seller. Without specific clauses, it is assumed that a sale implies all rights to use of the animal as a genetic resource

11 Such as the Plant Disease Act (Plantenziektenwet); the Animal Health and Welfare Act (Gezondheids- en welzijnswet voor dieren), and the Animal Act (Wet dieren).

12 For example the Nature Conservation Act (Natuurbeschermingswet).

13 Burgerlijk Wetboek, abbreviated "BW".

14 *Ibid.* Article 5:3.

15 *Ibid.* Articles 5:20(1)(f) and 5:1(3).

for the purpose of breeding, including obtaining progeny for commercial and private purposes.<sup>16</sup>

Plant genetic resources may occur *in situ*, either in farm lands, in home gardens (*e.g.* fruit trees) or in nature reserves. The owner of the land retains the right to allow or deny access to a prospected user of plant genetic resources occurring on his premises. Often the collecting serves the purpose of use of the genetic resource contained in the specimen rather than direct use for production purposes only. The same holds for forest genetic resources. Permission for collecting such resources, either in the form of whole plants or in the form of seeds or buds, needs to be agreed with the land owner.

Live bio-control agents, including insects and micro-organisms, may be sold for the purpose of use in production systems. Such transfer allows for cultivation and further reproduction and selection of the organisms involved, but this requires specialized expertise that only few users will possess.

No foreign parties have so far notified the Dutch government through the NFP or the CNA about an intention to collect genetic resources from *in situ* conditions, although enquiries about any conditions for such collecting have been made.

The use of contracts explicitly binding the buyer not to reproduce any of the materials referred to above (such as practiced by breeding companies in the USA for some of its protected crop varieties) has not been reported in the Netherlands.

## V Intellectual Property Rights and the Use of Genetic Materials

The plant breeding and animal breeding sector, as well as major companies in the food and beverage sector (*e.g.* Unilever and Heineken) and in the pharmaceutical industry, that make use of living organisms, regularly protect their products through intellectual property rights. Such rights therefore also bear on access to genetic resources.

The EU Biotech Directive 98/44/EC<sup>17</sup> provides for the granting of patents on biotechnological inventions, on products consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Excluded are inventions confined to particular plant and

16 Hiemstra, S.J., A.G. Drucker, M.W. Tvedt, N. Louwaars, J.K. Oldenbroek, K. Awgichew, S. Abegaz Kebede, P.N. Bhat & A. da Silva Mariante. 2006. Exchange, Use and Conservation of Animal Genetic Resources: Identification of Policy and Regulatory Options. CGN Report 2006/06.

17 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

animal varieties and essentially biological processes. Since its coming into force, Europe-wide over 100 patents have been granted on plants exhibiting native traits, in addition to patents granted on biotechnological processes and genetically modified plants. For all organisms protected by patents, the free use of such organisms in further research and commercialization of research products is prohibited, subject to a general research exemption.

This directive has been implemented in the Netherlands through the Dutch Patents Act of 1995.<sup>18</sup> A few years ago, a study was published at the request of the Ministry of Agriculture, Nature and Food Quality on the relationship between patent rights and plant breeder's rights.<sup>19</sup> The study concluded that amendment of regulations to increase the space for innovation in plant breeding was necessary, by restricting the scope of patents in plant breeding. New legislation to this effect has recently been adopted and introduced a limited breeder's exemption.<sup>20</sup> This will impact on the use of patent-protected plants for the purpose of new research and breeding as a patent exemption is created for all acts involving biological material that have the purpose of breeding, discovering and developing other plant varieties.

Recent discussions have focused on the issue that some of these patents offer protection to the patent holder on traits that do occur in public genebank accessions, and on the question to which extent such patents are technically and politically desirable. In particular, the question can be asked if such patents hamper the free access and use of public genebank accessions.

The Seed and Planting Materials Act of 2005 is the Dutch legislation on plant variety protection.<sup>21</sup> In line with the UPOV Act of 1991 and the EU Plant Variety Rights Regulation 2100/94,<sup>22</sup> it provides for plant breeder's rights. The plant breeding industry in the Netherlands makes extensive use of plant variety protection under the plant breeder's rights law. Two important characteristics of the plant breeder's rights legislation are the so-called breeder's exemption and farmers' privilege. The breeder's exemption allows the use of protected plant varieties for further research and breeding of new varieties, whereas the farmers' privilege allows under certain conditions for the use of

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18 The Rijksoctrooiwet 1995.

19 Niels Louwaars *et al.*, "Breeding Business, the Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeders Rights," *CGN report 14* (2009). Wageningen, the Netherlands.

20 By amendment to Article 53b of the Patents Act of 1995 which entered into force 1 July 2014.

21 Seed and Planting Materials Act of 2005 (Wet van 19 februari 2005, houdende een nieuwe regeling voor het toelaten van rassen, het in de handel brengen van teeltmaterialen en het verlenen van kwekersrecht, Zaaizaad- en plantgoedwet 2005).

22 Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights.



seeds obtained from a protected variety on a farmer's own land holdings. In practice, plant breeder's rights do not pose any restriction hampering the use of a protected variety as a genetic resource, *i.e.* for purposes of research and breeding. Some stakeholders have questioned the limitations in the farmers' privilege and have advocated more generous exemptions for the use of protected varieties by small-scale farmers.

## **VI Private Sector Position Regarding ABS**

Many companies in the Dutch plant breeding sector depend heavily on access to plant genetic resources. Therefore, the sector has closely followed international policy development in the area of access and benefit-sharing, showing an overall intention to comply with implemented policies. Regarding access to plant genetic resources from foreign origin, companies increasingly rely on collaboration with the public genebank CGN to obtain such genetic resources in accordance with the formal requirements, either through collecting missions or from foreign *ex situ* collections.

Over the last decades a number of larger companies have built their own collections due to uncertainty about continued accessibility of public collections.

Various industry sectors in the Netherlands that are regular users of genetic resources have voiced their concerns about the increasing workload and bureaucracy stemming from new regulations to arrange for the international exchange of genetic resources, in particular the Nagoya Protocol, and about the lack of legal certainty regarding the rights and obligations of users of genetic resources of foreign origin.

## **VII The New EU Regulation on the Implementation of the Nagoya Protocol**

The EU Regulation on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization in the European Union (511/2014) requires implementing rules and more formal oversight on activities regarding genetic resources in the Netherlands. Within its context, the Netherlands will opt for self-regulation where this is feasible and effective. The introduction of the concepts on due diligence, best practices (by stakeholder groups) and registered collections very well fits into a policy of self-regulation. Whereas the concept of best practices in the EU Regulation on ABS foresees a role for national governments in monitoring compliance of best practices

agreed in a specific sector, in addition the Netherlands' government may promote self-monitoring of compliance by relevant sector organizations, thereby reducing the work load for the authorities.

The EU Regulation on ABS allows for the current national free access policy to be maintained in future.

It seems clear that implementation of the concept of registered collections, within the scope of the EU Regulation, will result in an extra work load for collection holders, thereby unburdening recipients from their obligations under due diligence provisions. In other words, registered collection holders acquire the responsibility to verify and guarantee that the appropriate access and benefit-sharing conditions have been fulfilled and are communicated to users, and Material Transfer Agreements (MTAs) between registered collection holders and recipients would function as certificates of compliance.

Within government, preparations have been made regarding a new national law referring to measures and institutions needed to implement the monitoring of compliance by Dutch users of provisions agreed with foreign providers regarding Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT). The Netherlands Food and Consumer Product Safety Authority (NVWA) will be tasked with the execution of the government's monitoring obligations. Enforcement will likely include criminal sanctions and administrative fines in analogy to the CITES and EU Timber Regulation.<sup>23</sup>

In addition, consultations with major collection holders have been taken place to explore the consequences for Dutch collection holders of acquiring the status of trusted or registered collection. Dutch collection holders will have to adhere to the PIC and MAT requirements of the Nagoya Protocol regarding their collection materials, as reflected in the EU Regulation, and the government will have to monitor compliance with these requirements.

In its full implementation of the Nagoya Protocol through the EU Regulation, most effective and efficient policies and procedures will be sought, on the one hand ensuring provider countries about compliance by Dutch users and providing legal certainty to Dutch users, and on the other hand reducing the ensuing work load to the extent possible.

According to the Dutch interpretation, the Nagoya Protocol is understood as containing a general ABS regime. Therefore, specific ABS rules contained in other legal instruments such as for example the FAO International Treaty on

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23 Relevant policy in those cases involves that criminal measures for a crime may be a prison sentence of up to 6 years and sanctions of up to 81 000 EUR for individuals and 810 000 EUR for legal entities. For criminal offenses these are sums of 20 250 EUR and 81 000 EUR respectively.

Plant Genetic Resources for Food and Agriculture (ITPGRFA) or the International Union for the Protection of New Varieties of Plants (UPOV), prevail as *lex specialis*.

## VIII The International Role of the Netherlands Regarding Genetic Resources Conservation and Access and Benefit-Sharing

The policy document *Sources of Existence* illustrates how the Netherlands has so far approached its international obligations regarding genetic resources. The government declared as its intention to “stimulate cooperation between the parties involved on a national level, and create an infrastructure for the exchange of expertise and information internationally.”

As noted above, regarding activities of natural and legal persons under its jurisdiction, the Netherlands assumes care and abiding of the law by its citizens in operations in other countries. Such behavior has been incorporated in the policy of public institutions. However, no clear overview exists of activities of private persons or companies regarding the international exchange and use of genetic resources.

So far, no instruments exist for the government to monitor and enforce the conditions set by foreign PIC and MAT as applicable for users in the Netherlands. The government regards compliance with ABS agreements strictly as a responsibility of the parties to the contract. In one well publicised case,<sup>24</sup> a Dutch company negotiated an access and benefit-sharing contract with the Ethiopian authorities regarding the use of the small grain teff. When a conflict arose between the two contract partners, the Dutch government considered itself to be a non-party and – although actively facilitating dispute settlement – did not regard it appropriate to directly intervene in the conflict.

Whereas the government policy considered to review the need for further statutory agreements if, after a number of years since its introduction, it would be apparent that information on the exchange of specific genetic resources was not kept up to date or that it would appear difficult to confirm whether the obligations resulting from international agreements had been fulfilled, no such review has taken place. Such review has now in fact become irrelevant, given the national implementation of the EU Regulation on the implementation of the Nagoya Protocol.

24 Regine Andersen and Tone Winge, “The Access and Benefit-sharing Agreement on Teff Genetic Resources, Facts and Lessons,” *FNI report 6* (2012). Oslo, Norway.

Given the major interests of the Netherlands in the accessibility and exchange of genetic resources, parties in the Netherlands have traditionally invested considerably in the establishment of regional networks and other forms of international collaboration. By establishing such collaboration, the parties involved have usually promoted free exchange of genetic resources across borders.

In the same vein, the country has been traditionally very active in negotiating and implementing relevant international treaties, in particular the CBD, the ITPGRFA and the Nagoya Protocol.

Within the EU, the country has consistently promoted EU positions facilitating and enhancing the international exchange of genetic resources. Furthermore, the Dutch government has initiated bilateral collaboration to agree on transparent conditions for and facilitate international exchange of genetic resources with a number of strategic target countries and regions.

From the perspective of offering home to a major life industry, the aforementioned *Sources of Existence* document<sup>25</sup> notes that

proper cooperation is essential, both with countries from which materials originate and with countries that do not have the capacity available to manage their genetic resources properly or carry out international regulations.

The national policy also established a National Information Centre on Genetic Resources incorporating the role of NFP on ABS. CGN was tasked to function as the National Information Centre and early on established a website providing extensive information on collections of genetic resources in the Netherlands and the genetic material in those collections, as well as on *in situ* resources of national or international relevance.<sup>26</sup> The NFP also advises users of genetic resources in the Netherlands about access and benefit-sharing regimes in force in other countries, including through bilateral consultations.

## IX Policies on *ex Situ* Collections

No single genetic resources collection in the Netherlands is owned by the government. Nevertheless, a substantial number of public genetic resources collections of major importance is held in the Netherlands. These collections

25 "Sources of Existence: Conservation and the sustainable use of Genetic Diversity," p. 10, [http://www.dienstlandelijkgebied.nl/txmpub/files/?p\\_file\\_id=41182](http://www.dienstlandelijkgebied.nl/txmpub/files/?p_file_id=41182).

26 "ABS Focal Point," Wageningen UR, <http://www.wageningenur.nl/en/Expertise-Services/Legal-research-tasks/Centre-for-Genetic-Resources-the-Netherlands-1/Centre-for-Genetic-Resources-the-Netherlands-1/ABS-Focal-Point.htm>.

are formally owned by a legally autonomous public entity, but their maintenance is funded from government sources. These public collections include the collections of botanical gardens, many of which are part of universities, and of the CBS-KNAW Fungal Biodiversity Centre, the food and agriculture collections of CGN, as well as the national herbarium of the Naturalis Biodiversity Center, all managed by research organizations.

In addition, substantive collections are held in the private sector, but no details on the materials incorporated in such collections exist.

Finally, a large number of plant and animal genetic resources, mostly traditional breeds and varieties, are held by non-governmental organizations. A genebank for indigenous trees and shrubs is managed by the state forestry service Staatsbosbeheer, a public organization.<sup>27</sup>

As for its genetic resources occurring *in situ*, the Netherlands has opted for a policy of free access to its public genetic resources collections, for example those of CGN and of CBS-KNAW. The country has placed all relevant plant genetic resources maintained by CGN in the Multilateral System of the ITPGRFA, as has been notified to the Treaty's secretariat. The Dutch government has adopted the position that the ABS provisions of the CBD do not apply to genetic resources that have been acquired by Dutch parties before the entry into force of the Convention.

It has also adopted the position to distribute all remaining plant genetic resources according to the same terms and conditions as those of the Standard Material Transfer Agreement (SMTA) of the ITPGRFA, even if they do not fall under the scope of the Multilateral System of the Treaty. It has also signed a Memorandum of Understanding with AEGIS,<sup>28</sup> the European system of plant genetic resources collections, to that effect. Most botanic gardens in the Netherlands are part of the International Plant Exchange Network (IPEN) and have adopted the IPEN Material Transfer Agreement for the exchange of plant material, in fact limiting use to non-commercial research.

Both CGN and CBS-KNAW yearly distribute thousands of samples to users in a large number of countries worldwide, under the conditions of the SMTA of the ITPGRFA, and an institutional MTA respectively.

The national herbarium contains many samples originating from the Netherlands. The Netherlands has no legislation or policy consolidating ownership over plants occurring *in situ* and corresponding to herbarium specimens.

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27 Detailed information on collections in the Netherlands is available through the website of the NFP on ABS: <http://www.wageningenur.nl/en/Expertise-Services/Legal-research-tasks/Centre-for-Genetic-Resources-the-Netherlands-1/Centre-for-Genetic-Resources-the-Netherlands-1/ABS-Focal-Point/Genetic-Resources-held-in-the-Netherlands.htm>.

28 See "About AEGIS," AEGIS, [http://aegis.cgiar.org/about\\_aegis.html](http://aegis.cgiar.org/about_aegis.html).

Whereas international debate tends to focus on traditional knowledge associated with genetic resources, in the Netherlands much knowledge is also derived from scientific research regarding such genetic resources in its *ex situ* collections. Extensive information on genetic resources held in the Dutch public collections is made available through internet-accessible databases, as in the case of the CGN, CBS-KNAW and botanical garden collections. As a result of the high quality of its collections and the associated information, distribution from its collection, both nationally and internationally, is extensive.

The Netherlands actively contributes to the Global Biodiversity Information Facility (GBIF), a facility which allows the exchange of data on biodiversity by linking databases and making them readily accessible to interested users.

## X Conclusion

Domestic policies regarding ABS are strongly influenced by the overriding principle of self-regulation and the notion that only few valuable genetic resources occur *in situ*. Its international position regarding ABS has always been in favor of open access, reflecting the interests of its major plant and animal breeding industry.

## Norwegian Experiences with ABS

*Morten Walloe Tvedt*

Norway has played a leading role in the negotiations of the Convention on Biological Diversity (CBD) and its implementation and in the negotiations leading to the Nagoya Protocol. Norway has been committed to the implementation of Access and Benefit-sharing (ABS) since the negotiation of the CBD, and has played an important role in the negotiations leading to the International Treaty on Plant Genetic Resources (ITPGRFA) and in the work to implement it. Despite this commitment in the international arena, Norway has not been very rapidly to implement ABS in national legislation, but was still among the few countries to adopt user measures and has laws regulating access. This is largely because the government decided to incorporate rights and access to genetic resources in a more comprehensive piece of legislation, the Nature Diversity Act dealing with biodiversity-related issues as a whole. Nevertheless, Norway has achieved great more progress and has been far more progressive than any other OECD country (members to the Organization of Economic Cooperation and Development) in its implementation of user country measures with the objective of making ABS functional. Formulating the act proved a lengthy process legislators also had to deal with the highly contentious issue of compensation to landowners for restricting their use of their own land, which is a topic which has nothing to do with genetic resources issues. The main legal document regulating rights and access to genetic resources is hence the Nature Diversity Act, which came into effect in 2009.<sup>1</sup> As of 2014, a draft administrative order is awaiting finalisation by the Ministry of Environment and approval of the government before a fully developed ABS system is in place. Whereas the general biodiversity regulations in the Act are already operative, the access side of ABS is dependent on this administrative order to become functional. All administrative orders need to be sent out on a general hearing in society before adopted by the King in the meeting with the Parliamentary Government of Norway. Given the many critical responses in the official hearing consultations and the change of government in October 2013, the draft administrative order is more than likely to be

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\* The research behind this chapter was funded by the Norwegian Research Council, under the program ELSA, project Biotechnology in Agriculture and Aquaculture – Effects of Intellectual Property Rights in the Food Production Chain (Project number 220630/O70).

1 *Naturmangfoldloven/Nature Diversity Act*, Norway, LOV-2009-06-19-100.

amended again before finalisation. Thus, this survey of the legal situation in Norway, shall mainly explore the situation according to the legislation in force, and only use the text of the draft administrative order to show what the complete system might look like when it is finalised.

The management of genetic material in Norway is based on the following general principle:

[Genetic material] shall be utilised to the greatest possible benefit of the environment and human beings in both a national and an international context, also attaching importance to appropriate measures for sharing the benefits arising out of the utilisation of genetic material and in such a way as to safeguard the interests of indigenous peoples and local communities.<sup>2</sup>

This statutory principle informs the authorities' management of genetic material as a resource. How this will be taken into account in single decisions is a matter which is left to some level of discretion for the Ministries and the other public authorities. The idea is to use genetic material both as a means to create value today and manage the genetic heritage for coming generations. Interestingly enough, the principle refers to the actions of both Norwegian and foreign actors.

Norway is amongst the few countries which have implemented user legislation. By implementing a system to enforce the sovereign rights of other countries in domestic legislation, it is evident that Norway is taking its obligations as a resource user seriously indeed. This chapter looks first at the legal status of the genetic resources in Norway; then it looks at the framework for granting access, before going into the benefit-sharing requirements; fourthly, a closer look is offered on the rules to induce compliance with the regulation in other countries; a short look at the institutional structure in Norway is provided, before ending with a discussion on how the Norwegian system relates to the Nagoya Protocol and the final conclusions.

## **I      Legal Status of Genetic Resources and Traditional Knowledge in Norway**

While the legal status of genetic resources in Norway was long unspecified, Section 57 of the Nature Diversity Act spelt out the legal status of the "management of genetic resources": "Genetic material obtained from the natural environment is

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2 Nature Diversity Act Section 57, all the quotes of the Nature Diversity Act are from the translation provided by the Ministry of Environment, see <http://www.regjeringen.no/en/doc/laws/acts/nature-diversity-act.html?id=570549>, accessed 1. October 2014.



a common resource belonging to Norwegian society as a whole and managed by the state.”<sup>3</sup>

Note that the term used in the Act is “genetic material” rather than “genetic resources.” According to the preparatory works, this wording was not intended to imply any substantive difference between it and “genetic resources.”<sup>4</sup> In Norwegian legal tradition “preparatory works” are of considerable importance and weight for the interpretation of the wording of acts. When references are made to the preparatory works, it refers to the formal documents that form part of the making of the act and thus being of interpretative value.

Whereas the Nature Diversity Act applies to all living resources within the sovereignty of Norway, marine resources are specially regulated. The Parliament of Norway (the *Storting*) adopted this act in 2008. This Marine Resources Act determines the legal status of marine resources (hereunder “marine genetic resources”) in general. It establishes that these marine resources “belong to the Norwegian society as a whole.”<sup>5</sup> Here the right is defined as belonging to Norwegian society as a whole, which, according to its preparatory works (by the Ministry of Environment), means the same as the Nature Diversity Act’s conception of “common resources.”

It is pertinent to ask in a practical perspective whether genetic material is meant to be conceived as a “common resource” or a resource belonging to the community. The main idea was to make sure that the legal status provided a legal basis for the permit system for access while not disincentivising investment in exploration and exploitation of genes. In Norwegian legislation requiring any permit for private parties depends on the implementation in Norwegian legislation, due to the principle of legality in general administrative law.

In the preparatory works, however, the Ministry of Environment agrees with the drafting committee that the right to actively use and benefit from the genetic material follows from the legal possession of the biological material in which the genetic material is found.<sup>6</sup> The Ministry also explains that one person’s right to conduct research and make use of the material does not hinder the rights of others to do the same. There is a general clause that specifies that the right to genetic material being a common resource shall not prevent others from applying for intellectual property rights (IPRs) to the material.

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3 Nature Diversity Act Section 57.

4 Ot. Prp. 52 2008–9, p. 294.

5 *Havressurslova/Marine Resources Act*, Norway, LOV-2008-06-06-37, section 2, all the quotes of the Marine Resources Act are from the translation provided by the Ministry of Marine and Coastal Affairs, see <http://www.fiskeridir.no/english/fisheries/regulations/acts/the-marine-resources-act>, accessed 1. October 2014.

6 Ot. Prp. 52 2008–9, p. 295.

The status as common resources obliges the state to manage genetic material as a common resource, and thus establishes an onus on the government to facilitate resource management; it does not, however, confer any particular property right to the government. The idea of allocating the ownership to the government was suggested but explicitly rejected. This raises a complex question concerning the legal status of improved genetic material not covered by any form of intellectual property right, such as patents or plant breeders' rights. "Improved material" here means that the genetic material has been subject to work of humans and brought out of the wild ambient *in situ*. The use of improved, non-IPR protected genetic material is widespread in Norway, and of great economic importance. Huge investments have been made in the aquaculture industry (salmon breeding), and livestock sector (development of Norwegian Red and Norsvin) without IPR protection. Improved genetic material is not well regulated and there is no legal regime governing property rights to improved genetic material. In this situation, the common resources clause will apply as long as the biological material has been obtained legally.

The Act is acknowledging the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and its implementation, and leaves plant genetic material, even in collections, under the scope of those regulations. It specifies in Section 59.7 that:

With regard to the removal of genetic material covered by the International Treaty on Plant Genetic Resources for Food and Agriculture of 3 November 2001 or by another international agreement, the standard conditions laid down under the agreement shall apply.

In addition, an important rule on the relationship between the treaty and domestic legislation is set out in Section 61 of the Act (concerning the implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture).

The King may make regulations regarding the implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture of 3 November 2001 in Norwegian law. The regulations may make further clarifications and exemptions from the provisions of this chapter.

The government may thus derogate in an administrative order from the general ABS rules in this chapter of the Nature Diversity Act to make them consistent with the rules of the ITPGRFA without amending the act itself. Giving the competence for the Government to derogate from the law for particular objectives

implies that the Acts do not need to be amended by the Parliament, but that for these limited purposes the Government has the discretion to make rules that amend the general ABS rules as set out in the Act for the implementation of the ITPGRFA.

The Act does not differentiate the legal status of genetic material in protected areas, and the same general principle that applies to common resources also applies to protected species. The Act does differentiate in its rules governing access to genetic material from various types of biological material. These differentiations depend of the property to the biological material and are not made for specific sectors of users of genetic resources (which is the topic for the discussions in the Commission on Genetic Resources for Food and Agriculture under the Food and Agriculture Organization).

## **II The Regulation of Access to Genetic Resources and Associated Traditional Knowledge**

Having explored the legal status of the genetic material, the next step is to explore the rules regulating access to the genetic material. There are two major questions concerning access to genetic material in Norway. The regulation of access to genetic material depends of two other property right regimes. The owner of the biological material in which the genetic material occurs can control access to the biological material. The owner of lands can restrict the legal access to the genetic material in the land he controls.

Both the Nature Diversity Act and the Marine Resources Act independently of one another allow the government to establish a system regulating access to genetic material at its discretion. In the wording of the Nature Diversity Act:

The King may determine that the collection of biological material from the natural environment for the purpose of utilising the genetic material, or the utilisation of such material, requires a permit from the Ministry.

An administrative order needs therefore to be put in place before the government can require a permit for anyone to collect or utilize genetic material found in Norway. Thus, the obligations in the Act need to be clarified and specified in the administrative order to be enforced on private parties when collecting or utilising genetic material. According to the principle of legality in administrative law, the government must avail itself of its discretion to limit the legal position of a legal or physical person to access genetic material. In other words, until an administrative order is issued, bioprospecting remains

outside a permit system and is not illegal without a permit in Norway. Consultations on a draft administrative order began in 2013. However, in light of the 2013 general election, the subsequent change in government and critical responses of the consulted bodies, the administrative order is unlikely to come into force unchanged.

The Nature Diversity Act also specifies that

If a collection permit has been granted, no new permit is required for subsequent utilisation, but the conditions for the permit apply correspondingly to any person that acquires the material or results arising from the collection. Collection for use in public collections and for use and further breeding or cultivation in agriculture or forestry does not require a permit.

This seems to resolve the situation if the purpose of utilisation changes. But it also includes a reference to the situation in which an access permit was not given before the biological material was collected. In these cases, a permit will be required before the genetic material can be utilised. This is an interesting approach to regulating access and utilisation. Many countries involved in the Nagoya Protocol negotiations have claimed that it is the utilisation situation which requires the permit and triggers benefit-sharing. In Norway, the Act allows the government at its discretion to impose an obligation on parties to obtain a permit to utilisation of the material if no access permit had been granted before.

The Act assumes that in cases where first accessor passes the material on to others, the original terms and conditions will continue to oblige the second user and onwards. This sets a core rule for the legal situation in Norway when a permit system becomes adopted. The Act does not distinguish clearly between agricultural, marine, forest or other sectors of genetic material, beyond the generous exemptions for the implementation of ITPGRFA.

The element regarding access that is already binding on the bioprospector, is that access to the biological material in which the genetic material is found must be legal. There are two types of interest or property in the biological material that is protected by the Nature Diversity Act:

The first paragraph does not limit the right of any owner or other entitled person to deny access on other grounds (a) to the biological material, or (b) to the land[;] from which the genetic material is obtained.<sup>7</sup>

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<sup>7</sup> The translation is by the Ministry of Environment, for information purpose only, accessed 1. October 2014, <http://www.regjeringen.no/en/doc/laws/Acts/nature-diversity-act.html?id=570549>.

This refers to the right of the landowner to control access to land and thus indirectly to the biological and ultimately the genetic material. Access to certain forms of biological resource are governed by the everyman's right or public right of access (*allemansretten*), and therefore available to all. The everyman's right is a typical Nordic (Norway, Sweden and Finland) right entitling the public to use and roam across private land. Although the right is limited in certain respects, the public also have a right to collect certain species even on private, non-cultivated land.

Access to genetic material can also be governed through the right of the possessor of the biological material. In cases in which a person can prevent others from gaining access to the biological material, also indirectly access to the genetic material is restricted. Possessing rights on the biological material may justify restricting access to genetic material. This means that the permission to access the genetic material must be granted by the owner of the biological material. In one sense, this would be to give the holder of all genetic material (improved or wild) the right to control it through control of the biological material. This right ends, however, in situations in which the right holder cannot hinder access to the biological material. Anyone may legitimately catch an escaped bred salmon when the fish farmer has exhausted his right under the Aquaculture Act to re-capture the specimen. The person capturing that specimen will have the successive right to use its genetic material, even if the fish is the result of years of selective breeding. This situation would be different in a situation in which a patented invention had given rise to the salmon. In that case, patent law would regulate the rights to and obligations regarding its genetic material. When bred salmon are not protected by any IPRs, access to improved material is unimpaired.

The Ministry of Environmental Protection (now Ministry of Climate and Environment) and Fisheries Minister (now in the Ministry of Commerce) proposed a joint draft administrative order. The draft proposed a permit system, including a strict benefit-sharing obligation. Whether the new government, which took office in 2013, will maintain a permit system with benefit-sharing obligations on Norwegian and foreign users alike remain to be seen in a new draft administrative order.

### III Benefit-Sharing Requirements

The benefit-sharing principle is enshrined in the Nature Diversity Act.

Further provisions may also be made in the regulations regarding which conditions may be set, such as conditions to the effect that any benefits

arising out of the utilisation of genetic material collected from the natural environment within Norwegian jurisdiction shall accrue to the state.

The Act does not specify which types of benefits Norway expects to be shared or their scope. In the proposed administrative order, the ministries included a table linking specific percentages to different gross sales of products derived from genetic material from Norway. This proposal received negative comments, *e.g.* that this would leave a too uncertain legal situation for users of genetic material.

The Norwegian discussion of ABS is highly coloured by the often cited example of the Swiss researcher, while on holiday in Norway, discovered a fungus which became the basis of a drug marketed by Novartis worth billions. This example raises expectations and illustrates the potential of biodiscovery and the need to regulate benefit-sharing. How the administrative order will resolve this issue of benefit-sharing is still an open one.

#### IV Mechanisms to Induce Compliance with ABS<sup>8</sup>

Norway was among the first countries to enact foreign ABS in domestic legislation. Section 60 of the Norwegian Nature Diversity Act implements a general rule concerning genetic material from other countries.<sup>9</sup> The other two core

8 The author has dealt with this topic elsewhere, see Tvedt and Fauchald. "Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit Sharing in Norway" in *Journal of World Intellectual Property* 14 (2011): 5.

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

When genetic material from another country is utilised in Norway for research or commercial purposes, it shall be accompanied by information regarding the country from which the genetic material has been received (provider country). If national law in the provider country requires consent for the collection of biological material, it shall be accompanied by information to the effect that such consent has been obtained.

If the provider country is a country other than the country of origin of the genetic material, the country of origin shall also be stated. The country of origin means the country in which the material was collected from in situ sources. If national law in the country of origin requires consent for the collection of genetic material, information as to whether such consent has been obtained shall be provided. If the information under this paragraph is not known, this shall be stated.

user country measures are the disclosure requirements in Section 8b of the Patent Act<sup>10</sup> and Section 4(3) of the Act relating to the Plant Breeder's Right.<sup>11</sup> Section 60 of the Nature Diversity Act sets the most general and wide-reaching rule for ABS user-country measures in Norway. Despite going far to include a stand-alone user measure, the measures provided for in the Act did not in the opinion of the government "fully solve the challenge of meeting the obligation of fair and equitable benefit-sharing."<sup>12</sup> The government called on provider countries to provide the necessary tools, and recognize that the measures in Norway are merely subsidiary legal and political tools.

The main rule governing the implementation of ABS, is Section 60(1) of the Nature Diversity Act, which states:

The import for utilisation in Norway of genetic material from a state that requires consent for collection or export of such material may only take place in accordance with such consent. The person that has control of the material is bound by the conditions that have been set for consent. The state may enforce the conditions by bringing legal action on behalf of the person that set them.<sup>13</sup>

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The King may make regulations prescribing that if utilisation involves use of the traditional knowledge of local communities or indigenous peoples, the genetic material shall be accompanied by information to that effect.

When genetic material covered by the International Treaty on Plant Genetic Resources for Food and Agriculture of 3 November 2001 is utilised in Norway for research or commercial purposes, it shall be accompanied by information to the effect that the material has been acquired in accordance with the Standard Material Transfer Agreement established under the treaty." An English version of the Act is available at <http://www.regjeringen.no/en/doc/Laws/Acts/nature-diversity-act.html?id=570549>, accessed 1. October 2014.

10 An English version of the Patent Act translated by the Norwegian Patent Authority is available at <http://www.patentstyret.no/en/For-Experts/Patents-Expert/Legal-texts/The-Norwegian-Patents-Act/>, accessed 1. October 2014.

11 An English version of the Act relating to the Plant Breeder's Right is available at <http://www.ub.uio.no/ujur/ulovdata/lov-19930312-032-eng.pdf>, accessed 1. October 2014, translated by the Ministry of Foreign Affairs. Note that this translation has not been updated with the relevant provision on disclosure.

12 See Tvedt and Fauchald. "Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit Sharing in Norway" in *Journal of World Intellectual Property* 14 (2011): 5, p. 311.

13 The translation is by the Ministry of Environment, for information purpose only, accessed 1. October 2014, <http://www.regjeringen.no/en/doc/laws/Acts/nature-diversity-act.html?id=570549>.

This paragraph imposes two important obligations on any user of genetic material. Import of genetic material to Norway can take place only in accordance with prior informed consent (PIC), if the provider state's legislation requires it. After the import and at any point in time, any possessor of the material is bound by the conditions set out in the PIC. This works as a clear obligation on the user and instructs Norwegian courts and authorities to apply directly the terms set by the provider country. By giving legal effect to the PIC and MAT of another country under Norwegian jurisdiction by stating in the act that their terms and conditions are binding, a huge step forward in ABS implementation was taken. This obligation was implemented independently of the Nagoya Protocol as it passed the Parliament in 2009.

But as is stated in the preparatory work by the Ministry of Environment, even this approach cannot resolve all challenges to the implementation of ABS. There are three weaknesses:

- (1) the approach leaves the main burden on the provider country. If the provider country has no system for implementing PIC or MAT in place, the Norwegian Act will not provide for any benefit-sharing by itself;
- (2) it creates a level of uncertainty for Norwegian users and decision-makers. Access legislation will vary from country to country. This uncertainty is likely to increase significantly if the importer subsequently transfers the genetic material to a third party as the obligations follow the material inside Norway;
- (3) there is no specific minimum requirement to ensure fair and equitable benefit-sharing, either in the Norwegian Act or in the NP. The Act apparently assumes that benefit-sharing in accordance with provider-country requirements will be fair and equitable.

The last sentence sets out a procedural important rule: “[t]he state may enforce the conditions by bringing legal action on behalf of the person that set them.” The “person” here refers both to conditions set in a contract with a legal person or if the party to the contract is a country, on behalf of that country. This goes far in empowering the Norwegian state to take a Norwegian user of genetic resources sourced from another country to court in Norway on behalf of that other country. It recognises difficulties and expense of a procedure undertaken on behalf of a provider wanting to enforce a benefit-sharing clause in a foreign jurisdiction. The Norwegian Attorney General would be responsible for acting on behalf of the Norwegian government (the state).<sup>14</sup> Legal action on behalf of

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<sup>14</sup> There is currently no English-language version of the webpage of the Norwegian Office of the Attorney General, see <http://www.regjeringsadvokaten.no/>, accessed 11 March 2014.



the government would need to be initiated by another state organ. Another governmental body or institution must bring a case to the attention of the Attorney General, as the Attorney General is not empowered to pursue any claim he finds relevant. That said, a provider of genetic materials who wants to benefit from Section 60 of the Nature Diversity Act would probably be best served by contacting the Norwegian National Focal Point for Access and Benefit-sharing within the Ministry of the Environment.<sup>15</sup> The providing country can only bring a case to the attention of the Ministry. Whether the Ministry decides to use its discretion to initiate a case on behalf of a provider would depend on the merits of the case and will be determined politically by the government. According to the Public Administration Act, the authorities will have to provide a reasoned decision on whether to initiate a case or not, and the provider has the right of administrative appeal.<sup>16</sup> The competence of the provider country to take legal steps against a Norwegian user remains. If the government decides not to take the user to court, the providing country maintains its competence to take legal steps itself.

Section 60(2) of the Nature Diversity Act extends the importer's substantive obligation to subsequent users of the genetic material:

When genetic material from another country is utilised in Norway for research or commercial purposes, it shall be accompanied by information regarding the country from which the genetic material has been received (provider country). If national law in the provider country requires consent for the collection of biological material, it shall be accompanied by information to the effect that such consent has been obtained.

The idea behind this extension of the obligations is first to ensure that genetic material is accompanied by information about the criteria on which consent for its utilisation was given. This requirement would also seem to assume that genetic material comes in the form of physical samples and therefore gives less attention to information in the form of digitalised DNA or genes, as such intangibles can more easily be transferred without the use of paper. However, nothing would prevent countries from requiring documentation to accompany the

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15 See <http://www.cbd.int/doc/lists/nfp-abs.pdf>, accessed 11. March 2014.

16 See sections 24–32 of the Act of 10 February 1967 relating to procedure in cases concerning the public administration as subsequently amended, most recently by Act of 1 August 2003 No. 86 (short title: Public Administration Act), an unofficial English version of which is available at <http://www.ub.uio.no/ujur/ulovdata/lov-19670210-000-eng.pdf>, accessed 1. October 2014.

exchange of genetic resources in the form of information, independent of the biological material from which such resources were derived.

Section 6o(3) extends the information requirement to instances where a genetic resource has been imported via a third country:

If the provider country is a country other than the country of origin of the genetic material, the country of origin shall also be stated. The country of origin means the country in which the material was collected from in situ sources. If national law in the country of origin requires consent for the collection of genetic material, information as to whether such consent has been obtained shall be provided. If the information under this paragraph is not known, this shall be stated.

The obligation was widened to ensure more information on the origin of the material, not just on the provider. However, the requirement is not absolute and can be circumvented by the user simply by stating that the information is unknown to him. If the user is unaware of the information, he is not obliged to make an effort to find out. If he submits that he is unaware of the material's origin, he will still be complying with the rules. In a case in which a user states the origin is unknown, it will be rather difficult for the country of origin to raise a claim concerning benefit-sharing, as it will bear the burden of argumentation and proof that the material has a certain origin. "The effect of this rule," Fauchald and Tvedt concluded in 2011, "is thus likely to render Section 6o ineffective when the genetic material has been imported through a third country or where the origin of the genetic material is unclear."<sup>17</sup> It is useful to underline this because this limitation somewhat resembles the requirement discussed in the EU about due diligence. Stating the origin is unknown might become an easy way of sidestepping the obligations on the user side of the ABS balance.

Norwegian IPR systems have adopted two other practical mechanisms. They concern requirements in Norwegian legislation to disclose information on the origin of biological material, *i.e.* Section 8b of the Patent Act<sup>18</sup> and Section 4(3)

<sup>17</sup> Tvedt and Fauchald, "Implementing the Nagoya Protocol," p. 387.

<sup>18</sup> *Lov om patenter/Patent Act*, Norway, LOV-1967-12-15-9, as amended 18 December 2009 (no. 139) and 26 March 2010 (no. 8) Section 8b states the following: "If an invention concerns or uses biological material or traditional knowledge, the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the providing country). If it follows from the national law in the providing country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained.

of the Act relating to the Plant Breeder's Right.<sup>19</sup> The required disclosures under the Patent Act involve several different but complementary types of information:

The countries from which the inventor received or collected the biological material;

If prior informed consent is required in the provider country, information about the existence of such consent shall be included;

The country of origin, if different from the provider country; if information concerning the country of origin is not known, this shall be stated;

If prior informed consent is required in the country of origin, information about the existence of such consent shall be included;

If access to the biological materials has been provided in pursuance of Articles 12.2 and 12.3 of the ITPGRFA, a copy of the standard material transfer agreement shall be enclosed with the patent application.

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If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the application shall also state the country of origin. The country of origin means for biological material the country from which the material was collected from its natural environment and for traditional knowledge the country in which the knowledge was developed. If the national law in the country of origin requires that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.

The duty to disclose information concerning biological material under the first and second paragraphs applies even where the inventor has altered the structure of the received material. The duty to disclose information does not apply to biological material derived from the human body. When the biological material is acquired in accordance with Art. 12 No. 2 and 3 of the International Treaty on Plant Genetic Resources for Food and Agriculture of November, 3, 2001, a copy of a standard material transfer agreement according to Art 12.4 of the Treaty shall accompany the patent application instead of the information mentioned in paragraphs two and three.

Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 221. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents." (translated by the Norwegian Patent Authority,) available at <http://www.patentstyret.no/en/For-Experts/Patents-Expert/Legal-texts/The-Norwegian-Patents-Act/>, accessed 1. October 2014.

19 *Lov om planteforedlerrett / Plant Breeders' Rights Act*, Norway, LOV-1993-03-12-32, translated by the Ministry of Foreign Affairs, available on <http://www.ub.uio.no/ujur/ulovdata/lov-19930312-032-eng.pdf>, accessed 1. October 2014.

The same information requirements apply to parties making applications for plant variety protection. These obligations were not implemented in the Patent Act in direct response to ABS or NP, but were introduced in Norwegian legislation as a “counterbalancing measure,” as part of the political compromise for implementing the EC Directive on Biotechnological Patents in Norway as a member of the European Economic Area (EEA).

The focus of these obligations is *biological* material – not *genetic resources* or *material* as in CBD Article 15.7, the Protocol or the Norwegian Nature Diversity Act. This means that the disclosure obligations go beyond what is required for ABS purposes under the CBD. These obligations will also apply, for example, to instances in which an invention is based on a chemical or some other component found in the biological material.

The condition triggering the disclosure requirements is when “an invention concerns or uses biological material.” It implies a low level of dependency or similarity between the biological material and the invention. The Patent Act goes on to specify that the disclosure requirements also apply “where the inventor has altered the structure of the received material,” accentuating the legislator’s desire to widen the scope of the rule to include all genetic modifications. The obligation to disclose information is also triggered if the user country is not the same as the country “from which the material was collected from its natural environment.”

The Patent Act also requires the applicant to state whether prior informed consent exists in the form required by the country of origin. It is sufficient to state that consent has been sought; there is no need to state the conditions on which such consent was given. As we can observe again, mechanisms targeting the user in Norway are aimed at making enforcement by the provider easier, not to establish a perfect, self-executing, system. Similarly, there is no obligation to provide information on the level of benefit-sharing or any other sharing activity that is going on. ABS increases in complexity when biological material passes through a third party or third country, because it has the potential to water down the obligation.

The obligations contained in Section 8b of the Patent Act and Section 6o of the Nature Diversity Act do not create a functional regime for benefit-sharing on their own. They merely contribute to the provision of information which could hypothetically be used in an enforcement action under Section 6o of the Nature Diversity Act.

If the obligation to provide information is not met, the Norwegian authorities may invoke sanctions enacted in the penal code. In the case of a false statement, such as falsely stating that relevant information was not available, the patent applicant can be penalised by sanctions under Sections 73 and 75 of the

Nature Diversity Act or Section 166 of the General Civil Penal Code (in cases of non-compliance with the Patent Act and the Act relating to the Plant Breeder's Right). It is relatively difficult to apply penal sanctions because the judgement has to fulfil the evidentiary standards of *in dubio pro re* – i.e. one is assumed innocent until proven guilty. The prosecutor must establish whether the information is in fact wrongful and/or deliberately misstated, and provide sufficient evidence thereto, *beyond any reasonable doubt*.<sup>20</sup> The penalty for giving false statements about the origin or the provider or regarding prior informed consent is fines or imprisonment for a maximum of two years. Fines are paid to the Norwegian government. There is no procedure to ensure that benefits must be shared with the provider or the country of origin, nor rule whereby the guilty party is liable to pay compensation. There is thus a discrepancy between the objective of benefit-sharing and the procedures to be applied when the law is broken. This might lessen the effectiveness of the requirement.

One additional and significant reason why the disclosure requirements are unlikely to contribute effectively to benefit-sharing is the lack of specific and automatic legal consequences of non-compliance. As noted in the Patent Act, the consequence of not meeting the disclosure obligation “is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”<sup>21</sup> The same reservation is included in Section 4(3) of the Act relating to the Plant Breeder's Right.

The practical effect of the patent disclosure requirement as a functionally effective user-country mechanism is further constrained by its limited scope of application. Section 8b of the Patent Act applies only to patent applications addressed to and filed directly with the Norwegian Patent Office, not when patents are sent via the system under the Patent Cooperation Treaty (PCT).<sup>22</sup>

20 See General Civil Penal Code Section 40, “The penal provisions of this code are not applicable to any person who has acted unintentionally unless it is expressly provided or unambiguously implied that a negligent act is also punishable,” access, translated by the Ministry of Foreign Affairs, available on <http://www.ub.uio.no/ujur/ulovdata/lov-19020522-010-eng.pdf>, accessed 1. October 2014.

21 *Lov om patenter/Patent Act*, Norway, LOV-1967-12-15-9 § 8b, see also the *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions* [Directive 98/44/EC], 6 July 1998, [1998] OJ, L 213/13, entered into force 30 July 1998 which prohibits rejection of a patent application as a consequence of not complying with the obligation: (1) non-compliance “has no effect for the proceeding of the patent application”; and (2) lack of information shall not have any effect on the validity of a patent after it has been granted.

22 In such cases, Article 27 of the *Patent Cooperation Treaty* [PCT], WIPO, 19 June 1970, entered into force 24 January 1978, as amended on 28 September 1979, 3 February 1984

Moreover, the number of patents filed directly with the Norwegian Patent Office has declined significantly since Norway joined the European Patent Office (EPO).<sup>23</sup> The lack of a corresponding disclosure requirement in the European Patent Convention may motivate patentees to channel biotechnological patents through the European rather than the Norwegian system.

For the information gathered through the arrangement set up under the Patent Act and the Act relating to the Plant Breeder's Right to promote effective benefit-sharing, the relevant authorities would need to ensure that information is passed on to authorities tasked with ensuring compliance with Section 60 of the Nature Diversity Act.<sup>24</sup> As no procedures or information is available on the websites of the relevant Norwegian institutions, Fauchald and Tvedt asked various authorities in the previous study whether information concerning origin of genetic material was available in connection with patent applications and applications for plant variety rights, and whether there were procedures to make such information available to source countries or authorities responsible for implementing Section 60 of the Nature Diversity Act. The Ministry of the Environment, the Norwegian Industrial Property Office and the Norwegian Plant Variety Board told us that no procedures had been established to ensure availability and transfer of information. The Norwegian Contact Point to Access and Benefit-sharing had no information regarding intellectual property rights based on genetic materials originating outside Norway. The Norwegian Industrial Property Office informed us of the existence of 17 applications relevant to Section 8b of the Patent Act, which has been in force since 2003. Of these, 13 had been withdrawn or rejected, and information was thus not publicly available. Of the remaining four, two had included information on country of origin, one application had been rejected, and it was still so early in the application process of the second to make information available. The Norwegian Plant Variety Board informed us that they had no information available concerning the origin of genetic materials related to applications for plant variety rights.

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and 3 October 2001 prevents countries from imposing different or additional requirements to the content of a patent application than those listed in that treaty: "National Requirements (1) No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations."

23 The number of patent applications was expected to decline from around 6,000 to 6,500 applications to between 1,300 to 1,400 applications; see St.prp. no. 35 (2006–2007) concerning Norway's ratification of the European Patent Convention (in Norwegian) at 34.

24 This section is based on the findings presented in Tvedt and Fauchald, "Implementing the Nagoya Protocol," 383–402.

Against this background, Tvedt and Fauchald concluded in 2011 that, although Norway has adopted legislation that has been regarded as very advanced<sup>25</sup> and beneficial to benefit-sharing, little of significance has been done by the various bodies to ensure effective implementation.<sup>26</sup> The relevant legislation was adopted in 2003 (amendment to the Patent Act) and 2009 (the Nature Diversity Act and the amendment to the Act relating to the Plant Breeder's Right). The failure of Norwegian authorities to make progress is particularly troubling in light of the political importance of the amendment to the Patent Act<sup>27</sup> and the more than eight years spent on preparing the Nature Diversity Act.<sup>28</sup>

It is an open question whether the EU Regulation on ABS<sup>29</sup> will require Norway to water down or abandon any of the legal concepts described here. The Regulation is relevant to Norway as a member of the European Economic Area (EEA) and it will need further exploration to identify whether the Regulation will require Norway to relax its system of enforcement.

Concluding on the issue of user country mechanisms, considerable obstacles remain to achieving a legal and political situation whereby a providing country can effectively enforce its claims under Norwegian jurisdiction. In their 2011 article, Fauchald and Tvedt identified several legal technicalities still facing a provider country hoping to get a Norwegian court to enforce an ABS contract or administrative permit from that provider country.<sup>30</sup> Despite some steps that still are missing in the Norwegian implementation, it stands a prominent example on a user country trying to provide a legal situation where the providing countries may take care of their interests and enforce their sovereign rights. Many user countries could draw lessons from these implementing means.

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25 Norway's Nature Diversity Act was among six acts nominated for the Future Policy Award 2010: see <http://www.worldfuturecouncil.org/3454.html#c47432>, accessed 11 March 2014.

26 Tvedt and Fauchald, "Implementing the Nagoya Protocol," p. 390.

27 The 2003 amendment of the Patent Act was related to the decision of 31 January 2003 to include Directive 98/44/EC on the legal protection of biotechnological inventions in the Agreement on the European Economic Area (EEA, 1993). This was a highly controversial issue for the various political parties in Norway, and Section 8b of the Patent Act represented a significant element of the political compromise.

28 The Nature Diversity Act drafting committee was appointed in April 2001; see NOU 2004:28 Section 3.

29 EU Regulation No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union.

30 Tvedt and Fauchald, "Implementing the Nagoya Protocol."

## V Competence to Regulate ABS

As we have seen, the acts clearly designate the two competent Ministries in the field of ABS. In the proposed administrative order, two implementing governmental agencies outside the ministries are set to be the operative units with responsibility of a new ABS permit system. Respectively, the Norwegian Environment Agency<sup>31</sup> and the Norwegian Directorate of Fisheries<sup>32</sup> are foreseen as to be cooperating in executing the administrative order and permit system.

One criticism of the user country legislation is that no specific organ has been given responsibility for monitoring or enforcing compliance with the obligations. Any state body can exercise powers on the user side of ABS. This generalised competence whereby any state organ can prosecute breaches of ABS legislation of another country or a contract between a Norwegian user and a provider can easily lead to a situation where no entity is willing to shoulder the responsibility. To avoid this outcome, administrative organs need to have the required resources to conduct such activities and they also need to act only within the area defined by their legal capacity. Any powers or discretion allocated to all organs can easily result in the action of none. Special agencies should therefore be identified and allocated the necessary resources and responsibility.

## VI Conclusion

The Norwegian rules on the access side of ABS are currently based on a principle of open access. The fact that the law requires permission to access material without providing for a system of access and regulation creates a rather unclear legal situation. The system which is in place today clearly complies with the access side of regulations in the Nagoya Protocol.

It is more interesting to look at the user side. The system in Norway goes much further than the minimum requirements to a user country's legislation than follows from the Nagoya Protocol. The check points that are in force are the Patent Office (for Norwegian patent applications) and the Plant Breeder's Right Approval Office.

The work on traditional knowledge continues apace. It is currently too early to say how these rules will be made operational.

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31 See "Norwegian Environment Agency," <http://www.miljodirektoratet.no/english/>.

32 See "Directorate of Fisheries," <http://www.fiskeridir.no/english>.



Despite implementation in Norway being at a very early stage still, obstacles and hurdles remain before the legal situation in Norway can guarantee the provider country full implementation of the terms and criteria for the utilisation of genetic material. The relatively unfinished implementation of ABS even in a country like Norway with the strong interest of making ABS work shows that the negotiation phase of the Nagoya Protocol has held back work on the national level. Access and benefit-sharing of the dividends from genetic resources has now entered a critical phase following the entry into force of the Nagoya Protocol. One might expect that examples of functional benefit-sharing contracts would need to be seen in relatively short timeframe for the Nagoya system not to lose momentum and the CBD to retain credibility. If the current system for access and benefit-sharing in relation to genetic resources does not end up providing funds for conservation and sustainable use of biological diversity, a core *raison d'être* of the CBD is in jeopardy. It is therefore increasingly urgent for the CBD to make ABS work as was intended. The entry into force of the Nagoya Protocol represents a step in this direction. The new instrument, however, cannot reach these goals alone and so much will rely on functional implementation moving forward.

## Analysis of the ABS Framework in the United Kingdom

*Elta Smith*

The government of the United Kingdom signed the Nagoya Protocol on 23 June 2011 and is committed to its ratification. Nagoya Protocol implementation will primarily affect the UK as a user of genetic resources, with many sectors across the UK using genetic resources obtained overseas, both for commercial and non-commercial purposes. The pharmaceutical and agribusiness sectors in the UK are two of the largest and most important users of genetic resources in this country.

The UK does not have a great deal of *in situ* biodiversity, but some UK genetic resources have been used in scientific research and by industry. Landraces and cultivars are maintained by growers and amateur gardeners, and extensive land-race diversity exists for cereals, forage crops and fruit and vegetable species. There are also a significant number of crop wild relatives and native livestock breeds in the UK. The Overseas Territories are sources of bird and marine resources.

The UK's role as a provider of genetic resources mostly occurs via *ex situ* collections, however, and the UK holds some of the world's largest collections of living and preserved genetic resources. Biological materials are collected directly from "provider" countries and through intermediaries, and by supplying materials to third parties in the UK and overseas.

Historically, therefore, access and benefit-sharing (ABS) principles have been implemented by private actors in the UK and especially by those maintaining major collections of genetic resources. The UK government has not adopted legislation related to access and benefit-sharing for genetic resources or related traditional knowledge. It relies on its property and trespass laws, site protection and statutory protection of species to address issues related to access. UK laws do not protect traditional knowledge and there is no specified role for indigenous and local communities in the UK.

This chapter starts by reviewing the legal framework for ABS in the UK and then provides an overview of the status of genetic resources under UK law. It then assesses the conformity of the UK's current approach with the Nagoya

Protocol and concludes with the UK's proposals for its implementation under the EU Regulation on ABS.<sup>1</sup>

## I The Legal Framework for ABS in the UK

The UK has not introduced legislation that specifically regulates access to or use of genetic resources and associated traditional knowledge. Instead, the UK relies on existing property and trespass laws and statutory protection for species and special sites; these do not cover issues related to traditional knowledge associated with genetic resources.<sup>2</sup>

There are also no specific benefit-sharing obligations in currently applicable UK law regarding genetic resources or associated traditional knowledge, and no mechanisms to ensure compliance with ABS provisions. This includes measures that pertain to access to genetic resources within the UK's jurisdiction such as prior informed consent and the establishment of mutually agreed terms that may be required by the countries that provide genetic resources.

## II Ownership of Genetic Resources

As a consequence of the UK's reliance on existing domestic and EU rules, ownership of genetic resources falls under traditional property rights regimes. Ownership of *in situ* materials is typically assigned to the owner of the land from which those materials were obtained. This includes plants, microorganisms, domestic animals and livestock.<sup>3</sup> Genetic resources may also be subject to intellectual property rights, including patents for inventions involving new products or processes.<sup>4</sup> UK law flows from EU legislation: neither plants nor animals as such may be patented, nor can a patent cover a discovery of genetic

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1 Regulation N° 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

2 Defra, *Sharing the Benefits from Genetic Resources* London: House of Commons European Scrutiny Committee Eighteenth Report of Session 31 October 2012, [http://www.publications.parliament.uk/pa/cm201314/cmselect/cmeuleg/83\\_xix/8304.htm](http://www.publications.parliament.uk/pa/cm201314/cmselect/cmeuleg/83_xix/8304.htm), 2012.

3 *Ibid.*

4 The legislative framework for patent protection in the UK includes the Patents Act 1977, as amended by the Copyright, Designs and Patents Act 1988, the Regulatory Reform (Patents) Order 2004 and the Patents Act 2004.

material as it exists in nature or if it relates to something that is already known. Plant variety rights (PVRs) are closely related to patents and are also protected by UK laws. All plant genera and species can be protected under UK plant variety rights law.<sup>5</sup> PVRs do not extend to acts undertaken for private or non-commercial purposes, experimental purposes or the purpose of breeding another variety.

### III Access to and Use of Genetic Resources

The UK government maintains overall responsibility for ABS implementation although some aspects are devolved to Scotland, Wales and Northern Ireland. For example, the UK government retains competency and jurisdiction over the use of genetic resources while the devolved administrations are responsible for some issues related to access. And since property rights govern access to the majority of genetic resources in the UK, including *in situ* and *ex situ* materials, and in cases of both tangible and intangible property, access is subject to authorisation by the owner of those resources.<sup>6</sup>

#### 1 *The UK as a Provider of Genetic Resources*

The UK is not a significant provider of genetic resources. Nonetheless, extensive landrace diversity is maintained by growers and amateur gardeners for cereals, forage crops and fruit and vegetable species.<sup>7</sup> The UK has more than 200 native livestock breeds.<sup>8</sup> And in 2011, a new cancer treatment based on the chemical colchicine was announced, which was derived from a native British flower, the Autumn Crocus (*Colchicum autumnale*).<sup>9</sup>

5 UK Plant Varieties Act 1997.

6 Defra, *Access and Benefit Sharing: A Summary of Aspects of UK Law Touching on Access and Benefit Sharing* (London: Department for Environment, Food and Rural Affairs, 2010) <http://archive.defra.gov.uk/environment/biodiversity/geneticresources/documents/access-legal.pdf>.

7 Defra, *United Kingdom: Country Report on Plant Genetic Resources for Food and Agriculture* (London: Department for Environment, Food and Rural Affairs, 2010), <http://archive.defra.gov.uk/environment/biodiversity/geneticresources/documents/genetic-resources-country-report.pdf> (accessed 10 September 2013).

8 NSC, *Report on the Work of the National Standing Committee on Farm Animal Genetic Resources 2008–2011* (London: National Standing Committee on Farm Animal Genetic Resources, 2011).

9 Battison, L. "British Flowers are the Source of a New Cancer Drug," *BBC News, Science & Environment*, 12 September 2011.

Wild genetic resources may generally be accessed on private lands by obtaining the permission of the landowner, including for the purposes of collecting genetic materials, but in some cases, the species themselves or the land may be subject to protection and access may require the permission of a statutory authority in addition to permission required from the landowner.

Trespass laws in the UK are an area of tort law and cover most unpermitted activities on private lands, covering the land itself, the subsoil, the air and anything permanently attached to the land. Civil remedies may be sought by the landowner in cases of trespass and the owner may bring a claim without having to prove that any damage occurred. Criminal offences do not apply in the case of trespass, except in cases of trespass on Crown land.<sup>10</sup>

There is considerable countryside in the UK where rights of access to land are tolerated by landowners (*de facto* access) or have been formally recorded through third party contracts, statutory provisions,<sup>11</sup> practice or custom.<sup>12</sup> Right of access may be governed by restrictions or byelaws against taking or harming wildlife and this may constitute a criminal offence.

The Countryside and Rights of Way Act 2000 enables public access to the countryside in England. People may access mapped areas of common land and are not required to stay on paths. The Act came into effect in 2005 and specifically restricts collection of wildlife specimens but it also provides an exception for licenses for or tolerated research or scientific activities on these lands that came into effect prior to October 2005.<sup>13</sup>

There are also legal variations in the UK related to access to commons land. A commons refers to land that is owned by one or more persons but where others have certain rights or access to that land. Commons are legally recognised in the UK by the Commons Act of 2006.<sup>14</sup> Certain rights to the common (*e.g.* livestock grazing) are assigned to particular individuals, called “commoners,” while the landowner retains certain other rights (*e.g.* mineral or timber rights). The majority of commons land, about three-quarters, is found in National Parks (48 per cent) and Areas of Outstanding Natural Beauty (30 per cent).<sup>15</sup> Twenty percent of land designated as commons is also situated within Sites of

10 UK Serious Organised Crime and Police Act 2005.

11 For example, UK National Parks and Access to the Countryside Act 1949 and Wildlife and Countryside Act 1981.

12 Defra, *Aspects of UK Law*. For example, through countryside held by the National Trust or woodland held by the Woodland Trust.

13 Defra, *Aspects of UK Law*.

14 The Commons Act of 2006 replaced the Commons Act of 1285.

15 Natural England. “Common Land,” <http://www.naturalengland.org.uk/ourwork/landscape/protection/historiccultural/commonland/>, 2013.

Special Scientific Interest (SSSIs). There are 7,052 commons covering approximately 4,000 ha or about three percent of land in England. Some commons also have their own local or private acts of parliament.

The relevant Commons Registration Authority may be consulted to determine the requirements for access.<sup>16</sup> The authorities include county councils, metropolitan borough councils and London borough councils designated under the Commons Registration Act 1965. Their duties will eventually be superseded by those set out in Part I of the Commons Act 2006.

Access to genetic resources that involve protected species or protected sites may also require consents from the relevant Competent National Authority (CNA). Protected sites include European protected sites such as Special Areas of Conservation (SACs) and Special Protected Areas (SPAs), SSSIs which may also be part of a Natura 2000 site, National Nature Reserves (NNRs) and Local Nature Reserves (LNRs).

Protected species may be subject to the Wildlife and Countryside Act 1981 (WCA) or the Conservation Regulations 1994. The WCA fulfils the UK's obligations under the Birds Directive,<sup>17</sup> providing statutory protection to all wild birds, their eggs and nests. The WCA also covers those animals listed in Schedule 5 and the structures or places that they use for shelter or protection, as well as plants listed in Schedule 8.<sup>18</sup> The Conservation Regulations 1994 fulfils the UK's obligations under the Habitats Directive<sup>19</sup> regarding European protected species and their breeding and resting sites.

Access to some sites and species is regulated through overlapping protections, in which case activities related to accessing genetic resources must be in compliance with the requirements pertaining to each type of site and/or species protection. Access to *in situ* genetic resources on protected land or related to protected species may require the permission of the relevant statutory authority.<sup>20</sup> If access relies on undertaking what would otherwise be considered a prohibited activity, a license may be granted in certain circumstances. Access to genetic resources subject to the WCA may be granted in certain circumstances by obtaining a license from the relevant authority.<sup>21</sup>

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<sup>16</sup> Defra, *Aspects of UK Law*.

<sup>17</sup> Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds.

<sup>18</sup> Defra, *Aspects of UK Law*.

<sup>19</sup> Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora.

<sup>20</sup> Defra, *Aspects of UK Law*.

<sup>21</sup> *Ibid.*

Rules regarding access to protected sites apply to both land and marine areas up to 12 nautical miles from the coast and UK offshore waters more than 12 nautical miles from the coast.<sup>22</sup> This includes inland, coastal and territorial waters as well as the Exclusive Economic Zone.<sup>23</sup> Marine Conservation Zones and land protection that does not directly apply to wildlife protection including Areas of Outstanding Natural Beauty and National Parks have different access rules to those described for other protected sites.

The main government bodies responsible for providing access to *in situ* genetic resources where permissions other than those of the private land holder are required are devolved and fall to agencies in each of the devolved administrations.<sup>24</sup> Each of these bodies has guidelines for granting access regarding research on *in situ* genetic resources. For example, some agency guidelines require that the site manager take responsibility for granting scientific access to a site. But there are no procedures in place amongst any of the agencies regarding the use of any genetic resources obtained or recording of samples taken.<sup>25</sup>

There are also *in situ* genetic resources in the UK Overseas Territories<sup>26</sup> (approximately 340 endemic species) and Crown Dependencies,<sup>27</sup> particularly bird and marine resources. Extremophiles that have been discovered in the economic zones surrounding the UK Overseas Territories of South Georgia and the South Sandwich Islands may prove important in future research.

The UK government oversees obligations related to the Convention on Biological Diversity (CBD) and its implementation on behalf of the Crown Dependencies and the 13 Overseas Territories. The Dependencies are self-governing and thus are not part of the United Kingdom.<sup>28</sup> The Territories are

22 Joint Nature Conservation Committee, "SACs with Marine Components," <http://jncc.defra.gov.uk/page-1445>. 2013.

23 Defra, *Aspects of UK Law*.

24 The responsible agencies are: the Forestry Commission, Natural England, Scottish Natural Heritage, Countryside Council for Wales and the Northern Ireland Environment Agency.

25 Smith, Elta *et al.* *UK Implementation of the Nagoya Protocol: Assessment of the Affected Sectors, Final Report to Defra*, 2012.

26 The UK Overseas Territories are Anguilla, Bermuda, British Antarctic Territory, British Indian Ocean Territory, British Virgin Islands, Cayman Islands, Falkland Islands, Gibraltar, Montserrat, Pitcairn Islands (including Pitcairn, Henderson, Ducie and Oeno Islands), St Helena (including St Helena dependencies: Ascension Island and Tristan de Cunha), South Georgia and South Sandwich Islands, and Turks and Caicos Islands.

27 The UK Crown Dependencies are Jersey, Guernsey and the Isle of Man.

28 The Kilbrandon Report (Report of the Royal Commission on the Constitution, Part XI, Volume 1, 1973) provides a statement on the relationship.

semi-autonomous with their own written constitutions, and domestic matters are devolved to each territory's local government. In both cases, the UK government is responsible for defense and international relations: the CBD and therefore the Nagoya Protocol are considered to fall under this international relations aspect.<sup>29</sup>

## 2 *The UK as a User of Genetic Resources*

The UK is primarily a user of genetic resources that were obtained from other countries or territories, both for commercial and non-commercial purposes.<sup>30</sup> Most access to UK genetic resources therefore occurs through *ex situ* access to privately held collections. The main sectors involved in the use of genetic resources include pharmaceuticals, cosmetics, plant breeding (horticulture and agriculture), natural and traditional medicines, the wildlife trade, culture collections, zoos, aquaria, botanical gardens and universities.<sup>31</sup> The UK pharmaceutical and agribusiness sectors have long been identified as the largest and most important users of genetic resources in the country.

Access to genetic resources in these cases will therefore require authorization from the owner of the genetic material, rather than the landowner. For example, access to genetic resources for which a patent applies requires the permission of the patent holder, except in some cases where research exemptions or compulsory licenses apply.<sup>32</sup> As with patents, the permission of the plant variety right holder must be obtained in order to access applicable genetic resources, except in the case of compulsory licenses.

It is also possible under the EU legislative framework to have dual protection for plant varieties (*i.e.* a patent and a plant variety right covering the same genetic material).<sup>33</sup> The rules on the patentability of biotechnological inventions are governed by the EU Directive 98/44/EC on the legal protection of biotechnological inventions and the Directive has been implemented in UK national patent law.<sup>34</sup> Under the Directive, a plant or animal is not patentable

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29 Defra, *Aspects of UK Law*.

30 Smith *et al.*, *UK Implementation of the Nagoya Protocol*; IEEP, Ecologic and GHK, *ABS in the European Union*.

31 Smith *et al.*, *UK Implementation of the Nagoya Protocol*.

32 Defra, *Aspects of UK Law*.

33 Smith *et al.*, *Evaluation of the Community Plant Variety Rights Acquis, Final Report to DG SANCO* (Brussels: European Commission, 28 April 2011).

34 The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1994) is the multilateral mechanism for ensuring effective IPR systems under the WTO. The EU and its Member States are WTO members and party to the TRIPS Agreement. Article 27(1) of the TRIPS Agreement requires all WTO Members to provide



if it was obtained by “essentially biological processes.” This distinction means that a biotechnological invention may be patented if it does not relate to a single plant variety, but that plant patents can include a plant variety, without applying directly to that plant variety. Plant groupings of a higher or a lower taxonomic level than a variety can therefore be protected by a patent, if they have incorporated the patented genetic element. In cases of dual protection, permission from the rights’ holders of both the patent and the plant variety right must be sought.

Access to genetic resources protected by patents and/or plant variety rights often involves a material transfer agreement (MTA).<sup>35</sup> MTAs usually include a series of terms and conditions pertaining to the use of the genetic resources and may also include any benefit-sharing provisions. While MTA conditions often vary, they typically cover issues such as distribution, and require the user to confirm that they know their obligations under the CBD.<sup>36</sup> The parties to the MTA are responsible for identifying the specific terms and conditions for each agreement (including how the genetic resources can and cannot be used). For example, the National Collection of Industrial Food and Marine Bacteria (NCIMB) culture collection uses a standard MTA which does not restrict distribution and does not require that the provider in the country of origin directly benefits, although it does stipulate that the user acknowledges that they know the applicable obligations under the CBD.<sup>37</sup> Other organizations, such as the

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patent protection for inventions across all fields of technology, subject to the provisions of paragraphs 2 and 3 (the so-called “optional exclusions”). Article 27(3)(b) allows Members to exclude plants and animals but requires that plant varieties are protected either by patents or by an effective *sui generis* system or any combination thereof.

Article 27(2): “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such an exclusion is not made merely because the exploitation is prohibited by their law.”

Article 27(3): “Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, *Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof...*” [Emphasis added].

35 Smith *et al.*, *Community Plant Variety Rights Acquis*.

36 Smith *et al.*, *UK Implementation of the Nagoya Protocol*.

37 NCIMB MTA, <http://www.ncimb.com/Files/QF203%20-%20Material%20Transfer%20Agreement%20-%20NCIMB.pdf>, 24 May 2011.

Sir Harold Hillier Gardens typically exclude commercial use of a specimen or transfer of the specimen to another organization.

The use of genetic resources (and associated traditional knowledge) varies considerably amongst sectors in the UK: some small organizations may have only a few transactions<sup>38</sup> of genetic resources per year while the largest organization, the Royal Botanic Gardens, Kew, has approximately 90,000 transactions per year.<sup>39</sup> UK users of genetic resources and their associated traditional knowledge obtain genetic resources from countries all over the world. This includes relatively limited *in situ* collecting (*i.e.* bioprospecting), as well as extensive use of *ex situ* collections and access obtained from other organizations operating in the UK and across the EU. Together, botanic gardens and culture collections alone have obtained genetic resources from more than 130 different countries worldwide.<sup>40</sup> Ten to fifteen intermediaries may be involved in transactions involving the transformation of genetic resources before their ultimate utilization (*e.g.* commercialisation).

As a result of this variety, a range of institutional policies and codes of conduct have been developed by scientific research institutes, networks of *ex situ* collections and sector-specific industry groups to ensure that ABS provisions under the CBD are appropriately covered in any transactions of materials.<sup>41</sup> Botanical gardens and the pharmaceutical industry are the most advanced in terms of developing these policies and codes of conduct, but many organizations, whether public or private sector have developed ABS procedures including: model ABS agreements, best practice procedures, material transfer agreements, permitting procedures, codes of conduct, risk-based ABS approaches, and letters of understanding.

The ABS procedures that have been developed by industry and research organizations tend to be sector-specific and provide flexibility for the user to specify their own terms and conditions. They set out generic principles to assist the user in developing a complete and compliant approach to ABS. For example, Kew initiated a model ABS agreement to assist gardens and herbaria to develop their own ABS policies and procedures covering how to obtain prior informed consent both under *ex situ* and *in situ* conditions and share benefits from use, among other issues.<sup>42</sup> The framework was elaborated

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38 Transactions may be of any type, for example, those established through contracts or permits.

39 Smith *et al.*, *UK Implementation of the Nagoya Protocol*.

40 *Ibid.*

41 Smith *et al.*, *UK Implementation of the Nagoya Protocol*.

42 Botanic Gardens Conservation International (BGCI). *The Principles on Access to Genetic Resources and Benefit-sharing*, [http://www.bgci.org/resources/abs\\_principles/](http://www.bgci.org/resources/abs_principles/), no date.

and is adhered to by an international group of botanic gardens and herbaria.

Nonetheless, many UK sectors that are involved in the use of genetic resources are inexperienced with ABS policies and procedures and there are gaps in awareness of CBD and Nagoya Protocol obligations amongst sectors such as cosmetics, horticulture and university research sectors in particular.<sup>43</sup> For example, the UK National History Museum (NHM) has developed a risk-based approach to ABS and considerable experience with obtaining access to genetic materials, but has more limited experience with obtaining consent for the use of traditional knowledge. In the latter case, NHM does not have institutional policies or procedures and individual researchers have developed their own approaches. The agriculture and horticulture sectors have few policies in place beyond requirements set out under traditional intellectual property regimes and through the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

#### IV Conformity of Current Instruments with the Nagoya Protocol and the EU Regulation on ABS

The UK Government signed the Nagoya Protocol on 23 June 2011 and intends to ratify it. Council Conclusions confirm that the government is committed to the Nagoya Protocol's ratification and implementation and the Natural Environment White Paper emphasizes this commitment.<sup>44</sup> The White Paper is the government's statement on its vision for the natural environment for the next 50 years; it states that Nagoya Protocol implementation will help developing countries share the benefits arising from commercialization of genetic resources and provide access to the resources.<sup>45</sup> The UK government also expects implementation to support industry, and particularly the domestic pharmaceutical industry, to obtain reliable access to genetic resources.

UK Nagoya Protocol implementation is likely to mean that many ABS issues will remain covered by existing laws on property, trespass and species and site protection laws. A 2005 review of experience with ABS implementation in the UK concluded that this was adequate to meet the requirements of the CBD,

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43 Smith *et al.*, *UK Implementation of the Nagoya Protocol*.

44 Defra, *Sharing of Benefits, Documents Considered by the Committee on 30 October 2013*.

45 Defra, *What We are Doing Internationally – Access to Genetic Resources* (London: Department for Environment, Food and Rural Affairs, 2011) <http://www.defra.gov.uk/environment/natural/biodiversity/internationally/access-genetic-resources/>.

but the laws applicable to ABS will need to be reviewed again to assess conformity with the Nagoya Protocol and related EU Regulation.<sup>46</sup>

The CBD COP 5 requests parties to designate a national focal point (NFP) and one or more CNAs to take responsibility for ABS arrangements and provide information on those arrangements.<sup>47</sup> The role of the NFP should be to provide information on ABS procedures in a particular country and identify those CNAs or stakeholders from whom prior informed consent may be needed. The UK established an NFP for ABS related issues under the International Biodiversity Policy Unit, Science Directorate of the Department for Environment and Rural Affairs (Defra). The UK also designated a web-based ABS NFP, hosted by Defra, which provides information on the primary contacts for obtaining PIC and negotiating MAT, as well as guidance on access to UK genetic resources.<sup>48</sup>

The web-based ABS NFP will be included in an initiative by the UK government to transition Defra guidance to a new cross-governmental platform (gov.uk). This initiative, the Smarter Environmental Regulation Review (SERR) aims to facilitate access to information and compliance with environmental regulation for UK businesses and members of the public, thereby reducing burdens on the economy while meeting environmental objectives. ABS-related guidance documents will be streamlined and clarified to provide the best possible information to those who use the guidance. An archived version of the NFP website and related guidance is also available.<sup>49</sup>

The role of the CNA is to process and take decisions on applications for access to genetic resources. The UK designated the National Measurement Office (NMO), an Executive Agency of the Department of Business, Innovation and Skills (BIS) as the CNA with responsibility for coordinating ABS arrangements.<sup>50</sup>

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46 EU Regulation No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union.

47 CBD Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Nairobi, Kenya, 15–26 May 2000, (COP 5) Decision V/26.

48 CBD. "United Kingdom of Great Britain and Northern Ireland – Country Profile: Status and Trends of Biodiversity," Convention on Biological Diversity Country Profile, accessed 15 November 2013, <http://www.cbd.int/countries/profile/default.shtml?country=gb>.

49 Defra, *Archive: Genetic Resources: Access and Benefit Sharing*, London: Department for Environment, Food and Rural Affairs, 29 July, <http://archive.defra.gov.uk/environment/biodiversity/geneticresources/access.htm>, 2010.

50 Defra, *Implementing the Nagoya Protocol in the UK*.

National laws in other countries may require benefits to be shared according to mutually agreed terms, in accordance with any required prior informed consent.<sup>51</sup> This may extend both to the use of genetic resources and any associated traditional knowledge. So long as relevant access laws and contractual commitments are met, parties to an agreement are invited to be “as imaginative and ingenious as they are able” in how they define ABS principles and their mechanisms.<sup>52</sup> This suggests that agreements will continue to be made and any issues arising with foreign PIC and MAT will be settled on a case-by-case basis.

Benefit-sharing arrangements are currently led by private organizations and are expected to continue. No ABS agreements have been concluded to date for access to genetic resources that originated in the United Kingdom. But there are some examples of UK organizations working with provider country governments to develop ABS agreements.

For example, the Royal Botanic Gardens, Kew, has partnered with the Australian government and Wollemi Pine International Pty Ltd to commercialize the Wollemi Pine (*Wollemi nobilis*). The Pine was discovered in 1994 near Sydney, Australia and is one of the world’s oldest and rarest plants.<sup>53</sup> Kew was given specimen seeds in 1997 and again in 2005 in order to perform hardiness trials. By 2010, Kew had obtained a batch of Wollemi seeds from these trials and some of the seeds are stored in the Millennium Seed Bank.<sup>54</sup> Fewer than 100 adult trees are estimated to currently exist in the wild.<sup>55</sup> The Pine is being grown and sold to the public as a way to generate funds for conservation of wild plants in Australia.

Another example is the Eden Project, an eco-attraction located in Cornwall, in South West England, which has been working with the Seychelles government and other organizations since 2000 on conservation and restoration projects. This includes educational and public awareness programs, capacity-building and technical development, and facilitation and constituency-building.<sup>56</sup>

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51 Defra, *Aspects of UK Law*.

52 Defra, *Aspects of UK Law*.

53 BGCI. “The Eden Project,” accessed 29 December 2013, [http://www.bgci.org/ourwork/case\\_studies\\_commercialis/](http://www.bgci.org/ourwork/case_studies_commercialis/), no date.

54 Kew, “Wollemi Sets Seed,” *Kew Scientist* 40 (2011), [http://www.kew.org/kewscientist/KewScientist\\_40.pdf](http://www.kew.org/kewscientist/KewScientist_40.pdf) (accessed 22 December, 2013).

55 Wollemi Australia Pty Ltd., “Fast Facts,” accessed 22 December, 2013, [http://www.wollemipine.com/fast\\_facts.php](http://www.wollemipine.com/fast_facts.php), no date.

56 Eden Project. “Eden Project and the Seychelles,” accessed 29 December 2013, <http://www.edenproject.com/sites/default/files/documents/eden-project-and-the-seychelles.pdf>, July 2010.

A funded doctorate program was created in collaboration with the University of Reading, UK to support *in situ* plant conservation. A plant recovery plan was developed for the critically endangered *Impatiens gordonii* and a hybrid, *Impatiens* “Ray of Hope,” was bred to promote conservation issues in the Seychelles and to support fundraising initiatives.<sup>57</sup> The Eden Project obtained prior informed consent from the Seychelles Ministry of Environment in collaboration with the botanical garden in Mahé. The agreement stipulates that half of retail profits arising from the sale of the new variety are returned to the Seychelles to support plant conservation for rare and endangered species.<sup>58</sup>

Finally, the UK does not have any communities that consider themselves to be indigenous, traditional or local within the definition set out in the CBD, but the UK supports indigenous community development in other countries through the UK Department for International Development (DFID).<sup>59</sup> This includes participation in the Inter-American Development Bank’s Indigenous Strategy and the Darwin Initiative. The Darwin initiative assists countries to meet their objectives under the CBD, which includes access and benefit-sharing.

## V UK Proposals for Implementing the Nagoya Protocol under the EU Regulation

The government generally supports the European harmonized approach to ABS and particularly the due diligence approach. Prior to the initial European Commission’s proposal for a Regulation on ABS,<sup>60</sup> Defra commissioned an independent study in 2011<sup>61</sup> to assess the sectors most likely to be impacted by Nagoya Protocol implementation and to propose and assess potential implementation options for the UK. Following the European Commission proposal, Defra also began preparing an impact assessment to support the UK’s final negotiations at EU-level. The UK government has identified an implementation approach at national level to align with the EU Regulation on ABS.

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57 *Ibid.*

58 Eden Project. “Eden Creates Ray of Hope for Endangered Plant,” accessed 29 December 2013, <http://www.edenproject.com/blog/index.php/2011/03/eden-creates-ray-of-hope-for-endangered-plant/>, March 14, 2011; BGCI, “The Eden Project.”

59 CBD *UK Country Profile*.

60 Proposal for a Regulation of the European Parliament and of The Council on Access to Genetic Resources and the Fair and Equitable Sharing Arising from their Utilization in the Union, Brussels, COM(2012) 576 final.

61 Smith, Elta, *et al.*, *UK Implementation of the Nagoya Protocol: Assessment of the Affected Sectors, Final Report to Defra* (London: ICF GHK, 2012).

The 2011 study assessed the sectors that were most likely to be affected by implementation of the Nagoya Protocol and to identify and assess potential options for implementation.<sup>62</sup> The study considered a range of options, including regulation, and identified three options for the UK to fulfil its commitments under Nagoya Protocol Articles 15–18, which cover compliance, monitoring and enforcement of the utilization of genetic resources and associated traditional knowledge in the UK. The study did not assess the impact of EU Regulation on ABS nor did it consider implementation aspects related to specific issues that may arise in the devolved administrations of Scotland, Wales and Northern Ireland. The options considered included: non-legislative actions, amendments to current legislation and dedicated ABS legislation. The study considered that the business as usual scenario was not an option because the UK could not meet its Nagoya Protocol obligations in this case.

The UK government subsequently developed a proposal for implementing the Nagoya Protocol at national level and led a consultation to obtain feedback from stakeholders.<sup>63</sup> The proposal covers how the UK will enforce the EU Regulation's requirements and the UK's own civil sanctions regime for non-compliance.<sup>64</sup> The proposal seeks to complement existing national laws rather than supersede them, filling gaps where the Nagoya Protocol obligations are not already met by current laws.

Under the proposals, Defra will remain the NFP, and the NMO will be the CNA responsible for enforcing the EU Regulation under the Nagoya Protocol for England, Scotland, Wales and Northern Ireland. The NMO is expected to adopt a risk-based approach to compliance, focusing on ensuring that users are compliant, rather than imposing penalties or sanctions as a first resort. Compliance checks are expected to focus on sectors and users that are deemed the most likely to be non-compliant; those users following best practice are also expected to have positive "rewards" in terms of reduced checks or other benefits. The NMO will also verify registered collection status under EU Regulation Article 5.

Both Defra and the NMO will work with stakeholders to monitor due diligence under the Regulation. A dedicated ABS website will be developed by the UK government to supply guidance for users and for users to provide information to government as required.

The UK is not expected to establish a specific access regime for genetic resources and associated traditional knowledge under the Nagoya Protocol,

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62 Smith *et al.*, *UK Implementation of the Nagoya Protocol*.

63 Defra, *Implementing the Nagoya Protocol in the UK*, consult.defra.gov.uk, 2014.

64 Defra, *Implementing the Nagoya Protocol in the UK*.

but it will extend the EU regime for accessing traditional knowledge where it is not covered by a benefit-sharing contract that covers the associated genetic resources. The same due diligence rules will therefore apply to genetic resources and associated traditional knowledge regardless of whether they are identified together in a benefit-sharing agreement.

In order for the NMO to carry out its enforcement duties under the EU Regulation, it will likely be granted certain powers including powers of entry subsequent to notice being given, although exceptional conditions may occur for which no notice will be given, and powers of inspection to examine relevant documents and records.

Civil sanctions may also be applied including the following enforcement actions: enforcement undertakings, compliance notices, variable monetary penalties and stop notices. This approach was modelled on the UK's approach to enforcing the Energy-Using Product and Energy Labelling Regulations, which promotes compliance without frequent recourse to the courts. There is also the potential for criminal penalties in cases where users are repeatedly non-compliant with their obligations.

Potential offences under the UK's proposal include:

- Failing to exercise due diligence as detailed under the EU Regulation;
- Failing to seek, keep and transfer an internationally recognised certificate of compliance or other information listed in the Regulation to subsequent users;
- Failing to keep the information relevant for 20 years after utilization ends; and/or
- Failing to declare to the CNAs that utilization of genetic resources or associated traditional knowledge at the final stage of developing a product fulfils EU Regulatory obligations or submitting a false declaration.

These offences may meet with a term of imprisonment of up to two years and/or an unlimited fine if convicted in a Crown Court or a three month imprisonment term and/or a fine of up to £5,000 for conviction in a Magistrates Court. The penalties were designed based on those used under the European Union Timber Regulation.<sup>65</sup>

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65 Regulation (EU) No 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market.



## VI Conclusion

The UK government proposals for implementing the Nagoya Protocol seek to build on the existing legal framework and fill in the gaps where current rules do not sufficiently address ABS requirements. Use of a risk-based approach to monitoring and reporting, coupled with strong sanctions should help to ensure that ABS issues are addressed where they are most likely to arise without putting the burden on all users of genetic resources and associated traditional knowledge, since the majority of uses are likely not to infringe on ABS requirements from provider countries nor arise from access in the UK or its territories.

Additionally, since the UK is primarily a user rather than a provider of genetic resources, the government has focused on an implementation approach that can help ensure compliance with ABS requirements in other countries, from which UK users obtain genetic resources and traditional knowledge.

The UK government has undertaken some outreach and awareness-raising with stakeholders on ABS in the past and is likely to continue to do so. For example, an online consultation was held leading up to the proposal for Nagoya Protocol implementation.<sup>66</sup> Nevertheless, the government is likely to need to do more than it has already in order to bring all potential users into compliance with the Nagoya Protocol. This could include additional awareness-raising activities and providing opportunities for some of the smaller organisations that use genetic resources and sectors which have less well-developed procedures for ABS already in place to learn from the long-running and well-developed approaches established by organisations such as Kew. Many users are also far less aware of potential issues arising from the use of traditional knowledge associated with genetic resources and are likely to need focused information on ABS requirements in this area.

The UK is only at the beginning of the process leading towards implementation of the Nagoya Protocol, but many of the core elements have been decided or are already in place. Although the UK approach does not seek to go beyond the basic requirements of the Nagoya Protocol, the government has been proactive in working with stakeholders, assessing potential options and establishing an approach that will meet its obligations. The test will be whether existing legal structures supported by the proposed CNA and sanctions regime will be sufficient to identify and deter potential non-compliances while meeting their objective of not putting too great a burden on the wide range of users of genetic resources and traditional knowledge where such use does not contravene the Nagoya Protocol.

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66 Defra, *Implementing the Nagoya Protocol in the UK*.

# Implementing the Nagoya Protocol in Spain: Challenges Perspectives

*Luciana Silvestri and Alejandro Lago Candeira*

Following a description of Spain's unique role as a provider and a user of genetic resources, this chapter analyses the challenges the country faces as it puts into practice the Nagoya Protocol. Important difficulties arise, as national implementation is conditioned by the existing multi-level environmental competence system constituted by the upper governance level – the European Union – and the lower governance level – Spain's Autonomous Communities. Therefore, a deep examination on this matter is provided. Next, the chapter studies the legal and policy-related foundations on which the future Spanish regime on access to genetic resources and benefit-sharing will build. These are the Spanish Strategy for the Conservation and Sustainable Use of Biodiversity of 1999, Law 42/2007 on Natural Heritage, and the National Biodiversity Strategy and Action Plan 2011–2017. Finally, an evaluation is offered of the concrete steps Spain will have to undertake in order to develop ABS measures.

## **I Spain at the Crossroads: Striking the Balance between a Provider and a User of Genetic Resources**

Due to a unique combination of geographical location, topography, edaphic conditions, climate variability and insularity, Spain enjoys a unique biological diversity. Singled out as one of the most diverse countries in Europe – both in terms of natural and cultural heritage, the country is renowned for featuring one of the 25 biodiversity hotspots worldwide.<sup>1</sup>

Land and sea areas under Spanish jurisdiction include four of the nine biogeographic regions of the European Union (EU): the Atlantic, Alpine, Mediterranean and Macaronesian Regions; which have all contributed to the existence of a great variety of ecological niches where vegetation types and related fauna communities thrive. Vascular plants sum up to more than 8,000 species,

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<sup>1</sup> “The Biodiversity Hotspots,” Conservation International, accessed October 14, 2013, <http://www.biodiversityhotspots.org>.

accounting for 85% of the *taxa* at the European level. The rate of endemism is also significant, as some 1,500 of these species are unique to the country, a figure that amounts to half of all endemism at the EU level.<sup>2</sup> Likewise, fauna diversity is abundant. Some 57,600 terrestrial species and 1,790 marine *taxa* have already been identified, a total figure that accounts for 50% of fauna species at the EU level.<sup>3</sup>

It is not surprising then that, being a rich biodiverse country, Spain has become a main source of genetic resources for industry and scientific sectors involved in biotechnology research and development.

This comes in addition to the fact that Spain is considered to be one of the most culturally diverse countries in Europe. Iberians, Celts, Phoenicians, Greeks, Romans and Arabs have all lived in the Iberian Peninsula and have contributed along the centuries to build a unique cultural heritage; which in combination with a significant level of biodiversity, has resulted in an appreciable traditional knowledge associated to the use of plants, animals and fungi.<sup>4</sup>

Today for example, some 1,200 plant species are still used for medicinal purposes<sup>5</sup> and around 500 wild plant species are estimated to be edible.<sup>6</sup> As a consequence, Spain not only can be deemed as the depositary of a magnificent biodiversity, but also of significant traditional knowledge associated to the utilization of genetic resources.

On the other side of the coin, increasingly, Spain can also be considered a user of genetic resources. In the last decades, the Spanish economy has experienced such an unprecedented development that the sector currently counts

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2 Royal Decree 1274/2011, of 16 September, approving the Strategic plan on natural heritage and biodiversity 2011–2017, applying Law 42/2007, of 13 December, on Natural Heritage and Biodiversity (own translation). In Spanish: Real Decreto 1274/2011, de 16 de septiembre, por el que se aprueba el Plan estratégico del patrimonio natural y de la biodiversidad 2011–2017, en aplicación de la Ley 42/2007, de 13 de diciembre, del Patrimonio Natural y de la Biodiversidad.

3 Spanish Ministry of Agriculture, Food and Environment, “The State of Natural Heritage and Biodiversity in Spain 2011 Report,” accessed October 15, 2013, [http://www.magrama.gob.es/es/biodiversidad/publicaciones/IEPNB\\_2011\\_19marzo\\_tcm7-264661.pdf](http://www.magrama.gob.es/es/biodiversidad/publicaciones/IEPNB_2011_19marzo_tcm7-264661.pdf).

4 Manuel Pardo de Santayana *et al.*, “Etnobiología y biodiversidad: El Inventario Español de los Conocimientos Tradicionales,” *Revista Ambiente* 99 (2012).

5 Carlos Fernández López and Concepción Amezcúa Ogayar, *Plantas medicinales y útiles en la Península Ibérica 2.400 especies y 37.500 aplicaciones* (España: Herbario Jaén, 2007).

6 Ramón Morales *et al.*, “Biodiversidad y etnobotánica en España,” in *Biodiversidad: Aproximación a la diversidad botánica y zoológica de España*, ed. José Luis Viejo-Montesinos (Madrid: Real Sociedad Española de Historia Natural, 2011), 166.

with 700 companies<sup>7</sup> working in the field of biotechnology research and development.

Spain is therefore a unique country within Europe with regard to the access and benefit-sharing (ABS) conundrum. It is both a provider of genetic resources, and to a lesser extent of associated traditional knowledge, and a user at the same time.

The dual nature of Spain places the country at the crossroads. On the one hand, it shares similar environmental concerns with rich biodiverse countries and therefore, it desires to adequately regulate the access to its genetic resources and to take advantage from fructiferous benefit-sharing agreements. On the other hand, Spain shares analogous economic interests with some other European Members States who are predominately users of genetic resources. As such, the country wishes to keep users compliance measures as effective and efficient as possible in order not to hinder the development of its fast growing biotechnology sector.

## **II Spain and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization**

Spain signed the Nagoya Protocol on July 21, 2011. Immediately after that it started to work towards ratification and by 2012 all legal internal procedures were cleared out. Despite of these early actions, Spain still had to wait for the EU to move and propose a clear ABS legislation draft.

In October 2012, just before the 11th Conference of the Parties of the Convention on Biological Diversity (CBD) took place, the European Commission launched a legislative proposal for an EU Regulation on ABS, deemed “adequate enough” to implement at this level mandatory provisions of the Nagoya Protocol. At the same time, the European Commission asked Member States not to ratify the Nagoya Protocol before the EU did, setting a dangerous precedent to the letter and spirit of the Treaties and to the principle of shared competences, in particular with regard to the environmental sphere. In this context, the European Commission and the Member States eventually agreed to aim for a simultaneous deposition, to the extent possible, of the respective ratification

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7 MIT, “New Technologies in Spain: Biotechnology,” *Technology Review*, accessed October 15, 2013, <http://icex.technologyreview.com/articles/2009/03/biotechnology-in-spain/biotechnology-in-spain.pdf>.

instruments. Despite of this understanding, immediately after the adoption of Regulation No. 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (the EU Regulation on ABS),<sup>8</sup> the EU deposited its own instrument of approval on May 15, 2014, without awaiting or coordinating with Member States (only Hungary and Denmark ratified before the EU did on April 29 and May 1, 2014, respectively).

On June 3, 2014 Spain “finally” deposited its own ratification instrument to the Nagoya Protocol, once again demonstrating its continuous political commitment to the Nagoya Protocol.<sup>9</sup> Simultaneously, Spain has undertaken a strategic assessment in order to better understand what measures need to be adopted to fulfil obligations under the Nagoya Protocol and coherently adjust to EU legislation.<sup>10</sup>

The starting point of the strategic assessment has obviously focused, amongst other elements, on the legal basis from which a future ABS regime will built on. Those foundations mainly include the Spanish Strategy for the Conservation and Sustainable Use of Biodiversity of 1999,<sup>11</sup> Law 42/2007, of 13 December, on Natural Heritage and Biodiversity,<sup>12</sup> the National Biodiversity Strategy and Action Plan 2011–2017<sup>13</sup> and the EU Regulation on ABS.<sup>14</sup>

8 The European Parliament and the Council adopted Regulation No. 511/2014 on 16 April 2014. It entered into force on June 9, 2014 and it will apply once the Nagoya Protocol itself enters into force for the Union, *i.e.* on October 12, 2014. Some of the provisions of the Regulation will only become applicable one year after that as additional measures need to be put in place before they can be applied.

9 Alejandro Lago Candeira and Luciana Silvestri, “Challenges in the Implementation of the Nagoya Protocol from the Perspective of a Member State of the European Union: The Case of Spain,” in *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective. Implications for International Law and Implementation Challenges*, ed. Elisa Morgera *et al.* (Leiden-Boston: Martinus Nijhoff Publishers, 2013): 270–272.

10 Spanish Ministry of Agriculture, Food and Environment, “The State of Natural Heritage....”

11 Estrategia Española para la Conservación y el Uso de la Diversidad Biológica. (in Spanish).

12 Own translation. In Spanish: Ley 42/2007, de 13 de diciembre, del Patrimonio Natural y de la Biodiversidad.

13 Approved by the above-mentioned Royal Decree 1274/2011 of September 16, 2011.

14 Regulation No. 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (hereafter “EU Regulation on ABS”).

### III Environmental Protection in Spain: A Multi-Level Competence Shared between the European Union, the Spanish National Government and the Autonomous Communities

Before deepening into the concrete steps the country will have to undertake in order to develop ABS measures for the fulfilment of the Nagoya Protocol, it would be helpful to clarify how the existing multi-level governance context affects the distribution of environmental competence between the European Union and Spain (upper governance level) and between Spain and its Autonomous Communities<sup>15</sup> (lower governance level).

At the upper governance level, the environmental competence distribution is clearly stated to be a shared competence, since the Treaty on the Functioning of the European Union (TFEU) enacts that both the Union and the Member States “may legislate and adopt legally binding acts [in the area of environment].”<sup>16</sup> Complementary,

the Member States shall exercise their competence to the extent that the Union has not exercised its competence. The Member States shall again exercise their competence to the extent that the Union has decided to cease exercising its competence.<sup>17</sup>

According to this, Member States are free to regulate on environmental matters as long as there are no EU rules on a specific environmental subject matter. Coherently, if there is EU Regulation in place, Members States have to comply with it.

At the lower governance level, distribution of environmental competences between the national Government and the Autonomous Communities will also play a key role in ABS policy making and implementation. According to the Spanish Constitution, the national Government exercises exclusive competence over basic legislation on environmental protection, without prejudice to the powers of the Autonomous Communities to take additional protective measures.<sup>18</sup> Additionally, Autonomous Communities may assume exclusive

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<sup>15</sup> Autonomous Communities are the first level of administrative and political division in Spain under the national government.

<sup>16</sup> TFEU Article 4.2.e.

<sup>17</sup> TFEU Article 2.2.

<sup>18</sup> Spanish Constitution (1978) Article 149.1.23 (available in English at [http://www.congreso.es/portal/page/portal/Congreso/Congreso/Hist\\_Normas/Norm/const\\_espa\\_texto\\_ingles\\_o.pdf](http://www.congreso.es/portal/page/portal/Congreso/Congreso/Hist_Normas/Norm/const_espa_texto_ingles_o.pdf)).

power over the management of environment protection, something that all Autonomous Communities have assumed. An extreme example of this exclusive competence is the Judgment of the Spanish Constitutional Court in 2004 that recognized full competence to Autonomous Communities over the management of National Parks located under their territories,<sup>19</sup> this shows how the decentralized model of environmental competences in Spain can even go beyond the model established by federal States such as Germany or the United States of America, where no one would challenge the management competences of the federal government.

#### IV      **Setting the Foundations of the Future Regime on Access to Genetic Resources and Benefit-Sharing in Spain**

##### 1      ***The Spanish Strategy for the Conservation and Sustainable Use of Biodiversity of 1999***

The Spanish Strategy for the Conservation and Sustainable Use of Biodiversity of 1999 was the first political instrument to propose several measures to regulate access to genetic resources in Spain. After an initial diagnosis of the state of biodiversity in the country, including the situation of its genetic resources and of traditional knowledge associated to their utilization, the Strategy firstly mandated the drafting of specific regulation concerning the access to genetic resources based on the spirit of the CBD. For that purpose, it proposed the creation of a task force that would undertake the legal drafting and would monitor the implementation of envisaged measures. The adoption of an ABS legal regime was thought to be the cornerstone of the entire Spanish ABS strategy.

Secondly, the Strategy recommended the establishment of an administrative system to monitor access to the country's genetic resources. Interestingly, the system to be put in place was supposed to differentiate between "non-commercial access" (botanical gardens, zoological parks, universities and scientific research institutions, etc.) and "commercial access" (private and multinational companies, agents and individuals), just like the Nagoya Protocol now envisages.<sup>20</sup> However, the criterion for classification into "commercial" or "non-commercial access" does not seem proper, as it focuses on *who* requires access to genetic resources instead of focusing on the *intention* of the user (applicant) of genetic

19 Spanish Constitutional Court Judgement 194/2004 (available in Spanish at <http://hj.tribunalconstitucional.es/docs/BOE/BOE-T-2004-20437.pdf>).

20 Nagoya Protocol Article 8.a.

resources. An example will help to illustrate the point: even though in most of the cases a university will require access to genetic resources to conduct research without commercial purposes, this may not always be the case; and a university could intend to undertake research and development activities with commercial purposes as well. The same could be true for other actors operating in the biotechnology field. Therefore, a criterion based on the intent of the access and research appears to be more adequate for categorization.

Thirdly, the Strategy foresaw the set-up of a genetic resources network which would include germplasm banks, seeds and micro-organisms collections, botanical gardens, agricultural research centers, nurseries and herbaria. In addition, the network would comprise information on *in situ* genetic resources and on traditional knowledge associated to the utilization of genetic resources. Furthermore, the network would include a database with potential Spanish users of genetic resources.

Finally, the Strategy mandated the adoption of legislative, institutional and financial instruments to assure benefit-sharing and appropriate technology transfer.

Unfortunately, none of the measures foreseen by the Spanish Strategy for the Conservation and Sustainable Use of Biodiversity of 1999 was undertaken and only piecemeal awareness raising activities were somehow conducted.

## 2 *Law 42/2007 on Natural Heritage and Biodiversity*<sup>21</sup>

Almost a decade later, Law 42/2007, of 13 December, on Natural Heritage and Biodiversity timidly included few articles in relation to ABS. The Law does not set an ABS regime and it can be stated that its true value, at least in regard to the access to genetic resources, lies in establishing the foundations of what one day will be a complete and coherent ABS system.

The Law manifests in its preamble that it regulates, amongst other things, the access to genetic resources and benefit-sharing in accordance to the CBD. In reality, the only thing the Law does is to empower national authorities to further legislate on the topic in case the national Government decides to do so.

In addition to this “empowerment to legislate in case so is decided,” the Law foresees few general provisions that help framing the future regime. On the one hand, the Law stipulates that access to Spanish genetic resources will be in accordance to the CBD.<sup>22</sup>

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21 Own translation. In Spanish: Ley 42/2007, de 13 de diciembre, del Patrimonio Natural y de la Biodiversidad.

22 Law 42/2007 Article 68.1.



Furthermore, it establishes that access to Spanish genetic resources could be subject to PIC and MAT if that was to be required by a royal decree.<sup>23</sup> As a “royal decree” can only be enacted by the national Government, Law 42/2007 *de facto* closes the possibility for Autonomous Communities to regulate access to genetic resources until the national government has decided to do so. It is clear therefore, that regional authorities cannot proceed to regulate ABS until the existence of such royal decree. Despite of this, some Autonomous Communities (Catalonia, the Canary Islands and Andalusia) have adopted some ABS regulations that may end up being challenged by the national government at the Spanish Constitutional Court.<sup>24</sup>

Provided the national Government decides to regulate the access to genetic resources, Autonomous Communities will be competent for granting PIC and negotiating MAT over *in situ* genetic resources found in their territories and *ex situ* genetic resources kept in conservation institutions located in their jurisdiction.<sup>25</sup> As mentioned before, this competence is in line with Spanish Constitutional arrangements that prescribe that Autonomous Communities may assume competence over management of environmental protection.<sup>26</sup>

Now, independently of whether the national Government decides to exercise sovereign rights over its genetic resources and, therefore, to subject their access to PIC and MAT, Autonomous Communities could still establish restrictions to access *in situ* genetic resources when the collection of resources could affect their conservation and sustainable use.<sup>27</sup> These requirements or restrictions could refer, for example, to particular bioprospecting activities undertaken in relation to an endangered species or habitat. These measures will have to be communicated to the Ministry of Environment who will in turn duly notify the EU’s competent authorities and the Secretariat of the CBD.<sup>28</sup>

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23 Law 42/2007 Article 68.2.

24 It is surprising that the national government aware of the possible conflict of competences with these Autonomous Communities have not promoted a case against them before the Constitutional Court. A reason for that, and this is of course merely a supposition, is that the national government fears that if the conflict was brought before the Court, the Court’s decision could back trigger the National Government, since the latter has blocked for so long the legitimate interest of Autonomous Communities in regulating (and managing) access to their genetic resources in their territories as a result of its own inaction to regulate on the topic.

25 Law 42/2007 Article 68.2.

26 Constitution of Spain Article 148.1.9.

27 Law 42/2007 Article 68.3.

28 Law 42/2007 Article 68.3.

In conclusion, as it clearly stands from Law 42/2007, up to date, Spain has not yet exercised its authority to determine conditions to access its genetic resources since the national Government has not adopted so far legislation (in this case a royal decree) mandating that PIC and MAT are needed in order to access Spanish genetic resources. Therefore, it can be affirmed that access to genetic resources in Spain can be considered free. They are free in the sense they are not subject to any ABS legislation; however, compliance with some other legislation may still be required. For instance, if the genetic resources are located in private or public lands, permission to enter the area is needed according to property rights legislation. Furthermore, if the genetic resources are contained in a species under protection or located inside a protected area, legislation on species conservation or protected areas may indirectly affect the actual access to genetic resources, as applicants will still have to comply with these regulations.

At this point it is also worth mentioning that Spanish legislation does not expressly state who the owner of genetic resources is, either of the physical component or the informational element. This legal loophole will hopefully be addressed in the near future when ABS legislation is adopted. Nevertheless, this legal silence does not prevent property rights laws to be applicable when access to private or public land or biological components is involved (that for example would be the case if the applicant of access of a particular genetic resource needs to entry a private land in order to access the resource).

In regard to traditional knowledge associated to the utilization of genetic resources, the Law establishes that public agencies will preserve and promote consuetudinary knowledge and practices related to the conservation and sustainable use of biodiversity and promote that benefits derived from the utilization of that knowledge and practices are equitably shared.<sup>29</sup> In addition, the Law provides a definition of traditional knowledge. This is the knowledge, innovations and practices of local communities in relation to the natural environment and biodiversity, which has been developed from experience and adapted to the local culture and environment.<sup>30</sup> The latter definition could be helpful in order to implement ABS measures, since neither the CBD nor the Nagoya Protocol include such conceptualization.

Even though in theory both provisions sound good, as they seem to perfectly adjust to the CBD,<sup>31</sup> in reality things get sketchy. As it was mentioned before, Spain is rich in traditional knowledge associated to the use of biodiversity and

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29 Law 42/2007 Article 70.a and 70.b.

30 Law 42/2007 Article 3.4.

31 CBD Article 8j.

in particular to the utilization of genetic resources; however, this traditional knowledge, though plentiful and lively, does not pertain to indigenous communities and there are doubts about the existence of local communities as such. The problem arises because in fact Spain does not count in its territory with indigenous communities; therefore, there is no traditional knowledge associated to these communities that can be legally protected. On the other hand, the notion of traditional knowledge held by local communities also poses complex questions, as there is no international agreement on the definition of “local communities” or a national position on which these communities could be for the case of Spain.

Consequently, the next step for Spain in regard to traditional knowledge will be to answer two important questions: first, what should be interpreted by the term “local communities” in the Spanish context, and, depending on that answer, whether or not the country hosts “local communities” on its territory.<sup>32</sup>

At this point it is important to note that there are certain genetic resources that are excluded from the scope of Law 42/2007. Those genetic resources are:<sup>33</sup>

- Plant genetic resources for food and agriculture, regulated by Law 30/2006;<sup>34</sup>
- Fisheries resources regulated by Law 3/2001;<sup>35</sup>
- Zoo-genetic resources for food and agriculture, regulated by its specific rules.

Each of the previous exemptions entail a certain degree of confusion and legal uncertainty. The first one refers to plant genetic resources for food and agriculture. Law 42/2007 expressly excludes them from its scope and states that they are regulated by Law 30/2006. The problem is however, that Law 30/2006 itself excludes from its scope plant genetic resources for food and agriculture included in the multilateral system of the International Treaty on Plant Genetic Resources for Food and Agriculture for those States adhered to that Treaty.<sup>36</sup> This means that access to *in situ* plant genetic resources covered by the multilateral system of the International Treaty would be again covered by Article 68 of Law 42/2007.

32 There is no international definition of the concept “local communities” and this will be extremely hard to attain as the concept varies from culture to culture and region to region.

33 Law 42/2007 Third additional provision.

34 Law 30/2006, of 26 July, on seeds, garden plants and plant genetic resources (own translation). In Spanish: Ley 30/2006, de 26 de julio, de semillas y plantas de vivero y de recursos fitogenéticos.

35 Law 3/2001, of 26 March, on Marine Fishing by the State (own translation). In Spanish: Ley 3/2001, de 26 de marzo, de Pesca Marítima del Estado.

36 Law 30/2006 Article 45.3.

In practical terms this buried crossed reference could have an undesirable effect: the inexistence of a specific regulation for *in situ* access to the plant genetic resources covered by the Multilateral System of the International Treaty in Spain.

In regard to the second exception, Law 41/2010, of 29 December 2010, on Protection of the Marine Environment<sup>37</sup> has provided that marine genetic resources are regulated by general fishing laws and that they should be considered, as any other marine living resource.<sup>38</sup> This means that marine genetic resources are not understood in consideration to their specific true nature which is that of a container and/or a provider of very useful genetic information; but on the contrary, they are just considered as any other common marine biological resource, let's say for instance a fish. It is clear that the logic behind this is missing. Therefore, as the country prepares to adopt an ABS regime in fulfilment of the obligations set under the Nagoya Protocol, amendments to Law 41/2010 should be carefully considered.

The third one refers to zoogenetic resources for food and agriculture that will be covered by its specific rules, something that, for the time being, has not occurred.

In addition to the above mentioned core provisions, Law 42/2007 implemented one of the measures foreseen in the Strategy for the Conservation and Sustainable Use of Biodiversity of 1999, that is the set-up of a network of genes banks and an inventory. For the first case, the Law specifies that the National Commission on Natural Heritage and Biodiversity will promote the creation of a network that brings together banks that conserve biological and genetic material. The network will prioritize the conservation of endemic flora and fauna species under threat.<sup>39</sup> Autonomous Communities will keep a register of genes banks located under their jurisdictions and updated information on their collections.<sup>40</sup> The network, which is almost completed,<sup>41</sup> could play a key role in the development of the biotechnological sector of the country, if national biotechnology research centers could participate in research and development projects, at least during their initial stages, when Spanish genetic resources are involved.

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37 Own Translation. In Spanish: Ley 41/2010, de 29 de diciembre, de Protección del Medio Marino.

38 *Ibid.* First additional provision.

39 Law 42/2007 Article 60.1.

40 *Ibid.* Article 60.2.

41 The network is REDBAG (Red Española de Bancos de Germoplasma de Plantas Silvestres y Fito-recursos Autóctonos), accessed October 21, 2013, <http://www.redbag.es/index.htm>.

Secondly, the Law creates the Inventory of Biological and Genetic Resources pertaining to Wild Species. For its operation, Autonomous Communities<sup>42</sup> will be in charge of proving useful information to the Ministry of the Environment on three main categories:<sup>43</sup>

- a list of official institutions that conserve biological and genetic material;
- a catalogue and inventory of all biological and genetic material conserved in each institution;
- a list of species for which biological and genetic materials exists, including data on the type, quantity and origin of the samples conserved.

After seven years of the enactment of the Law, it can be stated that the development of the Inventory has been rather slow, as only basic rules for operation have been established.<sup>44</sup> Nevertheless, on the positive side at least some Autonomous Communities (Castile-La Mancha, the Canary Islands, the Basque Country, the Regions of Madrid and Murcia, and Andalusia) have already provided useful information on the conservation of existing genetic resources,<sup>45</sup> which will be soon fed into the Inventory.

Finally, it is worth mentioning that the Law foresees the creation of the Spanish Inventory of Traditional Knowledge on Natural Heritage and Biodiversity, a part of the more comprehensive Spanish Inventory of Natural Heritage and Biodiversity managed by the Ministry of Environment.<sup>46</sup> Here again, almost no developments can be reported, as the Inventory has not been set up yet<sup>47</sup> and only piecemeal provisions have been established to implement it.<sup>48</sup> Nevertheless, it should be mentioned that already some Autonomous Communities such as Castile-La Mancha, Murcia and Andalusia have supplied some ethnobotanical information that will be fed into the inventory once settled.

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42 Law 42/2007 Article 60.3.

43 Royal Decree 556/2011, of 20 April, for the Development of the Spanish Inventory of Natural Heritage and Biodiversity (own Translation). In Spanish: Real Decreto 556/2011, de 20 de abril, para el desarrollo del Inventario Español del Patrimonio Natural y la Biodiversidad. Annex I, heading 3.a.

44 Royal Decree 556/2011.

45 Spanish Ministry of Agriculture, Food and Environment, "The State of Natural Heritage...."

46 Law 42/2007 Articles 9.9 and 70c.

47 Spanish Ministry of Agriculture, Food and Environment, "The State of Natural Heritage...."

48 Royal Decree 556/2011. Annex I, heading 4.b.

### 3 *National Biodiversity Strategy and Action Plan 2011–2017*<sup>49</sup>

The third foundation of the Spanish ABS framework is the National Biodiversity Strategy and Action Plan 2011–2017.<sup>50</sup> This planning tool does not really advance further on the topic and basically reformulates the objectives of the Spanish Strategy for the Conservation and Sustainable Use of Biodiversity of 1999, demonstrating that a complete ABS system is not in place and that not much has been done so far. The basic objectives are:<sup>51</sup>

- adoption of specific regulation for the access to genetic resources;
- creation of a task force to monitor the implementation of envisaged measures;
- establishment of an administrative system to monitor access to the country's genetic resources.

In one word, as it may be seen from the analysis of the existing legal situation, the major cornerstone still needs to be settled. Consequently, a coherent, effective and complete national regime on access to genetic resources and traditional knowledge associated to the use of genetic resources and the fair and equitable benefit-sharing still needs to be adopted.

### 4 *The EU Regulation on Access and Benefit-Sharing*

As stated before (Section III), environmental legislation at the EU level has to be properly implemented by Member States, whom can only strengthen the level of environmental protection. In cases where no such legislation exists, Member States retain full competence on the topic, even in areas of shared competence such as is the case of environmental protection.

The recently adopted EU Regulation on ABS<sup>52</sup> deserves to be properly taken into consideration before further developments are undertaken at the national

49 Royal Decree 1274/2011, of 16 September, approving the Strategic plan on natural heritage and biodiversity 2011–2017, applying Law 42/2007, of 13 December, on Natural Heritage and Biodiversity (own translation). In Spanish: Real Decreto 1274/2011, de 16 de septiembre, por el que se aprueba el Plan estratégico del patrimonio natural y de la biodiversidad 2011–2017, en aplicación de la Ley 42/2007, de 13 de diciembre, del Patrimonio Natural y de la Biodiversidad.

50 In Spanish: Plan Estratégico del Patrimonio Natural y de la Biodiversidad 2011–2017.

51 National Biodiversity Strategy and Action Plan 2011–2017 Objective 2.7.

52 Regulation No. 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. [For a more in-depth discussion of the EU Regulation see contribution by Coolsaet to this volume (Conclusion).]

level. The exclusive focus of the EU Regulation is on “user compliance measures”; which in turn builds on the “due diligence obligation.”<sup>53</sup>

Even though the “due diligence obligation” aims to satisfy obligations set under the Nagoya Protocol,<sup>54</sup> it clearly creates a parallel system that fails to fulfil them. The main deficiency of the “due diligence approach” is that the Nagoya Protocol clearly provides that the necessary document to demonstrate that genetic resources have been legally accessed is the permit;<sup>55</sup> which later becomes the internationally recognized certificate of compliance.<sup>56</sup> Coherently, the main obligation of any user of genetic resources (industry, research institution, etc.) is to obtain from the Party where genetic resources are accessed, a permit. Despite of this, the entire EU “due diligence approach”<sup>57</sup> is constructed upon the exception (to obtain all kind of information,<sup>58</sup> to develop and implement codes of conducts or best practices,<sup>59</sup> or to access genetic resources from trusted collections<sup>60</sup>), rather than on the main obligation of the Nagoya Protocol, which is to obtain an access permit (later called internationally recognized certificate of compliance).

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53 The establishment of a due diligence obligation as central piece of an ABS system was originally part of the EU’s proposals during the negotiation of the Nagoya Protocol. Even though this option was discarded from the final text of the Protocol, the EU’s Regulation under analysis still builds the entire European ABS system around the due diligence obligation. This insistence can only be explained by the internal difficulties that the Commission is experiencing in initiating legislative proposals in the field of the environment. In this case, due diligence was considered to be the safest approach to ensure adoption of a proposal that features vague legal basis. A precedent of the due diligence obligation can be found in Regulation 995/2010, of 20 of October, laying down the obligations of operators who place timber and timber products on the market. [For a more in-depth discussion of the due diligence approach see contributions to this volume by Oliva (Chapter 12) and Godt (Chapter 13).]

54 Nagoya Protocol Articles 15.1 and 16.1.

55 A permit or its equivalent will be issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms. Nagoya Protocol Article 6.3.e.

56 An internationally recognized certificate of compliance serves as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent. Nagoya Protocol Article 17.3.

57 Regulation No. 511/2014 Article 4.

58 *Ibid.* Article 4.3.b

59 *Ibid.* Article 8.

60 *Ibid.* Article 4.7.

Another important shortfall exists in relation to checkpoints. Under the Regulation users are obliged to declare to competent authorities – established by Member States – that they have exercised due diligence when public research funding is involved<sup>61</sup> or at the stage of final development.<sup>62</sup> Competent authorities are obliged to transmit all collected information to the Commission and to the ABS-Clearing House of the CBD.<sup>63</sup> This seems to be much less stringent than the obligations established under Article 17 of the Nagoya Protocol regarding the type of information to be collected and to whom it should be transmitted.

Continuing with the EU Regulation, it is also worth mentioning that according to it, national authorities would have to carry out checks to verify that users comply with the due diligence obligation.<sup>64</sup> Member States would be required to set penalties for the infringements of the due diligence obligation and take all necessary measures to ensure that the due diligence obligation is implemented.<sup>65</sup> This is probably the most disappointing part, since if there is something at all that justifies the EU intervention, it is the need to ensure that users utilizing illegally acquired genetic resources are equally treated, prosecuted and sanctioned in all the Member States of the EU.

Another important shortfall of the EU Regulation on ABS is in regard to traditional knowledge as it applies to “...genetic resources over which States exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union...”<sup>66</sup> Even though this provision seems to be in line with the Nagoya Protocol, a careful reading of the article, which introduces a list of different definitions, reveals that it indeed very much limits the scope of the Regulation; as it conditions the existence of traditional knowledge to the description made of it in the mutually agreed terms applying to the use of genetic resources.<sup>67</sup> Therefore, in accordance with the Regulation, there will only be utilization of traditional knowledge if, and to the extent that, mutually agreed terms states so. This seriously deviates from the obligations set under the Nagoya Protocol as the main objective of the international instrument is in this regard, to fight against the misappropriation of the traditional knowledge, a circumstance that will fall out of the scope of the Regulation as it stands.

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61 *Ibid.* Article 7.1.

62 *Ibid.* Article 7.2.

63 *Ibid.* Article 7.3.

64 *Ibid.* Article 9.1.

65 *Ibid.* Article 11.1.

66 *Ibid.* Article 2.

67 *Ibid.* Article 3.7.



## **V Possible Immediate Actions to Allow for the Development of an ABS System in Spain**

It is quite clear now that most of the so called “user compliance measures” will come from the EU level. Nevertheless, it is very likely that some more elements will be needed at the national level. These are likely to revolve around the necessary operationalization of the procedures foreseen in the EU Regulation, such as the submission of information to the competent national authority or the periodically planned checks. One development seems to be clearly needed: that is the necessity to establish a system of sanctions for users who do not comply with the obligations contained in the EU Regulation. Therefore, the first change that should be introduced in the Spanish legislation is precisely the establishment of sanctions. This could be done through an amendment of Law 42/2007 or in a different piece of legislation.

The Spanish legislation should also try to cover the previously mentioned shortfalls of the EU Regulation on ABS. Otherwise, Spain could be in a situation of non-compliance with certain obligations under the Nagoya Protocol. The most evident at the time of the writing of this chapter is the limitation of the definition of traditional knowledge as it stands now at the EU’s legislation.

Thirdly, as there are no measures on access to genetic resources in the EU Regulation, Spain should take advantage of the momentum the Nagoya Protocol has created and allow the existing system to be operational. That could be easily made with a simple amendment of Law 42/2007 (Article 68.2); which in its new version could read that “access to genetic resources will be subject to PIC and MAT which will be established through a Royal Decree.” This change in practice will mean that the national government, instead of reserving its sovereign right to regulate access to Spanish genetic resources, has already exercised that right and that technical regulations will develop the access system. With this change, Autonomous Communities will be entitled to enact their own access procedures to grant access to genetic resources found in their territories, even in case the national government continues with its present paralysis to develop and adopt the access regulation (royal decree).

The fourth change to be made in Article 68 is the specification of the situations in which the national Government, through the Ministry of Environment, will be competent to grant PIC and MAT. It is clear that the Autonomous Communities will be competent to grant PIC and MAT over access to genetic resources found in their territories; however, Article 68 should still be improved to properly reflect the competences of the national government over certain resources. In this sense, the Spanish Ministry of Environment should have competencies over marine genetic resources as it is currently competent for all

marine biodiversity.<sup>68</sup> Secondly, the national government should be competent to grant PIC and establish MAT over the access of genetic resources found in rivers that flow through more than one Autonomous Community,<sup>69</sup> or in assets and goods belonging to the public national domain,<sup>70</sup> and over the access to *ex situ* genetic resources conserved at national institutions.

Finally, in order to avoid the unfortunate confusion created by Law 41/2011, a derogation of its first additional provision will be helpful.<sup>71</sup>

## VI Conclusions

After the enactment of Law 42/2007, Spain waited for the adoption of the Nagoya Protocol to develop its own ABS system. While the EU legislation on ABS was under discussion, the country, again, held back the legal procedures. Fortunately, today both instruments are a reality and have effectively entered into force on October 12, 2014. As a result, Spain will have to put in place effective measures for the implementation of ABS. Access to its genetic resources should be regulated in a simple way in order to be able to track their utilisation, effectively involve Spain's scientific research community, and generate the much needed extra funds for biodiversity conservation.

Providers and users of genetic resources at the national level are waiting for these developments to occur in order to improve the legal certainty of their transactions, and to add meaningful value to the rich Spanish biodiversity.

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68 Law 42/2007 Article 6.

69 Constitution of Spain Article 149.1.22.

70 Constitution of Spain Article 132.

71 In any case the interest of the fishing sector and fishing department would be still covered by the present third additional provision of the Law 42/2007 (fishery genetic resources regulated by Law 3/2001 are excluded from the scope of the Law 42/2007).

# The Legal Regime of Genetic Resources in Turkey: Opportunities for Access and Benefit-Sharing

*Fulya Batur*

With the recent signature of the Nagoya Protocol on access to genetic resources and the sharing of benefits arising from their use, the task at scholars' hand today is to determine whether the world's "gene centres," as identified by Dr. Nikolai Vavilov from the 1920's onwards, will convert into fortresses, shielding the gold of a new genetic "El Dorado" against those rich in technology but poor in genetic resources,<sup>1</sup> or whether biological prospection will provide for discoveries answering the needs of direct users, as well as the sick or the hungry, being perhaps paired with successful benefit-sharing arrangements. Turkey has been identified as the gene centre of wheat, but is also considered to harbour considerable genetic diversity. Due to its geographic position at a cross-road between extremely diverse climates ranging from Central Asian steppes to the Mediterranean Green Riviera, but also due to the existence of diverse natural ecosystems within its borders, the country has long been considered as one of the world's rare biodiversity havens.<sup>2</sup> With regards to the pre-identified biodiversity measuring method establishing biodiversity "hotspots", which takes into account the levels of species concentration, their richness and endemic nature, but also the dangers of extinction,<sup>3</sup> Turkey finds itself on several hot spots, namely the Mediterranean Basin, the Caucasus and the Irano-Anatolian Plateau. The number of plant taxa and species found within its territorial borders is said to reach more than an impressive twelve thousand, of

1 Heinrich Von Loesch, "Gene Wars: The Double Helix Is a Hot Potato," CERES 131, no. 23 (September-October 1991).

2 Turkish State Planning Organization, *The National Strategy and Action Plan for Biodiversity in Turkey*, 2001, p. 9.

3 The hot-spots approach was developed by Norman Myers, "Threatened Biotas: 'Hot Spots' in Tropical Forests," *The Environmentalist* 8(1988). See also Walter V. Reid, "Biodiversity Hotspots," *Trends in Ecology and Evolution* 13, no. 7 (1998), where the author guides us through the multiplicity of criteria available in the determination of hotspots, the means through which evaluation shortcomings might be overcome, and how designations should influence conservation policies. The hotspot evaluation method has since then been frequently used by environmental associations and international organizations alike, including the International Conservation Union.

which approximately four thousand have been classified as endemic, rivalling those found throughout the entire European continent.<sup>4</sup> Losses have been ascertained in most species and been attributed to excessive increases of population, misuse and decreases of agricultural lands, the acceleration of erosion, the destructive effects of road and dam construction, the collection of plants of economic importance,<sup>5</sup> excessive use of chemicals and fertilizers, cross-breeding with alien species, inadequate education, but also surprisingly political exploitation.<sup>6</sup>

In light of these considerations, the Turkish legislative order that dresses the contours of biological prospecting proves to be a challenging implementation forum, due to Turkey's clear position as a resource-provider country, its ambiguous negotiating stances in international environmental legal forums, as well as its more than fifty years' long association with the European Union, and its now ten years' long official candidacy to Union membership. The difficulties are heightened by a great lack of literature delving into the subject, whether from political science, legal or natural sciences scholarship. The currently applicable regime can nonetheless be defined as a very protective and defensive approach to access, with little if any formal consideration on procedures ensuring benefit-sharing or compliance. National legislative efforts seemingly wait for greater international action and cooperation, putting emphasis on the need for action against biological piracy. With specific regards to the access

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- 4 Studies and numbers vary between 9.000 and 13.000 species, and an accurate result is difficult to come about in the lack of national inventory. However, these numbers are repetitively mentioned in all official and scholarly documents. See *The National Strategy and Action Plan for Biodiversity in Turkey*, 2001; Frederic Mendail and Pierre Quezei, "Hot-Spots Analysis for Conservation of Plant Biodiversity in the Mediterranean Basin," *Annals of the Missouri Botanical Gardens* 84, no. 1 (1997). (especially the figures in p.118). Recent studies conducted throughout the year 2007 identified 12.476 taxons, of which 32.7 per cent, i.e. 4.080 have been categorized as endemic. (Neriman Özhatay, Sukran Kültür, and Serdar Aslan, "Check-List of Additional Taxa to the Supplement Flora of Turkey Iv," *Türkiye Florası Ek Ciltlerine İlave Edilen Taksonların Listesi IV*, 33, no. 3 (2009); and Ergin Hamzaoglu et al., "A New Record for the Flora of Turkey: *Scorzonera Ketzkhovellii* Grossh. (Asteraceae)," *Türkiye florası için yeni bir kayıt: *Scorzonera ketzkhovellii* Grossh. (Asteraceae)* 34, no. 2 (2010).)
  - 5 Several examples of over-exploitation attributed to social and culinary purposes have been identified; 38 species of orchids are for instance excessively picked to prepare a traditional Turkish drink, the "salep"; see Erkem Sezik, "Destruction and Conservation of Turkish Orchids," in *Biodiversity; Biomolecular Aspects of Biodiversity and Innovative Utilization*, ed. Bilge Şener (New York: Springer, 2002).
  - 6 These reasons are officially recognized by public authorities; see *The National Strategy and Action Plan for Biodiversity in Turkey*, 2001, p. 19.

and benefit-sharing regime for genetic resources, the 2009 fourth report to the Secretariat to the Convention on Biological Diversity (CBD) read

Turkey has very restricted access to other countries' genetic resources in agriculture and forestry sectors and its access is based on agreements on material transfer, therefore Turkey shares benefit with the resource-provider countries. However, the measures taken at the national level to control access by foreigners to genetic resources in Turkey and ensure benefit-sharing in this regard is not sufficient, since the sharing of benefits from genetic resources is directly related with taking measures to ensure the conformance of access countries to the Convention. As a result, lack of an effective international mechanism, involving sanctions against biological material smuggling is the major obstacle to achieve the related 2010 target.

It is in this context of high biological diversity unconcealed reluctance to provide access to genetic resources, and unexpected approach to benefit-sharing triggers that we shall attempt to shed some light on the currently applicable legal regime of genetic resources in Turkey, covering both the international and national tools regulating both the access to such resources, and regulating benefit-sharing arising from their use.

## **I International Legal Instruments and National Plans for Implementation**

Having duly signed the 1992 Convention on Biological Diversity, Turkey has ratified the Convention through Law no.4177 dated as of 29th August 1996,<sup>7</sup> which entered into force on 14th February 1997. The main institution responsible for policies regarding the conservation and sustainable use of biological diversity is the former Ministry of Environment and Forestry, which has been split into the Ministry of Forestry and Water Affairs on the one hand, and the Ministry of Environment and Urbanization on the other. It is for instance the latter's Directorate General for the "Protection of Natural Resources" which ascribes and monitors special protection areas, while the national focal points to the CBD are affiliated to the Ministry of Forestry and Water Affairs' Directorate General of Natural Protection and National Parks. The division powers that ensue have nonetheless not always been assessed as a positive

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<sup>7</sup> Law no. 4177 of 29th August 2006, *Resmi Gazete*, 22860, 27.12.1996.

development. The European Commission's latest progress report<sup>8</sup> asserts in this regard that

The split of the former Ministry of Environment and Forestry into two in 2011 and the further reorganizations within the new Ministry of Environment and Urbanization (MoEU) have substantially weakened Turkey's administrative capacity to pursue robust environmental and climate change policy. A balance has still to be found within the MoEU between the environment and development agendas. The very high rate of staff turnover is worrying, as it has resulted in a loss of competence in specialized units.

Turkey is also a party to the FAO 2004 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), having signed the international agreement on 4th November 2002 and ratified it on 28th October 2005.<sup>9</sup> The Ministry of Agriculture and Rural Affairs (MARA) is as a result the second most important institution that possesses authority and responsibility in the conservation and sustainable use of biological diversity. It especially plays an important role for drawing the contours of the country's access and benefit-sharing (ABS) regime.

In view of the aforementioned ratifications and in order to draw the general lines of national environmental policies, several general action plans have been enacted by Turkish authorities. These action plans relate both to environmental policy in general, and to the conservation and use of genetic diversity in particular. 1998 was a prolific year in this regard, as it saw the adoption of the "National Environmental Action Plan", as well as the "National Plan for In-Situ Conservation of Plant Genetic Diversity." In 2001, a "National Biological Diversity Strategy and Action Plan" was put forward around ten global objectives, which focused on conservation aspects directed at specific ecosystems, but also extended to the sustainable use of genetic resources. The goals reprised the terms of international agreements, not setting particular targets but urging for

8 Turkey 2013 Progress Report Accompanying The Document "Communication from the Commission to the European Parliament and the Council, Enlargement Strategy And Main Challenges 2013–2014 COM(2013) 700 Final, Brussels, 16.10.2013, SWD(2013) 417 Final, 16th October 2013.

9 Law no 5414 ratifying the International Treaty on Plant Genetic Resources for Food and Agriculture (Gıda Ve Tarım İçin Bitki Genetik Kaynakları Uluslararası Antlaşmasının Onaylanmasının Uygun Bulunduğuna Dair 5414 sayılı Kanun), *Resmi Gazete*, 25984, 02.11.2005.

further legislative work. The Ninth five-year Development Plan, which covers the years 2007 to 2013, includes the conservation and development of biodiversity as a priority. It states that “the activities regarding the investigation, conservation, evaluation and the addition of economic value to the biological diversity and genetic resources will be accelerated” (point 459). These endeavours are considered to include the revision of the 2001 National Biological Diversity Strategy and Action Plan, and the related preparation of a specific by-law concerning “genetic conservation and implementation of management areas.” In 2006, an “Integrated EU Environmental Compliance Strategy” was also drafted in parallel to cover the years 2007 to 2023, focusing more particularly on the transposition of the EU *acquis communautaire*. The Strategy includes the fight against biodiversity depletion within its general objectives, without touching upon the more specific issue of genetic resources use or the sharing of benefits deriving from such use. Following these general environmental strategy plans, the Ministry of Forestry and Water Affairs approved the National Biological Diversity Strategy and Action Plan in the field of nature conservation on 29 July 2008. The document serves as a guide for the implementation of the Convention on Biological Diversity in compliance with other obligations and in solving the problems caused by the loss of biological diversity.<sup>10</sup> Technical working committees have been established in order to create the implementation mechanism of the Strategy and Action Plan, but no official document has to our knowledge resulted from such activities, nor has it led to substantive legislative amendments in applicable legislation since 2008.

## II Legal Status of Genetic Resources, Conditions of Access and Benefit-Sharing Provisions

In light of its international obligations, Turkey has had to adopt appropriate legislation and also at times amend existing statutes, so as to provide concrete measures that not only frame the general legal regime appointing property rights over genetic resources, but also ensure that the principles of ensuring their access and use provide for enough legal certainty and ensure compliance.

### 1 *Constitutional Framework and the Property Regime*

Article 63 of the Turkish Constitution adopted on 18th October 1982 provides that the State shall protect historical, cultural and natural assets and take

<sup>10</sup> 2012 Progress report prepared by the Turkish General Secretariat of European Union Affairs, Chapter 27 of the negotiations, environment and climate change policy, pp. 196–197.

supporting measures for this purpose. This Article also extends to the conservation of species in their natural environments. The Constitution's Article 169 specifically relates to the conservation and development of forests. Furthermore, a number of additional constitutional provisions may also be pointed out even if they do not directly point to the conservation of biological diversity, such as Article 44, which concerns the efficient use of land, while Article 45 prevents the use of agricultural land, meadows and pastures for other purposes. Enacted on the premises of such global provisions ensuring the protection of natural resources, an Environmental Law was enacted as early as 1983,<sup>11</sup> in order to protect the environment, "the common asset of all living things, in accordance with the principles of sustainable environment and sustainable development." The statute determines and provides for the basic principles related to protecting and improving the environment and preventing its pollution.

With regards to property rights, Article 56 of the Constitution limits the exercise of private property rights in view of public benefit. It should also be noted that the property regime of genetic resources have been and could be additionally carved by intellectual property rights. These prerogatives may be granted either to the phenotype at hand, through plant variety right protection, or to specific combinations of genes and relevant information, through patent protection. The 2004 Turkish Law for the Protection of Breeders' Rights Concerning New Plant Varieties (Law No. 5042 dated as of 08.01.2004) conforms to the standards of the 1991 UPOV Convention. Patents are granted in accordance with the criteria set out by the 1995 Decree-law on patent protection,<sup>12</sup> while Turkey is also a party to the European Patent Convention, and therefore recognizes those patents awarded by the European Patent Office. The national framework has been under review for the past ten years, and a new legal tool is expected to see the light of day, with a specific section on biotechnology-related patents, mostly in order to conform to the precepts of the European Union Directive 98/44/EC.<sup>13</sup> It should be noted that the new draft gives large room to the so-called disclosure of origin in patents related to genetic resources, even though the fulfilment of this particular obligation is unlikely to neither prevent the grant of protection titles, nor trigger the control of the existence of prior informed consent or benefit-sharing arrangements with the country possessing sovereign rights over said resource. The obligation

<sup>11</sup> Law no 2872 on the environment, Resmi Gazete, 09.08.1983.

<sup>12</sup> Decree-law no 551 on patent protection, Resmi Gazete, 24.06.1995.

<sup>13</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, JOL 213, 30 July 1998, pp. 13–21.



is indeed more likely to take the form of a procedural requirement to disclose the source of the biological material, which may or may not coincide with the actual “origin” in the sense of the CBD or the Nagoya Protocol.

## 2 *Access to Genetic Resources, Benefit-Sharing and Compliance*

While the well-anchored principle pertaining to the free access to plant genetic resources continued to prevail well until the end of the 20th century, most States established a permit system requiring scientists to ask for permission to collect material from national authorities. Turkey is no exception to the rule, and principles governing the access to genetic resources are scattered around different legislation, much like in other countries. First, the *in situ* access to all kinds of genetic resources is governed by general principles of environmental conservation and the designation of areas requiring special protection. Then, specific rules apply in accordance with the kind of genetic resources that want to be accessed, whether *in situ* or *ex situ*, especially those agricultural ones. However, most of these provisions are not as straightforward as they could be, and, even though the compliance with the particular issue of access is closely and strictly monitored, applicable laws are worryingly silent on the issue of benefit-sharing.

### a General Provisions in Environmental Regulation and the Special Case of Protected Areas

As aforementioned, the most general statute on the protection of the environment dates back to 1983 in Turkey, and is fashioned in its general lines to act against pollution, based upon a polluter-pays principle, impact assessment obligations, and compensation standards aiming at the maximum restoration of caused damage. Its numerous by-laws (some of them having been adopted quite late in time), address the control of water pollution,<sup>14</sup> solid waste,<sup>15</sup> the establishment of wetlands,<sup>16</sup> procedures of environmental impact assessment,<sup>17</sup> or the permits and licenses to be obtained by entities whose activities have an impact on the environment.<sup>18</sup> The 2872 Environment Law does not address the ABS regime of genetic resources *per se*, nor does it delve upon the conservation of natural resources as such. A by-law dated as of 1989 does nonetheless establish

<sup>14</sup> By-law on Water Pollution Control, *Resmi Gazete*, 04.09.1988.

<sup>15</sup> By-law on Solid Waste Control, *Resmi Gazete*, 14.03.1991.

<sup>16</sup> By-law on the Establishment of Wetlands, *Resmi Gazete*, 05.04.1995.

<sup>17</sup> By-law on the Environmental Impact Assessment, *Resmi Gazete*, 06.02.2002.

<sup>18</sup> By-law on the Permits and Licenses foreseen by the Environmental Act, *Resmi Gazete*, 29.04.2009.

an “Environmental Protection Institution,” which is responsible for the determination and control of “Special Environmental Protection Areas,” where bio-prospecting and other activities are closely monitored. The by-law grants relative flexibility of action to ensure the protection of the different ecosystems in the area, even though no provision specifically addresses the issue of genetic resource access. In terms of compliance, the 2872 Environment Law determines the penalties that can be assigned when faced with a violation of its terms. In accordance with Articles 20 and 21 of the statute, quite significant administrative penalties can be imposed upon infringers by different public institutions, whether in cases of pollution or non-compliance with impact assessment or conservation obligations, while prison sentences can also be imposed by the judiciary in line with Article 26.

A number of amendments operated to the Environment Law in 2006<sup>19</sup> have specifically included provisions stating the importance of the protection of biological diversity in the newly redacted Article 9, which defines in greater detail what is covered by the “protection of the environment” in the statute. Stating its inter-generational approach to the conservation of ecosystems, the general precepts of the article enlarge the reach of “Special Environmental Protection Areas” that are now to be determined by a formal decision of the Council of Ministers,<sup>20</sup> all the while prohibiting the trade of “rare plant and animal species” that are under the threat of extinction (new Article 9(f)). Notwithstanding the clear enlargement operated on the reach of the 2872 Environment Law, the 2006 amendments have also raised the level of administrative sanctions against the destruction of biological diversity, when detected through inspection and audits, specifically stating that such violations can not only cover direct harm to biodiversity, but also the lack of regard for the rules governing Special Environmental Protection Areas, or the trade prohibition with regards to rare species (new Article 20 (k) of the 2872 Environment Law).

Additional types of protected areas have also been established around Turkey, and are subject to a specific regime when it comes to their management, including provisions on access to genetic resources, which tend to be really strict. The oldest of these instruments is the 1956 Forest Law,<sup>21</sup> which enacts principles regarding the planning, operation and conservation of forests, including so-called “gene protection forests and seed stands,” which places a very strong focus on the sustainable use of resources rather than their

19 Law 5491 amending the Environment Law, *Resmi Gazete*, 26.04.2006.

20 The latest list of such areas was published in July 2012: by-law on the identification, registration and approval of the protected areas, *Resmi Gazete*, 19.07.2012.

21 Law no 6831 on Forests, *Resmi Gazete*, 31.08.1956.

conservation *per se*. In the same line, the 1983 Law on National Parks<sup>22</sup> provides for the designation of national parks, nature parks, natural monuments and nature conservation sites with national and international value, and covers today an area of more than 870.000 hectares. The 1983 Law for the Protection of Cultural and Natural Assets<sup>23</sup> further defines the movable and immovable cultural and natural assets which require adequate conservation actions, especially if they are recognized as “heritage sites.” Within the statute, “natural assets” are defined as “valuables from geological, pre-historic and historic areas, on surface, under the ground or under water, of which the preservation is essential due to their unique features and beauty.” Interestingly, all natural and cultural assets covered by the law, whether they are known or discovered in the future, are considered to be state property, in accordance with Article 5. The sites and assets are determined by various Commissions established in 2011,<sup>24</sup> and essentially no “constructive and physical intervention” is allowed on such assets, the utilization of which is very firmly limited through Article 14 of the 1983 Law.

It should at this stage be noted that the Environment Commission of the Turkish National Assembly has adopted the “Draft Law on the Conservation of Nature and Biodiversity” in June 2012, which significantly changes the regime of protected areas, establishing clearer criteria for protection and operational principles, also partially addressing the issue of traditional knowledge, or at least the issue of local communities. It also provides for clearer provisions on the issuance of permits in protected areas, while unequivocally asserting that all activities pertaining to the collection of biological resources, except for agricultural ones, are conditional to the deliverance of permits by the Ministry of Forestry and Water Affairs in its draft Article 21. The text was expected to be adopted in 2013 but has not yet been discussed in plenary sessions, and has been retracted from the National Assembly’s agenda at the time of writing due to unrelated political turmoil and negative NGO reaction to the statutes’ provisions on privatization opportunities.

Notwithstanding all the aforementioned provisions on biodiversity conservation and resource collection, there are also additional requirements in effect for foreign researchers who wish to conduct research activities within the territory of Turkey, notwithstanding the scope of research to be undertaken in the field. The application and authorization procedures that need to be followed

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22 Law no 2873 on National Parks, *Resmi Gazete*, 09.08.1983.

23 Law no 2863 on the Protection of Cultural and Natural Assets, *Resmi Gazete*, 23.07.1983.

24 By-law on the establishment and functioning of Commissions regarding Preservation of Cultural and Natural Assets, *Resmi Gazete*, 28088, 18.10.2011.

by foreign scientists are determined by the “Principles Governing Foreigners Wishing to Undertake Scientific Research and Studies or to Shoot Films in Turkey, or Persons Applying in Their Name, and Foreign Press Members,” which were put into force through Council of Ministers Decision 88/12839 of 4 April 1988. The application procedure before the Ministry of Foreign Affairs is quite thorough, and has been known to cause some issues in obtaining permits to undertake *in situ* biodiversity prospection activities.

#### b Plant Genetic Resources

The first permit system regarding agricultural biological prospecting was established in Turkey through the 1992 by-law on the Collection, Conservation and Use of Plant Genetic Resources.<sup>25</sup> It sets forth the principles concerning their survey, collection, protection, production, replacement, characterization, assessment, documentation and exchange, including the delivery of permits for research on plant genetic resources. The recent National Gene Bank has been established under this Regulation. Article 5 of said by-law conditions access to plant genetic resources to the authorization from MARA. These systems were mainly launched to control germplasm flow, but the lack of subsequent verification by State authorities and that of tracking rendered the permits nearly useless in terms of regulating the genetic resources’ outflow.<sup>26</sup> The system is much more straightforward when it is concerned with *ex situ* material held in collections maintained by public authorities. Indeed, the materials held within the National Collection are exchanged on the basis of a material transfer agreement, which conditions the access to the submission of feedback, and to the communication of information of the characterization of material obtained through the research efforts using the accessed genetic resource; information that is made subsequently available through the National Database Management System.<sup>27</sup>

While agricultural plant genetic resources seem to benefit from a seemingly relaxed contract-based approach, the general understanding rests within the need to seek an official permit from MARA, a stance that is supplemented by

25 By-law on the Collection, Conservation and Use of Plant Genetic Resources dated as of 15.08.1992, *Resmî Gazete* no.21316, 15.08.1992.

26 Parry Bronwyn, *Trading the Genome: Investigating the Commodification of Bio-Information* (New York: Columbia University Press, 2004), pp. 204–205; where the author narrates the testimony of field researchers struggling with administrative hurdles to get national permits and not being faced with any official control at State borders.

27 Ayfer Tan, “Türkiye Bitki Genetik kaynakları ve Muhafazası” (Plant Genetic Resources in Turkey and their Conservation), *Anadolu Journal of AARI*, 20(1), 2010, at p. 26.

strict Customs Regulation and parallel training programs, crafting considerably strict border controls. The severe stance against biological piracy has been for instance echoed in the 2004 by-law on the Collection, Production and Exportation of Natural Flower Bulbs,<sup>28</sup> which sets forth principles concerning the collection from the wild of seeds, bulbs or other parts of natural bulbous flowers. It also deals with their production, cultivation, storage, domestic and foreign trade. The main aim of such regime is to avoid the destruction and depletion of these flowers' population, considering that many Turkish endemic species are bulbous flowers. The technical committee therefore not only acts in a conservatory capacity, but also decides the extent to which bulbs may be collected and produced through specific quotas. Their collection in all protected areas remains forbidden (Article 21). This by-law's most interesting provision lays in its Article 28 which states that all "illegal collections made without authorization or without respect for harvest plans shall be processed as the import of a species forbidden to trade under a falsified name in accordance with the provisions of the Anti-Smuggling Law." The reference to such 2003 law connects the very rigorous stance of customs' control with the regulation of access to genetic resources, establishing parallels between the fight against biological piracy and the trade of endangered species. This shift is epitomized by the quite vocally publicized cases of foreign nationals' arrests, such as the Dutch nationals tracked by GPS and then stopped at the Turkish-Greek border with more than five thousand seeds, bulbs and seedlings, including specimens of the endemic and endangered upside down tulip in 2011.<sup>29</sup> The suspects have been convicted to each pay damages amounting to 29.000 Turkish liras on account of having violated the 2872 Environment Law. A similar case was prosecuted in 2012, involving Japanese nationals collecting wild wheat specimens near the town of Gaziantep, with penalties reaching as high as 220.000 Turkish liras.

### c Animal Genetic Resources

Animal genetic resources have also received particular attention from Turkish authorities. The main law dates from 2001<sup>30</sup> and is implemented

28 By-law on the Collection, Production and Exportation of Natural Flower Bulbs, *Resmi Gazete*, 25563, 24.08.2004.

29 This case has been widely reported in mainstream Turkish media outlets; see for instance <http://www.cnnturk.com/2011/turkiye/06/19/hollandali.bitki.kacakcilari.sinirda.yakalandi/620591.0/> (accessed December 2013).

30 Law no 4631 on Animal Genetic Resources, *Resmi Gazete*, 24338, 10.03.2001.

through a specific by-law first adopted in 2002 and revised in 2003.<sup>31</sup> These instruments have established a National Committee on the protection of animal genetic resources, coordinated by MARA's Directorate general for Agricultural Research, TAGEM. It is responsible for the determination of actions directly targeting the protection of biodiversity (like the establishment of lists of species under threat of extinction and enact relevant conservation projects), but also take decisions regarding the import and export of animal genetic resources. Article 10 of the 2003 by-law conditions the access to animal genetic resources to the authorization from MARA. Species are registered in accordance with another by-law.<sup>32</sup> Additional decrees have been adopted regarding national domesticated animal genetic resources, both for their registration,<sup>33</sup> and also for their use and import.<sup>34</sup> All national domesticated animal genetic resources need to be registered by the Domestic Animals Registration Committee. Permits are required for all research activities conducted within or outside Turkish borders, including the genetic material held by gene banks. For the latter, the legislation states that requests will not be accepted if the gene bank stocks are considered to be limited (Article 4§12 of the 2012 by-law on the use and import of domesticated animal genetic resources).

#### d Marine Genetic Resources

Marine genetic resources fall under the global umbrella of the 1971 Law on Aquatic Products,<sup>35</sup> which includes basic provisions concerning the conservation, hunting, production, marketing, health and control of aquatic living organisms found in seas and inland waters. It also addresses marine pollution issues and establishes specific production areas. Recent by-laws were adopted in 2012, first in order to establish the rules and procedures surrounding the registration of new aquatic varieties,<sup>36</sup> and then on the Conservation and

31 By-law on the Protection of Animal Genetic Resources, *Resmi Gazete*, 24700, 19.03.2002, modified by the new by-law published in *Resmi Gazete*, 25145, 21.06.2003.

32 By-law on the Registration of Animal Species, *Resmi Gazete*, 25141, 17.03.2002, which is also to a certain extent complemented by the recent by-law on Rules Of Livestock Genogram Registration, *Resmi Gazete*, 28133, 05.12.2011.

33 By-law on the Registration of National Domesticated Animal Genetic Resources, *Resmi Gazete*, 28150, 22.12.2011.

34 By-law on the use and import of national domesticated animal genetic resources, *Resmi Gazete*, 28418, 22.09.2012.

35 Law no 1380 on Aquatic Products, *Resmi Gazete*, 23.03.1971.

36 By-law on the registration of aquatic genetic resources, *Resmi Gazete*, 28388, 18.08.2012.

Sustainable Use of Marine Genetic resources.<sup>37</sup> The former poses an obligation to register new aquatic genetic resources, in the form of varieties, lines or hybrids, for their use in inland and territorial seas, falling under the direct sovereignty of Turkey. Concerned rather by the identification, protection and sustainable use of aquatic genetic resources, whether new or old, the latter by-law appoints a Secretariat within MARA to carry out activities on the conservation of marine genetic resources, including in gene banks, and their sustainable use, developing economic, technical and technological opportunities for the use of resources without lessening their diversity in the long run. The by-law does not expressly mention access conditions, nor does it address benefit-sharing opportunities, but the general competence granted to the newly formed Secretariat of aquatic resources within the auspices of MARA, as well as the National Committee, which need to determine adequate policies for the conservation and sustainable use of said resources, could definitely include these aspects, leading to the enactment of specific legislation in the future.

#### e Benefit-Sharing Aspects

Even though a number of regulations seem to address the conditions under which genetic resources can be accessed, it is interesting to note that benefit-sharing is not mentioned at all in any of the aforementioned laws and by-laws as such. It seems that this issue is rather addressed through non-binding guidelines and through model contractual arrangements. As aforementioned, the most complete system is found in agricultural plant genetic resources, where materials are exchanged on the basis of a material transfer agreement, which determines benefit-sharing as the reception of feedback on the material itself, and the information of the characterization of material obtained through the research efforts using said resource.<sup>38</sup> Guidelines issued by the Turkish plant genetic resources research institute specifically require recipients to provide feedback data, publication credit, and even reserve the right to patents on the material for the Government of Turkey when germplasm is exchanged with foreign institutions.<sup>39</sup> Nothing seems nonetheless to indicate that a distinction is operated between the plant genetic resources that are included within the

37 By-law on the Conservation and Sustainable Use of Marine Genetic resources, *Resmi Gazete*, 28396, 29.08.2012.

38 Ayfer Tan, "Türkiye Bitki Genetik kaynakları ve Muhafazası" (Plant Genetic Resources in Turkey and their Conservation), *Anadolu Journal of AARI*, 20(1), 2010, at p. 26.

39 J.H. Barton and W.E. Siebeck, *Material Transfer Agreements in Genetic Resources Exchange: The Case of the International Agricultural Research Centres* (Rome: International Plant Genetic Resources Institute, 1994).

realm of the ITPGRFA's multilateral system of facilitated access or not; or whether the material transfer agreement used by Turkish institutes contains a viral license clause that would ensure better compliance with CBD principles. The general shortcoming stemming from the lack of distinct regulatory provision that would guide the content of contractual arrangements seems to be acknowledged by national authorities, which mention such lacuna in their national reports to the CBD.

### III Prospects for Nagoya Ratification and the European Union Process

Turkey has to this day of writing, not showed any positive signs to sign or ratify the Nagoya Protocol,<sup>40</sup> even though it has followed and participated to negotiations quite closely. During the negotiations, it was not associated with the coalition of "Like-minded megadiverse countries," but rather at times joined JUSCANZ, the group of non-EU industrialized countries.<sup>41</sup> This choice speaks volumes, as the approach of such coalition to the issue of ABS remains very much that of user countries with important product development industries relying on the use of genetic resources, rather than providing biological material upon which they may exercise their sovereign rights. Turkey, by joining the aforementioned coalition on certain issues, also distanced itself from the European Union position, which was seemingly more in favour of a legally binding ABS regime with minimum international standards that would not distort trade or research and development activities. Even though the General Directorate of Nature Protection and National Parks of the Forestry and Water Affairs Ministry recently convened a workshop dedicated to an impact and regulatory gap analysis in September 2014 with representatives from all concerned public institutions, Turkey has not shown an eagerness to sign the Protocol ahead of the 12th COP meeting of the CBD to be held in October 2014.

If the political tides decide to turn, major regulatory action would be needed in order to satisfy numerous obligations of the Protocol. First regarding traditional knowledge, on which legislation is today inexistent, even though the

40 The country had on contrast signed the Cartagena Biosafety Protocol quite rapidly, on 24th May 2000, depositing its ratification instrument on 24th October 2003 (with an entry into force determined to be 24th January 2004).

41 Linda Wallbott, Franziska Wolff and Justyna Pozarowska, "The Negotiations of the Nagoya Protocol: Issues, Coalitions, and Process," in , *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol*, eds. Sebastian Oberthür and G. Kristin Rosendal, (Abingdon: Routledge, 2014), 33–59.



country is actively involved in relevant international negotiations before the World Intellectual Property Organisation. Specific regulation should also indicate that access is granted on principle on the basis of prior informed consent on mutually agreed terms, a terminology that is today not echoed in applicable legislation, deciding more than probably that PIC would be looked for in accordance with existing by-laws. The entry into force of the 2012 Draft Biodiversity Law would have to a certain extent palliated such requirement. Another crucial point relates to the grant of facilitated access for research purposes in accordance with Article 8 of the Protocol, perhaps defining the concept of “non-commercial research” more thoroughly, as currently applicable legislation seems to point to the contrary, with the requirement of a second *ad hoc* permit for foreign researchers. Cross-cutting compliance mechanisms ought to be considered as well, perhaps in consideration of the proposed draft regarding patent legislation that includes a disclosure requirement. This procedural obligation would nonetheless need to be weighed in against existing private international law principles, within which provisions ensuring judicial redress opportunities for the violation of foreign ABS legislation and perhaps even contracts should be sought after.

The country has been an official candidate to the European Union since the 1999 Helsinki Summit, while the formal negotiation process was launched on 3rd September 2005. It should be noted that a Customs Union Agreement is still operational between Turkey and the European Union since 1996, ensuring the free circulation of goods between all States, notwithstanding the rights, obligations and limits put forward by the terms of Decision 1/95 of the EU-Turkey Association Council, which met in 1986 for the first time. Setting aside the wider bottlenecks surrounding the candidacy of Turkey to the European Union, the transposition of the *acquis communautaire* has been underway to different degrees of intensity throughout the wide array of negotiating chapters. Therefore, the future European Regulation that will deal with ABS issues following a potential entry into force of the Nagoya Protocol will have to be thoroughly studied and incorporated into the Turkish national legal order so as to conform to the needs of the adhesion process. Significant lacunas do already exist in the transposition of the European environmental *acquis* by Turkey to this day, which is dealt with in the 27th chapter of negotiations. With specific regards to the protection of biodiversity, the European Commission's latest progress report<sup>42</sup> states that

42 Turkey 2013 Progress Report Accompanying The Document “Communication from the Commission to the European Parliament and the Council, Enlargement Strategy And Main Challenges 2013–2014 COM(2013) 700 Final, Brussels, 16.10.2013, SWD(2013) 417 Final, 16th October 2013.

Framework legislation on nature protection, as well as the national biodiversity strategy and action plan have still to be adopted. The draft Nature Protection Law is not in line with the EU *acquis*. If adopted without secondary legislation, the draft will repeal the National Parks Law, causing a legal vacuum.

Even though numerous legislative proposals are on their way, Turkish authorities need to definitely make considerable efforts so as to ensure that their biodiversity-related legislation conforms to the needs of the Nagoya Protocol and its European implementation.

#### IV Conclusion

Despite, or perhaps because of its extremely rich biological diversity, Turkey's national legal framework regulating genetic resources is today very traditionally oriented towards restrictive and controlled access, and seems to forego the benefit-sharing aspect of genetic diversity use. This feature is nonetheless not completely delegated to self-regulation either, as such an attempt has neither been officially proclaimed, nor is historically part of Turkish policy-making tradition. Indeed, access is extremely thoroughly and restrictively regulated, including prospects of high penalties linked to smuggling attempts. Regulations nonetheless remain quite nebulous in designating actually competent authorities, in a context of Ministerial reshuffling, where the Forest and Water Affairs Ministry seems to coordinate all biodiversity policy while ABS remains the main preoccupation of the Ministry of Agriculture. These elements may hint at the reasons why the country has not given any official sign of signing or ratifying the Nagoya Protocol, the implementation of which would require significant regulatory intervention in terms of clarity of access conditions and prior informed consent rules, express facilitation of research-driven access, express mention of mutually agreed terms with potential guidelines, and lastly measures to ensure that the ABS legislation of third countries are complied with.

**PART 2**

*Implementing the Nagoya Protocol in the  
European Union*





## Privateer, Pirate or Ghost Ship? An Inquiry into the Complementarity between Community Law and French Law for the Benefit of the Indigenous People of French Guiana

*Philippe Karpe, Alexis Tiouka, Ivan Boev, Armelle Guignier and  
Florence Edouard*

Over the past three decades, the rights of indigenous peoples<sup>1</sup> have been gradually diversified, developed and updated. These rights are of different nature. They are as much political, economic, social as cultural: the right to autonomy and participation, the right to land, the right to language, etc. Every single one of the indigenous communities' rights today is becoming increasingly important, for instance, the right to heritage which can be defined as the right of indigenous communities to protect their traditional knowledge. This knowledge is currently being threatened.<sup>2</sup> In recent years, we can indeed notice numerous cases where non-indigenous people obtain intellectual property rights on traditional knowledge. This situation can be considered as an act of

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1 Indigenous or aboriginal people means any population that lived in territory prior to its occupation (whether or not it is a territory of the state in its current borders) compared to that which is currently dominant in it (social and cultural political and economic domination).

2 In summary, the many legal and doctrinal definitions which can be described as indigenous knowledge are those which in general are:

- Created, preserved and transmitted in a traditional context;
- Clearly associated with the culture of native community, which preserves and transmits it from one generation to the other;
- Linked to a native community which considers itself as the custodian or guardian of the knowledge or vested with a cultural responsibility in the matter (obligation to preserve the knowledge or awareness that misappropriation or demeaning use of such knowledge would be unlawful or offensive), this relationship maybe established officially or informally by customary law or practice;
- Form an intellectual activity in various social areas like social, cultural, environmental and technological and
- Recognized by the community of origin as traditional knowledge. (One reference for this approach: WIPO/GRTKF/IC/6/4 § 58).

“biopirating” or “biopiracy.” Mainly perpetrated by companies and researchers from developed countries, these usurpations are true in many areas of activity, and especially in those related to the food, cosmetics, and pharmaceutical industries. It is therefore important to promote and protect fair and equal use and benefits of traditional knowledge that include indigenous communities themselves. A special legal status is being developed to achieve this, both internationally and internally.

Like other indigenous communities, the Amerindians of French Guiana need to protect their traditional knowledge.<sup>3</sup> This entails not only the preservation and valorisation of their identity but equally the provision of instruments for their own development. Considering that France has ratified the Convention on Biological Diversity, (a fact which was long ignored by public authorities themselves), there is currently no unified and stated general status on the topic. In spite of this, as stated in the first part, the protection of traditional knowledge is still possible through the mobilisation of instruments of the written law. Their protective value could also be improved through the use of indigenous customary law and their existing autonomy. These two conditions are being recognised progressively in the French written law as written and recalled in the second part of this work. But this protection has many limitations. It would mean that, in particular cases, the relevant doctrinal interpretation could be given a contrary interpretation. The judicial validation of this interpretation is still uncertain and may take a long time. To date, this interpretation has not been validated by any court. The question therefore is whether the European Commission Regulation on compliance measures for users from the Nagoya Protocol<sup>4</sup> (now known as the “EU Regulation on Access and Benefit-sharing (ABS)”) will modify and improve this situation. An answer is proposed in the concluding part of this article.

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3 The overseas French department and region, French Guiana is “automatically” (official translation) subjected to the same laws that govern metropolitan France (paragraph 1 of Article 73 of the Constitution). Nevertheless, statutes and regulations “may be adapted in the light of the specific characteristics and constraints of such communities” (official translation) (paragraph 1 of Article 73 of the Constitution). On the other hand, considering its specificities, French Guiana “may be empowered by statute or by regulation, whichever is the case, to determine [itself] the rules applicable in [its] territory in a limited number of matters that fail to be determined by statute or by regulation” (official translation).

4 Regulation of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

## I The Provisions of French Law

Unlike other countries that have been preoccupied with indigenous people's right to their traditional knowledge for a long time, (Brazil, Panama, Peru etc.),<sup>5</sup> it is not until recently that France instituted a special regulation on the protection of the rights of traditional communities.<sup>6</sup> This absence, however, did not equate to a lack of suitable protective measures.

### 1 *The Basic Requirements for Protection*

The basic conditions for the protection of the right of indigenous heritage, their interrelation, and their scope, are now widely known, proven and understood. What is now left to be done is at the level of synthesizing and deepening. There are three basic cumulative conditions necessary for this protection. First of all, there is the recognition of the specific rights of indigenous people to their intellectual property. Secondly, there is the submission of this law to specific rules of rights of these peoples. Finally, standards should be applied for conflict resolution prior to the emergence of a new common law.

This implies recognition of the specific right of indigenous peoples to their intellectual property, followed by the regulation of this right by their own customary law, and finally, the application of rules for conflict resolution that pre-date the establishment of a new and real generally shared law. We do not know the full scope of these conditions yet; studies are still underway for clarification.<sup>7</sup>

Indigenous people can preserve and valorise their knowledge only if each individual benefits from the right to do so. Presently, no one contests the existence of this right: every exclusion or restriction to this right is impossible because indigenous peoples are considered human beings and citizens at the same time as everyone else. Recently, there has been increasing legal recognition of this right, a fact that is politically important (for example, Article 8j of the Convention on Biological Diversity).<sup>8</sup>

<sup>5</sup> See in particular WIPO/GRTKF/IC/2/5.

<sup>6</sup> For recent developments in ABS regulation in France, see contribution by Chiarolla to this volume (Chapter 3).

<sup>7</sup> See in particular the work in progress at World Intellectual Property Organization (WIPO – <http://www.wipo.int/tk/en/>) or the Secretariat of the CBD (<http://www.biodiv.org>).

<sup>8</sup> CBD Article 8j states: “Each contracting Party shall, as far as possible and as appropriate: Subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and

What remains now is to determine the legal structure of this right. There are essentially two different kinds of structures: the existing written law of intellectual property with some adaptations, and a totally new law specific to indigenous people.

It is possible to adapt and consequently improve the current legal development concepts and institutions of the written law on intellectual property in various specificities of traditional communities. Such a possibility can be explained, first, by the fact that, in general, it has been possible to simply reform substantive law to adapt it to newly expressed needs which are not yet covered (*e.g.* the case of musical exchanges via the internet). It could also be explained that, by virtue of the adjustments claimed on the current legal development, these concepts and institutions correspond to the characteristics already covered by the law, albeit in a different way. Under the patents or trademarks rules, for instance, the right of judicial persons, not just as a group of identifiable individuals, is already accepted (*i.e.* the collective nature of law).<sup>9</sup>

However, it is impossible to carry out a complete adaptation of the right to intellectual property of indigenous people, while at the same time making the right to intellectual property of these people fully protective. Indeed, generally speaking, the notions and institutions of the written law correspond to a world vision held by the Western world, a vision that is distinct from the spirit of Aboriginal and indigenous peoples worldwide. There exists what is termed a “cultural conflict” in the written law: a clear and sudden opposition between two visions of the world, which prevents the law from effectively protecting the rights of indigenous peoples and local communities. In this context, in order to fully and effectively ensure the right of local communities on their intellectual property, a legal framework should be established under the indigenous communities’ specific legal system.

While obvious, the legal improvement of the right to intellectual property of local communities in line with their specific legal system is not very likely to be applied. Regrettably, this solution will not allow for an efficient protection of the communities’ own rights. Indeed, its adoption and implementation would mainly lead to the communities’ isolation *vis-à-vis* other people, or, in case of interaction with one another, to the rights of the former to be protected at the complete detriment of the latter.

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practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices” (official translation).

9 Convention on the Grant of European Patents (1973) Article 58 and Treaty on trademark Law (1994) Article 3, (1) (a) (iv).



Under such conditions, and in case the right of local communities to the full submission to their own rules of law is outstanding, it is obvious that this right will not be absolutely applied. It is thus essential to accompany it with a set of rules specifically designed to meet and maintain the unavoidable, but also to establish desirable harmonious relations between populations (thereby avoiding conflicts of values and standards or law known as colonial conflict<sup>10</sup> or conflict of laws<sup>11</sup> in the specific context of colonization).

By its very nature, the principle of the rule of superiority of one law over another is unlikely to ensure the establishment and maintenance of harmonious relationships between different populations (local and others). Indeed, it must be kept in mind that, on the one hand, this principle operates in the context of opposition between two laws in culturally distinct spaces, while on the other hand it raises the prominence of one of these laws over the other.

It therefore seems necessary to proceed to the re-examination and renegotiation (this can be progressive) of the terms of both the subordinating law and the subordinated law. Only by confronting both laws will it be possible for a new law, shared by different people – local and other populations, to emerge. This specifically involves the recognition and effective implementation of local communities to benefit from equal rights to citizenship, *i.e.* the right to participate in any legislative process, free and equal participation with other people, and especially with different political authorities. The principle of partnership corollary of the right to self-determination or autonomy would be granted to them.

In the case where the new law needs to be exactly the same for both local communities and other populations, it could validly be suggested that, in the future, such a law could regulate not only the mixed relationship between them, but also the different internal laws that exist within the same local communities. It could well be argued that the mediation of cultural conflict in a spirit of coexistence appears to have been achieved only in the drafting and implementation of a truly written law for local communities and other people. Applying their own rule of law is, in this context, just a transitional stage while providing time for the preparation of a new written law.

10 See in particular Henry Solus, *Traité de la condition des indigènes en droit privé. Colonies et pays de protectorat (non compris l'Afrique du Nord) et pays sous mandat* (Paris: Librairie du Recueil Sirey, 1927): 6 and 7.

11 See in particular P.F. Gonidec, *Droit d'outre-mer. Tome II: Les rapports actuels de la France métropolitaine et des pays d'outre-mer* (Paris: Editions Montchrestien, 1960): 243.

## 2 *Rules, Laws and Principles of French Law Mobilized*

Not without some difficulties that can however be overcome, these basic conditions for the protection of intellectual property rights are met under French law. Indeed, not only are there currently no provisions excluding such protection, but there are also various laws, rules, principles and processes that can be positively used for this purpose. Among these is of course the right to intellectual property. There are also provisions for contracts law and the penal law. The contract is a legal tool widely used in the field, for example, the Shaman Pharmaceuticals case. Naturally, it would constitute a valuable tool to ensure the legal protection of the traditional knowledge of indigenous peoples and local communities. The two main reasons for this are:

- (1) Principle of consent:<sup>12</sup> There is no contract if there is no consent and valid consent for that matter, (free and informed). In other words, if the consent was given in error (incorrect assessment on the existence or the qualities of a fact or the existence or interpretation of a rule of law) or was extorted by violence or given under fraudulent circumstances, for example, a scam designed to deceive a party to a legal action to obtain his consent. In the absence of these elements, the contract can be cancelled;
- (2) The Mandatory nature of all contracts validly designed.<sup>13</sup>

There is also the penal law in the definition and sanction of theft,<sup>14</sup> fraud,<sup>15</sup> and breach of trust.<sup>16</sup> All these provisions also benefit traditional communities on account of the citizenship they possess and the principle of equality of all before the law stated in Article 1 of the Constitution.

Current standards of French law also allow for the mandatory consideration in the matter of customary law of indigenous communities. This faculty is generally dedicated as solemn and fundamental. This is especially seen in Article 75 of the Constitution and the reference to maintain the personal status of individuals: "Citizens of the Republic who do not have ordinary civil status, the sole status referred to in Article 34, shall retain their personal status until such time as they have renounced the former" (official translation).

There are also some texts and regulatory provisions such as Article D.34 and R.170-56 and others of the State Property Code, and Articles L.272-4 Code

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<sup>12</sup> Civil Code Articles 1108.

<sup>13</sup> Civil Code Articles 1134 and 1135.

<sup>14</sup> Penal Code Article 311-1 and following.

<sup>15</sup> Penal Code Article 313-1 and following.

<sup>16</sup> Penal Code Article 314-1 and following (s) seq.

(rights to usage) and L.272-5 (concessions/sales) of the Forestry Code. Indeed, these articles, on the one hand, distinguish the tribe (or community) from the association or society and, on the other hand, attribute her own rights, that is to say, a legal existence of its own, in addition to its collective character.

Furthermore, as part of a conscious and deliberate process to build a new community life, French law supports the emergence of a new written law.

As acknowledged, it recognizes the need, fixes principles and determines and guarantees tools and methods. All this solemnly and particularly springs from the preamble of the agreement on New Caledonia in which the concern to build a common destiny is repeatedly asserted:

If the Kanak access to state responsibilities remains insufficient and should be extended through proactive measures, the participation of other communities in the life of her territory also remains essential. It is today necessary to lay the foundations for New Caledonian citizenship, making it possible for the original inhabitants to form a human community with a common destiny with alien men and women [...]. Ten years later, it should open a new stage that is marked by the full recognition of the Kanak identity; a prerequisite for the rebuilding of a social contract among all communities living in New Caledonia through a shared sovereignty with France. This would be a march on the road to full sovereignty. The past was a time for colonization. The present moment is the time of sharing through readjustment. The future should be a time for identity, in a common destiny [...].<sup>17</sup>

One would also ask if the agreement on New Caledonia has any legally binding force. To answer this question, one would take a close look at Articles 76 and 77 of the Constitution, drawn from the revised constitution of 20 July 1998 on New

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17 Author's translation of the original text: "Si l'accession des kanak aux responsabilités demeure insuffisante et doit être accrue par des mesures volontaristes, il n'en reste pas moins que la participation des autres communautés à la vie du territoire lui est essentielle. Il est aujourd'hui nécessaire de poser les bases d'une citoyenneté de la Nouvelle-Calédonie, permettant au peuple d'origine de constituer avec les hommes et les femmes qui y vivent une communauté humaine affirmant son destin commun [...]. Dix ans plus tard, il convient d'ouvrir une nouvelle étape, marquée par la pleine reconnaissance de l'identité kanak, préalable à la refondation d'un contrat social entre toutes les communautés qui vivent en Nouvelle-Calédonie, et par un partage de souveraineté avec la France, sur la voie de la pleine souveraineté. Le passé a été le temps de la colonisation. Le présent est le temps du partage, par le rééquilibrage. L'avenir doit être le temps de l'identité, dans un destin commun [...]" (4<sup>ème</sup> alinéa).

Caledonia, which explicitly targets the Nouméa Accord in which several stipulations proved unconstitutional. Consequently, during the constitutional verification of the March 19, 1999 organic law on New Caledonia, the Constitutional Council made the Nouméa Accord a benchmark norm of its agenda 26. The solution implemented here is quite similar to those considered, with explicit reference to the rules laid down by the Treaty on European Union (EU) in Article 88-3 of the Constitution. It is worth deducing that, no matter the nature of the norm targeted by the constitution, be it drawn from an international or domestic document, it is likely to become a benchmarker for constitutionality. This is explained as follows: through a technique that refers to a standard that is external to the Constitution, the constituent power requires government, especially the legislature, to comply with a standard that is not included as such in the Constitution, but which is, by virtue of reference, a constitutional requirement. Therefore, the question of the legal status of the Nouméa Accord arises. If the Constitutional Council has not decided on the issue, the Supreme Court has stated clearly that the Nouméa Accord was constitutional under Article 77 of the Constitution.<sup>18</sup> In a second step the Constitutional Council upheld the constitutional “guidelines of the agreement.”<sup>19</sup>

This statement is no less questionable in the case where Article 77 of the Constitution requires the legislature to respect the Nouméa Accord, even when this does not necessarily imply that it must acknowledge the constitutional value of an agreement between the government of the day and the New Caledonian political parties. A constitutional obligation to respect a text does not make the content of the text a constitutional norm. Article 55 of the Constitution requires that laws must respect the international treaties and agreements regularly introduced into domestic law and subject to reciprocal application. Therefore, it is possible to consider it a standard reference for constitutionality under the constitutional obligation of the legislature to comply with the agreement. The content of the latter has not so far acquired a constitutional value.<sup>20</sup>

18 Court of Cassation AP, June 2, 2000, Miss Fraisse, Plén Bul, No Ass, 7.

19 29 December No. 2004–500 DC of 29 July 2004 Organic law on the financial autonomy of local authorities, Rec., p. 116.

20 Author's translation of the original text: “Cette affirmation n'en est pas moins contestable dans la mesure où, si l'article 77 de la Constitution fait obligation au législateur de respecter l'accord de Nouméa, il n'implique pas nécessairement qu'il faille reconnaître la valeur constitutionnelle d'un accord conclu entre le gouvernement de l'époque et les partis politiques néo-calédoniens. L'obligation constitutionnelle de respecter un texte ne fait pas du contenu de ce texte une norme constitutionnelle: en atteste l'article 55 de la

Of course, there are still some limitations to establishing any genuine written law. This is especially the maintenance of the rule of a certain conception of human rights. However, parliamentary debates relating to New Caledonia<sup>21</sup> as well as gender equality and secularism overseas<sup>22</sup> provides the possibility of reversing this to some extent.

Contrary to what might be believed, the absence of a special regulation on the protection of the intellectual property right of indigenous peoples does not imply the absence of any suitable protection. However, it would be advisable to adopt a special regulation on the matter. Such a development would at least ensure the unification of relevant standards in a coherent and specific set and in this way a better understanding of discrepancies and their remedies. Hence, the absence of such legislation may frustrate or undermine the protection of indigenous knowledge. More importantly, it would ensure discussions and

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Constitution qui implique que les lois doivent respecter les traités et les accords internationaux régulièrement introduits dans l'ordre interne et faisant l'objet d'une application réciproque. Aussi est-il permis de considérer qu'étant une norme de référence du contrôle de constitutionnalité en vertu de l'obligation constitutionnelle faite au législateur de respecter l'accord, le contenu de ce dernier n'a pas acquis pour autant une valeur constitutionnelle." Agnes Roblot-Troizier, "Réflexions sur la constitutionnalité par renvoi" *Cahier du Conseil constitutionnel* 22 (2007). Available online at: <http://www.conseil-constitutionnel.fr/conseil-constitutionnel/francais/cahiers-du-conseil/cahier-n-22/reflexions-sur-la-constitutionnalite-par-renvoi.50861.html>.

- 21 See: François Colcombet, MP. National Assembly Parliamentary debates. J.O.R.F. Constitution of 4 October 1958. 11th legislature. Ordinary Session of 1997–1998. 247th session. Full Report. Meeting on Thursday, June 11, 1998 (109th sitting day of the session). Year 1998. No. 61 AN (CR). June 12, 1998. p. 4963.
- 22 See: Report No. 2103 made by Bernard Roman on behalf of the Committee on Constitutional Laws, Legislation and General Administration of the Republic of: I. 1. The bill (No. 2012) designed to promote equal access of women and men to electoral mandates and elective functions, 2. The draft Law (No. 2013) designed to promote equal access of women and men in terms of membership of provincial assemblies and conventions of New Caledonia, the Assembly of French Polynesia and the Territorial Assembly of Wallis and Futuna, II islands. Legislative proposals: 1. (1268) by Pierre Albertini and several of his colleagues to amend Act No. 88-227 of 11 March 1988 on the financial transparency of political life and to ensure a balanced representation of women in politics, 2. (No. 1761) by Michel Hunault to establish parity in municipal elections, 3. (No. 1837) by Marie-Jo Zimmermann aimed at establishing genuine equality between men and women in political life, 4. (No. 1850) Marie-Jo Zimmermann aimed at establishing genuine equality between men and women in political life, 5. (No. 1895) of LeonceDeprez and others seeking to make the principle of equality between men and women in communities with more than 2,001 inhabitants. National Assembly. Constitution of 4 October 1958. Eleventh legislature. Registered to the Presidency of the National Assembly on 20 January 2000. p. 31.

position-taking on the ethical basis of the right to heritage of indigenous communities, which remains the foundation and the fundamental condition of its protection. This special regulation and the debate that accompanied it finally took place and the results are very far from expectations. Clearly, the status of indigenous peoples is clearly and extensively altered in the light of what it was or could be until now.

## II The Emergence of a Special Status for Indigenous Knowledge in French Law

### 1 *Applicable Rules in the Amazonian Park*

Regulations relating to national parks<sup>23</sup> have introduced into French law a special protection of the intellectual property right of indigenous communities. Although necessary, such protection was lacking until now. This is a true innovation, a real progress. Despite this commitment, this scheme does not constitute a general and adequate protection. Worse still, it represents a clear violation of the international commitments of France on the issue.<sup>24</sup>

#### a The New Spirit of the Law

From the outset, the State marked its firm commitment to promulgate into law the specificity of Guiana, which according to the State particularly resonates in the existence of indigenous communities and the need to preserve their own identity.<sup>25</sup> In a debate at the National Assembly, the Minister of Ecology and Sustainable Development asserted that:

The amendment proposed by the Government is intended to reflect the decision adopted by the Guianese elected congressmen at a meeting last October 18, during which, while giving a legal agreement to a national park project in Guiana, did report certain observations. These observations

<sup>23</sup> Law n°2006-436 of April 11th 2006, related to national parks, marine natural parks and regional natural parks, JORF n° 90 du 15 avril 2006, p. 5682 et suivantes.

<sup>24</sup> See in particular: P. Karpe, "L'illégalité du statut juridique français des savoirs traditionnels," *Revue juridique de l'environnement* 2 (2007): 173–186; P. Karpe and A. Tiouka, "La protection du patrimoine autochtone et traditionnel en Guiane française: un régime en cours de construction," *Policy Matters* 18 (2010): 30–32.

<sup>25</sup> Refer specifically to comments made during the debate in the National Assembly by the Minister of Ecology and Sustainable Development. National Assembly Ordinary Session 2005–2006, 87th session. Full Report. Second session on Thursday 1 December 2005, No. 101 [2] AN (CR), Friday, December 2, 2005, p. 7846.

mostly aimed at making the nation more aware of the specificities of the territory.

It in fact seemed to the government, as a resolution that discerned from congress. That even though the draft bill already expressed the will to consider the features of this overseas department, this was not sufficient and failed to substantially give real exceptional nature of the territory concerned with the park project and the living conditions of its inhabitants. The amendment I am setting out to present places Guianese national park project at the forefront in its South American context, by designating the Guiana "Amazonian Park." Secondly, it draws on the consequences of the Amazonian context, characterised by a very forest space, a weak population destiny, major traffic problems and the existence of the Amerindian and Black-brown population who maintain a relationship that is different from that which we are accustomed to.

Traditionally these indigenous communities rely on the forest for their subsistence. Their life style is also strongly anchored – reason why it should be preserved – and it is specially adapted to their exceptional environmental conditions. Be they Amerindians, Black-brown or Creole, human settlements in the Guianese humid tropical forest are only valuable through sustainable environmental knowledge which is unique to them, and acceptable forest practices as well as its ecology. The opportunity to create a national park in Guiana is to their advantage. The Guianese local government's desire for the acknowledgement of this Amazonian specificity and the adaptation of the laws in a way that would allow this population to have their full place in the future park is thus justified.

This amendment thus encompasses a number of necessary adjustments that would take account of all these aspects in the six articles of the environmental code.<sup>26</sup>

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26 Author's translation of the original text: "L'amendement proposé par le Gouvernement est destiné à tenir compte de la délibération adoptée par les élus de la Guiane réunis en congrès le 18 octobre dernier qui, tout en donnant un accord de principe au projet d'un parc national en Guiane, ont fait part d'un certain nombre d'observations. Celles-ci visent en particulier à faire davantage reconnaître par la nation les spécificités de ce territoire. Il est en effet apparu au Gouvernement, à la lecture de la délibération du congrès, que même si le projet de loi manifestait déjà la volonté de prendre en compte les caractéristiques de ce département d'outre-mer, cette prise en compte était insuffisante et ne rendait pas assez tangible le caractère tout à fait exceptionnel du territoire concerné par le projet de parc et des conditions de vie de ses habitants. L'amendement que je vous présente place en premier lieu le projet de parc national de Guiane dans son contexte à l'échelle du continent sud-américain, en le désignant comme « parc amazonien » de

Moreover, the State recognizes and clearly asserts its international commitments to Aboriginal and local communities. Despite some delays, France's international obligations in favour of these people are clearly and unanimously recognized both in the debates and in the provisions of the law. Reference is thus legally made to Article 8j) of the Convention on Biological Diversity in Article L.331-15-6 of the Environmental Code:

On the proposal of the Congress departmental and regional representatives provided for in Article L. 5915-1 of the General Code of the local government, the national park charter lays out the guidelines for the conditions of access and use of these resources, including the terms of the sharing of benefits that may result in compliance with the principles of the Convention on Biological Diversity of 5 June 1992, particularly as in "j" of its Article 8 and 15.<sup>27</sup>

A desire so strongly expressed and renewed may have an impact on the Law. It could lead to or help in the interpretation of the often vague rules on local

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Guiane. En second lieu, il tire les conséquences de ce contexte amazonien, caractérisé par un très vaste espace forestier, une densité de population très faible, de grandes difficultés de circulation et l'existence de populations amérindiennes et Noires-marrons qui entretiennent un rapport à la nature très différent de celui auquel nous sommes habitués. Ces communautés humaines tirent traditionnellement leurs moyens de subsistance de la forêt, leur mode de vie y est étroitement associé – d'où l'importance de la préserver – et il est particulièrement adapté aux conditions exceptionnelles du milieu. Qu'elles soient amérindiennes, noires-marrons ou créoles, les implantations humaines dans la forêt tropicale humide en Guiane ne sont viables qu'à travers le développement d'une connaissance du milieu qui leur est propre et les pratiques respectueuses de la forêt et de son écologie. L'opportunité de créer un parc national en Guiane leur doit beaucoup. Il est dès lors justifié, comme le demandent les collectivités territoriales de Guiane, de reconnaître cette spécificité amazonienne et d'adapter la législation pour que ces populations gardent toute leur place dans le futur parc. Cet amendement comprend donc une série d'adaptations indispensables pour tenir compte de tous ces aspects au travers des six articles dans le code de l'environnement." Assemblée nationale. Session ordinaire de 2005–2006, 87ème séance. Compte-rendu intégral. 2ème séance du jeudi 1er décembre 2005. Année 2005, n° 101 [2] A.N. (C.R.), vendredi 2 décembre 2005, p. 7846.

27 Author's translation of the original text: "Sur proposition du congrès des élus départementaux et régionaux prévu à l'article L. 5915-1 du code général des collectivités territoriales, la charte du parc national définit les orientations relatives aux conditions d'accès et d'utilisation de ces ressources, notamment en ce qui concerne les modalités du partage des bénéfices pouvant en résulter, dans le respect des principes de la convention sur la diversité biologique du 5 juin 1992, en particulier du j de son article 8 et de son article 15."



communities in a way that is most profitable to them. We may consider this view of the legal formula that has been constantly repeated for over twenty years as cryptic<sup>28</sup> “activity necessary for subsistence.” This comprises three notions: connectedness, necessity and subsistence.

More interesting, because it is more promising, the Government, supported by members of parliament, has indicated its commitment to include the French regulations within the mainstream thinking on protecting the rights of indigenous and local communities. In this respect, they clearly and constantly refer to the non-binding acts of the International Union for Conservation of Nature and Natural Resources (IUCN).<sup>29</sup> It even contributes to the development of regulations implementing the law.<sup>30</sup> Information provided during the debate in the Senate by the Minister of Ecology and Sustainable Development goes thus:

On my request, my services have already prepared a draft decree on which the consultation meetings with various stakeholders have already begun studying the text that came out of the joint committee. Thus the first working sessions, also positive, was held on March 8, 2006 with the French Committee of the World Conservation Union, IUCN, giving great importance to checking the adequacy of the proposed Decree on French national parks, of course, paying attention to international rules and standards.<sup>31</sup>

28 See the above Articles of the domain of the State Code and Forest Code.

29 Since 1975 (12th General Assembly of IUCN, N'Sele, Zaire), IUCN has recognized the rights of indigenous communities within the parks, including the right to identity, land ownership and in decision making (5th resolution “Protecting traditional lifestyles”). Thereafter, IUCN reiterated the terms of this recognition now focusing on two specific international standards: Convention No. 169 of the ILO and the United Nations Declaration on the Rights of Indigenous Peoples. By this reference, she admitted, and supported by others the right to self-determination of Indigenous Peoples (Resolution 1.55 “Indigenous Peoples and Forests” adopted in 1996 on the occasion of the 1st Session of the World Conservation Congress, held from 14 to 23 October 1996 in Montreal, Canada). This repeated recognition of the rights of indigenous communities has then led to the renewal of its categorization system incorporating protected now and in a positive manner the rights of its population areas. N. Dudley, *Guidelines for the application of management categories protected areas* (Gland, Switzerland: IUCN, 2008).

30 Information provided during the debate in the Senate by the Minister of Ecology and Sustainable Development: Senate. Ordinary session 2005–2006. Full Report. Sitting of Tuesday 14 March 2006 (80th sitting day of the session). 2006, No. 27S. (CR), Wednesday, March 15, 2006, p. 2064.

31 Author's translation of the original text: “À ma demande, mes services ont d'ores et déjà élaboré un projet de décret sur lequel les réunions de consultation avec les divers partenaires

Based on this determination, it could be argued that, even if not ratified or adopted, Convention No. 169 concerning indigenous and local people or even the United Nations Declaration on the Rights of Indigenous People constitute the legal framework of the French regulation on indigenous communities.

#### b Limited Rights of Indigenous Communities

The status of national parks lay bare the first steps in French law towards the recognition of a specific legal status of access to genetic resources and the financial conditions of their exploitation: Article L.331-15-6 of the Environmental Code states:

Access to genetic resources collected from the National Park and their use are subject to authorization. On the proposal of the elected departments and regions of Congress under Article L. 5915-1 of the General Code of local authorities, the National Park Charter lays down the guidelines for the conditions of access and use of these resources, especially regarding how to share resulting profits in compliance with the principles of the Convention on Biological Diversity of 5 June 1992, as found in Article 8 of j and Article 15. Licences are issued by the President of the Regional Council with the assent of the President of the General Council and in consultation with the public establishment of the national park, without prejudice to the provisions of the Code of intellectual property.<sup>32</sup>

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concernés ont déjà commencé dès la connaissance du texte sorti de la commission mixte paritaire. C'est ainsi que la première réunion de travail, d'ailleurs positive, a eu lieu le 8 mars 2006 avec le comité français de l'Union mondiale de la nature, l'UICN, compte tenu de la très grande importance de bien vérifier l'adéquation du projet de décret sur les parcs nationaux français avec les règles et standards internationaux, bien évidemment." Sénat Session ordinaire de 2005–2006. Compte-rendu intégral. Séance du mardi 14 mars 2006 (80ème jour de séance de la session). Année 2006, n° 27S. (C.R.), mercredi 15 mars 2006, p. 2064.

- 32 Author's translation of the original text: "L'accès aux ressources génétiques des espèces prélevées dans le parc national ainsi que leur utilisation sont soumis à autorisation. Sur proposition du congrès des élus départementaux et régionaux prévu à l'article L. 5915-1 du code général des collectivités territoriales, la charte du parc national définit les orientations relatives aux conditions d'accès et d'utilisation de ces ressources, notamment en ce qui concerne les modalités du partage des bénéfices pouvant en résulter, dans le respect des principes de la convention sur la diversité biologique du 5 juin 1992, en particulier du j de son article 8 et de son article 15. Les autorisations sont délivrées par le président du conseil régional, après avis conforme du président du conseil général et consultation de l'établissement public du parc national, sans préjudice de l'application des dispositions du code de la propriété intellectuelle."

It stipulates that the Park “will help protect [...] against the plundering of biological wealth.”<sup>33</sup> As seen above, the National Park Charter states the basic principle for this protection: “Access to genetic resources of species collected from the National Park and their use is subject to authorization.”<sup>34</sup> It already accurately determines the authorization procedure:

The permits are issued by the President of the Regional Council, following the approval of the President of the General Council and in consultations with the public office of the national park, without prejudice of the provisions of the Code of intellectual Property.<sup>35</sup>

As for the rest, it is left to the Charter to specify its role.<sup>36</sup> The rights of indigenous communities shall be defined in the Charter of the park.

In the preparation of this text, these people had no advisory role or decision on obtaining authorization and financial settlements. The situation is same

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33 Author's translation of the original text: “permettra de protéger [...] contre le pillage des richesses biologiques.” National Assembly Ordinary Session 2005–2006, 84th session. Full Report. First meeting of Wednesday, November 30, 2005, No. 100 [1] AN (CR), Thursday, 1 December 2005, p. 7741.

34 Author's translation of the original text: “L'accès aux ressources génétiques des espèces prélevées dans le parc national ainsi que leur utilisation sont soumis à autorisation.” Environmental Code Article L.331-15-6 paragraph 1.

35 Author's translation of the original text: “Les autorisations sont délivrées par le président du conseil régional, après avis conforme du président du conseil général et consultation de l'établissement public du parc national, sans préjudice de l'application des dispositions du code de la propriété intellectuelle.” Environmental Code Article L.331-15 paragraph 3.

36 Environmental Code Article L.331-15-6 paragraph 2; “The charter is the project of sustainable development and protection of natural heritage, landscape and cultural rights for the territories of French Guiana Amazonian Park [...]. Charter is a process that leads to a contractual document to be signed by the common wishing to join, the Guiana Amazonian Park and the Prime Minister (decree of the Council of State.) It is a roadmap for the intervention of the public establishment of Guiana Amazonian Park and its partners for 10 years. Orientations, objectives and measures set out in the Charter will be implemented on a partnership through concrete actions in the service of communes having made the choice to join the Charter” (“La charte des territoires,” Parc Amazonien de Guianne, <http://www.parc-amazonien-guiane.fr/le-parc-amazonien-de-guiane/la-charte-des-territoires>). These goals, objectives and actions include the fight against illegal mining, improving the quality of life of people drinking water, electricity, waste management, etc., the appropriate local economic development, and protection of the forest and streams and recovery of cultural treasures.

with other people and authorities of Guiana and the park.<sup>37</sup> In fact, they act indirectly through a decentralized political organ of the territory of Guiana (Elected County and Regional Congress) and the decision-making and advisory bodies of the Park (Public Establishment such as its Board of Directors, its Scientific Council Committee and local life committee). Their rights and claims are therefore diluted and are likely to be ignored or violated. This is most likely because the indigenous communities do not always have guaranteed representation in these bodies. Nothing is thus legally fixed and imposed on the composition of the local committee. For now, it is only recommended that it should include “the different actors in the national park: people, users, economic actors, associations,”<sup>38</sup> including “communities of people present in the Amazon rainforest.”<sup>39</sup> When indigenous communities are legally represented in these bodies, they have at most a small sphere of influence and not a real decision-making power. Thus, they can serve on the Board of Directors of the park and therefore participate in its work through the “members chosen for their competence” which include “representatives of associations of environmental protection, owners, residents and operators, professionals and users.”<sup>40</sup> Better still, in addition to this general and common representation at the assembly of people who are interested in the park or those present therein, are a particular representation of traditional, political and cultural authorities.<sup>41</sup> This particular representation is expected to at least facilitate the evocation of the specific interests and wishes of local and indigenous communities. However, even with the deciding vote of the Chair of the Board of Directors in

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37 Amazonian Park: articles L331-15-1s of the Environmental Code and Décret n°2007-266 du 27 février 2007 créant le parc national dénommé “Parc amazonien de Guiane.”

38 J.P. Giran, *National Parks. A Reference to France. A Chance for Its Territories*. Reports to the Prime Minister. June 2003.

39 Author’s translation of the original text: “les forces vives du parc national, habitants, usagers, acteurs économiques, associations [y compris les] communautés d’habitants présentes dans la forêt amazonienne.” No. 159 Report on behalf of the Committee on Economic Affairs and Planning (1) of the bill, passed by the National Assembly after Emergency Declaration relating to national parks and marine parks, with M. Jean Boyer, Senator. Senate. Ordinary Session 2005–2006, Mission to the creation of the National Park of Guiana, 2005. Draft for the creation of the national park Guiana. Book 1, The proposed national park in Guiana.

40 Author’s translation of the original text: “membres choisis pour leur compétence [lesquels comprennent] notamment des représentants des associations de protection de l’environnement, des propriétaires, des habitants et exploitants, des professionnels et des usagers.” Environmental Code Article L.331-8 paragraph 1.

41 Environmental Code Article L.331-15-4 paragraph 2.

the event of a stalemate,<sup>42</sup> indigenous communities do not pull sufficient weight to be sure to get decisions in accordance with their wishes.<sup>43</sup>

Specifically concerning the licensing system, the law gives local and indigenous communities no clear advisory or decision-making power. Being thus already determined by law, the Charter of the park cannot also come back on the issue. They have no power to issue opinions through the Park organs. Again, this fact indicates a high risk of ignorance or violation of rights of indigenous people, and all the more so because the given advisory role is not accompanied by the authority granted in this case. Only the opinion of the President of the General Council is solicited as a binding decision in this case. Initially, however, preparatory works show that indigenous communities would have had their own power of decision-making and control through their traditional political authorities.<sup>44</sup>

Accepted in principle, its methods have been challenged by parliamentarians.<sup>45</sup> The fact that it led to the privatization of wealth from this heritage was questioned. According to the parliamentarians, only the “micro- local populations inhabiting the park”<sup>46</sup> should benefit from this wealth.<sup>47</sup> They further argued that it was necessary to make these national property, that is to say, to ensure that ownership was “by all Guianese”<sup>48</sup> and the wealth be managed accordingly by decentralized authorities of that territory. This view has finally triumphed, with the law recognizing no advisory or decision-making power for local and indigenous communities. By so doing, the law does not take into consideration the provisions of Article 8j of the Convention on Biological Diversity on the right to intellectual property of indigenous and local communities. Given the terms of this right to property,<sup>49</sup> in fact, it may even be said that it violates them.

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42 Environmental Code Article R.331-28.

43 Article 27 of Decree No. 2007-266 of 27 February 2007 establishing the “Guiana Amazonian Park” called national park Members of the Board of Directors of the Public Establishment of the Guiana Amazonian Park. 20/10/2013. [http://www.parc-amazonien-guiane.fr/assets/membres-ca\\_pag.pdf](http://www.parc-amazonien-guiane.fr/assets/membres-ca_pag.pdf).

44 Proposed Amendment No. 217 (2nd corrigendum) by the Government: Proposal Article L.331-15-6-I of the new Environmental Code.

45 See the discussion: National Assembly. Ordinary Session 2005-2006, 87th session. Full Report. Second session on Thursday 1 December 2005. 2005, No. 101 [2] AN (CR), Friday, December 2, 2005, p. 7846-7851.

46 Author's translation of the original text: “populations micro-locales habitant le parc.”

47 Idem., p. 7849.

48 Author's translation of the original text: “par l'ensemble des Guianais.” Idem.

49 Karpe P., Lefebvre T., Community rights, intellectual property rights, in *Proceedings of the Conference Research and Exploitation of Forest Products: What Equitable Approach?* eds. Fleury M., Moretti C., (Gadepam: Cayenne, 2006): 43-57; Karpe P. (2008), Indigenous communities. L'Harmattan. Collection “Logiquesjuridiques.”

### Box 1 *The confusion of the Charter of the Amazonian Park*

The Guiana Amazonian Park recently adopted its Charter on October 28th, 2013.<sup>50</sup> Between 2009 and 2012, under the guidance of the Board of Directors and the President, this project was developed by a team of officers of the National Park with the contribution of all stakeholders in these territories: local authorities (municipalities, municipal associations, county, and region), traditional authorities, associations, socio-professional, the people, government departments and public institutions.

The terms of the project on access and benefit-sharing were contested during the public inquiry process by the City of Camopi, the Advisory Council of Amerindian and Bushinenge populations and by the Environmental Authority in charge of the Environmental Assessment of the draft Charter. They defended the project's contradiction with international standards ratified by France, in particular Article 8d) of the Convention on Biological Diversity which poses the right to informed consent of indigenous communities. Indeed, even though it commits itself to respect the said article, the draft Charter under public investigation does not give these people a right to be consulted. Indeed, at the request of the Region, the Amazonian Park had amended its draft charter by removing the principle of prior informed consent of indigenous people that had been initially registered.<sup>51</sup>

Following these criticisms, the Guiana Amazonian Park has committed itself to correct the draft Charter, replacing the right to be consulted by that of consent and thereby to bringing the project into compliance with the CBD.

Finally, the Charter currently in force has been modified and now clearly requires the free prior informed consent of indigenous and local communities. The Charter is now consistent with international law commitments of France, but goes contrary to the provisions of the Environmental code.

Finally, indigenous communities will always have a way of ensuring that the application of any law that is adverse to their own standards is practical, flexible and adapted to their own circumstances. Indeed, it is now required

50 For more information on the Charter of national parks, see, Guignier A., Prieur M. (2011), Legal Framework for Protected Areas: France, IUCN-EPLP n°81 ([http://cmsdata.iucn.org/downloads/france\\_en.pdf](http://cmsdata.iucn.org/downloads/france_en.pdf)).

51 See: Answer of the Chairman of the Board of Directors of the PAG in the opinion of the City Council Camopi on the draft charter PAG. Letter of 4 January 2013.

that the agents of a given park have “experience and knowledge of the natural, cultural heritage as well as the landscape”<sup>52</sup> of the specific park concerned.<sup>53</sup> Strongly contested, this new requirement for the public warrants “a mastery of the terrain”<sup>54</sup> to “better deal with customs,”<sup>55</sup> to show the “subtlety”<sup>56</sup> indispensable in the field.<sup>57</sup>

The realities in the field require both knowledge of the natural environment, the ability to live there and an understanding of the social organization, which is difficult to acquire through a simple school program or an administrative competition or bringing in statutory requirements.<sup>58</sup>

This is “absolutely essential”<sup>59</sup> especially in the Guianese context.<sup>60</sup> Anything short of this will cause the park to “crash.”<sup>61</sup> It should be noted that there is no requirement to recruit among indigenous communities.

## 2 *The Rules Applicable in the Territory of French Guiana: Proposals of the Region*

This special system applies only to indigenous knowledge within the area covered by the Amazonian Park. Article L.331-15-6 of the Environmental Code

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52 Author's translation of the original text: “expérience et des connaissances du patrimoine naturel, culturel et paysager.”

53 Law No. 2006–436 of 14 April 2006 on national parks, marine parks and regional parks, Article 26.

54 Author's translation of the original text: “la compréhension du terrain.”

55 Author's translation of the original text: “mieux composer avec les us et coutumes.”

56 Author's translation of the original text: “subtilité.”

57 National Assembly Ordinary Session 2005–2006, 87th session. Full Report. Second session on Thursday 1 December 2005.2005, No. 101 [2] AN (CR), Friday, December 2, 2005, p. 7831.

58 Author's translation of the original text: “La réalité des terrains demandent à la fois une connaissance du milieu naturel, une capacité à y vivre et une compréhension de l'organisation sociale, qu'il est difficile d'acquérir par un simple cursus scolaire tout autant que de sanctionner par un concours administratif ou de faire entrer dans des contraintes statutaires.” No. 159 Report on behalf of the Committee on Economic Affairs and Planning. Op. cit.

59 Author's translation of the original text: “absolument indispensable.”

60 National Assembly Ordinary Session 2005–2006, 87th session. Full Report. Second session on Thursday 1 December 2005.2005, No. 101 [2] AN (CR), Friday, December 2, 2005, p. 7831.

61 Author's translation of the original text: “se planter.” *Ibid.*

is indeed inserted in sub- Section 3 entitled “Amazonian Park in Guiana.” Indigenous knowledge of other countries remains well protected through the evoked use of multiple laws, rules, principles and processes.

During the environmental conference<sup>62</sup> for ecological transition held on 14 and 15 September 2012 in Paris (France), it was decided in a “consensus”<sup>63</sup> that the future framework law on biodiversity presented by the Council of Ministers in March 2014<sup>64</sup> would include a pre-ratification of the Nagoya Protocol by France on ABS:

The Government will establish an access to genetic resources and sharing of benefits arising from their use for the ratification of the Nagoya Protocol’s legal framework for access to resources and benefit-sharing (ABS) will be enshrined in law<sup>65</sup>

Earlier on, aware of its biodiversity riches and the traditional know-how related to them and the damaging legal vacuum in this area, the Guianese local authority have set their guidelines for the ABS system,<sup>66</sup> which they recalled during the participatory and decentralized preparation<sup>67</sup> of the national legal system on ABS.<sup>68</sup>

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62 “Repeated each year, the Environmental Conference is to discuss the work program of the Government’s sustainable development, in particular to sort and isolate the priority issues to address key environmental challenges, to agree on the objectives to be pursued, specific implementing measures and to take immediate consultations, and to take stock of all that has been achieved” (<http://www.developpement-durable.gouv.fr/Conference-environnementale-la.html>).

63 Roadmap for ecological transition, adopted after the Environmental Conference for ecological transition held on 14 and 15 September 2012 in Paris, France. p. 3.

64 [For an analysis of the new French Biodiversity Law see contribution by Chiarolla to this volume (Chapter 3)].

65 Author’s translation of the original text: “Le Gouvernement mettra en place un régime d’accès aux ressources génétiques et de partage des avantages issus de leur utilisation en vue de la ratification du Protocole de Nagoya. Le dispositif juridique d’accès aux ressources et de partage des avantages (APA) sera inscrit dans la loi.” Information submitted by the Committee on European Affairs on the ratification and implementation of the Nagoya Protocol, and presented by Danielle Auroi, Member Report. p. 37.

66 See, for example: Report to the Congress elected in Guiana. Device access to biological resources and benefit-sharing (ABS). July 21, 2011.

67 Roadmap for the transition écologique France. Op. cit., p. 3.

68 This contribution is not unique. Thus, in view of the implementation of the CBD and the Nagoya Protocol, “the Ministry of Ecology, Sustainable Development, Transport and Housing (MEDDTL), national co-focal point of the ABS with the Ministry of Foreign and



Basically, elected Guianese affirm the need for a specific ABS device in Guianese fashion “with/and notably: a regulation for the entire country, a regulation which focuses on genetic and biological resources, local regional management of authorization schemes and equitable sharing of benefits by regional political authorities.”<sup>69</sup> According to them, this specialty will facilitate the proper taking into account of the specific realities of the territory.<sup>70</sup> To this end, they ask

Parliament to enable the Regional Council of French Guiana on the basis of Article 73, paragraph 3, of the Constitution and Articles LO 4435-1 of the General Code of Territorial Units in order to set rules on access to biological resources, associated traditional knowledge, and the fair and equitable porting ensuing from their use specifically for the territory of Guiana.<sup>71</sup>

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European Affairs, launched in November 2009 a tender for a study on “the appropriateness and legal and institutional feasibility of a device ABS overseas, on the genetic resources and associated traditional knowledge.” Foundation for Research on Biodiversity (FRB), winner of the tender, proposed a multi-disciplinary expertise and multi-stakeholder approach in order to produce an analysis of the all expressed needs and demands” (Report of the Foundation for Research on Biodiversity, 2011. Report on the relevance and legal and institutional feasibility of an access and benefit-sharing overseas device on genetic resources and traditional knowledge. Commissioner-General for Sustainable Development Department of the economy, evaluation and integration of sustainable development. Studies and Documents, No. 48, September 2011. p. 13). Comments were made regarding the right of indigenous heritage. But is less detailed than those made by elected Guianese, the choice is made to present only the latter.

69 Author's translation of the original text: “avec et notamment: une réglementation pour l'ensemble du territoire; une réglementation qui porte sur les ressources génétiques et biologiques; une gestion régionale locale de régimes d'autorisation et de juste partage des avantages par l'autorité politique régionale.” Biodiversity Framework Act. Paper. Contribution of Guiana Region.p. 5.

70 *Ibid.*, 7.

71 Author's translation of the original text: “au Parlement d'habiliter le conseil régional de la Guiane sur le fondement de l'article 73, alinéa 3, de la Constitution et des articles LO 4435-1 et suivants du code général des collectivités territoriales aux fins de fixer spécifiquement pour le territoire de la Guiane des règles sur l'accès aux ressources biologiques, aux connaissances traditionnelles associées et sur le portage juste et équitable découlant de leur utilisation.” Article 1 of Decision No. 003673 December 21, 2012 Board regional Guiana on access to biological and genetic resources and benefit-sharing ABS – request for authorization. Official Gazette No. 0069 of March 22, 2013 pages 4939–4941. Text No. 102.

Developing the structure of their device, they specify the rights of indigenous Guianese communities. They attempt, in this regard, to create a balance, often difficult and delicate among all interests. First, they provide a description of their indigenous knowledge and practices designed to optimize protection. Indeed, they do not exclude any particular knowledge from protection. Moreover, regarding the use of this knowledge, they do not subject themselves to any regulation and therefore to any restriction, prohibition or payment to those made inside the communities.<sup>72</sup>

While we may even assume the willingness of local communities to fully and effectively demarcate indigenous knowledge and its uses at the base, elected Guianese confess a real difficulty in the delimitation and the need to enrich the current description in the future.<sup>73</sup> The definition of indigenous knowledge and its use will undoubtedly be completed during the forthcoming debate in Guiana on the framework law.

Concerning the rights of indigenous communities to their intellectual property, the Region of Guiana sincerely and fully emphasizes all relevant issues, namely:

How could the Nagoya Protocol be respected? How can good representation of indigenous and local communities in the framework be ensured? How can we ensure that the implementation tools (regulations, procedures, authorities, etc.) involve a correct level of indigenous and local representation? How can a representation of indigenous and local communities and traditional authorities be built?<sup>74</sup>

Without being able to provide all the answers to these questions due to their complexity, especially on the nature and terms of the representation of Aborigines, it gives some detailed, useful and innovative features. For example, it affirms the principle of collective ownership of a community's indigenous knowledge: "even if it is held by a single member of the community."<sup>75</sup>

72 Biodiversity Framework Act. Paper Contribution of Guiana Region. p. 25.

73 *Ibid.*, p. 25.

74 Author's translation of the original text: "Comment respecter le Protocole de Nagoya? Comment s'assurer de la bonne représentativité des populations autochtones et locales dans le dispositif? Comment s'assurer de la mise en place des outils (réglementation, procédures, instances, etc.) en impliquant un niveau correct de représentativité autochtone et locale? Comment construire une représentation des populations autochtones et locales et des autorités coutumières?" *Ibid.*, p. 35.

75 Author's translation of the original text: "même s'il n'est détenu que par un seul membre de la communauté." *Ibid.*, p. 25.

It also recognizes the diversity of modes of acquisition of indigenous knowledge: survey, interview and image capture (video, photos, etc.).<sup>76</sup> Under the licensing system, it advocates and provides for the specific participation of indigenous communities, even in the absence of the indigenous knowledge in question. In the latter case described as a simplified procedure, the bio-pro prospector must inform and train people indigenous to the area where he does his research. Moreover, these people must be consulted before the authorization decision is made as long as they are managers of the land on which the prospector is working. It is, however, a simple notice. In contrast, in a situation where indigenous knowledge is concerned and considered as the appropriate procedure, indigenous communities must agree to their acquisition and use by a prospector. Moreover, this must comply with the Bonn Guidelines, although strictly voluntary, to further develop its strategies. What this provides for is nothing more than an adaptation to Guiana realities.<sup>77</sup> Finally, it firmly asserts that, the status of indigenous people cannot be truly and fully protective until the trans-boundary nature of these people and their knowledge<sup>78</sup> are “virtually [and] always”<sup>79</sup> considered.

The entire ABS system is enriched with a sketch of the special control and punishment procedure so far non-existent in French law. However, the Region of Guiana does not have special rules for indigenous communities for now. To conclude, it should be noted that Aboriginal communities contribute to the definition of the final ABS system.<sup>80</sup>

### III The Impact of European Community Law

#### 1 *A Reduced Legal Interest*

In relation to European legislation concerning the right of French indigenous communities to protect their traditional knowledge, France remains the sole master of her destiny.

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<sup>76</sup> *Ibid.*, p. 25.

<sup>77</sup> *Ibid.*, pp. 27, 28 and 30.

<sup>78</sup> *Ibid.*, pp. 25 and 35.

<sup>79</sup> Author's translation of the original text: “pratiquement [et] systématiquement.” *Ibid.*, p. 35.

<sup>80</sup> 15th contributor of Decision No. 003673 December 21, 2012 of the Regional Council of French Guiana on access to biological and genetic resources and sharing of benefits ABS – request for authorization. Official Gazette No. 0069 of March 22, 2013 pages 4939–4941. Text No. 102.

a           The Legal Impact of European Union Laws

In the field of environmental protection on which the intervention sought for by the EU on ABS depends primarily, though not exclusively, states are not to exercise their powers on shared competence or competitors, as long as and in case the Union has not yet intervened in the field in question.<sup>81</sup> Thus, the jurisdiction of the EU is gradually replacing or substituting the State authority, if it is at the end of a given transitional period. However, the Lisbon Treaty, for the first time, also provides for a possible return to the domestic expertise in the area of shared competence if the Union has ceased to exercise its own domestic expertise.

By signing the Nagoya Protocol in June 2011, the EU has committed itself, along with its Member States, to the ratification process. In accordance with Article 218 of the Treaty on the Functioning of the European Union (TFEU) on the conclusion of international agreements in an area that falls within the competence of the Union, such ratification required a decision of the Council. As concerns the promulgation of the Nagoya Protocol into EU law, it had to be done through a Regulation, the source of legislation referred to in the Treaties to legislate in such issues.

Let us first recall that on a formal level, the Regulation constitutes a legal instrument whose application is general. Adopted by the institutions, it targets categories of recipients envisaged in an abstract manner to go by the formula laid out in Article 288 of TFEU. But it is especially a legally binding instrument in its totality and directly applicable in each of its Member States, upon its entry into force in the EU itself. Again, according to the principle of primacy, it is by definition, like all sources of EU law, above internal law. What particularly results from this is the obligation of national authorities, the judiciary in particular, to put aside any contrary national law.<sup>82</sup>

The EU Regulation on ABS, as adopted by the European Parliament and the Council, thus preserves the freedom granted to Member States to introduce this rule (prior and informed consent with regard to genetic resources which they own). This freedom is also consistent with the obligation of the Union listed in Article 4 of the Treaty on European Union (TEU) to “respect [the] national identities [of Member States], inherent in their fundamental structures, political and constitutional, inclusive of regional and local self-government. It shall respect their essential State functions, including ensuring the territorial integrity of the State.” However, the strong legal impact that it will have on Member States when it comes into force fully justifies the

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81   Treaty on the Functioning of the European Union (TFEU) Article 2 §2.

82   See in particular: Ivan Boev, *Droit Européen* (Paris: Editions Breal, 2012): 191.

relatively long time preceding the final adoption of the text that is essential to the effective inclusion of all interests, including those of indigenous people.

Finally and most importantly, based on the special rules established by the treaties on the application of EU law on the so-called outermost territories reminiscent in Article 349,<sup>83</sup> France does not recognize the competence of the EU to legislate on French indigenous knowledge in its place. In the light of discussions on each of the legal tools, this is not a serious concern.

#### b Division of Power

While the Council had excluded indigenous knowledge under the sovereignty of member states from the jurisdiction of the Union in 2009,<sup>84</sup> the

83 Article 349 states: "Taking account of the structural social and economic situation of Guadeloupe, French Guiana, Martinique, Réunion, Saint-Barthélemy, Saint-Martin, the Azores, Madeira and the Canary Islands, which is compounded by their remoteness, insularity, small size, difficult topography and climate, economic dependence on a few products, the permanence and combination of which severely restrain their development, the Council, on a proposal from the Commission and after consulting the European Parliament, shall adopt specific measures aimed, in particular, at laying down the conditions of application of the Treaties to those regions, including common policies. Where the specific measures in question are adopted by the Council in accordance with a special legislative procedure, it shall also act on a proposal from the Commission and after consulting the European Parliament."

84 The Council of the EU authorised the Board in 2009 and again in 2010 to Participate in the Nagoya Protocol negotiations on behalf of the Union with respect to matters falling within EU competence (CEU 2011). At the Council's insistence, Article 175 (1) EC (now Art 192 (2) TFEU), the environmental competence norm, in Conjunction with Art 300 (1) EC (now Art 218 (1) TFEU) (one external competence for the conclusion of international agreements of) provided the Legal basis Conducted for the negotiations by the Commission (CEU, 2009).

The Negotiating Guidelines issued by the council recognised that the protocol's operational provisions would affect several areas under U.S. jurisdiction. These include environment, public health, common trade policy, customs cooperation, free movement of persons, agriculture, approximation of laws, development cooperation and research and technological development. Nearly all of these are areas of shared competence between the Union and the Member States, as defined in the Lisbon Treaty. The only area Explicitly excluded from the Commission's Negotiating mandate was traditional knowledge associated with genetic resources Held by indigenous and local communities, All which was Directly handled by the Member State holding the Presidency of the Council' (CEU, 2009/CEU (2009), "Council Decision on the Participation of the European Community in Negotiations on an International Regime on Access and Benefit-sharing in the Framework of the Convention on Biological Diversity." Council of the European Union, doc.14456/09, 15 October 2009); IEEP, Ecologic and GHK, *Study to analyze legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union* (Brussels/London, 2012): 14.

EU Regulation nevertheless seems to include it. There is however no explicit exclusion of indigenous knowledge from the Jurisdiction but rather an implied inclusion. Instead, it uses the most general formulation. Moreover, it expresses its full competence in the field.<sup>85</sup>

One can at least stress that the EU Regulation should apply, “without prejudice, to the competence and responsibility of the Member States for matters relating to traditional knowledge associated with genetic resources and the implementation of measures to safeguard indigenous and local communities’ interests.”<sup>86</sup>

On the occasion of the debate on the proposed text of the Regulation, the French Members of Parliament (MPs) strongly challenged the competence of the EU to secure the internal status of indigenous knowledge, especially in its overseas territories.<sup>87</sup> This opposition was recalled in the legislative resolution project of the European Parliament on the initial proposal for a Regulation.

Even when, during discussions, the parliamentarians considered that the European legislative proposal respected the division of power under the Treaty of Union, they justified it on the grounds that the proposal complied with the freedom of Member States to legislate their Indigenous Knowledge.<sup>88</sup>

Finally, we must remember that in case of contestations of the competence of the EU after the entry into force of the Regulation as set out by the latter, France would still be able to appeal to the Court of Justice of the European Union (ECJ). However, the actions which may be brought before the ECJ

85 EU Regulation on ABS, recital 35 and Articles 1 and 2.

86 EU Regulation on ABS, recital 20.

87 See especially to: Information Report No. 396 filed by the Committee for European Affairs on the ratification and implementation of the Nagoya Protocol. *Op. cit.*, pp. 33–34, No. 174. Senate. Ordinary Session of 2012–2013. Proposal for a European Resolution reasoned opinion filed on behalf of the European Affairs Committee in accordance with Article 73 of Regulation on compliance with the subsidiarity principle of the proposed regulation on access to genetic resources and the fair sharing and equitable sharing of benefits arising from their use in the EU (COM (2012) 576) presented by Jean Bizet, Senator. Registered as President of the Senate on November 29, 2012, p. 4–5; Senate. No. 65. Ordinary session 2012–2013. European Resolution motivated on compliance with the subsidiarity principle of the proposed regulation on access to genetic resources and the fair and equitable sharing of benefits arising from their use in the EU (COM (2012) 576) notice. Adopted on 20 December 2012; This approach is based on legally recognized by the Treaty of Lisbon, the new powers of national parliaments to monitor compliance with the principle of subsidiarity by the institutions. This control – political in nature – can lead to a referral to the Court of Justice of the European Union through the Member States.

88 See: National Assembly. XIV Legislature Account. European Affairs Committee. Tuesday, 13 November 2012, 16h 30, Report No. 14, p. 20.

(the action for annulment<sup>89</sup> and the proceedings for failure to act<sup>90</sup>) remain subject to restrictive conditions, namely respecting a two month' deadline in which to bring the action for annulment and having an interest in taking action in order to be able to bring proceedings before the Court of Justice.<sup>91</sup> Moreover, the use of non-contractual liability could also lead to actions against institutions for damages caused by any unlawful conduct.<sup>92</sup> The two appeals are also available to individuals.

c            Expansion of the Protection of French Indigenous Knowledge to  
Align with or Exceed European Protection

The essential points of the right of indigenous communities to protect their indigenous knowledge, namely prior consent, collective ownership, benefit-sharing and indigenous participation in the standardization process are provided for in the French legislation under preparation. Considering that they are not yet specified or final, it becomes difficult to make any assessment. However, they must comply with the relevant international standards, in particular, Article 8j) of the CBD. In addition, France seems to want a much more demanding, detailed and binding law, for itself and for Europe, than what the European institutions are currently offering.<sup>93</sup>

The main difference between the two draft judicial systems, the French and European, lies in their respective foundations. Unlike the French authorities, European institutions base their legal status on indigenous knowledge on the two main international instruments concerning them, namely, the International Labor Organization (ILO) Convention No. 169 on the Rights of

89 "The action for annulment is one of the actions which may be brought before the Court of Justice of the European Union. Through this action, the claimant requests the annulment of an act adopted by a European Union institution, body, office or organization" ([http://europa.eu/legislation\\_summaries/institutional\\_affairs/decisionmaking\\_process/aio038\\_en.htm](http://europa.eu/legislation_summaries/institutional_affairs/decisionmaking_process/aio038_en.htm)).

90 "Proceedings for failure to act are one of the actions which may be brought before the Court of Justice of the European Union. These types of proceedings are carried out against the inaction of a Union institution, body, office or agency. If this inaction is illegal under European law, the Court shall confirm the failure to act and the institution, body, office or agency concerned must take appropriate measures" ([http://europa.eu/legislation\\_summaries/institutional\\_affairs/decisionmaking\\_process/aio038\\_en.htm](http://europa.eu/legislation_summaries/institutional_affairs/decisionmaking_process/aio038_en.htm)).

91 TFEU Article 263.

92 TFEU Article 268, competence of the ECJ relating to TFEU Article 340.

93 See especially the Minutes of the meeting of 13 November 2012 of the European Affairs Committee of the National Assembly, National Assembly. XIV Legislature Account. European Affairs Committee. Tuesday, 13 November 2012, 16h 30, Report No. 14. pp. 17, 18, 20 and 21.

Indigenous and Local People in Independent Countries and the United Nations Declaration on the Rights of Indigenous Peoples.<sup>94</sup>

From a strictly legal point of view, these foundations are not really helpful to effectively protect indigenous knowledge in France. They might even be counter-productive. Indeed, their assertions will conceal the pro-active potentials inherent in the French law. But most essentially, it will give the status of the French indigenous people a meaning contrary to that which it truly seeks.

## 2 *A New Political Forum?*

"Given its assumed specificity by countries which are both providers and users of biological resources,"<sup>95</sup> France wants to be the engine of Europe with regards to the protection of indigenous knowledge. The question then is how the European initiative and drafting process can enable France to go further in her own legislation, how France can be convinced to enrich and deepen the status of the indigenous people beyond what she initially wanted, and what would she be able to achieve alone. The Regulation will be of interest. In fact,

it is clear that apart from the judgments of the European Court of Human Rights, the recommendations, resolutions and reports of the Council of Europe generally do not have the same visibility and impact as the European Union. In the twenty-seven Member States, the European Union' acts are more compulsory.<sup>96</sup>

94 See: 3rd recital of the Regulation of the European Parliament and of the Council on access to genetic resources and the fair and equitable sharing of benefits arising from their use in the EU, Amendment 8 – Proposal for a regulation – Considering 3 and Amendment 14 – Proposal for a regulation – Recital 4 d (new) Draft legislative resolution of the European Parliament on the proposal for a Regulation of the European Parliament and of the Council on access to genetic resources and the fair and equitable sharing of benefits from their use in the EU (European Parliament 2009–2014 A7-0263/2013, 07.16.2013 Op. cit., pp. 4–131).

95 Author's translation of the original text: "Compte tenu de sa spécificité revendiquée de pays à la fois fournisseur et utilisateur de ressources biologiques." Information Report No. 396 filed by the Committee for European Affairs on the ratification and implementation of the Nagoya Protocol. Op. cit., p. 36.

96 Author's translation of the original text: "[force] est de constater qu'en dehors des arrêts de la Cour européenne des droits de l'homme, les recommandations, résolutions et rapports du Conseil de l'Europe ne jouissent généralement pas de la même visibilité que les demandes émanant de l'Union européenne. Dans les vingt-sept États membres, la contrainte de l'Union européenne oblige sans doute davantage." No. 199. Senate. Ordinary Session of 2012–2013. Information report on behalf of the European Affairs Committee on Roma integration: a challenge for the European Union and its Member States, by Michel Billout, Senator. Recorded at the Presidency of the Senate on December 6 2012. p. 6.



a           The General Principles of Community Law

In the general principles of community law, the respect for human rights is fully involved. The enforcement of the work of the Court of Justice of the European Union (CJEU) was initially done through the consecration of the general principles of Community law. The respect for human rights was later considered as prerequisite for the legality of institutional acts. With the Charter of Fundamental Rights, the EU has a catalogue on the subject. This catalogue acquired constitutional significance with the entry into force of the Lisbon Treaty on 1 December 2009. Article 6 TEU actually introduces the Charter into the primary law of the EU.

On the same platform, the right to ownership will be transposed in Article 17 of the Charter of Fundamental Rights. It specifically recognizes the right to the protection of intellectual property. After the entry into force of the Lisbon Treaty, the ECJ already had the opportunity to rule on this legal basis.<sup>97</sup> However, it is worth recalling that, long before now, the right to ownership was already widely asserted through court cases as a general principle of EU law revealed by the court in accordance with established practices, both from Article 1 of the additional Protocol to the European Convention on human Rights and the common constitutional traditions of the Member.

b           The Court of Justice of the European Union

After the entry into force of the regulation implementing the Nagoya Protocol, in principle, the non-observance of indigenous knowledge of indigenous communities may lead, on this basis, to a possible referral of the case to the ECJ. In addition to the afore-mentioned direct action, cancellation and/or deficiency and the use of contractual liability (compensation) shall be available but subject to restrictive eligibility conditions. That is why it is especially the preliminary ruling option that appears to be of interest mainly because of its accessibility to individual applicants. Benefitting from direct applicability, the regulation could be invoked in a case pending before a national court. Concerning the interpretation or validity of that regulation as the case may be, it could confront the latter both against a violation of national law and against EU treaties in force. The national court would still have to decide on the merits, but taking into account the judgment of the ECJ. In order to take full advantage of these mechanisms available to indigenous communities before the ECJ, the next step to take will be to ensure and promote access by indigenous communities to state justice at the national level.

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97 See ECJ, judgment of 18 April 2013, Case C –565/11 Mariana Irimie c. Administratia Finantelor Publice Sibiu.

### 3 *The Indispensable Construction of a Native French and European Citizenship*

The Guianese situation remains special. The indigenous people are discreetly under a policy of re-instatement of their rights. This discretion is absolutely necessary given the specificity of the local, political and social contexts.<sup>98</sup> Is it then possible to take into account this specificity? In other words, could the future EU Regulation destroy the current wave of the protective decolonization of indigenous people?

#### a The Renewal of the Status of Outermost Regions

Article 349 of the TFEU can largely adapt<sup>99</sup> European legislation to local realities of the outermost regions (ORs), which include Guiana. It provides that

the Council, on a proposal from the Commission and after consulting the European Parliament, [can stop] specific measures aimed, in particular, at establishing the conditions for the application of [EU rules] taking into account characteristics and constraints of the outermost regions without undermining the integrity and coherence of the Union's legal order, including the internal market and common policies.

Unfortunately though, these measures are rarely adopted. The European Commission, “in its capacity as carrier institution of legislative initiative”<sup>100</sup> provides a “narrow range”<sup>101</sup> in this article.

98 P. Karpe and A. Tiouka, “Beyond legalism: Progressive Decolonization Indians in French Guiana,” in *Aboriginal issues in the Guiana Shield*, ed. Maude Elfort and V. Roux (Aix-Marseille: Collection Law of overseas territories. University of Aix-Marseille presses, 2013).

99 See: No. 378. Senate. Ordinary Session of 2012–2013. Information report on behalf of the European Affairs Committee of the policies of the European Union in the outermost regions: Guiana in search of his singularity, By Georges Patient and Simon Sutour, Senators. Registered as President of the Senate on 20 February 2013. Appendix 4. Senate. European resolution of July 3, 2012 to obtain the recognition by the EU of the realities of fishing French outermost regions (AND E 6449 E 6897). p. 60.

100 Author's translation of the original text: “en sa qualité d'institution porteuse de l'initiative législative.” No. 378. Senate. Ordinary Session of 2012–2013. Information report on behalf of the European Affairs Committee of the policies of the European Union in the outermost regions: Guiana in search of his singularity, By Georges Patient and Simon Sutour, Senators. Registered as President of the Senate on 20 February 2013. Appendix 5. Position of the Guiana Region on the EU strategy for the outermost regions. p. 70.

101 Author's translation of the original text: “portée restrictive.” *Ibid.*, p. 59.

The “philosophy” behind [the action of the European Commission] continues to support the regions in the convergence towards a common market and the gradual implementation of EU legal instruments of law (and not the sustainable taking into account and development of the specificities of ORs with the aim of adapting policies and tools). Thus, the implementation of the common law is preferred to the adoption of sector-specific frameworks to maximize the potential of the legal base provided for by Article 349 [above].<sup>102</sup>

This situation may change in the future. Indeed, in its Circular, “The outermost regions of the EU: towards a partnership for smart, sustainable and inclusive growth,”<sup>103</sup> the Commission acknowledged “the diversity of situations in each OR.” In its introduction, it states that “each OR is different and specific tracks must be considered for each of them.” The Commission adds that, “each OR must find its own path to greater prosperity, according to its features,” but felt that the ORs “are sometimes better supported by adaptations of EU rules or the taking into account of their specific needs at the time of implementation.”<sup>104</sup>

#### b The Principle of Participation

One of the fundamental conditions of the effectiveness of European law on knowledge is the specific involvement of indigenous people in the construction of European legislation for the “defence of [their] moral and material interests.”<sup>105</sup> France has already expressed the need for it and her concern to ensure effectiveness and efficiency:

The participation of indigenous groups in the consultation process [the ABS], however, remains uneven from one territory to another, The Kanaks were better represented in the French delegation to the [Conference of

<sup>102</sup> “La “philosophie” qui sous-tend [l’action de la Commission européenne] demeure l’accompagnement des régions dans la convergence vers le marché commun et la transposition progressive des instruments juridiques communautaires de droit commun (et non la prise en compte pérenne et la valorisation des spécificités des RUP avec le souci de l’adaptation des politiques et des outils). Ainsi, la transposition du droit commun est préférée à l’adoption de cadres sectoriels spécifiques permettant d’exploiter au maximum tout le potentiel de la base juridique offerte par l’article 349 [susmentionné].” *Ibid.*, p. 70.

<sup>103</sup> SWD (2012) 170 final Bruxelles, 20.6.2012 – COM (2012) 287 final.

<sup>104</sup> *Idem.*, p. 27.

<sup>105</sup> Author’s translation of the original text: “défense [de leurs] intérêts matériels et moraux.” Information Report No. 396 filed by the Committee for European Affairs on the ratification and implementation implementation of the Nagoya Protocol. *Op. cit.*, p. 38.

Parties] in Hyderabad, than other French indigenous communities – notably those from Guiana. The difficulty in collecting representative notice must be overcome.

[One] of the challenges to ensure indigenous communities' rights lies in the modes of political representation of such groups, which do not have direct access to international negotiations but are defended only through national authorities which are sometimes insensitive to their cultural differences.<sup>106</sup>

General procedures and institutions already exist in Guiana though with some reservations,<sup>107</sup> for example the Advisory Council on Native American populations and Bushinenguées.<sup>108</sup> This has been clearly established to ensure a particular representation to communities that do not have any. But at the debate on the draft European legislation on ABS, French parliamentarians suggested to innovate on this area to enhance participation.<sup>109</sup> The development of this participation has not yet been outlined. Is it planned? How can it be built? What would be its useful form? Can we be satisfied with a simple process of enhanced participation as envisaged in the recently renovated Advisory Council of Native American populations and bushinenguée<sup>110</sup> where referral is required, but opinion remains advisory?<sup>111</sup> Must it comply with relevant international standards which require the “free, prior and informed” consent<sup>112</sup> of indigenous people during “[the adoption and application] of legislative or

106 Author's translation of the original text: “L'association des groupes autochtones aux processus de consultation [sur l'APA] reste toutefois inégale d'un territoire à l'autre. Ainsi, si les Kanaks étaient représentés en tant que tels dans la délégation française à la CdP d'Hyderabad, la structuration d'autres communautés – notamment celles de Guiane – est traditionnellement moins bien charpentée, ce qui rend plus hypothétique la prise en compte de leurs intérêts. Cette difficulté à recueillir des avis représentatifs doit être surmontée. [L'une] des difficultés à surmonter pour garantir leurs droits réside dans les modes de représentation politiques de ces groupes humains, qui n'ont pas accès directement aux négociations internationales mais ne sont défendus que par l'intermédiaire d'autorités nationales parfois insensibles à leurs spécificités culturelles.” *Ibid.*, pp. 36, 37 and 38.

107 Karpe and Tiouka, “Beyond legalism.”

108 General code of local authorities Article L4436-1s.

109 Conclusions of the European Affairs Committee of the National Assembly. 12th recommendation. National Assembly. XIV Legislature Account. European Affairs Committee. Tuesday, 13 November 2012, 16h 30, Report No. 14. p. 20.

110 Article L.71-121s new General Code of Territorial status – Law No. 2011-884 of 27 July 2011 relating to local authorities in French Guiana and Martinique.

111 Karpe and Tiouka, “Beyond legalism.”

112 UN Declaration on the Rights of Indigenous Peoples Article 19.

administrative measures which may concern [them]”?<sup>113</sup> But is this possible or simply required in French Guiana?<sup>114</sup>

Undoubtedly, indigenous people have contributed to the development of European legislation. Certainly, without benefitting from specific conditions, they were obviously a group of actors specifically targeted by the public meetings<sup>115</sup> launched in the last quarter of 2011 (October 24 to 19 December) to explore the possible effects of the Protocol and gather concrete proposals on the practical challenges associated with the implementation of the Nagoya Protocol. Unfortunately, in the end, they had limited contributions during these meetings.

The Commission received 42 responses to the questionnaire, and one contribution by the Government of Norway. The relatively small number of replies received actually represents a much broader number of

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<sup>113</sup> *Ibid.*

<sup>114</sup> Karpe and Tiouka, “Beyond legalism.”

<sup>115</sup> “The interim period, which is the actual development of the [European legislation] usually, sees the draft submitted for public consultation via the Internet, the Commission reserves the possibility to organize meetings between holders divergent interest. However, the Commission has always refused to ‘juridiciser’ this phase of consultation by a regulation of general application to him. But accession to the Aarhus Convention has caused the adoption of Regulation 1367/2006, which indicates in particular that ‘the Community institutions or bodies provide the public, when all options are still open, a real opportunity to participate earlier in the development, modification or review of plans and programs relating to the environment’ (Article 9). Generally, Article 1 § 2 of Regulation 1367/2006 states that ‘the institutions and bodies shall endeavor to assist and advise the public to enable them to access information, participation in decision making and access to justice’ (author’s translation) “La période intermédiaire, qui est celle de l’élaboration proprement dite voit le plus souvent le projet de texte soumis à consultation publique via internet, la Commission se réservant la possibilité d’organiser des réunions entre porteurs d’intérêts divergents. Toutefois, la Commission s’est toujours refusée à ‘juridiciser’ cette phase de consultation par un règlement de portée générale à son égard. Mais l’adhésion à la convention d’Aarhus a provoqué l’adoption du règlement 1367/2006 qui indique en particulier que ‘les institutions ou organes communautaires donnent au public, lorsque toutes les options sont encore possibles, une réelle possibilité de participer au plus tôt à l’élaboration, à la modification ou au réexamen des plans et des programmes relatifs à l’environnement’ (article 9). De manière générale, l’article 1 § 2 du règlement 1367/2006 dispose que ‘les institutions et organes s’efforcent d’aider et de conseiller le public afin de lui permettre d’accéder aux informations, de participer au processus décisionnel et d’accéder à la justice’”; G. Monédiaire, “La participation du public organisée par le droit: des principes prometteurs, une mise en œuvre circonspecte,” *Participations* 1 (2011): 134–155, [www.cairn.info/review-equity-2011-1-page-134.htm](http://www.cairn.info/review-equity-2011-1-page-134.htm).

Respondents, since more than 40% of the replies came from stakeholder associations with hundreds or thousands of members each. The breakdown of the respondents is as follows:

- Associations of stakeholders: 17 replies (41% of the total answers);
- Universities, collections and Research Institutions: 17 replies (40% of the total answers);
- Individual Industries: 4 replies (10% of the total answers);
- EU Working Groups on genetic resources: 2 replies (5% of the total answers);
- NGOs: 1 reply (2% of the total answers);
- Indigenous and local communities: 1 reply (2% of the total answers).<sup>116</sup>

It is planned to involve them in the specific implementation of European legislation.<sup>117</sup> In a non-exhaustive list, this may include the right to “[help] to define and review the delegated acts [on benefit-sharing<sup>118</sup> and control<sup>119</sup> procedure] and the implementation [...] of possible guidelines for the establishment of agreed terms by mutual agreement.”<sup>120</sup> The terms of this particular participation are not yet specified. The EU Regulation states that the participation shall be “balanced” and that participants shall meet in a consultation forum.<sup>121</sup>

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<sup>116</sup> European Commission. Brussels, 4.10.2012. SWD (2012) 292 final. Commission Staff Working Document. Impact assessment. *Accompanying the document*. Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization in the Union Part 2 – NOTES {COM (2012) 576 final} {SWD (2012) 291 final}. Annex 3: Results of the public consultation Conducted in Support of the IA. p. 17.

<sup>117</sup> EU Regulation on ABS Article 15.

<sup>118</sup> Draft legislative resolution of the European Parliament on the proposal for a Regulation of the European Parliament and of the Council on access to genetic resources and the fair and equitable sharing of benefits arising from their use in the EU: Amendment 52 – Proposal for a regulation – Article 4 – paragraph 4 a (Id., pp. 4–131).

<sup>119</sup> Draft legislative resolution of the European Parliament on the proposal for a Regulation of the European Parliament and of the Council on access to genetic resources and the fair and equitable sharing of benefits arising from their use in the EU: Amendment 63 – Proposal for a regulation – Article 9 (*Ibid.*, pp. 4–131).

<sup>120</sup> Draft legislative resolution of the European Parliament on the proposal for a Regulation of the European Parliament and of the Council on access to genetic resources and the fair and equitable sharing of benefits arising from their use in the EU. Amendment 75 – Article 15 a (new) pp. 4–131.

<sup>121</sup> EU Regulation on ABS Article 15.

Such a “consultation forum” should follow the model used for the Ecodesign Consultation Forum.<sup>122</sup> The Rules of Procedure of the Consultative Forum state that “in order to ensure a balanced participation of relevant stakeholders concerned [...] the President may invite interested non-party members to consider at some meetings, specific points on the agenda.”<sup>123</sup> This could also be provided for under the European Regulation on ABS, thereby allowing indigenous communities to participate in the forum and to enrich the debates and opinions of the consultation forum.

#### IV Conclusion

The real link between Community law and French law with specific regard to the protection of indigenous knowledge in Guiana is not marked in a complementary relationship or hierarchy, whether spatial or temporal. Neither a privateer, nor pirate, nor ghost ship, the European legal order, together with the French law, rather forms a pedalo or a skiff with two oars, each making the effort which is expected of it, in coordination with each other, and certainly progressing slowly but truly and effectively in the direction of recognition and a deepening of the protection of indigenous Guianese. It is more of a process than a package. We would like to acknowledge the emergence of a specific legal status for indigenous peoples in Europe. This status is based on internationally recognized principles. It is adjusting, not only to the fundamental constraints or requirements of states, but at the same time, and especially, to the realities and aboriginal claims of European indigenous peoples themselves. In this way, a native Guianese, French and European citizenship are being built simultaneously.

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<sup>122</sup> Commission Decision of 30 June 2008 on the Ecodesign Consultation Forum. Official Journal of the European Union, L 190.18.7.2008. pp. 22–26.

<sup>123</sup> Rules of Procedure of the Consultative Forum Article 5§1.

# Private Standards and the Implementation of the Nagoya Protocol: Defining and Putting in Practice Due Diligence in the EU Regulation on ABS

*María Julia Oliva*

In implementing access and benefit-sharing (ABS), the need for practical guidance has proved as significant as challenging to address. The different types of genetic resources, the range of motives for their use, and the many actors and economic sectors engaged in biodiversity-based activities raise equally numerous and varied questions on how regulatory frameworks should establish the scope, procedures and requirements on ABS.<sup>1</sup> The lack of certainty on the precise implications of ABS has discouraged companies and other organizations working with biodiversity in engaging in related discussions and actions.<sup>2</sup>

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) aims to provide additional guidance on ABS through various tools and mechanisms, including voluntary norms. Article 20 of the Nagoya Protocol encourages Parties to support the development and use of voluntary norms such as codes of conduct, guidelines, best practices and standards in relation to ABS.<sup>3</sup> A prospective role is thus established for these instruments in supporting the implementation of international, regional and national laws and regulations on ABS.<sup>4</sup>

There is considerable potential in the interaction between traditional and innovative approaches to regulation. The value of new forms of instruments to advance public policy is increasingly recognized in environmental and sustainable development regimes.<sup>5</sup> In the ABS context, rules and practices developed

1 Secretariat of the Convention on Biological Diversity, "Use of Genetic Resources," in *The ABS Information Kit* (Montreal: Secretariat of the Convention on Biological Diversity, 2011), 4.

2 María Julia Oliva, *Access and Benefit Sharing: Principles, Rules and Practices* (Geneva: Union for Ethical BioTrade, 2010), 6.

3 Nagoya Protocol Article 20.

4 Thomas Greiber *et al*, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing* (Gland: IUCN, 2012), 195.

5 Jason Morrison and Naomi Roht-Arriaza, "Private and Quasi-Private Standard Setting," in *The Oxford Handbook of International Environmental Law*, eds. D. Bodansky, J. Brunnée, and E. Hey (Oxford: Oxford University Press, 2007), 498–527.



by the actors concerned with biodiversity-based activities – a “bottom-up” approach to implementation – could help interpret legal requirements for a more practical and effective application.<sup>6</sup> Given the lack of trust among stakeholders in the lead up to the Nagoya Protocol, as well as questions still unresolved, voluntary norms – especially those developed through multi-stakeholder consultations – could also provide a useful platform for further discussion and support of policy processes.<sup>7</sup>

With the Regulation on ABS for the European Union (EU Regulation on ABS), there is already initial consideration of how voluntary norms may support the implementation of ABS requirements.<sup>8</sup> The Regulation includes due diligence requirements that would oblige users of genetic resources and associated traditional knowledge to gather and present information on access and compliance with applicable legal requirements.<sup>9</sup> To comply, the Regulation foresees that users could build on existing guidelines and practices developed for different sectors.<sup>10</sup> Associations of users could present their procedures for recognition as best practices and take a role in monitoring how these practices and due diligence requirements are implemented.<sup>11</sup>

This chapter examines how voluntary norms might support the implementation of the due diligence requirements in the EU Regulation, as well as user measures in the Nagoya Protocol more broadly. Among voluntary norms, this chapter focuses on the possible role of private standards. As other voluntary norms, private standards establish good practices, often related to social or environmental topics. Yet standards tend to be more influential in changing practices than other voluntary norms as a result of broader multi-stakeholder engagement and transparent and accountable processes in making and

6 María Julia Oliva, “The Implications of the Nagoya Protocol for the Ethical Sourcing of Biodiversity,” in *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective*, eds. Elisa Morgera, Matthias Buck, Elsa Tsioumani (Leiden: Martinus Nijhoff, 2012), 384.

7 Indeed, voluntary norms, particularly standards, have been found to promote, rather than undermine, the further development of legal requirements. See, e.g., Graeme Auld *et al.*, “Can Non-State Governance ‘Ratchet-up’ Global Standards?” *Review of European Community and International Environmental Law* 16 (2007): 158–172.

8 Regulation No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

9 EU Regulation on ABS Article 4.

10 EU Regulation on ABS Article 8.

11 EU Regulation on ABS Article 9.

applying their rules.<sup>12</sup> In the ABS context, private standards may be a particularly useful tool to bring providers, users and other stakeholders together, build on the experience and expertise of these different actors, and provide more precise and effective guidance for putting ABS in practice in the various sectors working with biodiversity.

After this introduction, the chapter will look at private standards and how they are supporting public policy goals, including ABS. Then, the chapter will turn to the EU Regulation on ABS and consider how private standards might facilitate and optimize its implementation. The concluding remarks include considerations on addressing the interaction of private standards with the EU Regulation – and ABS requirements more generally – towards more practical and effective implementation.

## I Private Standards in the Implementation of ABS

### 1 *Users and Voluntary Norms in the Nagoya Protocol*

Companies and institutions conducting biodiversity-based research and development – the “users” of genetic resources – play a fundamental role in putting ABS in practice. Under the Convention on Biological Diversity (CBD), States establish legal requirements and administrative procedures for access to genetic resources and associated traditional knowledge.<sup>13</sup> Yet, States need to consider the actors that must make sense of ABS provisions in their legal, business, and financial strategies on biodiversity. This is essential in establishing a regulatory environment that enables access to genetic resources, facilitates research and development, promotes the creation and sharing of benefits and leads to the conservation and sustainable use of biodiversity.<sup>14</sup>

Under the contractual approach established by the CBD, users of genetic resources are responsible for jointly establishing and implementing the conditions for access and the arrangements for sharing the resulting benefits. Moreover, users of genetic resources, their suppliers, and their clients need to gather and provide information regarding access permits and benefit-sharing agreements, monitor and evaluate fulfilment of related requirements and take

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12 The following section defines private standards and explains the characteristics that distinguish them from other voluntary norms, making them particularly interesting from an ABS perspective.

13 Convention on Biological Diversity Article 15.1.

14 Convention on Biological Diversity Article 15.2.

measures to prevent illegal use.<sup>15</sup> As a result, the effective implementation of ABS cannot rely solely on government measures, but also on the active involvement of the users of genetic resources, including the private sector.<sup>16</sup>

The Nagoya Protocol recognizes the role of users in ABS implementation in various provisions. For example, Articles 15 to 18 address compliance, considered the “core of the core” of the Nagoya Protocol.<sup>17</sup> These provisions require countries in which the utilization of genetic resources takes place – “user countries” – to adopt measures that ensure compliance with ABS requirements in their country of origin. These measures must be “appropriate, effective and proportionate.” Although the Nagoya Protocol does not establish criteria for what constitutes “appropriate, effective and proportionate,” these parameters would likely require considering the implications of compliance measures not only for the implementing States, but also for other actors. For instance, “appropriate” has been understood to refer to the suitability of measures to the particular legal and economic context, as well as to avoiding too much bureaucracy.<sup>18</sup> Such a determination would require considering the actors and activities subject to ABS-related requirements and procedures. Similarly, “proportionate” is interpreted as calling for consideration of different interests and creating no more burden than necessary.<sup>19</sup>

Other articles focus directly on the users of genetic resources themselves – putting forth “practical solutions” for companies and institutions conducting biodiversity-based research and development.<sup>20</sup> For example, Article 19 of the Nagoya Protocol supports the development and use of model contractual clauses for mutually agreed terms on ABS. This aims to promote legal certainty, reduce transaction costs and facilitate monitoring for both users and providers.<sup>21</sup>

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15 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization Article 16.d.

16 Catherine Monagle, “Articles 19 and 20 of the Nagoya Protocol on Access and Benefit-sharing – Survey of Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and Standards” (paper presented at the Informal Meeting for the Implementation of Articles 19 and 20 of the Nagoya Protocol, Tokyo, March 25–26 2013).

17 Gurdial Singh Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries* (Geneva: South Centre, 2011), 5.

18 Greiber *et al.*, *Explanatory Guide to the Nagoya Protocol*, 161.

19 Greiber *et al.*, *Explanatory Guide to the Nagoya Protocol*, 162.

20 Greiber *et al.*, *Explanatory Guide to the Nagoya Protocol*, 193.

21 Though this chapter focuses on challenges and opportunities in the work of users of genetic resources, many of the points are equally valid for private actors functioning as

Article 20 of the Nagoya Protocol is another provision aimed at facilitating ABS implementation. It calls on Parties to encourage the development and use of voluntary norms such as codes of conduct, guidelines, best practices and standards in relation to ABS. By definition, these norms are not legally-binding. Moreover, they are often established by non-state actors, rather than by States themselves. Yet, in ABS as in other sustainable development frameworks, there is growing recognition of the potential for positive synergy between regulatory and such voluntary instruments.<sup>22</sup> For example, voluntary norms have proved useful in providing information and incentives to improve environmental procedures and performance in pollution control, natural resources management and reducing carbon emissions.<sup>23</sup>

All the various types of voluntary norms mentioned in Article 20 have the potential to help put ABS in practice. There are several examples of how voluntary norms are already contributing to ABS implementation. For instance, the Belgian Coordinated Collections of Micro-organisms have developed a Micro-Organisms Sustainable use and Access regulation International Code of Conduct (MOSAICC), which establishes the terms of access to microbial genetic resources for all members, including on benefit-sharing.<sup>24</sup> Similarly, guidelines such as those prepared by the German research foundation or the Swiss Academy of Sciences provide information and orientation on the ABS system, as well as requiring researchers to address ABS as a prerequisite of funding.<sup>25</sup>

Nevertheless, different types of voluntary norms differ significantly in rationale, approach, credibility and influence – and thus in their promise for ABS implementation. For example, guidelines are simply rules, principles or pieces of advice: their role or effect on how they are developed and monitored. Similarly, the term “standards” broadly refers to rules on the characteristics of

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“providers” under ABS regulations. Therefore, for instance, Article 12 on traditional knowledge also deals with model contractual clauses, calling on Parties to support indigenous and local communities in the development of these tools.

22 Greiber *et al.*, *Explanatory Guide to the Nagoya Protocol*, 195. See, also, United Nations Environment Programme, *The Use of Economic Instruments in Environmental Policy: Opportunities and Challenges* (Geneva: United Nations Environment Programme, 2004).

23 Thomas Sterner, *Policy Instruments for Environmental and Natural Resources Management* (Washington DC: RFF Press, 2003), 122.

24 The Micro-Organisms Sustainable use and Access regulation International Code of Conduct is available at <http://bccm.belspo.be/splash.php>. [See also the contribution by Pitseys *et al.* to this volume (Chapter 1).]

25 The DFG guidelines are available at [http://www.dfg.de/download/formulare/1\\_021\\_e/1\\_021e\\_rtf.rtf](http://www.dfg.de/download/formulare/1_021_e/1_021e_rtf.rtf). The Swiss Academy of Sciences guidelines are available at [http://abs.scnat.ch/downloads/documents/ABS\\_GoodPractice\\_2009.pdf](http://abs.scnat.ch/downloads/documents/ABS_GoodPractice_2009.pdf).

products or related processes, such as safety, quality, environmental performance or labour practices.

Yet a certain type of standards – which this chapter refers to as “private standards” – have distinct influence and credibility among actors, built on their governance and monitoring mechanisms. Currently, few private standards include requirements on ABS, but the number and potential is growing. For example, a recent study found that 20 out of 36 sampled environmental standards made reference to the Convention of Biological Diversity.<sup>26</sup> An informal expert meeting on the Nagoya Protocol noted that private standards may have a distinctive role in implementing ABS.<sup>27</sup> As a result, the following subsections focus on private standards as one of the voluntary norms included in Article 20 of the Nagoya Protocol, explore their defining characteristics and potential role in ABS implementation.

## 2 Defining “Private Standards”

Standards have long existed as criteria for the manufacture and supply of products and services.<sup>28</sup> Their aim is to make developing, manufacturing, and supplying products and services more efficient, safer and cleaner. As such, standards have proved useful to industrial and business organizations, governments and other regulatory bodies, and to people in general in their roles as consumers.

In recent decades, standards have also emerged as tools for sustainable development. As other innovative policy instruments, standards look to markets not only as part of sustainability challenges, but also as part of the solution.<sup>29</sup> Sustainability standards work through establishing parameters to assess the environmental performance of a product and using a logo or label to distinguish environmentally friendlier products.<sup>30</sup> The principles and criteria in

26 United Nations Environment Programme-World Conservation Monitoring Centre (UNEP-WCMC), *Review of the Biodiversity Requirements of Standards and Certification Schemes*, (Montreal: Secretariat of the Convention on Biological Diversity, 2011).

27 The informal expert meeting on the implementation of Articles 19 and 20 of the Nagoya Protocol took place in March 2013 in Tokyo, convened by the government of Japan, in collaboration with the CBD Secretariat and the United Nations University Institute of Advanced Studies (UNU-IAS). More information is available at [http://www.ias.unu.edu/sub\\_page.aspx?catID=8&ddlID=2509](http://www.ias.unu.edu/sub_page.aspx?catID=8&ddlID=2509).

28 Roger Frost, “Profile of the International Organization for Standardization (ISO),” *Qual Assur J* 8 (2004): 198.

29 Robert N. Stavins, *Experience with Market-Based Environmental Policy Instruments* (Washington DC: Resources for the Future, 2001), 1–3.

30 Arthur E. Appleton, *Environmental Labelling Programmes: International Trade Law Implications* (London: Kluwer Law, 1997), 1–2.

standards have thus become a way to incorporate, verify and recognize social and environmental considerations in business policies and practices – thus improving and promoting sustainable practices.<sup>31</sup>

One pioneering example of sustainability standards are eco-labels. Eco-labels were initially developed as government-managed “seals of approval” for products, based on assessing their environmental impacts.<sup>32</sup> Early eco-labels include Blue Angel, a certification program for environmentally friendly products and services established in Germany in 1978. There is now a wide range of eco-labels, focusing on various issues and managed by different types of actors. Ecolabel Index, a global directory of eco-labels, currently tracks 441 eco-labels in 197 countries and 25 industry sectors.<sup>33</sup>

As labels and standards have proliferated, they have also evolved. Standards have matured in line with broader trends, including on globalization and governance. Many standards now have an international scope. For example, the FairTrade International system, which manages the FAIRTRADE mark, includes three producer networks with over one million farmers in 66 countries, and 19 national FairTrade organizations covering 24 countries.<sup>34</sup> Standards now also tend to focus on specific issues, including fair trade, organic, fishing, forest management or sustainable tourism. This is partly due to specific consumer interests, but also to the need to separately and more efficiently address these complex topics.<sup>35</sup>

Another significant development is that sustainability standards are increasingly non-state initiatives. This is in keeping with general trends towards more inclusive and decentralized governance systems for sustainability.<sup>36</sup> These “private” standards have proved no less legitimate because of their development or

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31 International Standardization Organization, ISO 14001: Environmental management systems, (Geneva, ISO: 2004), Introduction.

32 United States Environmental Protection Agency, Environmental Labeling Issues, Policies, and Practices Worldwide, (Washington DC: EPA, 1998), 11.

33 The Ecolabel Index is available at <http://www.ecolabelindex.com/>.

34 “Who we are,” FairTrade International, accessed 12 October 2013, <http://www.fairtrade.net/who-we-are.html>.

35 Appleton, *Environmental Labelling Programmes*, 8–9.

36 Steven Bernstein and Benjamin Cashore, “Can Non-state Global Governance be legitimate? An Analytical Framework,” *Regulation & Governance* 1 (2007): 347–348. See also Kenneth W. Abbott and Duncan Snidal, “Hard and Soft Law in International Governance,” *International Organization* 54/5, no. 3 (2000): 423. Abbott and Snidal look at the importance of soft law in international relations and find it may – in certain cases – provide superior institutions arrangements, particularly as a more effective way of dealing with uncertainty and a tool for mutually beneficial cooperation among different actors.

operation through entities outside of government. This is because their authority relies not on state sovereignty, but on factors such as transparency, multi-stakeholder governance, synergy with public policy, engagement of economic actors, and third-party verification of compliance.<sup>37</sup>

These standards also benefit from embodying the knowledge, experiences and commitment of the range of actors actively taking part in their development and implementation. For example, actors involved in the Forest Stewardship Council (FSC), a standard promoting responsible forest management include workers, communities, businesses and end users.<sup>38</sup> These actors put their expertise together to develop a practical and effective system for tracing and monitoring the origin and nature of timber.<sup>39</sup>

All these characteristics – an international scope, a focus on sustainable and a multi-stakeholder, non-state governance – distinguish this new generation of standards from earlier standards and other voluntary norms. Comparing these novel standards with other types of business engagement in social and environmental issues, Auld *et al.* characterize them as the “hard law” of corporate social responsibility.<sup>40</sup> This is because, though voluntary, these standards create enduring and prescriptive rules.<sup>41</sup> For example, the Sustainable Agriculture Network (SAN), a coalition of non-profit organizations, has standards with social, economic and environmental criteria for agricultural products. Implementing these standards is not compulsory.<sup>42</sup> Nevertheless, if farms want to use the Rainforest Alliance Certified seal for their agricultural products, they must implement these standards and accredited certification bodies must verify their compliance.<sup>43</sup>

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37 Several authors have sought to identify the source of legitimacy for private standards. See, e.g., Bernstein and Cashore, “Non-state Global Governance”; David Vogel, “The Private Regulation of Global Corporate Conduct: Achievements and Limitations,” *Business and Society* 49 (2010).

38 “Our history,” Forest Stewardship Council, last accessed 12 October 2013, <https://ic.fsc.org/our-history.17.htm>.

39 Sander Chan and Philipp Pattberg, “Private Rule-Making and the Politics of Accountability: Analyzing Global Forest Governance,” *Global Environmental Politics* 8 (2008): 112.

40 Graeme Auld, Steven Bernstein, and Benjamin Cashore, “The New Corporate Social Responsibility,” *Annual Review of Environment and Resources* 33 (2008): 413–435.

41 *Ibid.*

42 “Mission and goals,” Sustainable Agriculture Network, last accessed 25 January 2014, <http://www.sanstandards.org/sitio/subsections/display/1>.

43 “Standards for Sustainable Agriculture,” Rainforest Alliance, last accessed 25 January 2014, <http://www.rainforest-alliance.org/agriculture/standards>.

Vogel calls this type of private, non-state and market-based regulatory frameworks “civil regulation.”<sup>44</sup> Bernstein and Cashore describe standards as non-state, market-driven governance systems.<sup>45</sup> This term recognizes that, in addition to binding and enforceable rules, these standards also entail systems, which are the multi-stakeholder institutions charged with standard-setting, impact evaluation and certification processes.

There is no single, widely used denomination for this new generation of standards.<sup>46</sup> This chapter uses the term “private standard,” which is the more commonly used terminology and the more consistent with the language used in the Nagoya Protocol. With “private standard,” this chapter thus refers to non-state, market-driven, sustainability standards, which – as described above – are considered authoritative because of their influence, enforceable rules and multi-stakeholder governance.

The legitimacy, governance and implementation of private standards give them particular potential to contribute to public policy objectives. Indeed, the objective of many private standards is to advance sustainability goals enshrined in international or national laws or policies, through tools that complement legal requirements or procedures. The next subsection analyzes the interface between private standards and public policy, in order to draw initial conclusions on the potential of private standards as tools for ABS implementation.

### 3 *Private Standards and Their Role in Public Policy*

As tools to promote sustainability, private standards exist in the web of inter-governmental agreements, national laws and other public policies addressing similar environmental and social issues. For example, there are six international conventions focusing on biodiversity issues, including the CBD. At the national level, the range of biodiversity-related measures includes National Biodiversity Strategies and Action Plans adopted by over 170 countries.<sup>47</sup> Furthermore, there is also a plethora of private standards themselves, as biodiversity-related requirements are found in 36 different standards functioning in eight business sectors.<sup>48</sup> These requirements include restrictions on

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44 Vogel, “The Private Regulation.”

45 Bernstein and Cashore, “Non-state global governance.”

46 United Nations Forum on Sustainability Standards, *Voluntary Sustainability Standards: Today's Landscape of Issues and Initiatives to Achieve Public Policy Objectives*, (Geneva: UNFSS, 2013), 15.

47 “National Biodiversity Strategies and Action Plans,” Secretariat Of The Convention On Biological Diversity, Last Accessed 12 October 2013, <http://www.cbd.int/nbsap/>.

48 UNEP-WCMC, *Review of the Biodiversity Requirements of Standards*.



the conversion of habitats, criteria for operating near protected areas, and measures to protect threatened species.

In some instances, private standards arise to fill gaps in areas of environmental and social policy in which international or national law has not proved feasible or effective. For example, the lack of an international agreement on forests led to the creation of FSC.<sup>49</sup> On topics in which international or national rules do exist, private standards may seek to implement these requirements.<sup>50</sup> For example, in the context of the United Nations Framework Convention on Climate Change (UNFCCC), several initiatives and standards guide the implementation of mechanisms for the reduction of greenhouse gas emissions from deforestation, degradation, and the conservation and sustainable management of forests.<sup>51</sup>

Of course, private standards cannot replace regulatory requirements. Yet, private standards can and often do support public policy objectives. This is because private standards predominantly based on international rules.<sup>52</sup> According to the ISEAL Alliance Code of Good Practice on standard-setting, private standards “shall seek to complement and build on relevant regulatory requirements.”<sup>53</sup> Standards “shall require practices that meet or exceed existing regulatory requirements,” in order to ensure the relevance and contribution of private standards to international and national social and environmental goals.<sup>54</sup> Abbott notes that private standards “act as force multipliers” for requirements in international agreements, supporting their goals and amplifying their impact through mechanisms such as certification and labelling.<sup>55</sup>

Studies have also confirmed the role of private standards in advancing public policy goals. For example, private standards on food quality proved to facilitate compliance with related legal requirements, even in cases in which

49 “Our history,” Forest Stewardship Council, last accessed 12 October 2013, <https://ic.fsc.org/our-history.17.htm>.

50 Kenneth W. Abbott and Duncan Snidal, “Strengthening International Regulation Through Transnational New Governance: Overcoming the Orchestration Deficit,” 42 *Vand. J. Transnat’l L.* 501 (2009).

51 These initiatives and standards for REDDplus include the Social and Environmental Principles and Criteria of the UN-REDD Programme; Common Approach for Strategic Environment and Social Assessment of the Forest Carbon Partnership Facility; The Climate Communities, and Biodiversity Standard; and the Verified Carbon Standard.

52 Vogel, “The Private Regulation.”

53 ISEAL Alliance, *Setting Social and Environmental Standards v5.0* (London: ISEAL Alliance, 2010), 15.

54 ISEAL Alliance, *Setting Social and Environmental Standards*, 15.

55 Abbott and Snidal, “Strengthening International Regulation.”

their requirements are identical.<sup>56</sup> In forest management, private standards have improved implementation of national legal regimes through strengthening social and environmental commitments of actors, improving the quality of monitoring and enforcement, and allowing learning and knowledge brokering.<sup>57</sup>

Indeed, private standards are seen to contribute to more effective legislation.<sup>58</sup> For example, private standards excel at producing and disseminating knowledge and information, including on legal and regulatory requirements.<sup>59</sup> Broad stakeholder engagement means private standards help to increase commitment and ownership of social and environmental requirements. By engaging actors involved in and affected by activities in their particular spheres, standards tap into a range expertise, including essential information about the operations in which legislation must be implemented. Standards are also able to provide guidance in relation to the concrete activities and circumstances covered by their provisions. Independent verification lowers the costs of monitoring for economic actors, and may also be taken into account to reduce the burden of enforcement on governments.<sup>60</sup>

Of course, private standards are not all necessarily supportive of public policy. Looking at voluntary norms more generally, Trubek and Trubek note that these instruments could pose a rival or exclusive option to regulation – for example, if they adopt contradictory or simple disparate approaches.<sup>61</sup> Other authors detect the risk of voluntary norms reducing momentum for the development or implementation of legal requirements.<sup>62</sup>

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- 56 Garry Smith, "Interaction of Public and Private Standards in the Food Chain," *OECD Food, Agriculture and Fisheries Working Papers* 15 (2009).
  - 57 Philipp Pattberg, "Private Governance and the South: Lessons from Global forest Politics," *Third World Quarterly* 27:4 (2006): 579–593. See, also, Lars H. Gulbrandsen, "Overlapping Public and Private Governance: Can Forest Certification Fill the Gaps in the Global Forest Regime?" *Global Environmental Politics* 4 (2004): 75–99.
  - 58 Abbott and Snidal, "Strengthening International Regulation."
  - 59 Philip Pattberg, "The Institutionalization of Private Governance: How Business and Nonprofit Organizations Agree on Transnational Rules," *Governance: An International Journal of Policy, Administration, and Institutions* 18 (2005): 589–610.
  - 60 Christine Carey and Elizabeth Guttentstein, *Governmental Use of Voluntary Standards: Innovation in Sustainability Governance* (London: ISEAL Alliance, 2008).
  - 61 David M. Trubek and Louise G. Trubek, "New Governance and Legal Regulation: Complementarity, Rivalry, or Transformation" (paper presented at conference on Law in New Governance, University College, London, May 26–27, 2006).
  - 62 Dara O'Rourke, "Outsourcing Regulation: Analyzing Nongovernmental Systems of Labor Standards and Monitoring," *The Policy Studies Journal* 31, no. 1 (2003).

Indeed, private standards cannot replace regulatory requirements. Nevertheless, private standards may be seen as useful tools that may be considered and harness to contribute to the implementation of regulatory requirements and sustainability objectives. Such interaction would generate opportunities for mutual learning and support, leading to more practical and effective mechanisms to achieving public policy goals.<sup>63</sup> The following subsection will consider whether such opportunities for mutual learning and support exist in the context of ABS implementation.

#### 4 *A Role for Private Standards in ABS?*

ABS has been called the “missing pillar of the CBD.”<sup>64</sup> Implementation of access requirements and benefit-sharing arrangements remains limited. A recent study noted only 60 countries have laws or regulations on ABS in place, with a large number still facing fundamental questions on putting in practice relevant procedures.<sup>65</sup> There are few successful ABS cases.<sup>66</sup>

The Nagoya Protocol set the basis to promote ABS implementation. It addressed critical issues, such as the scope of ABS requirements and the rights of indigenous and local communities. It also advanced provisions on clear and transparent access requirements, a possible multilateral benefit-sharing mechanism, and tools to promote guidance, legal certainty and lower transaction costs for the utilization of genetic resources.<sup>67</sup>

Yet the Nagoya Protocol remains an initial step. Its provisions and approaches will need to be rendered into functional regulatory instruments. In this process, enhancing the link between ABS rules and the social, environmental and economic context in which they operate is seen as fundamental. A study commissioned by the CBD emphasized the importance of improving knowledge about the market, industry and societal trends for meaningful and appropriate rules on ABS.<sup>68</sup> Creating a dialogue with

63 Andreas Rasche, “Collaborative Governance 2.0,” *Corporate Governance* 10 (2010): 500–511.

64 Secretariat of the Convention on Biological Diversity, *Global Biodiversity Outlook 3* (Montreal: SCBD, 2010), 6.

65 Jorge Cabrera Medaglia, Frederic Perron-Welch and Olivier Rukundo, *Overview of National and Regional Measures on Access to Genetic Resources and Benefit-sharing* (Montreal: Centre for International Sustainable Development Law, 2012), 6.

66 Secretariat of the Convention on Biological Diversity, *Access and Benefit-sharing in Practice: Trends in Partnerships Across Sectors*, (Montreal: SCBD, 2008).

67 See, e.g., Nagoya Protocol Articles 6, 10, 19 and 20.

68 Sarah Laird and Rachel Wynberg, *Bioscience at a Crossroads: Implementing the Nagoya Protocol on Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change*, (Montreal: SCBD, 2012), 9.

companies and other actors is one tool used to promote more constructive policies on ABS.<sup>69</sup>

Yet the scope for business engagement in ABS is much greater. As explained, users of genetic resources play a fundamental role in ABS implementation. Private standards have already proved to be useful platforms and instruments for engaging actors and finding practical solutions in other social and environmental contexts. As the Nagoya Protocol enters into force, private standards may be also prove an important tool to help develop and put in practice its implementing laws and regulations on ABS.

Through platforms such as private standards, users of genetic resources are already playing a substantial role in promoting engagement towards new rules on ABS. In Brazil, for instance, where the ABS framework is under revision, private companies, industry associations and multi-stakeholder groups have been brought together under a “Biodiversity Coalition.”<sup>70</sup> This group is actively exchanging ideas with the government and other stakeholders and submitting specific proposals on mechanisms to implement ABS requirements and arrangements. At the international level, technical discussions and exchanges of experiences are also supporting mutual understanding and building consensus on ABS.<sup>71</sup>

Once laws and regulations implementing the Nagoya Protocol are in place, private standards would continue to provide necessary support to implement the legal and regulatory requirements. For example, to date, it is the sectors with involvement in the use of private standards and other voluntary norms, such as the cosmetics sector, that show more significant commitment

69 For example, the ABS Capacity Development Initiative organized its third “ABS Business Dialogue” in 2013. The invitation to the meeting, which took place in Copenhagen, noted that there is growing dialogue and co-operation between policy makers, regulators and the private sector on ABS. However, it recognized that concrete implementation options remain a challenge, which should be addressed in close cooperation between the public and the private sector. More information is available at <http://www.abs-initiative.info/>.

70 See, *e.g.*, Portal PROTEC, “7º ENIFarMed: Ministério do Meio Ambiente e entidades civis elaboram proposta para facilitar o acesso à biodiversidade,” 28 October 2013, available at <http://www.protec.org.br/noticias/pagina/29625/7-ENIFarMed-Ministerio-do-Meio-Ambiente-e-entidades-civis-elaboram-proposta-para-facilitar-o-acesso-a-biodiversidade>.

71 See, *e.g.*, Union for Ethical BioTrade (UEBT), “Supporting improved ABS practices in natural ingredients,” Report of UEBT training and information exchange, 18 April 2013, available at [http://ethicalbiotrade.org/dl/benefit-sharing/UEBT\\_April%2018%20training%20on%20ABS\\_final%20report.pdf](http://ethicalbiotrade.org/dl/benefit-sharing/UEBT_April%2018%20training%20on%20ABS_final%20report.pdf).

to ethical practices linked to biodiversity, including on ABS.<sup>72</sup> Further development and use of private standards would continue to enhance capacities and supporting compliance with ABS requirements. In particular, private standards may provide practical guidelines for ABS implementation, including support on applying ABS requirements in different stages along the value chain.<sup>73</sup>

Another important contribution for private standards may be to ensure that ABS implementation is sufficiently supportive of practices for conservation and sustainable use of biodiversity. Though many ABS laws and regulations refer to the other two pillars of the CBD, the link between access requirements and benefit-sharing arrangements with conservation and sustainable use is minimal in practice. Private standards, which tend to include social, environmental and economic requirements, may support or provide guidance on enhancing such link. For example, the Ethical BioTrade Standard includes, in addition to benefit-sharing requirements, principles and criteria on the conservation and sustainable use of biodiversity, which call for sourcing activities to respect local conservation strategies and be based on sustainable management plans.<sup>74</sup>

Finally, private standards may have a role in monitoring and evaluating ABS implementation. Private standards indeed require traceability – that is, identifying each step, actor and dynamic in the supply chain. They generally include reporting requirements, as well as independent monitoring of compliance through third-party audits.<sup>75</sup> Such information and mechanisms, considered essential to ascertain and address adverse social or environmental impacts, are equally relevant in the ABS context. For example, these mechanisms may provide much-needed ways to collect information on the origin of genetic resources, their terms of utilization, and any associated traditional knowledge.

The following section considers in more detail how private standards could support Nagoya Protocol requirements on monitoring the utilization of genetic resources and ensuring compliance with applicable ABS requirements.

72 Rachel Wynberg and Sarah Laird, *Bioscience at a Crossroads: Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change: The Cosmetics Sector*, (Montreal: SCBD, 2013).

73 UEBT, “Supporting improved ABS practices.”

74 Union for Ethical BioTrade (UEBT), “Ethical BioTrade Standard,” STD01 – Ethical BioTrade Standard – 2012-04-11, available at [http://ethicalbiotrade.org/dl/membership/STD01-Ethical-BioTrade-Standard\\_2012-04-11\\_ENG.pdf](http://ethicalbiotrade.org/dl/membership/STD01-Ethical-BioTrade-Standard_2012-04-11_ENG.pdf).

75 See, e.g., ISEAL Alliance, “Assuring Compliance with Social and Environmental Standards,” (London: ISEAL Alliance, 2012).

In particular, it looks at how private standards may support the due diligence system established in the EU Regulation on ABS.

## II Private Standards in the EU Regulation on ABS

### 1 *The Compliance Challenge*

The focus of the EU Regulation on ABS is on compliance. Its approach is comprehensive insofar as it aims to enable the European Union to ratify the Nagoya Protocol, which requires implementation regulation to be in place. It also provides a thorough basis for the European Union and its Members States to implement their obligations under the Nagoya Protocol.<sup>76</sup> Yet compliance constitutes the fundamental concern. In part, this is because provisions on compliance are central to the more effective, international ABS system sought by the Nagoya Protocol.<sup>77</sup> Many biodiversity-rich developing countries see ABS compliance measures for research, development and commercialization as prerequisites for rules enabling access and utilization of biodiversity.<sup>78</sup>

Additionally, the European Union, as the location of significant biodiversity-based research and development activities, recognizes its responsibility in advancing respect for ABS requirements, as well as legal certainty for these activities.<sup>79</sup> A study considered in the elaboration of the initial proposal of the EU Regulation revealed biodiversity-based activities in a variety of economic sectors in Europe, including academic research, pharmaceuticals, plant breeding, biotechnology and food and beverages.<sup>80</sup> European actors engage directly in bioprospecting and collecting of biodiversity. In addition, companies and institutions in the European Union are also leaders in basic and applied

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76 European Commission, *Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*, COM (2012) 576, Explanatory Memorandum.

77 Greiber et al., *Explanatory Guide to the Nagoya Protocol*, 160.

78 Nijar, *The Nagoya Protocol on Access and Benefit Sharing*, 5.

79 Hugo-Maria Schally, "The implementation of the Nagoya Protocol in the EU," presented at the side event on "Implementing the Nagoya Protocol at the interface of different policy areas – how to make it work?" Hyderabad, 10 October 2012, available at [http://isp.unu.edu/news/2012/files/nagoya-protocol/07\\_EU.pdf](http://isp.unu.edu/news/2012/files/nagoya-protocol/07_EU.pdf).

80 IEEP, Ecologic and GHK, *Study to analyse legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union*, Final report for the European Commission, DG Environment, (Brussels and London: Institute for European Environmental Policy, 2012), 173.

research on biodiversity and develop new ingredients, components, varieties and products based on such research.

The choice of the approach to implement ABS requirements will significantly impact European companies and institutions. A sound framework for ABS requires enhancing opportunities for nature-based research and development, as well as for the sharing of resulting benefits.<sup>81</sup> The EU Regulation therefore also considers issues such as promoting high legal certainty, safeguarding the competitiveness of European research and development, and establishing a level playing field for different sectors and types of companies.<sup>82</sup>

## 2 *The Due Diligence Approach*

On the basis of the Nagoya Protocol and these considerations, the EU Regulation adopts a due diligence approach in setting out obligations for the utilization of genetic resources and associated traditional knowledge. “Due diligence” refers to obligations to meet a certain standard of care. Originally, it evolved as the process for the disclosure or collection of information in legal and business transactions, aimed at minimizing or avoiding risks.<sup>83</sup>

More recently, due diligence has become an approach used in the social and environment context, in order to ensure that sourcing of natural resources is in compliance with applicable law. For example, due diligence is at the core of the European Union regulations on timber and diamonds, as well as the guidelines for mineral supply chains of the Organization of Economic Cooperation and Development (OECD).<sup>84</sup> In social and environmental contexts, due diligence generally implies companies or other organizations developing and using policies and procedures to systematically ensure that their decisions and actions are supported by adequate information. Through such a process, due diligence seeks to ensure that companies identify, prevent and address impacts on legality, good governance, environment or human rights.<sup>85</sup> At the same

81 EU Regulation on ABS Preamble.

82 European Commission, *Impact Assessment Accompanying the document “Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union,”* SWD (2012) 292 final (Brussels: European Commission, 2012).

83 Linda S. Spedding, *The Due Diligence Handbook: Corporate Governance, Risk Management and Business Planning* (Oxford: Elsevier, 2009), 3.

84 For a comparison of these due diligence systems and the obligations in the initial proposal of the EU Regulation on ABS, please see IIEP, Ecologic and GHK, *Study to analyse legal and economic aspects of implementing the Nagoya Protocol*, 117.

85 OECD, *OECD Guidelines for multinational enterprises* (Paris: OECD, 2011), 23.

time, the specific steps or procedures to implement due diligence are generally left to the actors, which can take into account factors such as size, context of activities, and the severity of impacts.<sup>86</sup> For example, the OECD guidelines for mineral supply chains distinguish between upstream and downstream companies and then includes specific recommendations for different types of actors, including exporters, traders and smelters.<sup>87</sup>

In the EU regulation on ABS, companies and other organizations involved in biodiversity-based research and development must exercise due diligence to ascertain the legal acquisition of relevant genetic resources and associated traditional knowledge. Companies and institutions conducting biodiversity-based research and development in the European Union would be required to ensure that access to genetic resources and associated traditional knowledge took place in accordance with the ABS requirements in the country of origin.<sup>88</sup> Obligations would include seeking, keeping and transferring information relevant for determining whether the resources or knowledge is in legal compliance with applicable requirements.<sup>89</sup> Such information might include the date and place of access; description of the genetic resources or associated traditional knowledge; supplier and subsequent users along the value chain; presence or absence of rights and obligations related to ABS; and any access permits or mutually agreed terms. If there were indications that access did not take place in compliance with ABS requirements, users would be obliged to obtain relevant authorizations and contracts or discontinue use of the genetic resources or traditional knowledge.

Due diligence would be monitored, with users required to make a declaration of due diligence at certain “check points.”<sup>90</sup> For example, companies would need to make a declaration at the time of requesting market approval or commercialization. In addition, EU Member States would be required to check on compliance, looking at measures taken by a user to exercise due diligence and relevant documentation and declarations.<sup>91</sup> These checks would be conducted in accordance with a periodically reviewed, risk-based plan.

In the context of ABS, the due diligence approach has certain advantages. The due diligence obligation would generate ABS-related information throughout

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86 OECD, *OECD Guidelines*, 24.

87 OECD, *OECD Due Diligence Guidelines for Responsible Supply Chain Management of Minerals from Conflict-Affected and High-Risk Areas* (Paris: OECD, 2013), 37.

88 European Commission, *Proposed EU regulation on ABS*, Proposal summary.

89 EU Regulation on ABS Article 4.

90 EU Regulation on ABS Article 7.

91 EU Regulation on ABS Article 9.



biodiversity-based activities in the European Union, regardless of the scope of ABS requirements. This is because companies and other organizations would need to set up data collection systems to cover all their use of biodiversity, in order to determine whether and which ABS requirements are applicable.<sup>92</sup> The due diligence approach also allows adapting and reviewing the standard of care on ABS. The availability of information on ABS requirements is still limited, but it will significantly increase with implementation of the Nagoya Protocol in different Parties. The perception of what constitutes due diligence would thus evolve alongside international and national rules and best practices.

The due diligence approach also provides the flexibility required for measures in different sectors and situations.<sup>93</sup> For example, even within the European seed sector, conventional plant breeding uses biodiversity in a fundamentally different way than breeding based on DNA recombination. The seed industry in Europe also includes different types of companies, from small enterprises to large multinational companies.<sup>94</sup> With a due diligence approach, compliance measures apply to all users, while allowing consideration of different types of actors, sectors and other relevant factors in determining what works best in different circumstances.<sup>95</sup> As will be seen below, the EU Regulation also seeks to enhance how user measures are implemented and monitored in different contexts through provisions on best practices.

### 3 *Best Practices in Implementing Due Diligence*

In the EU Regulation, an important role is given to best practices. Companies and institutions using genetic resources and associated traditional knowledge would be able to develop due diligence systems on the basis of existing standards, guidelines and codes of conducts on ABS. This is important because preliminary studies showed that European actors have already developed or adopted a range of tools on ABS for the academic sector or particular industries.<sup>96</sup> Around a quarter of botanic gardens in Europe work in line with the International Plant Exchange Network (IPEN) Code of Conduct, which facilitates the exchange of living plant material between botanic gardens while respecting ABS requirements.<sup>97</sup>

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92 European Commission, *Impact assessment*, 30.

93 European Commission, *Proposed EU regulation on ABS*, Explanatory Memorandum.

94 IIEP, Ecologic and GHK, *Study to analyse legal and economic aspects of implementing the Nagoya Protocol*, Annex 3.

95 EU Regulation on ABS Preamble.

96 IIEP, Ecologic and GHK, *Study to analyse legal and economic aspects of implementing the Nagoya Protocol*, Annex 3.

97 The IPEN Code of Conduct is available at <http://www.botgart.uni-bonn.de/ipen/criteria.html>.

The Natural Resources Stewardship Circle (NRSC) is formed by the chief executive officers of several European companies in the cosmetic sector, which undertake joint projects based on guidelines for the sustainable management of resources and respect for traditional knowledge.<sup>98</sup>

Best practices would provide guidance for users on appropriate measures, information and monitoring for their activities and value chains. In other due diligence systems, as will be seen below, the need and value for technical guidance and support on how to gather, structure and track information have proved far-reaching. In the ABS context, such best practices developed could help identify due diligence measures that are particularly suitable for achieving compliance with ABS, with legal certainty and lower costs.<sup>99</sup>

At the same time, as has been discussed above, best practices, guidelines or other voluntary norms vary in approach and credibility. For this reason, the Regulation establishes the possibility of the official recognition of best practices. Associations of users would be able to request recognition by the European Commission for a specific combination of procedures, tools or mechanisms as best practice for due diligence requirements.<sup>100</sup> It is likely that private standards, given their particular transparency, governance and assurance mechanisms, would be favoured for such official recognition.

This is important given that the Regulation calls for Member States to consider the implementation of a recognised best practice in ascertaining the risks of non-compliance.<sup>101</sup> The idea is that associations of users would advance compliance among their members, allowing Member States to pay additional attention to other companies or institutions outside of such systems. Yet, as noted by certain civil society organizations, whether due diligence fulfils the European Union's obligations under the Nagoya Protocol will depend on how it is monitored.<sup>102</sup> The point is made in support for additional checkpoints, yet it is equally valid for considering the types of associations of users conducting the checks. Private standards, which have independent verification mechanisms to assess compliance, would be particularly valuable in this regard.

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98 More information on the NRSC is available at <http://www.nrsc.fr/>.

99 EU Regulation on ABS Preamble.

100 EU Regulation on ABS Preamble.

101 EU Regulation on ABS Article 9.

102 Natural Justice and the Berne Declaration, "Letter of Concern Regarding the Proposed Regulation of the European Commission on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization in the Union," 26 February 2013, available at <http://naturaljustice.org/wp-content/uploads/pdf/Letter-concern-EU-NJ.pdf>.

The EU Regulation contemplates additional measures to support the development and adoption of best practices. Article 13 calls for encouraging the development of sectorial codes of conduct, model contractual clauses, guidelines and best practices, particularly where they would benefit academic researchers and small and medium-sized enterprises. Such support would also advance the implementation of the European Union's obligations under Article 20 of the Nagoya Protocol.

In sum, the EU Regulation on ABS explicitly recognizes the role best practices, and voluntary norms – and particularly private standards – will have in establishing and monitoring due diligence on ABS. In this regard, it is useful to look at the experience of other due diligence systems in Europe, such as the one established by the European Union Timber Regulation, and related initiatives.

### III Due Diligence in the European Union Timber Regulation

The objective of the European Union Timber Regulation (EUTR), adopted in 2010, is supporting compliance with forestry laws around the world.<sup>103</sup> The EUTR recognizes if the European Union, as a critical export market for timber, adopted a “no questions asked” attitude to legal compliance, it would hinder efforts against illegal logging in other countries.<sup>104</sup> To counter the trade in illegally harvested timber, the EUTR imposes several obligations, including the requirement for operators – those who place timber products on the EU market for the first time – to exercise due diligence.<sup>105</sup>

The due diligence system in EUTR includes several elements.<sup>106</sup> First, it requires operators to have and provide information about the sources and suppliers of the timber. Second, on the basis of this information, operators must assess the risk of illegally harvested timber or timber products being placed on the market. Finally, if a non-negligible risk is identified, operators must mitigate such risk in a manner that is adequate and proportionate.<sup>107</sup>

103 Regulation (EU) No 995/2010 of the European Parliament and of the Council laying down the obligations of operators who place timber and timber products on the market (EU Timber Regulation), 20 October 2010, Preamble.

104 “Why do we need a new law?” European Commission, available at [http://ec.europa.eu/environment/eutr2013/index\\_en.htm](http://ec.europa.eu/environment/eutr2013/index_en.htm).

105 EU Timber Regulation Article 2.

106 EU Timber Regulation Article 6. An implementing regulation (No 607/2012) lays down detailed rules concerning the due diligence system.

107 EU Timber Regulation Article 6.

There are interesting considerations resulting from a comparison between the due diligence approach in the EUTR and the due diligence provisions in the EU Regulation on ABS. In the EUTR, as in the Regulation on ABS, there is an emphasis on gathering information and identifying risks or uncertainties. In the timber context, this is relevant because there is no relevant international agreement and many differences among countries in the development and implementation of forestry laws. In the ABS context, the Nagoya Protocol is advancing the development of access requirements and benefit-sharing arrangements, but legal and policy frameworks take time to develop and be put in practice. In the meantime, due diligence requirements ensure the pertinent questions are asked and considered in decision-making on biodiversity-based research and development.

Another point in the EUTR is the distinction between operators and traders. Operators are subject to due diligence obligations, while the obligation of traders – those who buy or sell timber and timber products already on the market – is to keep information about their suppliers and customers to make timber easily traceable.<sup>108</sup> This distinction is important given the transformation of timber products before and after they are placed on the market. To avoid imposing any unnecessary administrative burden, the due diligence system focuses on operators, while subsequent actors in the supply chain are obliged to support traceability.

In biodiversity-based research and development, the range of genetic resources, types of utilization and actors along value chains is even more complex. For example, the starting point for the process of developing a single fragrance may be wood, seeds, fruits, leaves and other plant parts from as much as 250 species.<sup>109</sup> There are numerous actors and intervening research and development activities. The EU Regulation on ABS establishes a broad scope for due diligence, particularly with the definition of “user” in the text amended by the European Parliament, which includes companies or institutions that are not involved in the “utilization of genetic resources” but rather in prior or subsequent commercialization.<sup>110</sup> A question remains as to whether it would not be more effective to distinguish the different types of actors along biodiversity-based value chains. Whether or not such a distinction is made, the complexity of biodiversity value chains is likely to increase

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<sup>108</sup> EU Timber Regulation Article 5.

<sup>109</sup> Christian Eberhard, “The Smell of Equity,” presentation at the Third ABS Business Dialogue in Copenhagen, 4 September 2013.

<sup>110</sup> Committee on Environment, Public Health and Food Safety, *Report on Proposal for EU regulation on ABS*.

the need for sectorial best practices on who and how these obligations are implemented.

### 1 *Best Practices in the European Union Timber Regulation*

In the due diligence established in the EUTR, there is significant consideration for best practices, as well as for the constructive role that standards and certification could play in improving forestry practices. Associations with due diligence systems that comply with the EUTR, and the necessary expertise and capacities, may be recognized as “monitoring organizations.”<sup>111</sup> Monitoring organizations have the responsibility to develop and maintain a due diligence system, granting operators the right to use it in certain conditions and under certain controls. Their responsibility also includes verifying proper use of the due diligence system and take appropriate action in case of lack of compliance.

Certification or other third party verified schemes that include verification of legal compliance and meet certain criteria are specifically mentioned as possible elements to assess and mitigate risk.<sup>112</sup> Implementing rules clarify the criteria that certification schemes must meet in order to be used as a risk assessment and risk mitigation tool.<sup>113</sup> These criteria include transparency and addressing all applicable legal requirements. Certification systems must also include means to trace timber at any point in the supply chain and keep illegally harvested timber from entering the supply chain.

The rationale for recognizing best practices in the EUTR is manifold. For example, the EUTR considers that acknowledging existing good practices is a way to credit companies that pioneered environmentally appropriate and socially beneficial management of forests. It explains that operators already using systems or procedures which comply with its requirements should not be required to set up new systems, in order to avoid any unnecessary administrative burden.<sup>114</sup>

<sup>111</sup> EU Timber Regulation Article 8. Article 6 of the EUTR establishes clear requirements that associations must meet for recognition of monitoring organizations and a process to apply for, monitor, and, in case of lack of compliance, withdraw such recognition. These procedures and requirements are further developed through regulations for the recognition and withdrawal of recognition of monitoring organizations (Commission delegated regulation N° 363/2012).

<sup>112</sup> EU Timber Regulation Preamble and Article 6.

<sup>113</sup> Commission Delegated Regulation (EU) No 363/2012 on the procedural rules for the recognition and withdrawal of recognition of monitoring organisations as provided for in Regulation (EU) No 995/2010 of the European Parliament and of the Council laying down the obligations of operators who place timber and timber products on the market, 23 February 2012.

<sup>114</sup> EU Timber Regulation Preamble.

In the EUTR, best practices do not replace measures to ensure compliance with legal requirements. Nevertheless, there is recognition of the role of voluntary norms, particularly private standards, in ensuring and proving due diligence.<sup>115</sup> For example, private standards such as FSC already include requirements for compliance with applicable laws, regulations, and agreements.<sup>116</sup>

Best practices have also been central to ensuring that adequate information and training for legal compliance was provided to key actors.<sup>117</sup> For example, guidelines on sustainable forestry management have addressed issues such as defining a breach of law and managing conflicts between legislation, procedures and customary laws, by placing these questions in the context of broader sustainability and ethical criteria.<sup>118</sup>

Significantly, private standards are based on traceability. They require and independently monitor information-gathering and measures to address any problems with legal compliance, thus contributing to meeting due diligence. Such minimum requirements, along with third-party verification, make private standards particularly relevant to establishing and monitoring due diligence.<sup>119</sup> For example, FSC has found that – even if there is no “green lane” for certification schemes in due diligence – its certification can form an important part of due diligence systems and ensure that any remaining risks of illegal logging are negligible.<sup>120</sup>

Indeed, a consequence of rules on legal compliance of timber products in the European Union, as well as in the United States, has been the reinvigoration

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- 115 Benjamin Cashore and Michael W. Stone, “Can Legality Verification Rescue Global Forest Governance? Analyzing the Potential of Public and Private Policy Intersection to Ameliorate Forest Challenges in Southeast Asia,” *Forest Policy and Economics* 18 (2012), 18.
  - 116 Forest Stewardship Council, Principles and Criteria for Forest Stewardship: FSC-STD-01-001 (V5-0) (Bonn: FSC, 2012).
  - 117 Jon Buckrell and Alison Hoare, “Controlling Illegal Logging: Implementation of the EU Timber Regulation,” *Chatham House Briefing Paper EERG IL BP 2011/02* (London: Chatham House, 2011), 10.
  - 118 Frank Miller, Rodney Taylor and George White, *Keep It Legal: Best Practices for Keeping Illegally Harvested Timber Out of Your Supply Chain* (London: WWF Global Forest & Trade Network, 2006), 14–15.
  - 119 Duncan Brack, *Due Diligence in the EU Timber Market: Analysis of the European Commission's Proposal for a Regulation Laying Down the Obligations of Operators who Place Timber and Timber Products on the Market* (London: Chatham House, 2008), 9.
  - 120 John Hontelez, *Implementation Guide for FSC Certificate Holders and other Companies selling FSC products in the EU* (Bonn: FSC, 2013), 5.

of private standards.<sup>121</sup> This has also meant that operators actually go beyond removing illegal timber from the market – the requirement of legal compliance rules – and towards adopting the economic, social, environmental practices required by sustainable forestry certification.<sup>122</sup>

## 2 *Lessons for ABS Implementation*

The approach and experience with due diligence, best practices and private standards in the context of the forestry context has important lessons for the EU Regulation on ABS. The EUTR, through its provisions on best practices, aimed to recognized efforts already undertaken by companies towards sustainable forestry. Similarly, in the ABS context, there has also been significant adoption of voluntary norms. Examples already mentioned include the IPEN Code of Conduct and the Swiss Academy of Sciences guidelines. Other relevant initiatives include the “Guidelines for Bioprospecting for BIO members,” issued by BIO, the world’s largest biotechnology association; the “Guidelines for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization” of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); the Guidelines on the Access to Genetic Resources and their Transfer developed by a group of French public research institutes working with living plant, animal and microbial genetic resources; and the FairWild Standard, which assesses the harvest and trade of wild plants against various ecological, social and economic requirements.<sup>123</sup> Recognizing the investment and experiences that have gone into developing and putting these tools in practice is essential to ensure more effective regulations, as well as to encourage actors to engage in finding solutions and pioneering best practices.

In EUTR implementation, the aim has been to identify and build on synergies between legal requirements and voluntary norms. In particular, private

121 Cashore and Stone, “Can Legality Verification Rescue Global Forest Governance?” 18. See, also, Duncan Brack, “Controlling Illegal Logging: Consumer-Country Measures,” *Chatham House Briefing Paper EERG IL BP 2010/01* (London: Chatham House, 2010), 8.

122 Cashore and Stone, “Can Legality Verification Rescue Global Forest Governance?” 15.

123 The BIO guidelines for bioprospecting are available at <http://www.bio.org/articles/bio-bioprospecting-guidelines>. The IFPMA guidelines are available at <http://www.ifpma.org/innovation/biodiversity.html>. The guidelines developed by CIRAD, INRAD and IRND in France are available at <http://www.cirad.fr/actualites/toutes-les-actualites/articles/2011/ca-vient-de-sortir/lignes-directrices-pour-l-acces-aux-ressources-genetiques-et-leur-transfert>. The FairWild Standard is available at <http://www.fairwild.org/documents/>. All websites accessed: 18 October 2013.

standards have proved to have potential to support legal requirements, including obligations on due diligence. Similarly, in the ABS context, private standards should be considered as tools to support implementation of legal requirements, monitor actors' compliance and advance the public policy goals enshrined in these obligations.

As discussed above, private standards call for – rather than undermine – compliance with applicable legislation.<sup>124</sup> This is also the case in the context of biodiversity-based research and development. For example, the Ethical BioTrade Standard, which applies to the use of natural ingredients in the cosmetics, food and pharmaceutical sectors, requires companies to establish measures for compliance with “legislative or regulatory requirements on access to biodiversity and associated traditional knowledge for research and development and the sharing of resulting benefits.”<sup>125</sup> In addition, the Ethical BioTrade Standard includes requirements relating to international agreements on biodiversity, including the Nagoya Protocol, national regulatory requirements on the use and trade of natural ingredients, and the rights of indigenous and local communities, as defined by UNDRIP, ILO 169 and national laws.<sup>126</sup>

Private standards also increase awareness and facilitate implementation of ABS requirements. Of the various industry sectors using biodiversity for research and development, those in which companies and other actors already use private standards have already proved to have higher levels of awareness and adoption of practical tools for putting in practice ABS.<sup>127</sup> The impact assessment for the initial proposal of the EU Regulation on ABS also found that promoting best practices, which are used across national boundaries, would also improve awareness and implementation of ABS beyond the European Union, including in countries that have not signed, ratified or implemented ABS provisions in the CBD and the Nagoya Protocol.<sup>128</sup> Working with private standards in ABS implementation is also a way to tap into the different actors and their information and experience-exchange networks towards more rapid and effective awareness and measures.

In the ABS context, the use of private standards also enhances the contribution of ABS practices to the conservation and sustainable use of biodiversity. For example, the FairWild Standard requires collection practices to maintain wild plant resources and be based on adaptive and participatory

<sup>124</sup> ISEAL Alliance, *Principles for Credible and Effective Sustainability Standards Systems*.

<sup>125</sup> Union for Ethical BioTrade, *Ethical BioTrade Standard* (Geneva: UEBT 2012), Criterion 3.5.

<sup>126</sup> UEBT, *Ethical BioTrade Standard*, Criteria 5.1, 5.3 and 6.2.

<sup>127</sup> Laird and Wynberg, *Bioscience at a Crossroads*, 9.

<sup>128</sup> European Commission, *Impact Assessment*.



management.<sup>129</sup> Moreover, once requirements on legal compliance generate a level-playing field on ABS, companies focused on green or ethical products will be encouraged to take additional steps, further improving their conservation, sustainable use and benefit-sharing practices in order to maintain their market leadership. Indeed, the main reasons for companies choose to adopt private standards – rather than merely comply with legal requirements – including meeting more stringent sourcing policies of some clients, supporting producers to obtain higher quality and limit the risk of supply failure, and differentiating their brand in the market.<sup>130</sup>

Finally, private standards – through their traceability, transparency and independent verification requirements – could also be harnessed to contribute to monitoring compliance with ABS, implementing due diligence and diminish risks of misappropriation of genetic resources and associated traditional knowledge. For such positive interaction, it is necessary to address and incentivize the link between private standards and regulatory requirements on ABS. Indeed, as legal compliance requirements may promote best practices, there is also the danger of undermining these efforts, particularly if not sufficient recognition is granted by governments or consumers for measures going beyond legal compliance.<sup>131</sup> The concluding section will mention some possible measures to this effect in the EU Regulation and the Nagoya Protocol.

#### IV Conclusion

The EU Regulation on ABS is an important step towards implementing the Nagoya Protocol in the European Union. Yet it is even more consequential given that its measures, particularly those to ensure compliance with access requirements and benefit-sharing arrangements, will set the basis for an effective international system on ABS. In order to fulfil national, regional and international expectations, the EU Regulation must establish rigorous requirements for actors to gather, present and adequately consider information on the origin

129 FairWild Foundation, *FairWild Standard Version 2.0* (Weinfelden: FairWild Foundation, 2010), Principles 1 and 9.

130 Jason Clay, "Making the Business Case for Certification," *The Guardian*, 8 February 2013, available at <http://www.theguardian.com/sustainable-business/blog/making-business-case-certification-consistent-price>.

131 Diego Florian *et al.*, "How to Support the Implementation of Due Diligence Systems through the EU Rural Development Programme: Problems and Potentials," *Italian Journal of Forest and Mountain Environments* 67–2 (2012), 196.

and legal status of genetic resources and associated traditional knowledge. To be effective, these requirements must also adequately reflect the realities of the utilization of genetic resources, including different types of actors; evolving legal frameworks; and a range of research, development and commercialization activities.

It is not a minor challenge, yet the due diligence approach in the EU Regulation provides such a substantial yet flexible foundation for ABS implementation. In particular, the consideration of best practices as a tool for establishing and monitoring due diligence has several advantages. For example, it provides a platform for the engagement of the various actors concerned with biodiversity-based research, development and commercialization. Such engagement promotes much-needed awareness of the importance, concepts and requirements of ABS among companies and organizations involved in the utilization of genetic resources. It generates critical trust among stakeholders. Recognizing best practices also allows building upon the experience and expertise of these companies and organizations in addressing the practical challenges that have limited ABS implementation to date. Best practices, particularly those developed through initiatives involving users of genetic resources, are an opportunity to develop precise guidance on ABS for different types of actors and activities, in a way that the regulatory framework would not be able to do on its own.

Private standards, as a particular kind of best practice or voluntary norm, have additional benefits towards compliance with ABS requirements. Private standards commit their members or clients to ethical and sustainable practices, including – more and more – on ABS. These requirements are developed through multi-stakeholder consultation processes and must make express reference to international, national and customary law. In meeting the challenge of monitoring and evaluating utilization of genetic resources for compliance with ABS requirements, private standards bring to bear relevant traceability systems, reporting requirements and independent audits.

The EU Regulation already features important measures to recognize and promote the synergy between private standards and regulatory requirements on ABS. These measures include recognition of private standards and best practices in the application and monitoring of the due diligence system. Similarly, the measures to support stakeholder awareness, voluntary norms and tools for tracking the utilization of genetic resources are fundamental. Such measures provide necessary incentives for companies to mainstream due diligence in their systems, as well as to go beyond legal compliance, building a business case for the ethical use of biodiversity.

These considerations are equally valid as Parties to the Nagoya Protocol discuss the implementation of Article 20. Article 20 of the Nagoya Protocol calls on Parties to periodically take stock of the use of voluntary norms. Such “taking stock” could be as simple as inviting Parties and other stakeholders to submit occasional reports. Nevertheless, Parties to the Nagoya Protocol may choose to take this opportunity to truly harness the potential of voluntary norms for ABS implementation. Measures to note at the international and national levels include recognizing specific voluntary norms on the basis of substantive and procedural criteria, publicizing available tools and their different approaches, and providing incentives for companies to engage in recognized systems. Beyond specific measures chosen, what is critical is for Parties to consider the role of voluntary norms in promoting public policy objectives and addressing these tools as a way to find practical and effective solutions to ABS implementation.

# The Multi-Level Implementation of the Nagoya Protocol in the European Union

*Christine Godt*

The European Union and its 28 member states are preparing to implement the “Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization” (hereinafter referred to as the “Nagoya Protocol”),<sup>1</sup> the second protocol<sup>2</sup> to the Convention on Biological Diversity (CBD) of 1992. Whereas a few member states hurried ahead,<sup>3</sup> most of them awaited the implementation concept of the EU, which was adopted by the Council on 14 April 2014 (hereinafter referred to as the EU Regulation on ABS).<sup>4</sup> The Nagoya Protocol entered into force on October 12, 2014, 90 days after the deposition of 50th document (ratification) was submitted to the secretariat.<sup>5</sup> Since the European Union did not wish to be the last in line to deposit a document, it was eager to finalize the legislative process before the entry into force. The Nagoya Protocol concretizes Article 15 of the CBD, which stipulates that

each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources

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\* Part 3 of this contribution is based on an expert consultation commissioned jointly to the author and Franziska Wolff (senior consultant with the Ökoinstitut e.V., Berlin) by the German Federal Government, Ministry of the Environment, delivered in two separate papers: Christine Godt, Davor Šušnjar, Franziska Wolff, *Umsetzung des Nagoya-Protokolls ins Deutsche Recht* (Study I, submitted 9.3.2012), and Christine Godt, Tim Torsten Schwithal, Franziska Wolff, *Umsetzung des Nagoya-Protokolls ins Deutsche Recht* (Study II, submitted 29.6.2012).

1 Adopted on 29 October 2010 in Nagoya, Japan, as the Second Protocol to the Convention on Biological Diversity of 1992.

2 The first one is the Cartagena Protocol on Biosafety of 2000, in force since 11 September 2003 (ILM [2000] 1027).

3 See Norway (Norwegian Nature Diversity Act of 2009) and Denmark; [For an in-depth discussion on ABS in Denmark and Norway, see contributions to this volume by Koester (Chapter 2) and Tvedt (Chapter 7).]

4 Regulation No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

5 Nagoya Protocol Article 33 Sec. 1

utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing (ABS) legislation or regulatory requirements of the other Party.

The EU Regulation on ABS relies on a concept of centralized regulation and de-centralized enforcement. In its initial proposal, the European Commission opted for the technical instrument of a regulation, rather than a directive. The focus of the Regulation is on user measures, and prudently leaves the regulation of access to EU-genetic resources to the member states. Its concept rests on the duty to exercise due diligence to ascertain that genetic resources and associated traditional knowledge are accessed in accordance with applicable ABS legislation. I argue that the EU approach camouflages a simplistic understanding of how the uses of genetic resources are regulated in detail. The approach relies on a narrow understanding of applicability and scope, has broad exceptions, and grants overbroad privileges to the research community. Most importantly, it ignores the administrative set-up of various pre-existing procedures, which fine-tune in many ways, the quality control of research and production. The approach wilfully downplays the difficulties of the information flow, and gives broad leeway to circumvention. Moreover, it does not install self-regulatory measures that deserve the label of due diligence so as to cushion the information problem. Thus, the draft as a user measure is not ambitious enough to complement existing and future provider measures. The analysis imposes that the EU wilfully slows down the ABS process for the sake of its research community and its industry.

This chapter substantiates this critique as follows. It will first solidify the content of the Nagoya Protocol by analysing its ambitions and shortcomings, comparing it to the Bonn Guidelines I. It will describe the concept of due diligence on which the EU Regulation on ABS is based II. It follows a counter-proposition labelled as “integrative” or “piggy-back,” which cushions the duty to ascertain Nagoya Protocol-compliance within existing procedures III. A reflection on the respective information paradigm concludes the Chapter IV.

## **I      The 2010 Nagoya Protocol and the 2001 Bonn Guidelines Compared**

Various dissenting points made the Nagoya Protocol negotiations dreadful. Consensus has remained fragile about central questions as to if the Nagoya Protocol applies to material stored in collections after 1992 (or only

after 2014),<sup>6</sup> if it applies to derivatives,<sup>7</sup> and what the status of “privileged collections”<sup>8</sup> might be. The trade-off for making the ABS Regime internationally binding is that documents under international law only bind the treaty parties, *i.e.* member states rather than the private sector. The interesting feature about the (non-binding) predecessor, the Bonn Guidelines of 2001, was that those stipulated the transnational duties of private corporations directly.<sup>9</sup> But since the Bonn Guidelines remained largely ignored, the Conference of Parties to the CBD had to step back to classic international legal language and formulate the duties of states, thus disrupting the immediate bilateral approach of a relationship of “the provider” and “the user.”<sup>10</sup> Evidently, it is far beyond

6 Greiber and Moneno distinguish between accessions made after the Nagoya Protocol came into force (Nagoya-ABS) and those accessions made between the entry into force of the CBD in 1992 and the entry into force of the Nagoya Protocol (CBD-ABS-regime). See Thomas Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing* (Gland, Switzerland: IUCN, 2012); Gerd Winter and Evanson C. Kamau, “Von Biopiraterie zu Austausch und Kooperation: Das Protokoll von Nagoya über Zugang zu genetischen Ressourcen und gerechtem Vorteilsausgleich,” *Archiv des Völkerrechts* 49 (2011): 373–398; Michael Frein and Hartmut Meyer, *Wer kriegt was? Das Nagoya Protokoll gegen Biopiraterie. Eine politische Analyse* (Bonn: Evangelischer Entwicklungsdienst e.V. (EED), 2012): 13 argue that the trigger for the Nagoya Protocol is not the former accession of a sample, but the actual “access” to the sample. Hartmut Meyer *et al.*, *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization: Background and Analysis* (Berne Declaration (BD), Brot für die Welt, ECOROPA, TEBTEBBA and TWN, 2013): 57, document that drafters of the Nagoya Protocol conceived the temporal scope of the Nagoya Protocol to be identical to the CBD scope; “Retroactivity” (applicability of the CBD to pre-CBD-material) is strongly opposed by Matthias Buck and Claire Hamilton, “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,” *Review of European Community & International Environmental Law [RECIEL]* (2011): 57. Whereas this question will become central for benefit sharing, access requirements are already broadly met, since most collections treat pre- and post CBD-material alike, see Christine Godt, “Networks of *Ex Situ* Collections in Genetic Resources,” in *Common Pools of Genetic Resources*, ed. Gerd Winter and Evanson C. Kamau (Abingdon/Oxon: Routledge, 2013): 246–267.

7 Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol*, 28; Hartmut Meyer *et al.*, *Nagoya Protocol*, 35.

8 How big are options for circumvention, see Godt, “*Ex situ* collections,” 261.

9 Christine Godt, “Biopiraterie zum Biodiversitätsregime – Die sog. Bonner Leitlinien als Zwischenschritt zu einem CBD-Regime über Zugang und Vorteilsausgleich,” *Zeitschrift für Umweltrecht (ZUR)* (2004): 202–212.

10 Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol*, 13.

the capacities of international negotiations to find a common ground on the internal implementation of duties.

The most important short-coming, however, is the novel and restrictive definition of “utilization” in Article 2 of the Nagoya Protocol. The term is important as Article 15 of the CBD links ABS duties to utilization. However, whereas Article 6 of the Nagoya Protocol requires prior informed consent only for “access” in utilization cases, Article 5 is compliant with Article 15 Sec. 7 of the Convention, which requires that “[...] benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared [...]”.<sup>11</sup> Thus, the Nagoya Protocol creates a double distinction (access/benefit-sharing and commercial/non-commercial) and it submits ABS to different rules. “Access for their utilization” (*i.e.* research and development, R&D) is only submitted to prior informed consent; benefits are to be shared which arise from “utilization of genetic resources” (*sic* R&D) and commercialization. Commentators focus on the indeterminacy (and the omission of the initially proposed list),<sup>12</sup> and on consequences for the later procedures of market approval.<sup>13</sup> More important, the re-definition of utilization creates a distinct situation for access and benefit-sharing. It implements the normative idea that the person who accesses the resource is not necessarily the same who owes the sharing of benefits. Thus, a time lap is created and duties become differential. As long as the normative idea prevails that the conditions for ABS are identical, the scope of duties to be met by those who access a resource (“accessors”) and users are identical. The Nagoya Protocol bows to reality, which is that bio-prospectors, be they scientists or contractors, seldom generate “profits” from commercial utilization. Bio-prospectors either add value to the resource by accumulating information of it, or sell it. The split redistributes responsibilities. Accessors are *primarily* responsible for assuring that access requirements are met, and *not* for securing the sharing of benefits. Utilizers become *primarily* responsible for sharing benefits, and *not* for securing that access conditions were met. The normative split has two consequences.

11 CBD Article 15 Sec. 7, which reads: “Each Contracting Party shall take [...] measures [...] with the aim of sharing in a fair and equitable way the results of research and development *and* the benefits arising from the commercial *and* other utilization of genetic resources with the Contracting Party providing such resources [...]”.

12 Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol*, 63; Hartmut Meyer *et al.*, *Nagoya Protocol*, 33.

13 Most contestable, Buck and Hamilton, “The Nagoya Protocol,” 52 argue that approval procedure were excluded from the term “utilization” (against this interpretation: Godt, Šušnjar and Wolff, “NP-Umsetzung,” 32 *et seq.*)

The accessors' (primarily scientists) burden to share benefits is reduced to share those benefits which he/she generated (regularly non-monetary benefits); the later utilizer is relieved from access compliance. (2) The split of duties creates an "information delta" with the risk that information gets lost (without the need to be retrieved). The unitary duty to secure ABS is dissolved into two separate duties which follow each other in time. This creates a novel need to secure the transfer of information and record tracking in both directions. The utilizer (in order to fulfil his sharing duty) needs to know which ABS requirements were negotiated when the resource was accessed. The provider needs to know *who* (finally) utilizes and commercializes the resource. The split re-nationalizes the duties: access regulation becomes a responsibility of provider states, whereas benefit-sharing becomes a responsibility of user states. This way, the idea that providers must have the option to decide about ABS (access *and* benefit-sharing) is diluted into differentiated member state implementation duties. User countries may focus on the implementation of benefit-sharing duties ("user measures"), but are not responsible for securing claims of providers ("access regulation"; realization of provider claims: tracking and enforcement).

## II The EU Regulation on ABS

The EU Regulation on ABS is based on Art. 192 TFEU, and implements a concept of due diligence: "Users shall exercise due diligence to ascertain that genetic resources [...] were accessed [legally] and that [...] benefits [...] are shared [...]"<sup>14</sup> It uses the term "users," not "utilization." "Users" have to "exercise due diligence" to ascertain ABS. In contrast to the Nagoya Protocol, the draft refrains from regulating ABS in two separate articles. "Due diligence" alludes to a concept used in prior regulations for the tracking of "blood" diamonds<sup>15</sup> and uncertified (illegal) tropical timber.<sup>16</sup> In those two regulations, due diligence referred to a self-regulatory scheme, in which monitoring was delegated to private

<sup>14</sup> EU Regulation on ABS Article 4 Sec. 1.

<sup>15</sup> EC Regulation 2368/2002, Off. J. L 358/28 of 31 December 2002, implementing the so called Kimberley-Process into EC law, Joost Pauwelyn, "Non-Traditional Patterns of Global Regulation: Is the WTO 'Missing the Boat'?" in *Constitutionalism, Multilevel Trade Governance and International Economic Law*, eds. Christian Joerges and Ernst-U. Petersmann (Cambridge: Hart Publ., 2006): 199.

<sup>16</sup> EC Regulation 995/201, Off. J. L 295/23 of 12 November 2000. [See also contribution by Oliva (Chapter 12) to this volume.]



organizations.<sup>17</sup> However, the EU Regulation is silent about the private monitoring scheme; it only refers to “associations of users” for the establishment of “best practices.”<sup>18</sup> It only grants leeway to existing (self-regulated) *sui generis* regimes (as provided for in Article 4 Sec. 2 Nagoya Protocol) as “Union trusted collections”<sup>19</sup> by granting them special treatment and reversing the burden of proof for acquisition therefrom.<sup>20</sup> Regarding implementation, the Regulation contents itself with commanding member states to designate competent authorities.<sup>21</sup> The European Commission will designate a “focal point.”<sup>22</sup> The national authorities will transmit the information received to the European Commission.<sup>23</sup>

The Regulation on ABS departs from its predecessors in various ways. It does not install a straight forward prohibition to use illegal material.<sup>24</sup> In contrast, it installs a duty to “exercise due diligence to ascertain that [resources and knowledge...] were accessed in accordance to access and benefit legislation [...]”<sup>25</sup> Thus, the due diligence duty is different from its predecessors in two distinct ways. First, due diligence does not refer to a self-monitoring scheme. Only Article 8 of the EU Regulation mentions a private association of users. It may submit “best practices” to the Commission, which might be recognized and then considered the standard of care. A self-regulatory supervising organization is neither stipulated nor prohibited. Thus, due diligence is a flexibility mechanism for the duty of care. The duty of care is to ascertain that resources and knowledge were accessed in accordance to access and benefit legislation. Article 4 Sec. 3 of the Regulation stipulates that “users shall seek, keep, and transfer to subsequent users” information relevant for ABS. The stipulated duty is not a (normative negative) prohibition (“Don’t do!”), but a (positive) obligation to “seek, keep, and transfer information,” thus record keeping.

17 EC Regulation 995/2010 Article 8 and EC Regulation 2368/2002 Article 17.

18 EU Regulation on ABS Article 8. For a thorough analysis of concepts labeled as “due diligence,” see Christine Godt, “Due Diligence – Modernes Umweltmanagement oder Regulierungsverweigerung?” in *Der Rechtsstaat zwischen Ökonomie und Ökologie – Festschrift Götz Frank*, eds. Rainer Wolf and Ulrich Meyerholt (Tübingen: Mohr Siebeck, 2014) (forthcoming).

19 EU Regulation on ABS Article 5.

20 EU Regulation on ABS Article 4 Sec. 7.

21 EU Regulation on ABS Article 6 Sec. 1.

22 EU Regulation on ABS Article 6 Sec. 3.

23 EU Regulation on ABS Article 7 Sec. 3.

24 Regulation 995/2010 Article 4 and Regulation 2368/2002 Article 3 and 11.

25 EU Regulation on ABS Article 4 Sec. 1. Arguably, because the primary “duty to obey the law” is owed to the provider state, the conceived user state duty is adjacent, self-standing and monitoring in nature.

The monitoring concept of the EU Regulation is not one of self-regulation, but rests on two pillars of administrative control (“check-points”).<sup>26</sup> Recipients of public research funding are submitted to the duty to declare *ex ante* to have exercised due diligence.<sup>27</sup> *Ex post* duties are not installed.<sup>28</sup> The respective agency is not explicitly named. The text only obliges “member states and the Commission [to] request [...] that [the recipients of public research funding] will exercise due diligence.” All other users are submitted to a duty to declare *ex post*. Article 7 Sec. 2 demands that they “declare to the competent authorities established under Art. 6(1) that they have fulfilled the obligation under Article 4” on the occasion of requesting market approval for a product or at the time of commercialization where market approval is not required.<sup>29</sup> Article 7 is complemented by Article 9 which provides for checks on user compliance by the competent authorities.<sup>30</sup>

This due diligence concept for the EU Regulation is questionable for the following four reasons.

(1) The scope of the duty of care is not clear enough. The “duty to exercise due diligence to ascertain” has two elements, the “duty to ascertain” and “the exercise of due diligence” (standard of care). At the outset, the “duty to ascertain” requires clarification. It was criticized that the initial draft of the Regulation refrained from a general prohibition of illegal use (following its predecessors).<sup>31</sup> Although the respective penalty may extend to the “suspension of use activities,”<sup>32</sup> the duty itself refers to three specific *information* duties “seek, keep, transfer,”<sup>33</sup> and a duty to remedy a situation “where it appears that

26 Thus, it mixes two approaches that were earlier labeled in an assessment report as “upstream focus” and “downstream focus.” IEEP, Ecologic and GHK, *Study to analyze legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union* (Brussels/London, 2012).

27 EU Regulation on ABS Article 7 Sec. 1.

28 This concept seems to be a constitutionally-demanded privilege of science, and approved by member states (e.g. for Germany cf. the answer from the German federal government to a parliamentary questionnaire [27 June 2013], Drs. 17/14245 [p. 6]).

29 A formulation was proposed for tightening by the European Parliament’s Committee on Development (30 May 2013, PE 508.195v03-00) as novel Article 7 Sec. 2 “users shall declare that they have complied with.”

30 checking on their due diligence, EU Regulation on ABS Article 9 Sec. 4.

31 WWF, *Recommendation on amendments for ENVI vote on Regulation on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*, of 1 July 2013 (on file with the author); Report of the European Parliament, new proposal Recital 8a, (PE 508.195v03-00 of 16 July 2013), 10.

32 Initial proposal for a Regulation by the European Commission, Article 11 Sec. 2.

33 EU Regulation on ABS Article 4 Sec. 3 lit. a and b.

access was not in accordance with applicable ABS legislation [...].” Thus, the EU law defines positive duties of behaviour with a focus on information. It is not a straightforward prohibition of utilization of illegal material, as defined by the provider state’s laws. This is a conceptually important difference; it creates a self-standing domestic duty of care and refrains from directly linking domestic legal consequences to a violation of a foreign country’s laws. With regard to the principle of common but differentiated responsibilities under international environmental law,<sup>34</sup> is the resistance to connect domestic legal consequences directly to a violation of foreign laws still timely?<sup>35</sup> I argued earlier that conflicts of laws<sup>36</sup> allow and the underlying international law principle requires a closer collaboration of provider and user states. Parties to Multilateral Environmental Agreements bear complementary (differentiated but related) duties, requiring recognition of extraterritorial effects.<sup>37</sup> However, the implementation process has to respect the contested negotiation history of the Nagoya Protocol. Industrialized countries strongly opposed the so-called “tripod”, requiring user states to make domestic users disclose the country of origin, the compliance with access rules, and the negotiated contractual agreement.<sup>38</sup> The legal implementation of a self-standing duty, rather than a prohibition linked to foreign law, mirrors the rejection of the “tripod” rule. The Nagoya Protocol does not demand a broad prohibition of illegal use.<sup>39</sup> Therefore, if the European Union now implements the duty variant (instead of the straightforward prohibition), I argue that the legislative decision commands respect, even if one may criticize it for not being ambitious enough. As

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- 34 Though not recognized as a rule yet, but only as a principle, Ellen Hey, “Common but differentiated responsibilities,” *Max Planck Encyclopedia of Public International Law*: MPEPIL (Oxford: Oxford Univ. Press, 2012) (last update February 2011): (447); T. Honkonen, *The Common But Differentiated Responsibility Principle in Multilateral Environmental Agreements – Regulatory and Policy Aspects* (Alphen aan den Rijn: Kluwer Law Int’l, 2009).
- 35 However, there are precedents which link the domestic prohibition to a violation of foreign laws, the diamonds regime and the timber regime, cf. Godt, “Due Diligence.”
- 36 C. Godt, “Enforcement of Benefit Sharing Duties in User Countries Courts,” in *Genetic Resources, Traditional Knowledge & the Law – Solutions for Access & Benefit Sharing*, eds. E. Kamau and G. Winter (London/Lifting V.A.: Earthscan, 2009): 419–438.
- 37 C. Godt, *IPRs and Environmental Protection after Cancún* (paper presented at the International Conference ‘Moving forward from Cancún – The Global Governance of Trade, Environment and Sustainable Development,’ Berlin, Germany, October 30–31 2003). Available online: <http://ecologic-events.eu/Cat-E/en/documents/Godt.pdf> (Nov. 2003).
- 38 For a detailed in depth analysis cf. Christine Godt, *Eigentum an Information* (Tübingen: Mohr Siebeck, 2007): 316.
- 39 Nagoya Protocol Article 5 Sec. 2: “Each party shall take [...] measures, as appropriate, with the aim of ensuring that benefits arising from the utilization [...] are shared [...].”

a matter of practice, one may wonder about the real life implications. Under the EU Regulation, users are under the duty to inquire, keep records, and transfer information. Article 4 Sec. 3 of the Regulation neatly specifies the information to be recorded: date and place of access, the description, the source, rights and obligations, and mutually agreed terms. If the use of illegal material is detected, the burden of proof shifts to the holder of the resource to show that he/she could not know, a difficult task in most cases. As much as a prohibition, the documentation duty exerts preventive effects, and triggers the industry to secure compliance along the production chain, also in provider states.<sup>40</sup> The “duty to ascertain” compared to a broad prohibition makes only a difference to enforcement agencies. Other agencies not being “the ABS entrusted agency,” like permit approval agencies, cannot examine “illegal use” (enforcing the prohibition). I argue that this lower standard is acceptable although second best. The transposition as domestic legal duty is consistent with the concept of state sovereignty.

More problematic is the second element, the standard of care. “Due diligence” refers here to a negligence standard, which refers to the individual duty of care in a given situation. This concept is a tort concept, and deviates from the standard regime of administrative offenses of which the duty is the same to everybody (phrased as a prohibition, *e.g.* to use illegal material). Adherence to best practices will, as a general rule, satisfy the standard of care.<sup>41</sup> Thus, where information is not available with due diligence, the access permit cannot be obtained and mutual agreed terms not be established, Art. 4 sec. 5 of the Regulation now commands the utilisation to be discontinued.

(2) In the case of the EU Regulation on ABS, the due diligence monitoring system rests on two pillars, on the declaration duties of users and on checks by the competent authority.<sup>42</sup> The responsible agency to which the user has to declare is not the agency responsible for market approval, but the (separate) national ABS authority (most probable the nature conservation agency).<sup>43</sup> The applicant will face a double administrative burden. The EU Regulation does not make the documentation of the declaration to the competent ABS agency a constitutive part of the approval file. There is no legal base for a

40 On the legal implications of “duties” and the dialectic function of the standard of care and burden of proof, Gert Brüggemeier, “Organisationshaftung – Deliktische Aspekte innerorganisatorischer Funktionsdifferenzierung,” *Archiv civilistischer Praxis (AcP)* 191 (1991): 33; transferred to the context of environmental liability: Christine Godt, *Haftung für Ökologische Schäden* (Berlin: Duncker & Humblot, 1997): 188 et seq.

41 EU Regulation on ABS Article 8 Sec. 4, also Godt, *Haftung für Ökologische Schäden*.

42 EU Regulation on ABS Article 9 Sec. 1.

43 EU Regulation on ABS Article 7 Sec. 2.

denial of the market approval. Since the duty is not formulated as a prohibition to use illegal material, a denial would even not be possible in exceptional cases where the law requires the examination of *all* public duties.<sup>44</sup> The declaration that due diligence is exercised<sup>45</sup> is a self-standing duty, penalized on its own merits according to Article 11 of the Regulation. The enforcement of the “declaration duty” and the “duty to ascertain” information about ABS compliance are restricted to administrative penalties established under Article 11. These might finally be severe (*e.g.* fines, immediate suspension of use activities, confiscation of illegally acquired material), but are not directed at remedying any illegal situation.<sup>46</sup> The competent agencies face several problems: Since the Regulation does not require the permit approving agency to ask for the declaration (the duty “shall declare” is one to the competent ABS agency),<sup>47</sup> it is unclear how the information about an application for product approval will be conveyed to the competent agency. The EU Regulation on ABS is silent on how to structure the information transfer between agencies. This is a severe lacuna, since most product approvals with relevance to ABS compliance are regulated on the EU level. It is an open question how the communication between product regulation agencies and ABS agencies shall be installed. In practice, it is quite dubious how competent ABS agencies shall know about possible violations of duties both, under Article 4 and Article 7 Sec. 2 of the Regulation. Commercialized products do not reveal in themselves the illegal use of genetic resources in either the R&D or the production process. The monitoring will depend on inspections of firm labs which require highly specialized expertise to detect possible violations of ABS ascertainment duties.<sup>48</sup>

(3) In cases where a market approval is not required, it is unclear which exact point in time is determined as “the stage of final development.” Is it the

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44 We found one single example in German law which is open enough to take prohibitions of adjacent laws on board (allowing the denial of a permit based on the non-declaration or inconsistent declaration or documentation of prior ABS-compliance): § 11 Sec. 1 No. 6 German Biotechnology Act (*Gentechnikgesetz*) demands that other norms do not stand against approval. It applies to labs of safety level 3 and 4 (which are submitted to *ex ante* approval). It reads: The approval is to be granted, if „andere öffentlich-rechtliche Vorschriften und Belange des Arbeitsschutzes der Errichtung und dem Betrieb der gentechnischen Anlage nicht entgegenstehen“.

45 EU Regulation on ABS Article 7 referring to Article 4 Sec. 1.

46 Even penalty fines (in German ‘*Zwangsgelder*’) aimed at enforcing a positive behavior (not the omission) do not help to achieve the goal since the duty is confined to ascertainment (not ABS-compliance).

47 EU Regulation on ABS Article 7 Sec. 2.

48 EU Regulation on ABS Article 9.

first market placing of a product in the sense of the IP-exhaustion principle, or does it start with the application for a patent, as the European Court of Justice adjudicated when interpreting Article 6 Sec. 2 lit.c of Directive 98/44/EC?<sup>49</sup> Even the European Parliament has called for a better information exchange with the European Patent Office.<sup>50</sup> The central problem with enforcing the EU Regulation is its design of information flow. Agencies will not know *who* utilizes genetic resources in the first place. The draft is narrowly focused on (self)-declaration duties and on the detection of violations by public administration. No technical scheme of information transfer between agencies is put in place. It remains unclear on which data the “periodically reviewed plans following a risk-based approach” can be based.<sup>51</sup> Providers, private users or consumers have no access to information. Most probable, little information will be communicated, and the ABS user compliance for the territory of the 28 EU member states is not secured.

(4) Due to the exacerbated split between access in provider states and benefits generated in user states, the pursuit of provider claims for benefit-sharing will be cumbersome – not only for legal,<sup>52</sup> but already for factual reasons. The EU Regulation on ABS only requires users to “exercise due diligence to ascertain that genetic resources [...] were accessed in accordance with access and benefit-sharing [regulations...].”<sup>53</sup> The information is to be reported “at the stage of final development [...] to the competent authorities.”<sup>54</sup> The competent agency will report to the Commission and the ABS Clearing House.<sup>55</sup> The declarations will not be made public. No safeguards are taken that information

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49 Case 34/10, *Brüstle v Greenpeace*, [2011] ECR I-821, following the opinion of AG Bot. The decision is highly contested: Concurring: Ingrid Schneider, “Das EuGH-Urteil ‘Brüstle versus Greenpeace’: Bedeutung und Implikationen für Europa,” *Zeitschrift für geistiges Eigentum/ Intellectual Property Journal* 3 (2011) 475; Rejecting: Jochen Taupitz, “Menschenwürde von Embryonen – europäisch-patentrechtlich betrachtet,” *GRUR* 114 (2012) 1; Aurora Plomer, “After Brüstle: EU accession to the ECHR and the future of European patent law,” *Queen Mary JIP* 2 (2012): 110; prior to the ECJ judgment, supporting the plaintiffs position: Joseph Straus, “Zur Patentierung humaner embryonaler Stammzellen in Europa. Verwendet die Stammzellenforschung menschliche Embryonen für industrielle oder kommerzielle Zwecke?” *GRURInt* 59 (2010): 911.

50 Opinion of the European Parliament’s Committee on Agriculture and Rural Development (published as part of the Report of the European Parliament, *supra* note 5), 22.

51 EU Regulation on ABS Article 9 Sec. 3a.

52 Godt, “Enforcement of Benefit Sharing.”

53 EU Regulation on ABS Article 4 Sec. 1.

54 EU Regulation on ABS Article 7 Sec. 2.

55 EU Regulation on ABS Article 7 Sec. 3.

about uses in user states is transparent and accessible.<sup>56</sup> Providers will depend on accidental discovery of use and commercialization. No means for structured monitoring and tracing of use allowances is put in place. The ABS Clearing House, which was installed to enhance the flow of information between provider and user states by Article 14 of the Nagoya Protocol, will primarily support users in tracking information about (provider state) legislation and about restrictions in access permits. Since transparent information about uses is not required by the Nagoya Protocol, the ABS clearing house will do little to respond to the information needs of providers. Yet, the underlying idea of the ABS mechanism rests on the back-flow of benefits from user states to provider states as an incentive mechanism for nature preservation. It is a common misunderstanding to conceive the duty to share benefits as a source of income for provider states to their free disposition, in their own interest. Benefit-sharing is primarily in the common interest of biodiversity protection of all Parties to the CBD. Therefore, it is sensible to earmark funds raised for the preservation of biodiversity. This is also true, if claims are raised by a state, and then resemble a transnational tax which a private entity owes to a foreign state.

### III The Alternative: “Piggy-Back”-Procedures

The better alternative to the implementation approach taken by EU Commission is the integration of the duty to disclose information about ABS compliance into existing procedures, in which genetic resources and products based or derived from genetic resources are accessed, stored, analysed, developed, and make their way up to market commercialization, *coupled* with general rules which allow providers to seek judicial redress.<sup>57</sup> This idea departs from a different regulatory concept. Neither is it reduced to documentation duties of the utilizers, nor is the “illegal use” made the center of the user country’s Nagoya Protocol-measure. It aims at facilitating the enforcement of legitimate claims by providers in user countries, regardless whether they are states, private entities or communities. This approach would complement the provider state measures by user state transparency rules.

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<sup>56</sup> A mechanism, however, could be the searchable patent data banks.

<sup>57</sup> The analysis is based on a one year expert consultation of the authors commissioned by the German federal government, prior to the publication of the EU Regulation (*cf. supra* note 1). The task was to identify implementation schemes for the Nagoya Protocol which could comply with the European multilevel governance scheme and take residual national competences on board. The central findings are in the process of publication (2014).

States already control the use of biological and genetic resources by various procedures, although for different purposes. States record patents for innovation purposes; for security reasons they control dangerous behaviour and dangerous substances; for reasons of fostering research and economic growth, states subsidize research and industrial projects.

The central idea of the “piggy-back” approach is to utilize the existing procedures for more transparency, thus enabling providers to pursue their claims and, by employing these, to keep products off the market which were developed based on illegally acquired material. Research funding grants and IP granting procedures make the (potential) use of a resource public at a very early point in time. Later product approval procedures signal the market entry of a resource. Research funding and public procurement procedures can be utilized to submit applicants to documentation duties, thus enhancing information distribution, and could require that mutual agreed terms are stipulated which ensure that future benefits will either be invested in biodiversity protection or at least benefit biodiversity long-term.<sup>58</sup>

Therefore, the central idea of the “piggy-back” concept is to enable the pursuit of legitimate provider claims. However, the availability of this information about the granted access and benefit conditions is also in the interests of users along the production chain who utilize genetic resources commercially. It is in their interest to avoid biopiracy, and that is only possible if they have appropriate information. If disclosure were required in patent and in market approval procedures, the exploitation of genetic resources in the R&D-process and in testing would be made public in most instances.<sup>59</sup>

It is a different question whether these disclosure duties are to be complemented by a “general duty to comply,” since many uses do not come in contact with any administrative procedure. Both concepts do not exclude each other; they can be combined. A good reason to do so is to avoid lacunae in the control of uses, and to submit all users to “the same” duty. It also might be in the interest of the user state to transpose, as an own sovereign act, the duty to comply with a foreign state’s rule into a domestic duty (*supra*).

In an earlier expertise, the author examined, whether amendments requiring the disclosure of information on benefit-sharing compliance (justified by environmental policy goals) can be implemented into existing regulations based on

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58 Respective requirement could be modeled on ‘equitable licensing’, cf. Christine Godt, “Equitable Licenses – Conceptualizing a New Model – Resolving Some Early Legal Problems,” *GRUR Int.* (2011): 377–385.

59 This scheme risks utilizations protected by a business secret to remain undetected.



other competences rules than environmental protection.<sup>60</sup> The conclusion was that amendments can be installed to rules which pursue product safety or the promotion of innovation due to the integration clause for environmental protection.<sup>61</sup> With regard to consumer products, legislative competences for consumer protection and environmental protection do not differ in scope. We found only one single exception in which an amendment is not possible due to the specific (German) regulatory set-up of public procurement of pharmaceuticals under German social security rules (*Sozialgesetzbuch-V*).<sup>62</sup> The declaration duties integrated in product permit procedures should be complemented by a general prohibition of illegal use, stipulated either in existing nature protection laws or in self-standing ABS rules. It forms the legal base for subsequent declaration duties. The reference to foreign law is legitimized by the accession to the Nagoya Protocol, which rests on the principle of joint but differential duties of contract parties. A system which resorts to complementarity rests on the reference to the other system (of which legitimacy can still be independently controlled by the user state). In addition, procedural rules are to be clarified with regard to the standing of providers with regard to benefit-sharing claims. Due to the questionable public-private nature of financial claims raised by states, civil procedure rules need to clarify their legitimacy in advance.<sup>63</sup>

Where legally possible, the “piggy-back”-implementation is conceptually preferable for several reasons: it is advantageous for users and providers alike, and creates a robust implementation scheme for ABS compliance. However, it also encounters some limits.

(1) The “piggy-back”-implementation reduces costs for users, since they need to communicate with only one agency. The declaration can to be delivered at the occasion of approval application. Approvals granted have to be made public referring to the declaration. For providers, this installs a regular and reliable scheme for information disclosure which makes information available in a structured, transparent way. Patent information is structured by IPC codes mirroring technological sectors. Documentation in product approval procedures would guide inquiries into respective industry sectors

60 Godt, Šušnjar and Wolff, *NP-Umsetzung (Study I)*.

61 TFEU Article 11. Explicitly European Court of Justice with regard to the European competition law framework of national public procurement in C-513/99, decision of 17 September 2002, ECR 2002 I-7213 – *Concordia Buses Finland*.

62 The supply with pharmaceuticals in the German system is based on a public social insurance model which provides for strong patient protection, which eventually prompts environmental protection, Godt, Šušnjar and Wolff, *NP-Umsetzung (Study I)*, 117.

63 Godt, Šušnjar and Wolff, *NP-Umsetzung (Study I)*, 139.

(pharmaceuticals, food ingredients and additives, chemicals and cosmetics). Complemented by funding organizations and *ex situ* collections,<sup>64</sup> a transparent data record would be built up.<sup>65</sup>

(2) It makes implementation more robust, as it slims down the ABS administration apparatus, sets true compliance incentives, and redirects the implementation focus. Although the legislative burden to implement documentation duties of ABS compliance in each procedure is high in the short term, it will reduce administrative operation costs in the long term. The national competent agency would not be flooded with declarations of legal use (by users), regulatory agencies would either report to the ABS competent agency where illegal use is detected,<sup>66</sup> (or report to it in a structured way: legal use *vs.* illegal use). In addition, since the permit could be withheld unless information is produced, a sincere incentive for users to comply is created. This is at least possible in pharmaceuticals and food additives regulations, as well as for permits which allow experiments with pesticides<sup>67</sup> and biocides,<sup>68</sup> as these are concrete, individual decisions and allow for declarations as to the origin/source of genetic resources as “raw material” and to use restrictions.<sup>69</sup> It is not cogent to finally deny the permit where information is *not* available. Various possibilities are conceivable to bridge the information delta. The central national focal point could convey information to the provider state, self-declarations could be accepted as substitution in case of credible affirmation that formal access requirements *could not* be met, and the payment of lump sums could be required to the biodiversity fund. Such a transnational information scheme would make the intergovernmental communication as required by the Nagoya Protocol operational.<sup>70</sup> More importantly, the administrative impulse would be

64 On collections see Godt, Šušnjar and Wolff, *NP-Umsetzung (Study I)*, 117 et seq; Godt, “Ex Situ Collections.”

65 We advised clear legal wording which submits *ex situ* collections to ABS-rules (notwithstanding to privileged “trusted ones”), and (often privately organized) funding organizations (not only “public” research funding); and not only duties to declare of recipients – as in the EU Regulation on ABS.

66 Godt, Šušnjar and Wolff, *NP-Umsetzung (Study I)*, 5.

67 EU Regulation 07/2009 Article 54, Off. J. L 309/1 of 24 November 2009.

68 EU Directive 98/8/EC Article 17, Off. J. L 123/1 of 24 April 1998.

69 This is in contrast to general-abstract lists of approvals (as with the cosmetics, biocides, pesticides, chemicals). The violation of a use restriction of a general-abstract list registration does not allow for a recall of a substance from the list. However, the documentary value of the ABS-information would helpful. If the restriction is too narrow, the information might trigger re-negotiations with the provider state. Individual violations can be sanctioned with fines, Godt, Šušnjar and Wolff, *NP-Umsetzung (Study I)*, Annex 27.

70 Godt, Šušnjar and Wolff, *NP-Umsetzung (Study I)*, 48.

different. The focus of the national competent ABS agency would neither be the documentation of voluntary declarations, nor costly (since expert skills are required) inquisitorial inquiries in firm labs,<sup>71</sup> nor would agencies be stuck with the a possible blind documentation of resource use (which is already possible *de lege lata*,<sup>72</sup> and to which states would already be obliged by the Nagoya Protocol) without ABS focus.<sup>73</sup> The agency could focus on remedying the lacking consent and negotiations with providers – in contrast to the fuzzy penalization of declaration and documentation duties. It could re-direct administrative activity to providing information to users on how they can get (also *ex post*) proper ABS certificates (documenting ABS compliance). The regular declarations (recorded by regular civil servants) can still be recorded by the ABS agency. It should be noted, however, that the primary regulatory aim of approval procedures is product safety (enforced by prohibitions and limits). Therefore, many genetic resources enter the market place without procedural control. This, in turn, clarifies the nature of ABS requirements in product approval procedures. It is a check-point enabling transparency and enforcement where necessary. It cannot be the primary (and only) instrument of enforcement. The implementation scheme should equally take patent procedures and research control on board.

(3) An installed EU system would utilize the existing dynamics of the European multi-level governance system. That is to say, that the existing structures of strong product regulation on the EC level should be used without neglecting the opportunities for a sensible ABS management “above,” “below” and “across” the EU level in respect of the national and private sovereignties. “Above” the EU level, member states and the EU should engage in negotiating amendments to the (intergovernmental) European Patent Convention.<sup>74</sup> The patent registries are a central source of technical data to which ABS information can be added. “Below” the central EU level, national governments should implement ABS user measures in areas of their own jurisdiction, in order to install experimental legislation on which future regulation could draw.<sup>75</sup> In our study of 2012, we identified several areas which have remained sovereign areas of

<sup>71</sup> EU Regulation on ABS Article 9 Sec. 3b.

<sup>72</sup> Godt, Šušnjar and Wolff, *NP-Umsetzung (Study I)* (documented for several areas of laws).

<sup>73</sup> Since the agency would not be allowed to inquire about the country of origin and not request evidence for legal access and mutual agreed terms.

<sup>74</sup> Which not even includes a voluntary disclosure rule similar to § 34a German Patent Act. This is in need of reform (see *supra* notes 27 and 28 for respective critiques of the EP-Agricultural Committee and NGOs).

<sup>75</sup> Therefore, I support the EU Regulation on ABS in that it refrained from a pure central implementation scheme.

national law making (notwithstanding overarching EU law): national patent law, animal protection, research funding, residuary areas in biotechnology, public procurement, international development assistance, corporate governance codices, and civil procedure.<sup>76</sup> Yet within the EU realm, regulatory structures are not neatly separated; three structural types of procedures are distinguished:

- (1) pure EU procedures (EU law *and* EU implementation, examples: biotech, pharmaceuticals, EU research funding);
- (2) mixed multi-level procedures qualified by EU law with national implementation (example: food control); and
- (3) mixed multi-level procedures with complementary legislation (example: biocides). Cross-cutting are (private) managerial schemes like corporate social responsibility.<sup>77</sup>

Whereas this article is not the right place to fully present the possible amendment to existing procedures, market approvals are of special concern for eventual benefits generated by the utilization of genetic resources and associated traditional knowledge. Three product sectors are of special interest: pharmaceuticals, foods, and the chemical sector in the broad sense (including inter alia pesticides and cosmetics). Relevant are the following regulations and directives:

- (a) for the pharmaceuticals sector (providing for central procedure with European Medical Agency,<sup>78</sup> and for de-centralized, but orchestrated procedures<sup>79</sup>);
- (b) food production (five regulations, one directive);<sup>80</sup>
- (c) chemical industry.<sup>81</sup>

<sup>76</sup> Godt, Šušnjar and Wolff, *NP-Umsetzung (Study I)*.

<sup>77</sup> For a concise overview: Godt, Šušnjar and Wolff, *NP-Umsetzung (Study I)*, 148–155.

<sup>78</sup> EU Regulation 726/2004, Off. J. L 136/1 of 30 April 2004.

<sup>79</sup> EU Directive 2001/83/EC Pharmaceuticals for human use, Off. J. L 3011/67 of 28 November 2001; EU Directive 2001/82/EG Veterinary medicinal products, Off. J. L 3011/1 of 28 November 2001.

<sup>80</sup> EC Regulation No. 178/2002 on general principles, Off. J. L 31/1 of 1 February 2002, revised by EC-Reg. No. 575/2006 (contaminants in foodstuffs), Off. J. L 100/3 of 20 December 2006; EC Regulation No. 1333/2008 on food additives, Off. J. L 354/16 of 31 December 2008, revised by EU-Reg. No. 238/2010, Off. J. L 75/17 of 23 March 2010; EC Regulation No. 258/97 on novel foods, Off. J. L 43/1 of 14 February 1997; EC Regulation 1332/2008 on enzymes, Off. J. L 354/7 of 31 December 2008; and Directive 2002/46/EC on food supplements, Off. J. L 183/51 of 12 July 2002.

<sup>81</sup> REACH Reg. 1907/2006 on chemicals, Off. J. L 396/1 of 30 December 2006; Dir. 76/768/EC on cosmetics, Off. J. L 262/169 of 27 November 1976; Dir. 98/8/EC on biocides, Off. J. L

As noted earlier, only permits for pharmaceuticals, food additives and research experiments can be retained for not producing evidence of ABS compliance. The other product approval procedures can only serve as depository of information with regard to the country of origin and eventual use restrictions, thus making the utilization of genetic resources and associated traditional knowledge more transparent and enabling providers to pursue given claims.

Considering the transparency advantages of the “piggy-back” approach, one could argue that its disadvantage is its focus on the “extremity” of the genetic resource use chain. This argument caters to the criticism that benefit-sharing comes too late and should not be limited to financial benefits. However, neither does the “piggy-back” approach limit the sharing duty to financial benefits, nor is it limited to financial flows attributed to speculative royalties of some lucrative end products sometime in the future. Already the sale of a given substance as a diagnostic kit would be covered in most cases. The simple use of a substance *in the process* could be detected if it were subject of a patent claim. Otherwise, the (illegal) use of resources in processes would only be detectable once the end product becomes marketed. Since disclosure rules do not focus on the end product itself, but on the “utilization of genetic resources” (including the production chain), they embrace processes as well as products, even if genetic resources are not part of the end product.

#### IV Conclusion

The biggest challenge to the implementation of Nagoya Protocol-compliant user measures is transparency which allows the pursuit of claims by providers. The EU Regulation on ABS is too narrowly focused on declaration duties and on the detection of violations by public administration. In contrast, an intelligent and transparent flow of information primarily between users along the production chain, and additionally between agencies is essential. A well-designed information system is not only in the interest of providers, but it is also in the interest of commerce as a protection against unsubstantiated accusations of biopiracy, and in the public interest of biodiversity protection as such, considering that the ABS mechanism was put in place as a means for preservation, not as a goal in itself. Since the Nagoya Protocol installs a truly

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123/1 of 24 April 1998; Reg. 1107/2009 on pesticides, Off. J. L 309/1 of 24 November 2009; Dir. 2009/41/EC on contained use of genetically modified organisms, Off. J. L 125/75 of 21 May 2009; Dir. 2001/18/EC on deliberate release of genetically modified organisms, Off. J. L 106/1 of 17 April 2001; and again EC Reg. No. 258/97 on novel foods, Off. J. L 43/1 of 14 February 1997.

novel instrument, it is evident that there are high risks for the Nagoya Protocol to be misused as an impediment to innovation, to stifle entrepreneurial development, and as an undue source of income. However, the whole idea was to install a financial mechanism to transfer benefits, thus, some sort of transnational (earmarked) tax. The underlying idea is that a more fair and equitable distribution of wealth will hold the further depletion of biodiversity. It would certainly raise adherence of users could they trust that money which is transnationally transferred is benefiting biodiversity protection. The instrument to achieve this goal is not only provider states' regulation (and safeguards against corruption), but also mutually agreed terms which are interested in the way benefits are invested. Parties to the Nagoya Protocol *and* corporate governance remain under pressure to develop the Nagoya Protocol into this direction. The engagement of corporate governance to install functional ABS schemes would help. Workable EU-user measures are one brick in the whole edifice of employing ABS as a means for biodiversity protection.

# Collecting Plant Genetic Resources in Europe: A Survey of Legal Requirements and Practical Experiences

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## I Rationale for a Survey on Collecting Plant Genetic Resources in Europe

Collecting plant germplasm from the wild and farmers' fields is an essential task for the acquisition of genetic resources for conservation and use. Until recently, this activity has been carried out within and across countries in a largely unregulated fashion. We have focused our study on understanding how the current regulatory framework is affecting germplasm collecting in Europe.

Most of the studies around Access and Benefit-sharing (ABS) regulations and their effect on research and development activities have focused on developing countries. Very few works provide a comprehensive account of policies and laws regulating the conservation and use of genetic resources in Europe,<sup>1</sup>

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1 D. Lange, *Europe's medicinal and aromatic plants: their use, trade and conservation* (Cambridge (UK): TRAFFIC International, 1998); Thomas Geburek, and Jozef Turok, eds., *Conservation*

and they tend to limit their analyses to the normative texts, providing little information about how implementation takes place in practice, in line and/or beyond the written norms. This situation has partially contributed to generate a common belief or impression that collecting genetic resources in European countries is much easier, legally speaking, than in other countries. But is this really the case?

In order to answer this question, we approached our study of the European ABS legal landscape from a very practical angle: how do genebank curators who are in charge of conserving plant genetic resources describe the rules applied to the collection of plant germplasm in their own countries? How do they describe the legal procedures imposed by other countries, according to their own experiences? Are there concrete cases that illustrate the actual experience of plant germplasm collectors when seeking compliance with ABS rules in Europe?

Our article is structured as follows: initially, through an historical excursus we retrace the importance in the international context of plant germplasm collecting activities and their continuing need, including in Europe. Then, we relate how political and regulatory changes have affected activities related to the genetic resources and we focus our analysis on the perceived practical consequences for plant germplasm collecting. Furthermore, we describe the methodology that we adopted to obtain information from genebank curators on existing national laws and rules and their implementation. Finally, we analyse the replies to a questionnaire sent to 43 member countries of the European Cooperative Programme for Plant Genetic Resources (ECPGR) and discuss the results obtained, also in light of possible new regulatory changes that might be introduced for the implementation of the Nagoya Protocol. In two separate boxes we provide a practical account about what happens “on the ground” when specific international collecting missions are organized to acquire plant germplasm material. On the basis of the information gathered in this study, we conclude our chapter with a set of recommendations directed to political authorities and legislators, in order to improve facilitated access in harmony with existing international principles.

## **1      *Collecting Crop Diversity to Prevent Genetic Erosion***

Collecting genetic resources from the wild and farmers' fields and moving germplasm from one to a different area of the world has been practiced since

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*and Management of Forest Genetic Resources in Europe* (Zvolen: Arbora Publishers, 2005); Jorge Cabrera Medaglia, Frederic Perron-Welch, and Olivier Rukundo, *Overview of National and regional Measures on Access to Genetic Resources and Benefit-sharing* (Montreal: Centre for International Sustainable Development Law, 2012).



the early days of history. Plucknett *et al.* 1987 describe how plant collecting has evolved along history, from the earliest collecting expeditions in the Sumerian, Egyptian, Greek and Roman times to Vavilov's extensive exploration missions around the world in the first half of the 20th century. The first "plant introduction stations" were formally established in the United States and other "new countries" in the 19th century with the strategic role of importing genetic diversity to be tested and crossed to improve crop production. In parallel with the development of plant breeding as a scientific and economic undertaking during the early part of the 20th century, genebanks were created to provide scientists and breeders a promptly available supply of germplasm to be used for breeding and research purposes. A number of international technical meetings organized by the United Nations between 1961 and 1972 raised the international concern over the risk to permanently lose genetic diversity, owing to the replacement of diverse traditional varieties or landraces with fewer modern high yielding lines or hybrids, as well as due to the loss of wild habitats.<sup>2</sup> The Consultative Group for International Agricultural Research (CGIAR), an international consortium of country governments, institutions, and philanthropic foundations dedicated to research for agricultural development, established the International Board for Plant Genetic Resources (IBPGR) in 1974. The IBPGR, based at the Food and Agriculture Organization of the United Nations (FAO) in Rome, had the task to promote and assist in the worldwide effort to collect and conserve the plant germplasm needed for future research and production.<sup>3</sup> One of IBPGR's most important tasks was the funding of collecting missions of traditional varieties and landraces cultivated by farmers and their wild relatives, which were being lost from fields and natural habitats. Since 1974, IBPGR (thereafter International Plant Genetic Resources Institute (IPGRI), and since 2006 Bioversity International), sponsored more than 500 collecting expeditions from national and international institutions to most countries of the world, during which over 225,000 plant samples were gathered.<sup>4</sup> This wealth of landraces and wild relatives was distributed to 49 selected genebanks to conserve the germplasm for the long-term and to over 500 genebanks for conservation and use.

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2 Robin Pistorius, *Scientists, Plant and Politics – A History of the Plant Genetic Resources Movement* (Rome: International Plant Genetic Resources Institute, 1997).

3 Technical Advisory Committee (TAC), *The Collection, Evaluation and Conservation of Plant Genetic resources*, report of TAC Ad Hoc Working Group held in Beltsville, USA, 20–25 March 1972.

4 Imke Thormann *et al.*, "Digitization and Online Availability of Original Collecting Mission Data to Improve Data Quality and Enhance the Conservation and Use of Plant Genetic Resources," *Genetic Resources and Crop Evolution* 59 (2012): 635–644.

Plant germplasm collecting activities have multiplied in the last 30 years, not only as a result of international efforts (IBPGR and other CGIAR centres), but also through national efforts as almost every country decided to establish its own national genetic resources conservation system. According to the Second Report on the State of the World's Plant Genetic Resources for Food and Agriculture,<sup>5</sup> there were at the time of publication more than 1750 reported individual genebanks or germplasm collections worldwide, conserving an estimated number of about 7.4 million accessions, that is 1.4 million more than were reported in 1996 by the First State of the World Report.<sup>6</sup> For Europe these figures are approximately 1.9 million accessions maintained in more than 500 genebanks or collections.<sup>7</sup> The FAO reported a trend of declining internationally sponsored collecting initiatives and an increase of national ones in the last 30 years.<sup>8</sup> The increasing number of accessions conserved in a proliferating number of genebanks around the world is accompanied by an estimate that only 25–30% are distinct accessions, the remainder being duplicates. For Europe, 38% of the germplasm holdings are made up by accessions that are indigenous to Europe.<sup>9</sup>

## 2 *Collecting Plant Diversity is Still Needed*

From a global biological perspective, while for many major crops a large part of the genetic diversity is currently represented in the *ex situ* collections, sometimes even over-represented due to duplication, for many others, especially minor crops and the crop wild relatives, considerable gaps remain.<sup>10</sup> Environmental degradation and climate change are also persisting elements inviting for a continuing attention to securing threatened germplasm in genebanks as well as to searching for useful traits for adaptation to warmer and drier climates.<sup>11</sup> The Second Global Plan of Action for Plant Genetic Resources

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5 FAO, *The Second Report on the State of the World's Plant Genetic Resources for Food and Agriculture* (Rome: Food and Agriculture Organization of the United Nations, 2010).

6 FAO, *The State of the World's Plant Genetic Resources for Food and Agriculture* (Rome: Food and Agriculture Organization of the United Nations, 1998).

7 WIEWS, "World Information and Early Warning System on Plant Genetic Resources for Food and Agriculture," accessed December 20, 2013, <http://apps3.fao.org/wiews/wiews.jsp>.

8 FAO, *Second Report*.

9 *Ibid*.

10 C. Khoury, B. Laliberté and L. Guarino, "Trends in *ex situ* Conservation of Plant Genetic Resources: A Review of Global Crop and Regional Conservation Strategies," *Genetic Resources and Crop Evolution* 57 (2010).

11 FAO, *Second Report*.

for Food and Agriculture<sup>12</sup> lists a number of reasons supporting the need for continuing targeted collecting of Plant Genetic Resources for Food and Agriculture (PGRFA), including the existing gaps in collections of regionally important crops and minor and underutilized crops, as well as the suboptimal conditions in many genebanks that may have led to the loss of collected material. An international initiative responding to this need has been recently launched by the Global Crop Diversity Trust, with the support of the Government of Norway and in partnership with the Millennium Seed Bank of the Royal Botanic Gardens, Kew. The project will first identify those crop wild relatives of 29 crops of major importance to food security that are missing from existing collections, that are most likely to contain diversity of value for adapting agriculture to climate change, that are most endangered. National project partners predominantly of countries that are Parties to the International Treaty on Plant Genetic Resources for Food and Agriculture (the Treaty) will then collect them from the wild and conserve them in genebanks.<sup>13</sup>

In the specific case of the European region, during a Symposium on the implementation of the Global Plan of Action in 1998, it was confirmed that the area is very rich in PGRFA and that although a lot of material had been already collected, the number of accessions in the actual collections did not represent at all the genetic diversity of several important economic crops. The situation was even worse for crop wild relatives.<sup>14</sup> The Second State of the World report,<sup>15</sup> indicated that several missions had been undertaken in Europe, specifically covering Hungary, the Nordic countries, Poland, Romania, Slovakia and neighbouring regions. However, a comprehensive and updated measure of the extent of remaining gaps in the European genetic diversity is very difficult or impossible to estimate with any real precision in the absence of hard baseline data and of agreed indicators for the total existing genetic diversity. Based on the knowledge of experts expressing their views in the Working Group meetings of the ECPGR (a European plant genetic resources network composed of over 40 participating countries), several gaps still remain, especially regarding

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12 FAO, *Second Global Plan of Action for Plant Genetic Resources for Food and Agriculture* (Rome: Food and Agriculture Organization of the United Nations, 2012).

13 "Global Crop Diversity Trust – Wild relatives," accessed January 20, 2014, <http://www.crop-trust.org/content/wild-relatives>.

14 Vojtech Holubec, "Principal Collecting Needs in Europe," in *Implementation of the Global Plan of Action in Europe – Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture. Proceedings of the European Symposium – 30 June–3 July 1998, Braunschweig, Germany*, eds. Thomas Gass et al. (Rome: International Plant Genetic Resources Institute, 1999): 145–155.

15 FAO, *Second Report*.

vegetables and fruit landraces and their wild relatives. For example, the Balkan and Caucasus areas, as well as marginal areas of the Mediterranean basin still offer a wealth of diversity that is otherwise not available from genebanks and that seems to be threatened.

### 3 *Genetic Resources Become an International Political Issue*

For thousands of years plant collecting and the movement of germplasm were unregulated activities, which coincided with the movement of people across the globe, either as immigrants, missionaries, armies, explorers or professional plant hunters commissioned by their governments or institutions. The level of general benefit that has derived from the free global flow of germplasm should be estimated by keeping in mind that no country or region of the world is entirely self-sufficient in terms of the plant genetic resources needed to sustain and improve its major crops.<sup>16</sup> The establishment of extensive global collections of germplasm collected in the second half of the 20th century, conserved by the CGIAR centres and available to everyone has certainly prevented the extinction of numerous landraces and other materials. These collections have also enabled the possibility to repatriate original collected samples to countries that have lost their resources due to environmental or more likely human-driven accidents (wars, civil unrests and political turmoil in general).

In 1983, the FAO Conference adopted the International Undertaking on Plant Genetic Resources, a non-binding instrument that recognized plant genetic resources, including improved and commercial varieties, as a common heritage of mankind, and sought to guarantee its freedom of exchange without restrictions. However, the rapid scientific and technological advances in the 1960s and the 70s had raised tensions about intellectual property rights and perceived inequities concerning who bears the cost of conserving genetic resources and who benefits (commercially) most from its use. Most biological diversity is located in the tropics, in developing countries, and is often in areas inhabited by the poorest, most marginalized people in those countries. The centres of diversity of most domesticated crops are located in developing country regions.<sup>17</sup> However, the technological capacity to exploit biological diversity for commercial gain resides principally in developed countries. The emergence of biotechnology contributed to a further disproportionate concentration of

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16 Cary Fowler, "Rights and Responsibilities: Linking Conservation, Utilization, and Sharing of Benefits of Plant Genetic Resources," in *Intellectual Property Rights III. Global Genetic Resources: Access and Property Rights*, eds. S. Eberhart, H. Shands, W. Collins, and R. Lower (Madison: Crop Science Society of America, 1998): 34–35.

17 J. Harlan. *Crops and Man*, 2nd edition (Madison: American Society of Agronomy, 1992).

plant technological capacity in the North, and to increment the discomfort of developing countries to provide intellectual property protection to such technology without getting any recognition for the biological diversity (including crop diversity) conserved in their territories and available for technological development.<sup>18</sup> Therefore, the notion of common heritage established in the International Undertaking did not last long, and was soon replaced by the principle of countries' national sovereignty over genetic resources, which was internationally recognized in the Convention of Biological Diversity (CBD) adopted in 1992. In line with this principle, the CBD stated that countries can regulate the access to the genetic resources within their territories, and that access to such resources should be based on the fair and equitable sharing of the benefits arising from their utilization. More recently, in 2010, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization, was adopted by the parties to the CBD to spell out the general provisions of the CBD regarding access and benefit-sharing. The Protocol seeks to ensure legal certainty regarding the terms and procedures for access and benefit-sharing as well as to the genetic resources having been acquired with the prior informed consent (PIC) of the country providing them and with mutually agreed terms (MAT).

The International Treaty on Plant Genetic Resources for Food and Agriculture, adopted in 2001 and in force since 2004, established an access and benefit-sharing system that, based on the CBD's general principles, was designed taking into account the particular characteristics of plant genetic resources for food and agriculture, and the particular needs of the users of these resources. This system is based on the multilateral facilitated access to a pool of genetic resources of certain crops (listed in Annex I of the Treaty) and the multilateral sharing of the monetary and non-monetary benefits arising from the use of such genetic resources in research and breeding for food and agriculture. The transfer of samples from the multilateral pool of plant genetic resources is done through a Standard Material Transfer Agreement (SMTA) whose text was agreed by the Treaty members and whose provisions cannot be negotiated by the provider and the recipient of the samples. The Treaty represents a compromise

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18 J. Esquinas-Alcazar, A. Hilmi and I. López-Noriega, "A Brief History of the Negotiations on the International Treaty on Plant Genetic Resources for Food and Agriculture," in *Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance*, eds. M. Halewood, I. López-Noriega, and S. Louafi (London and New York: Routledge, 2013); Sebastian Oberthür and Kristin Rosendal, eds., *Global Governance of Genetic Resources. Access and Benefit Sharing After the Nagoya Protocol* (New York and London: Routledge, 2013).

between the situation that prevailed before the proliferation of intellectual property and access and benefit-sharing laws, when all PGRFA were *de facto* considered public domain and free to use by all, and the scenario that ensued since 1980s as a result of the increase of different forms of control over plant genetic resources. However, to date, many countries have not effectively engaged in the Treaty's multilateral system of access and benefit-sharing, which has limited the Treaty's potential to lessen the trend towards "hyperownership"<sup>19</sup> of plant genetic resources triggered by the CBD and the international agreements on intellectual property rights, and the subsequent tendency of countries to "hyper-regulate" the access to such resources.

The actual scope of these three treaties' ABS provisions cannot be defined in absolute terms, and they share overlapping areas in relation to plant genetic resources. In fact, the ABS principles of the CBD apply to all genetic resources, and the Treaty ABS provisions are in harmony with those principles. However, only plant genetic resources included in the multilateral system of the Treaty, and which are to be used for the purposes spelled out in the Treaty, are not subject to the bilateral ABS provisions of the CBD and/or the Nagoya Protocol;<sup>20</sup> for all the other plant genetic resources the CBD and the Nagoya Protocol apply, in those countries which have ratified them. At the same time, for those countries which have not ratified the Treaty, all plant genetic resources are subject to the CBD and the Nagoya Protocol, except for those plant genetic resources that are acquired from other countries through an SMTA, which obliges the recipient of the resources to pass them on to further recipients under a subsequent SMTA, and therefore subject to the terms and conditions of the Treaty's multilateral system, independently from his or her countries' status in relation to the Treaty.<sup>21</sup> If we take into consideration international

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19 S. Safrin, "Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life," *American Journal of International Law* 98 (2004):641.

20 Not all plant genetic resources for food and agriculture of the species listed in Annex I of the Treaty are automatically included in the multilateral system of the Treaty, but only those which are under the management and control of the governments of the contracting parties and in the public domain, according to Article 11.2 of the Treaty. For all the other plant genetic resources (inside or outside Annex I), countries may decide to put them in the multilateral system on a voluntary basis or to regulate its access according to the CBD and the Nagoya Protocol rules. The access to plant genetic resources (again, Annex I and non-Annex I) that are subject to intellectual property rights are at the discretion of the rights' owner, unless countries' legal frameworks establish something different.

21 Matthias Buck and Claire Hamilton, "The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the

conventions on intellectual property rights and other international agreements that may influence the legal status of plant genetic resources, the pattern can be even more complex than indicated here, which is anyway sufficient to unravel how intricate the international legal scenario is.

The resulting international legal framework that is to be applied to the collecting of plant genetic resources from *in situ* conditions has been thoroughly described by Moore and Williams<sup>22</sup> in the updated technical guidelines for collecting plant genetic diversity. These authors have developed guidelines to help plant collectors comply with access and benefit-sharing requirements that countries may have put in place pursuant to the CBD. Unfortunately, the rules to be applied to plant genetic resources of Annex I crops growing *in situ* (including wild plants, as well as traditional crop varieties obtained from farmers or markets) are still not totally clear under the Treaty. According to the Treaty's rules on access and benefit-sharing, the system of facilitated access to plant genetic resources applies to those resources which are under the management and control of national governments, and in the public domain, regardless of where they are found (*ex situ* or *in situ* conditions). At the same time, the Treaty states that access to PGRFA found *in situ* should be provided according to national legislation or in the absence of such legislation, in accordance with the standards set out by the Governing Body. However, these standards have not been developed yet.<sup>23</sup> The conclusion of Moore and Williams<sup>24</sup> is that the international system governing plant germplasm collecting is currently a patchwork of provisions from the CBD, the Nagoya Protocol and the Treaty and that ample work and political will is needed to ensure that these regimes can be implemented in a harmonious and mutually supportive manner.

#### 4 *Practical Consequences on Plant Germplasm Collecting Practices*

The practical consequences of the paradigm shift described above on those working with plant germplasm have been tremendous. The vast literature on the

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Convention on Biological Diversity," *Review of European Community and International Environmental Law* (2011): 47–61; Thomas Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing* (Gland, Switzerland: IUCN, 2012).

22 Gerald Moore and Karen A. Williams, "Legal Issues in Plant Germplasm Collecting," in *Collecting Plant Genetic Diversity: Technical Guidelines – 2011 Update*, eds. Luigi Guarino, V. Ramanatha Rao and Elizabeth Goldberg (Rome: Bioversity International, 2011).

23 Article 12.3.h of the Treaty says that "Without prejudice to the other provisions under this Article, the Contracting Parties agree that access to plant genetic resources for food and agriculture found in *in situ* conditions will be provided according to national legislation or, in the absence of such legislation, in accordance with such standards as may be set by the Governing Body."

24 Moore and Williams, "Legal Issues in Plant Germplasm Collecting."

development and implementation of international, regional and national access and benefit-sharing (ABS) regulations highlights the difficulties involved in getting access and benefit-sharing regulations developed, implemented and known about by the broad range of users who were used to collect, exchange and utilize plant genetic material without any relevant interference from public policies.<sup>25</sup> As has been shown in chapters 2 to 11 of this book, and as we will further illustrate with concrete examples below, when institutions try to access plant genetic resources from outside their countries, and sometimes even within their own countries, they encounter, as a general rule, multiple authorities issuing different permits, unclear procedures, lack of standardized agreements/formats, absence of clear focal points and different overlapping regulations. This seems to be particularly true when dealing with collecting crop wild relatives *in situ* and their transfer across borders, as these genetic resources are placed “in the border line” of competences of different national authorities (typically, ministry of environment vs. ministry of agriculture; central government vs. regional governments vs. local authorities) and international regimes (CBD vs. Treaty).

Concerns and anxieties created by the current ABS context have been expressed by corporations and researchers in a public consultation in November 2011 promoted by the European Commission on the Implementation and Ratification of the Nagoya Protocol on Access to Genetic Resources and Benefit-sharing arising out of their utilization.<sup>26</sup> Their main concerns relate to the multiplication of administrative procedures, red tape, lack of or not clear or not transparent standardized contracts and procedures; lack of or unclearly identified authorities, and difficulties to obtain PIC and comply with benefit-sharing demands. In particular, a common concern refers to which authorities have the responsibility to grant access and on what basis such authorities would undertake negotiation in order to establish

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- 25 S. Carrizosa *et al.*, *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementation of the Convention on Biological Diversity* (Gland, Switzerland, and Cambridge, United Kingdom: International Union for the Conservation of Nature, 2004); M. Halewood *et al.*, “Implementing “Mutually Supportive” Access and Benefit Sharing Mechanisms Under the Plant Treaty, Convention on Biological Diversity, and Nagoya Protocol,” *Law, Environment and Development Journal* 9/1 (2013): 64; P. Le Prestre, “The Convention on Biological Diversity: Negotiating the turn to effective implementation,” *Isuma: Canadian Journal of Policy Research* 3 (2002): 92–98; R.J. Lewis-Lettington and S. Mwanyiki, eds., *Case Studies on Access and Benefit-sharing* (Rome: International Plant Genetic Resources Institute, 2006).
- 26 Public Consultation on the Implementation and Ratification of the Nagoya Protocol on Access to genetic resources and Benefit Sharing arising out of their utilization (ABS), [http://ec.europa.eu/environment/consultations/abs\\_results\\_en.htm](http://ec.europa.eu/environment/consultations/abs_results_en.htm). The consultation was open from 24/10/2011 to 30/12/2011.



mutually agreed terms. Moreover, "...the rules may differ considerably from country to country which entails that every bilateral negotiation is a new journey to the unknown."<sup>27</sup> Also, negative impact of ABS regimes were perceived in terms of biodiversity conservation, since in some cases "access to genetic resources is no longer possible in a practical time, despite its potential positive impact on biological diversity conservation and sustainable use of resources even inside the European Union (EU)."<sup>28</sup> In general, respondents to the above public consultation felt that the administrative requirements might cost more time and resources to comply with rules that many small research centres and botanic gardens would have difficulties to spend. Different legislations and interpretations within the EU were also considered an additional cost and burden that should be avoided.

## II Methodology for the Survey on Collecting Germplasm in Europe

We developed a questionnaire and distributed it to European genebanks of ECPGR member countries in 2012, with the aim of obtaining information related to the current level of collecting activities, experiences or constraints encountered when collecting in different countries, and the existence and content of legal requirements currently enforced within their territories in relation to the collecting of *in situ* plant germplasm. The choice of respondents was made under the assumption that genebanks are primarily interested to maintain collections of diverse material and in many cases they are the ones organizing collecting missions. Thus, this is a coherent group of institutions that should be familiar with ABS and other legal requirements related to collecting within and/or outside of their respective countries. It is important to point out that by targeting European national genebanks the survey did not tap into the experience and opinions of a wider range of actors, who collect germplasm in Europe and whose knowledge and experiences are probably very different from those of national genebank curators, such as small breeding companies, botanical gardens and university departments.

The questionnaire was meant to inquire about:

- (1) Collecting priorities at the given genebank (reasons for collecting, focus on particular species; target area for collecting);

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27 Excerpt from the reply of Plantum (Dutch association for the plant reproduction material sector) to the EC consultation on the implementation of the Nagoya Protocol.

28 Excerpt from the reply of CIRAD (French research centre for agricultural development) to the EC consultation on the implementation of the Nagoya Protocol.

- (2) Genebank's collecting record/experience (number of missions carried out and number of requests from foreign countries to carry out collecting during the period 2007–2011; restrictions faced due to laws and regulations);
- (3) Procedures to obtain collecting permits in each country, based on relevant laws and regulations as well as on administrative written and non-written procedures and practices (specific laws or regulations, authority providing permits, requirements to obtain permission from local communities, rate of requests from abroad for collecting).

Our survey was accompanied by a literature and law review, which helped us design the survey itself and eventually shape the final discussion and recommendations.

The questionnaire was sent in March 2012 to curators of the main genebanks or collection holding institutes in 43 countries that are part of the ECPGR Network: Albania, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Lithuania, Former Yugoslav Republic (FYR) of Macedonia, Moldova, Montenegro, The Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and United Kingdom. Recipients of the questionnaire were invited to either respond themselves or to indicate the most appropriate authority that could take up this task in their country.

By the end of June 2012, we received a partial or complete reply from 36 countries. No responses were received from Croatia, Denmark, Iceland, Ireland, Moldova and Ukraine. The United Kingdom pointed us to an online "Summary of aspects of UK law touching on access and benefit-sharing."<sup>29</sup> The majority of the responses were compiled by germplasm collection curators and only in a few cases the officially designated ABS, CBD or Treaty focal points provided their own responses. The replies therefore reflect mostly the knowledge of the operators in the field, who were in some cases not very familiar with laws and procedures in their countries. In the analysis that follows we did not try to complement the replies with the information gathered through the law and literature reviews. This choice was

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29 DEFRA, *Access and Benefit Sharing. A Summary of Aspects of UK Law Touching on Access and Benefit Sharing* (London: Department for Environment Food and Rural Affairs, 2010), accessed February 20, 2015, <http://archive.defra.gov.uk/environment/biodiversity/geneticresources/documents/access-legal.pdf/>.

made in order not to distort the survey results with other sources of information. In any case, we realized that the most important or interesting issues in relation to laws and procedures were clearly raised by the survey respondents. All replies received from a given country were compiled and considered as “country replies.” The reader should therefore keep in mind that this is an “artificial approximation” that does not necessarily reflect an official country’s position.

In addition to the responses received to the questionnaires, a limited number of individuals were asked to describe their or their colleagues’ experience on the procedures followed and the experiences gained with respect to the legal requirements of collecting in one or more countries. These responses have been collated in two boxes.

### III Analysis of Survey Results

#### 1 *Collecting Priorities of European Countries and Targeted Geographical Areas*

The large majority of the genebanks indicated that germplasm collecting is an ongoing activity which is part of their institutional mandate. The main reason to organize collecting missions is to fill gaps in the existing collections with the purpose of conservation of wild or cultivated material that is threatened by genetic erosion and/or for targeted use in plant breeding programmes, as specified by 31 countries. Additional specific purposes were mentioned, such as documenting the distribution of crop wild relatives (Armenia, Azerbaijan, France, Greece and Romania), direct use for agriculture (Cyprus, Czech Republic, Greece and Hungary), pre-breeding (Armenia), taxonomic research (Belarus, France) and education (Norway).

The most quoted types of materials that were targeted by the collecting missions were landraces and crop wild relatives. Overall Europe, all types of crops were targeted, including in particular fruit crops, forages, cereals, legumes, and medicinal plants, but also small fruits, industrial crops, grapes, hops and spices. Most of the respondents focused their attention on PGRFA, but in a few cases the collecting of the local wild flora (Hungary, Israel) and of ornamentals (Norway and Sweden) were also quoted.

The majority of the collecting activities took place within national boundaries. A few countries expanded their collecting activity abroad, but generally this is limited to the neighbouring areas. For example, the Nordic and Baltic countries only focus their interest to the Nordic (Denmark, Finland, Iceland, Norway and Sweden) and Baltic (Estonia, Latvia and Lithuania) regions;

Hungary extends its collecting activity to the Pannonian Basin. Poland, Portugal, Romania and Slovenia organized missions to the neighbouring countries. Several missions were organized as multi-national joint missions by the members of the SEEDNet (South East European Development Network), focusing on Southeast Europe. A few countries holding germplasm collections with a wide geographical and multi-crop scope, organized distant missions with the purpose of completing diversity gaps in their collections of specific crops. For example, during the five years covered by the questionnaire, Bulgaria collected not only all over the Balkan area, but also in China; The Netherlands organized missions to Greece, the Caucasus and Central Asia; Germany collected in Armenia, Georgia, Iran, Jordan, Russia and Poland; Italy went to Georgia, Greece and African countries. Russia collected in the Republics of the former USSR (Union of the Soviet Socialist Republics), but also in Canada; Czech Republic and Slovakia organized missions to neighbouring areas, but also extended the collecting to the Balkans and to Russia, the Caucasus and Central Asia. Only a few countries indicated that they had no interest in organizing collecting missions (Austria and Switzerland) or a limited priority, depending on very specific interests (France) or only offering their availability to support occasional research missions (Lithuania). In the case of Norway, germplasm was gathered through public calls for old/rare materials.

## 2 *Extent of Collecting within Europe during 2007–2011*

Overall, according to the survey responses, more than 400 collecting missions were organized by the European countries during 2007–2011, of which about 30% were joint multi-national missions and about 10% were directed to non-European areas (Central Asia, Southwest Asia, China and North America). The most targeted area during the surveyed five years was Southeast Europe (over 100 missions in five years, also facilitated by the activities of SEEDNet), followed by the Caucasus (over 60 missions) and the Pannonian and Carpatian area (over 60 missions). Turkey was also intensely collected (about 45 missions organized by the national genebank). Significant activity also went on in Belarus (19 missions) and Russia (12 missions), as well as in the Iberian peninsula (20 missions) and Italy (9 missions). The Nordic and Baltic area is also known to have been extensively collected, although precise numbers were not received, except from Estonia (7 missions). The importance of collecting within the European territory is shown by the interest of institutions from outside of Europe that were involved. In particular, Japanese institutions have collected cereals in Armenia, US institutions collected wild cereals and orchard crops in the Caucasus, cereals, wild beet, medicinal plants and forage legumes in Greece and *Armoracia* in Romania; Australian institutions collected forage

legumes in Greece and Israel, Canadian institutions collected cereals, legumes, *Brassica*, forage legumes and *Linum* in Greece. The most attractive areas for foreign (either European or extra-European) collectors were the East-Southeast part of Europe, from the Carpatian area down to the Balkan Peninsula (for all types of crops), and the Caucasus area (mainly for wild cereals, fruit crops and vegetables such as asparagus, lettuce, spinach, etc.).

### 3 *Trends of Foreign Collecting Activity in Europe*

Our questionnaire asked about the average number of requests received from foreign institutions to organize collecting missions and whether this average over the last 5 years was known to be higher or lower than 15 years before. Armenia, Italy, Portugal, Romania and Turkey registered a diminishing trend, with the annual averages specifically dropping from 3–4 to 1–2 in Turkey, and from 2–3 to 1 in Italy. Armenia recorded a diminishing trend, but still showing a high average of 5–6 requests per year. An increasing trend was instead perceived in the case of Macedonia (FYR) (currently 6–8 requests per year), Azerbaijan (2–5 per year) and Cyprus (one per year). In other cases the number of requests either remained stationary or it was not known whether they had changed in time: Russia (3 per year); Albania (2–3 per year); Spain (one per year); Israel (less than 10 in five years); The Netherlands (less than 5 in five years); Montenegro and Czech Republic (one request in five years); Estonia (no applications since 2006).

### 4 *Rules and Procedures for Collecting Plant Genetic Resources in situ in Europe*

Few European countries have included in their legal frameworks provisions dealing unequivocally with access and benefit-sharing rights and obligations as established in the CBD and other international legal instruments in line with the CBD. In these few countries, ABS-related provisions are commonly very general ones, included in national laws and regulations that refer to nature and biodiversity protection (Bulgaria, Croatia, Portugal, Spain). Despite the absence of rules clearly described as ABS regulations, we cannot say that the access to genetic resources is a not regulated activity in most European countries. As described in depth in the first part of this volume, collecting plant germplasm from *in situ* conditions is subject to terms and conditions established by public law and administrative rules in most European countries.

Very few countries, like Finland, Germany, Latvia and Sweden, do not require a permit to collect plants in nature, as long as they are not protected species and that land ownership laws, habitat conservation and phytosanitary

requirements are observed. In Switzerland, this permissive approach is applied to collecting missions for research purposes, but not for those that have a final commercial aim.

A number of countries do not have any specific regulation spelling out the requirements to be fulfilled for collecting plant germplasm, but this activity is still subject to permission according to written or customary rules of various national administration bodies, which usually include the national genebanks or national research institutes. This is the case of Albania, Armenia, Czech Republic, France, Greece, Italy, Macedonia (FYR), Portugal and Spain. As several respondents to the survey pointed out, the involvement of the national genebanks and/or research institutes responds to the common practice that foreign institutions get in touch with them to collaborate in the organization of the collecting mission. This enables the collectors to get information about *in situ* and *ex situ* conservation of the target species and about the administrative processes that they need to follow, including those to get the phytosanitary permits. The national genebanks or research institutes receive, in turn, duplicate samples of the specimens collected, and related information. In this situation, it is common that the collector is requested to sign a framework agreement with the genebank or research institute.

a. Box 1: *Case study: Collecting wild Lonicera in the Far East, Russia*

**Reasons for the mission**

The Genebank Department of the Crop Research Institute (CRI) at Prague Ruzyně has a declared policy since the 90ties to increase the proportion of crop wild relatives (CWR) in its collections. At first the implementation of the policy consisted of an intensive collecting programme within the Czech Republic and its bordering/Central European countries, including Slovakia, Poland, Hungary, Austria and Slovenia. These collecting activities outside the Czech Republic were based on good personal contacts between genebank staff in the respective countries, especially the agro-botanically oriented members. Most missions were based on and financed by short bilateral projects, agreed upon by the Ministries of Education in the corresponding countries. In a similarly way a cooperation with Russia has been recently established. The N.I. Vavilov Institute of Plant Industry (VIR), St. Petersburg, organizes collecting missions for CWR and landraces to botanically rich regions in its territory. The Institute also organizes special expeditions on request of foreign scientists.

The historically very good contacts between CRI and VIR were renewed with an intention to submit a collaborative bilateral project. It was based on the old inter-governmental treaty on research and technical cooperation between the Ministry of Education of the Czech Republic and the Ministry of Research and Technical Policy of the Russian Federation (1995) and reworded to set out the conditions for transferring the germplasm.

### **Seeking compliance with legal framework**

Czech Republic is a party to the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture. Russia is a party to the Convention on Biological Diversity. The bilateral project with Russia additionally required preparing and signing a Memorandum of Understanding (MOU) between the directors of CRI Prague and VIR St. Petersburg. The MOU specifies the main activities of interests: Joint cooperative research projects; Exchange of plant germplasm and biotechnological products thereof; Cooperative enhancement and improvement of crop varieties; Joint evaluation and characterisation of plant germplasm and ecological tests; Exchange of researchers and technical specialists; Collecting plant genetic resources; Exchange of information; and Other cooperation specified by separate contracts. The MOU furthermore spells out that "Germplasm supplied by either party shall be the subject of a Material Transfer Agreement tendered as an attachment to this agreement, which shall govern all access to plant germplasm held in the possession to the parties, including utilization, improvement, regeneration, disposal and other operations with such germplasm." "Authorship, if any, of any cultivar, hybrid or biotechnology product bred or produced on the basis of plant germplasm belonging to either party shall be established and registered in accordance with the applicable international practice. The Parties agree not to release to any other party any improved plant varieties bred or selected, etc. without the express approval of that organization." In a separate Material Transfer Agreement, terms and conditions for providing germplasm are being established, including that "The Parties agree to make the plant germplasm held in their possession, available to each-other freely and without compensation", "Legal protection of any germplasm by intellectual property rights shall be consistent with applicable international and national laws and the provisions of the Convention on Biological Diversity" and "Germplasm materials shall be used for research and breeding purposes only. The recipient may reproduce the germplasm exclusively for long-term maintenance, characterization, scientific evaluation or testing." Therefore, this MOU followed the principles established by the CBD and specified activities expected to be done.

### Implementation of requirements and procedures

The project proposal written in English by Vojtech Holubec and Tamara Smekalova was submitted to the call for Czech – Russian joint programmes, to both Ministries. It was accepted by the joint Russian – Czech Commission, consisting of members of both Ministries, and a proposed methodology was agreed. All legal aspects of joint research and collecting of wild material and exchange of cultivated material were covered by the MOU and the MTA, and therefore there was no need of other agreements. After the project was accepted by the joint Commission, it was necessary to submit a full research project to get funding from the Ministry of Education in the Czech Republic. The call for bilateral projects with listed priority countries is “Kontakt II” and it included standard format from “the state of art up to deliverables.” For this project, other Czech partners were invited as collaborators: Research Institute for Pomology (RBIP) Holovousy and Silva Tarouca Research Institute for Ornamental Gardening and Landscaping (RIOG) Pruhonice. They were responsible for special tasks of propagation and *in vitro* cultures in order to safeguard valuable collected material. When this second step was agreed by the Czech Ministry of Education, all needs from the Czech side were fulfilled.

The next step was to process invitation and permits from the Russian side. It was necessary to get a special visa for foreign participants for the research exchange visits upon application made by VIR. For the collecting visit to the controlled area of Sakhalin and Kuriles it was necessary to get an invitation by the local institution and a permit from the Foreign Police (OVIR) and it was required to submit registration forms after arrival. Local guides in Sakhalin were organized by VIR through former members of the Far East VIR Department. For the collecting visit to Kamchatka there were no special requirements.

### Research and collecting programme

In some regions of Russia (North, Far East, Siberia) *Lonicera coerulea* and *Vaccinium* species are traditionally the main source of vitamins for the local population, also considering that the berries are early maturing and hardy to cope with the local severe climate. The project was titled “Taxonomic, evolutionary and phytochemical questions of *Lonicera kamtschatica/coerulea* complex as genetic resource for fruits.” It was devoted to research within the Far East distribution area (Kamchatka, Sakhalin and Kuriles), where only sweet honeysuckles are present. Interestingly, within the whole distribution area, including boreal Asia and America and extending into the mountains of Central Asia and Himalaya, the *Lonicera coerulea* berries are strongly bitter, with exceptions of



very rare mutations. Tamara Smekalova, VIR, St. Petersburg collated distribution locations from the literature and herbarium resources.

Three collecting missions to Sakhalin and Kamchatka were undertaken by the authors. Before the expeditions, small experiments with the vegetative propagation of honeysuckles were made in order to test various pre-transport treatments and propagation methods, including cuttings, grafting and *in vitro* methods. Expeditions were planned for the fruiting period of honeysuckles.

Six localities in Sakhalin and thirteen localities in Kamchatka were visited. Ecological conditions and vegetation (phytosociology) on each site were noted, the best and variable genotypes were selected, evaluated, fruits measured, cuttings and root sprouts collected, fruits collected for seeds and herbarium voucher specimens were taken. Tamara Smekalova was responsible for the herbarium specimens and Vojtech Holubec for collecting the plant material for cultivation. Collected plant material was divided between both parties and was taken to Czech and Russian germplasm collections for multiplication by cuttings, grafting and tissue culture. The combination of methods was used because transported cuttings had partly damaged leaves and it was not easy to raise plants. Multiplication was done in cooperating institutions RIOG Pruhonice (grafting and cutting) and RBIP Holovousy (*in vitro*).

Leaves from collected cuttings were used for genetic analysis (via Amplified Fragment Length Polymorphism), in CRI. Available fruits from cultivated ecotypes were analysed for qualitative traits. At the end of the project, morphological evaluation and genotyping of wild collected ecotypes and cultivated material is going to be used for taxonomical evaluation of the Far East *Lonicera coerulea* populations.

### Concluding remarks

The project was designed to visit three places in the Far East distribution area of the sweet fruiting *Lonicera coerulea* complex: North – Kamchatka, Central – Sakhalin and South – Kuril Islands. It was known that there is considerable difference of morphological types present in the north, often associated with the local type *L. kamtschatica*, compared to those present in the south, associated with *L. edulis*. Unfortunately, the visit to the Kuril Islands failed due to a bad meteorological situation and missing of local flights from Sakhalin. Apart from this not fully completed programme, it was possible to complete a wide range of scientific measurements and results, as well as to obtain a wide range of collected material. The work continues in the nurseries of CRI and VIR and in their laboratories. Results will be published jointly by both parties. Collected material contains promising ecotypes suitable for breeding and direct selecting as new

cultivars. To the authors' knowledge and experience, the three missions have been successfully implemented in full agreement with the concluded MOU and the current international agreements to which both parties are members.

*Vojtech Holubec*

*Gene Bank, Crop Research Institute, Prague Ruzyně, Czech Republic, Tamara Smekalova, VIR St. Petersburg, Russian Federation*

However, often this genebank or research institute is only one of the national entities in charge of processing the request for germplasm collection and granting or denying the collecting permit.<sup>30</sup> Sometimes, the genebank or research institute which is requested assistance and guidance in the first place is not even one of the national entities involved in processing the collecting permit. Usually, the request is considered and the permit issued by the Ministry of Environment (for example in the case of Albania, Armenia, Belarus, Estonia, Georgia, Hungary, Norway, Serbia and Slovakia), or the Ministry of Agriculture (Israel, Poland, Turkey), or both (Cyprus, Greece, Montenegro, Portugal, Spain). If the collecting is planned to take place in a protected area, like a national park or a special natural or genetic reserve, usually the written or customary rules require that the governing body of the protected area be also involved in the process. Some respondents pointed out that in their countries "national park" does not necessarily mean that the whole territory of the park is always owned or managed by public entities and that it is therefore necessary to obtain the permission of both the private and the public institutions that own and manage the national park territory or parts of it.

In countries with federated or semi-federated regimes like Italy, Germany, Spain, Sweden and Switzerland, the autonomous regions (*regione, Länder, comunidad autónoma, län, canton*) may have developed regional laws and procedures applicable to collecting activities and they may require the collector to get a permit from the bodies of these decentralized administrations. In some of these countries, like Switzerland and Sweden, the authority for processing and granting the permits falls entirely on the regional government structures, while in others, like Spain, permits from both the central and the regional governments may be required.<sup>31</sup> Our survey did not ask about the existence of a national focal point for collecting activities, but some of the respondents

<sup>30</sup> [For a comparative analysis of access conditions in Europe see contribution by Coolsaet to this volume (Conclusion).]

<sup>31</sup> [For a comparative analysis of the division of ABS-related competence in Europe see contribution by Coolsaet to this volume (Conclusion).]

recognized that such an office did not exist, or was not easily identifiable, in their countries.

### b. Box 2: *Case study: Collecting wild Brassica in Spain*

#### Reasons for the mission

As part of a study carried out by Bioversity International in collaboration with the Swedish University of Agricultural Sciences and the Nordic Genetic Resource Center, two colleagues from these organizations and I organized a collecting mission to collect wild *Brassica oleracea* ssp. *oleracea* growing on the rocky slopes of the Atlantic coast of Northern Spain, in July 2011. As the research project included population genetics and genetic diversity studies of several wild populations in Europe, the purpose of our mission was to collect fresh seed samples in the natural habitat of the subspecies for molecular analysis to be carried out at a laboratory in Denmark. It would have not been practical or meaningful in this case to request accessions from genebanks, considering that the selected analysis model required keeping the seed samples derived from each individual plant separate and that individual populations would be very carefully sampled. Moreover, our expedition also included the ambition to monitor the level of (potential) genetic erosion and to search for still unidentified populations, following up from previous collecting missions by Spanish scientists.<sup>32</sup>

#### Seeking compliance with legal framework

Spain is a Party to both the CBD and the Treaty.<sup>33</sup> The specimens we wanted to collect were in the wild, *i.e.* in their natural habitat or “*in situ*.” The International Treaty in its provisions related to facilitated access states that “...the Contracting Parties agree that access to plant genetic resources for food and agriculture found in *in situ* conditions will be provided according to national legislation or, in the absence of such legislation, in accordance with such standards as may be set by the Governing Body” (Article 12.3.(h)). Therefore, we realized that the

32 César Gómez-Campo, José L. Itziar Aguinagalde, Almudena Lázaro Ceresuela, Juan B. Martínez-Laborde, Mauricio Parra-Quijano, Ester Simonetti, Elena Torres, and María E. Tortosa. 2005. An Exploration of Wild *Brassica oleracea* L. Germplasm in Northern Spain. *Genetic Resources and Crop Evolution* 52:7–13

33 [For an in-depth overview of the ABS regime in Spain see contribution by Silvestri and Lago Candeira to this volume (Chapter 9).]

procedures to follow would depend on Spanish legislation on access to genetic resources, which we were not familiar with.

Rather than seeking advice from the CBD Spanish Focal Point, we decided to use a contact that was more familiar to us, *i.e.* the ECPGR National Coordinator who is based at the National Institute for Agricultural Research (INIA), Madrid. We got in touch with him by email in March 2011.

### Implementation of requirements and procedures

Thanks to Mr Fernando Latorre, the ECPGR National Coordinator, who was also a member of the Spanish delegation to the International Treaty, we learnt that according to Spanish legislation,<sup>34</sup> access to Spanish plant genetic resources in *in situ* conditions, *i.e.* natural areas, required that a permit to collect was sought from the Spanish autonomous regions in the territory of which the collecting would take place. After internal consultations within the Ministry of Environment and Agriculture (Agriculture and Biodiversity branches respectively) and INIA, the National Coordinator proposed a simplified process to speed up the paper work. Given the particular nature of this expedition (very small, academic and scientific), and being well-acquainted with the experts, the National Coordinator offered to act, exceptionally without a formal framework, as liaison person with the different authorities involved in the autonomous regions to seek the necessary permits.

We were therefore requested to meet the following obligations, in order to act in accordance with the CBD, the Treaty and national laws and their interpretations:

- Provide information on the exact itinerary (dates and locations of collecting sites) and target taxa, including the quantity of material that was expected to be collected;
- Leave a duplicate of the collected material in a genebank in Spain that maintains collections of those species;
- Explain the research to be carried out on the material by each of the scientists and the expected outputs/products of such research;
- Sign the SMTA of the International Treaty;
- Obtain any necessary permit and respect requirements provided by the authorities of the autonomous regions visited prior and during the collecting mission, respectively.

34 Ley 30/2006, de 26 de julio, de semillas y plantas de vivero y de recursos fitogenéticos; Ley 42/2007 del Patrimonio Natural y de la Biodiversidad.

Thanks to Mr Latorre, permissions from the Departments of Environment of the Governments of Asturias and Cantabria were obtained without difficulty, by means of a formal exchange of letters describing the material, precise locations and time scale of the mission. The Basque Country did not require a specific permit. Letters were sent, in Spanish language, respectively to the Dirección General de Montes y Conservación de la Naturaleza, Consejería de Ganadería, Pesca y Desarrollo Rural, Gobierno de Cantabria and to Consejería de Medio Ambiente, Ordenación del Territorio e Infraestructuras, Gobierno del Principado de Asturias. Hence, the collecting permits were received within one to four weeks, just in time before the start of the collecting mission. The authorization obtained included a partially standardized text referring to all the relevant laws, together with specific indication of the authorized time period, target taxon and locations, names of participants in the collecting mission, request to provide a report of the mission, and requirement to mention the collecting authorization in all publications derived from this mission. An additional request was made by the government of Cantabria, *i.e.* that the collectors should inform the authorities through a dedicated telephone number about the actual date and location of their visit. The obligation to make available the deposited seed to the competent authority of Asturias whenever requested was also added as a condition. The exploration was carried out without obstacles. Afterwards, we completed all the obligations only through INIA and were never contacted again by the regional authorities. In particular, we dispatched to the Centro Nacional de Recursos Fitogenéticos (CRF) of INIA Madrid a report of all the visited sites and information about the amount of seed collected, together with a duplicate sample of the seeds. By exchange of letters, we then signed an SMTA, including as an annex the list of collected samples. INIA then provided copies of the mission report to the regional authorities.

### Concluding remarks

This was a positive experience: we obtained collecting permits within a reasonable time, in compliance with international rules and national requirements. In this case, a combination of provisions from the CBD and the Treaty, as translated into domestic legislation, was applied. A constraint was that we did and could not know in advance how the entire procedure was going to be, we had to discover by doing it, which made us feel somewhat uncertain about the feasibility of carrying out the mission in the planned period. The fact that we personally knew the ECPGR National Coordinator for Spain, and also that we were familiar with general ABS principles in the CBD and the Treaty, allowed us to identify the entry points. Getting the permits would have not been possible without the

advice and help of the ECPGR National Coordinator, who was willing and available to liaise with regional authorities, up to the extent of translating letters from English to Spanish and personally making sure that the process would follow through. Had the focal point not been so dedicated to the specific case, it would have not been possible to complete the procedure of obtaining the permissions in the 4 months' time we had planned to obtain the papers for the mission. The existence of better standardized rules for obtaining permits at the national or ideally international level would have facilitated the task of the National Coordinator, the regional administrators and ours, as the collectors of PGRFA. However, we can affirm that INIA's exceptional flexibility in this particular case and the simplified process that they proposed accommodated our needs and the particular nature of our small collecting mission.

*Lorenzo Maggioni*

*Biodiversity International, Rome, Italy and Swedish University of Agricultural Sciences, Alnarp, Sweden*

Local authorities are the ones that issue the collecting permits in Germany and in Romania when the collecting takes place in a protected area (usually also with the managers of such area). In addition, a number of countries request that the collector obtains permission from the owner of the land where the target specimens are found: Estonia, France, Hungary, Latvia, The Netherlands, Poland, Russia, Serbia, Slovakia, Slovenia and United Kingdom. The respondent from Germany clarified that, generally, the owner of the land will be considered the owner of the biological resources found in his or her land. Therefore, in this country, access to plant genetic resources in private property is in general at the discretion of the owner. Possibly the land owner's permit is required in most European countries, based on land property law. Our survey did not ask about this aspect explicitly.<sup>35</sup>

When a collecting permit is required, these are the most common conditions that collectors must meet in order to obtain the permit:

- The collecting plans will be organized together with a national research institution and the collectors will be accompanied by one or more national scientists;

<sup>35</sup> [For a more in-depth overview of ABS-related property rules in Europe see contribution by Coolsaet to this volume (Conclusion).]

- National authorities will be present during the collecting (this is common when the collecting takes place in protected areas);
- The collector will have to demonstrate his/her knowledge or familiarity with the target species to be collected and with the methods of collecting;
- The collector will have to indicate the plans for the field mission (when and where exactly);
- The collector will have to indicate the varieties/populations and the amount of specimens to be collected;
- The collector will have to deposit or leave a duplicate of the specimens and related information at the national genebank or in a national institution within the country where the collecting takes place.

With only few exceptions, guidance on the national rules applied to *in situ* collecting of genetic resources cannot be found in English on the Internet. In the case of Germany, The Netherlands, United Kingdom and Switzerland, the procedures are not explained step by step, but the main rules are clearly presented in English on Internet.

When the collector plans to take the material to a country outside the EU, s/he will probably have to obtain a phytosanitary certificate issued by the plant health authority. This formal legal document certifies that the plants collected are free from quarantine pests and diseases. In some countries an import permit issued by the plant health authority of the destination country will also have to be obtained prior to the shipment of the collected material. Permissions by the custom services of the collecting country may be also needed if the specimens collected are of species included in the Convention on International Trade in Endangered Species of Fauna and Flora (CITES).

## 5 *Experiences of Limitations from Laws and Policies*

To the question asking whether policies and laws were affecting collecting activities within Europe, the respondent from The Netherlands confirmed the need to make an arrangement with the Greek government in case the collecting party wished to commercialize the products arising from the use of the resources (*i.e.* wild leek). The respondent from Poland testified that it had become more difficult in general to obtain the help of local Polish communities and the permission to take away the collected material.

The responses from the person from Czech Republic indicated that within the EU, simple bilateral agreements were sufficient and that a MOU was required to be signed with Russia, while Balkan countries and former USSR Republics had offered “insufficient collaboration.” A French respondent

admitted that the lack of clear rules and procedures in France were possibly a hindrance to foreign collecting missions in France. No specific restrictions or limitations were faced by respondents from Bulgaria, Czech Republic, Germany, Portugal, Romania, Slovakia and Slovenia.

Laws and procedures regulating plant germplasm collecting are therefore not seen as a major impediment by national genebanks. Instead, some of them pointed out that in those cases where a decrease of collecting activities had been observed, the main cause was the lack of financial resources.

## IV Discussion

### 1 *Discussion of the Results of the Survey*

The replies to the questionnaire have revealed that collecting germplasm in Europe is still a very significant activity, which is exercised by the vast majority of the European countries. Although the bulk of this activity was exercised by local institutions within their own national borders, at least 30% of the missions were organized as multi-national projects involving foreign collectors and thus cross-borders germplasm movements. Sub-regional collaboration in Eastern Europe was very frequent, with joint multi-national missions organized between neighbouring countries. The areas where requests from foreign collectors have diminished correspond to areas where national activity has been very intense, even though there is no proof of a cause and effect relationship among these two phenomena. Overall, it seems that joint missions and joint research projects constitute the majority of the collecting initiatives abroad. This practice is evidently the best way to go in order to more easily meet the legal and bureaucratic requirements, as it can be imagined that the partner in the country of collecting would take care of channelling the necessary paper work to the respective national authorities and facilitate obtainment of collecting permits (such as within the SEEDNet network). This is a possible interpretation of the minimal concern that was registered through our questionnaire for the increased regulation of this sector. The situation becomes less straightforward, but can still be effective, when collecting missions are organized to more distant countries, when the objectives of the mission are determined by the primary interest of the collector, such as in the case of The Netherlands collecting in Greece, Italy collecting in Spain (see Box 2), Czech Republic collecting in Russia (see Box 1).

As explained in the introduction, *in situ* plant genetic resources for food and agriculture, especially those growing in natural habitats (*i.e.* crop wild relatives), lie at the cross-section of the scopes of different international ABS



regimes (*i.e.* the CBD, the Nagoya Protocol and the International Treaty). In addition, European regional and national pre-existing laws, regulations and administrative practices influence and add complexity to the implementation of international conventions at the national level. One result of this situation is that the responsibility to monitor the collecting of plant genetic resources *in situ* usually falls under the competences of different ministries, usually those of agriculture and environment, which are often advised by specialized institutes, committees or councils. Furthermore, our study has shown that requests for permission to collect in European countries often involve also authorities at different levels of governance (national, regional, local). Moreover, in many, if not all countries, the collectors are requested to get the permit from the owner of the land where the plant samples are found. This introduces the additional difficulty of identifying who owns the land. Therefore there are very different rules for obtaining collecting permits across the European region, ranging from a very liberal approach (in Sweden, the “right of public access” grants the freedom of collecting plants and mushrooms in nature)<sup>36</sup> to rather restrictive conditions, with complicated and time-consuming procedures to follow, involving multiple authorities.

A clearly identifiable focal point providing guidance to the prospective collectors on the correct procedures to follow to obtain collecting permits is either lacking or not immediately evident in some countries. The fact that countries have designated CBD and ABS focal points and that their names have been made available on the CBD web site does not automatically mean that these individuals are knowledgeable and available to provide effective guidance to the prospective collectors. These focal points were often not mentioned nor consulted by the respondents of our survey, which suggests that even within the country there is no clarity on the responsibilities of different offices. Except for a few countries, equally lacking is the availability of published procedures.

Even though the procedural itinerary to organize collecting missions in Europe revealed to be far from being simple in many countries and it is not standardized across all of them, respondents to our questionnaire tended to imply that collectors commonly seem to know where to go to get information and help. As we pointed out before, it should be kept in mind that our survey was addressed to one particular group of professionals, *i.e.* national genebank curators, for whom collecting expeditions are facilitated by their formal or informal international networks and by their specific experience regarding collecting. In this way national genebank curators usually know or find the

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36 [Other Nordic countries have similar rules in place; see contributions to this volume by Koester (Chapter 2) and Tvedt (Chapter 7).]

right channels to overcome possible bureaucratic difficulties. The same experience might not be shared by other actors not included in our survey (research institutions other than the national genebanks, such as independent scientists, small breeding companies, botanic gardens, non-governmental organizations, etc.).

Most of the rules regulating access to *in situ* germplasm in Europe are not presented or designed explicitly as ABS rules. Only very few European countries have explicitly provided for national ABS legislation, *i.e.* Croatia, Bulgaria and Spain, but generally without detailed procedures being developed. Some countries are in the process of streamlining their ABS regimes, in order to ensure compatibility among existing legislation and international conventions to which they are parties. Whether existing or newly developed rules and legislation are in place, the emerging picture shows a complicated and uncertain patchwork across Europe, with some of the national regimes being comparable to the ABS regimes of other countries around the world, which have been described as complex and burdensome by public and private organizations and ABS experts. In some countries it has been concluded that no specific ABS legislation is needed as existing laws, including property and customary laws, are in place and would not require additional legislation (*e.g.* Germany, Latvia and Sweden). However, the absence of ABS rules may not necessarily lead to “facilitated collecting.” In fact, whether the complexity of some European countries’ rules is a consequence of the CBD legal framework is not totally evident, since in many cases the principal requirements for collectors do not pertain to strictly speaking ABS regimes applied to genetic resources, but rather to biodiversity protection, land property rights and phytosanitary requirements. Certainly the CBD-inspired measures have added more layers of complexity and the involvement of more public and private institutions to be considered before undertaking collecting missions.

## 2 *Possible Implications of the Nagoya Protocol and the EU Regulation on ABS on the Collecting of Plant Genetic Resources in Europe*

The adoption of the Nagoya Protocol and its imminent entry into force raises the expectation that more predictable conditions for access to genetic resources will be applied once the Protocol member countries start implementing it. Countries that are members to the Nagoya Protocol are not obliged to regulate the access to genetic resources within their territories, but if they require collectors to get prior informed consent and to negotiate mutually agreed terms, they must follow the terms and conditions set up by the Protocol. Its Article 3 says that:

...each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures (...), to: (a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements; (b) provide for fair and non-arbitrary rules and procedures (...); (c) provide information on how to apply for prior informed consent; (d) provide for a clear and transparent written decision by a competent authority in a cost-effective manner and within a reasonable period of time.

Therefore, countries' obligations to ensure legal certainty regarding access and benefit-sharing are very clearly and explicitly spelled out in the text of the Protocol. Furthermore, Article 8 on "Special Considerations" states that parties shall create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, including through simplified measures on access for non-commercial research purposes. It also says that parties shall consider the importance of genetic resources for food and agriculture and their special role for food security. These provisions demonstrate negotiators' awareness of the unnecessarily negative impact that long and complex ABS procedures can have on activities related to the collecting, conservation and research of genetic resources, and of the need to prevent this negative impact particularly on activities dealing with plant genetic resources for food and agriculture. We can then conclude that plant germplasm collecting in Europe should be favourably affected by the implementation of the Nagoya Protocol by European countries, as long as the mentioned articles effectively inspire national policies, laws and administrative procedures oriented to their efficient implementation.

The Nagoya Protocol entered into force in October 2014. The EU is a party to the protocol, but not all the EU countries have ratified it. Outside the EU, Albania, Belarus, Norway and Switzerland have become full members, while Armenia, Azerbaijan, Georgia, Iceland, Lebanon, Macedonia (FYR), Moldova, Montenegro, Russian Federation, Turkey and Ukraine have not ratified or not signed.

The EU Regulation on ABS was expected to facilitate EU countries' implementation and subsequent ratification of the Nagoya Protocol as well as influence other European countries' positions in relation to the Protocol and its domestication at the national level. The EU Regulation (No. 511/2014) was published on 16 April 2014. This Regulation focuses on measures that users of genetic resources need to adopt to ensure due diligence, and not on measures to facilitate access for collectors to genetic resources in Europe. The text addresses access issues only partially, based on

the recommendations arising from two impact studies commissioned to inform the discussions.<sup>37</sup> The studies concluded that there was no need for the Union to take binding Union-level measures on access and instead favoured the establishment of a discussion space to narrow the differences among countries that decided to regulate access to their genetic resources.<sup>38</sup> It is interesting to note that these studies were based on the analysis of the legal regimes of a limited number of EU countries.<sup>39</sup> Without questioning the final conclusions and recommendations of the studies, we have our reservations about their narrow approach, both in geographical terms and content-wise. As we have explained, many of the public rules governing the access to and the use of genetic resources in Europe are not listed as access and benefit-sharing laws. Unless one opens the scope of the analysis to other types of legislation, it is not possible to get a comprehensive idea of how things work in practice.

The most important reason for leaving access measures outside the EU Regulation is, however, of rather political nature: EU members' fears of the European Commission interfering in the exercise of their sovereign rights over genetic resources within their territories made them reject the initial proposal of the Commission to establish a EU platform for discussing access measures and sharing best practices among EU member states. The platform was one of the four possible options that the Commission considered and studied prior to submitting the draft for public consultations and discussions at the EU Council and Parliament, and it was selected by the Commission as the most appropriate one based on the conclusions of the studies mentioned above and also on the Commission's own awareness that a more rigid approach to access measures would cause a strong reaction among EU members. The other three options were:

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37 IEEP, Ecologic and GHK, *Study to analyze legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union* (Brussels/London, 2012); EC, *Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*, Commission Staff Working Document SWD (2012) 292 Final.

38 EC, *Impact Assessment Accompanying the Proposal for a Regulation*.

39 Belgium, Bulgaria, France, Germany, The Netherlands, Poland, Spain and United Kingdom. As the authors of the studies point out, "(...) the country studies have been conducted in the second half of 2011 and have not been updated since then. Therefore the country studies may not take into account recent legislative and policy developments in the countries studied." IEEP, Ecologic and GHK, *legal and economic aspects*.

- (a) no EU-level action on access measures;
- (b) the EU sets minimum standards for those member states that choose to opt for requiring PIC and MAT; and
- (c) the EU sets up minimum standards for PIC and MAT in order to achieve a harmonised access system throughout the member states.

According to the studies requested by the EU Commission, option (b) was the one that would have offered the most apparent benefits for sectors dealing with genetic resources within Europe, in particular *ex situ* collections and small seed breeding companies. However, in the end, the agreed text of the Regulation reflects EU member states' strong political preference for option (a). In fact, Article 2.3 of the Regulation clarifies that

This Regulation is without prejudice to Member States rules on access to genetic resources over which they exercise sovereign rights within the scope of Article 15 of the Convention on Biological Diversity (...)

In consequence, the Regulation does no longer provide for a space to attempt the simplification and standardization of rules applied to plant germplasm collecting in and across EU countries in the context of the implementation of the Nagoya Protocol.

Therefore, the standardization efforts at the EU level only focus on the obligations that genetic resource users must observe. The Regulation seeks to prevent the utilization of genetic resources that were not accessed in accordance with national ABS legislations and to improve the conditions for legal certainty in connection with the utilization of genetic resources. Article 4 (Obligation of Users) is probably the provision that will have a greater impact on collectors' activities in EU countries. This Article is inspired by Article 17 of the Nagoya Protocol, which spells out countries' obligation to monitor the utilization of genetic resources. Article 4 of the Regulation requires that users of genetic resources are able to demonstrate

...that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.

In order to do this, users shall seek, keep and transfer to subsequent users an internationally recognized certificate of compliance or information and documents that show the source of the genetic resources and that they were acquired in accordance with national legislations on ABS. Collectors will therefore, in the first place, have to be certain about the existence or not of national ABS laws and then make sure that they get the necessary documentation to show that they have followed the required ABS procedures, or that no procedure was requested by national authorities. In order to show compliance with national rules, collectors will largely depend on the national authorities that issue agreements and permits for the collecting. As a practical example, we can use the experience described in Box 2 of this paper and evaluate to what extent the procedures followed in that case and the documents obtained from national and regional administrations would satisfy the Regulation's requirements under Article 4.

*Brassica oleracea* and its wild relatives are included in Annex I of the Treaty. Therefore, the access to genetic resources of *Brassica oleracea* which are in the public domain and under the management and control of governments of EU countries falls outside of the scope of the Nagoya Protocol and the EU Regulation, and is regulated by the multilateral system of access and benefit-sharing of the Treaty. Access to *in situ* samples of Annex I crops is, according to the Treaty, subject to national legislation in the first place, which, in the case of Spain, refers to regional governments for the collecting of specimens in nature. In the case we are looking at here, the permits issued by the Spanish regional governments of Asturias and Cantabria included a clear explanation of rights and obligations related to the access to the target species, but did not indicate any obligation related to benefit-sharing. Moreover, the Basque Country did not express the need to prepare and release a formal permit. This situation could create difficulties for the collectors at the time of showing the following aspects required by Article 4 of the EU Regulation: (iv) the presence or absence of rights and obligations related to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialization; and (vi) mutually agreed terms, including benefit-sharing arrangements, where applicable. However, the decision made in 2011 by the Spanish national authorities to sign a Standard Material Transfer Agreement under the Treaty's multilateral system between the collectors and INIA for the transfer of the samples of *Brassica oleracea* allows the collectors to demonstrate the "due diligence" requested by the EU Regulation and the Nagoya Protocol. Had the Spanish national authorities limited the requirements to the obtainment of access permits from the regional governments, without signature of an "umbrella" SMTA, the collecting team would have remained in an uncertain situation in relation

to their ABS obligations. They could have found themselves in a paradoxical situation where, albeit having followed all the required procedures, they would not have sufficient information to prove the legality of access, if requested by a further user of the resources, a national competent authority, a provider of research funds or a collection included in the “register of collections” to be created by the EU Regulation and maintained by the EU Commission.

This example shows that with the EU Regulation on ABS, collectors in Europe will probably have to more intensively seek not only compliance with ABS rules but also the evidence of having complied. In the current situation, which we have described in earlier sections of this chapter, this task can be very challenging when procedures involve different ministries and levels of governance, and even more when rules are not openly spelled out or responsibilities are not clearly assigned to particular organizations.

Another issue that can create further difficulties for collectors in Europe refers to the laws, regulations and administrative procedures that are not strictly about ABS, but regulate the collecting of plant germplasm. Will collectors have to show due diligence in relation to these laws, regulations and administrative procedures? In European countries where the granting of a collecting permit is subject to laws and regulations on nature and species protection, land property and other matters, can and should the collecting permit be considered “prior informed consent?” If the answer is yes, what are the practical implications of this for both collectors and public and private organizations in charge of granting the collecting permits, including the owners of the land where the resources are found? Our reading of the Nagoya Protocol text and our common sense tell us that the implementation of the monitoring provisions of the Protocol and the EU Regulation on ABS should be limited to the national laws and regulations through which contracting parties have clearly demonstrated their intentions to regulate the access to genetic resources in the sense of the CBD and the Nagoya Protocol. Laws, regulations and administrative procedures which do not deal with ABS strictly should be left outside the monitoring mechanisms that countries will put in place for the implementation of the Nagoya Protocol, starting with the EU Regulation. Going back to the collecting of *Brassica oleracea* in Spain in 2011, the procedures and permits issued by the regional governments seem to respond to the regions’ objectives in relation to nature conservation in general rather than to an intention to regulate the access to their genetic resources for the purposes of monitoring their utilization and ensuring the sharing of the benefits arising from their use. In fact, we cannot say that mutually agreed terms were adopted by the collectors and the regional authorities in this case. For this reason, we think that both the regulations under which these permits were issued and the permits

themselves should remain outside the monitoring efforts under the Nagoya Protocol and the EU Regulation. INIA's request to sign an SMTA with the collectors was the only clear manifestation of the national intention to regulate the access to Spanish genetic resources and the sharing of the benefits arising from their use.

Finally, let us consider the cases where the national legislation does not require fulfilling any formal obligation. We are referring for example to Sweden, where freedom of collecting plants and mushrooms in nature is granted, provided they are not threatened or protected by law; or to Germany, where, in general, the only obligation is to receive the permission from the (private) owner of the land.<sup>40</sup> These cases can be considered the most favourable scenarios for the collector, from the point of view of minimum bureaucracy. We wonder if with the Nagoya Protocol and the EU Regulation this level of liberalism might backfire against the collectors, who might be left without sufficient means to certify their compliance and due diligence. In general, one could ask about the implications of Article 4 of the EU Regulation and Article 17 of the Nagoya Protocol for European countries which do not want to require prior informed consent and mutually agreed terms. They may be forced to adopt some administrative measures for genetic resource users to be able to show that the original collectors of the resources did not breach any ABS rule. The open attitude of some European countries in relation to collecting activities within their territories is at risk of not being sustainable in the post-Nagoya scenario.

## V Recommendations

The practice of collecting plant genetic resources within and across countries for the purpose of conservation and use in research, breeding and training remains a critical activity to safeguard these resources and is beneficial to food security and progress in science and agriculture in general. In the sections above, we have presented and analysed current and potential difficulties for collecting plant germplasm *in situ* in Europe. These difficulties are the result of the combination of international rules on access and benefit-sharing with pre-existing national laws and administrative procedures that both add complexity and influence the way international conventions are implemented. In this section, we would like to offer some ideas about how the objective of providing facilitated access to plant genetic resources, which is embraced by the CBD,

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40 [For an overview of ABS regulation in Germany see the contribution by Rodríguez, Dross and Holm-Mueller to this volume (Chapter 4).]



the Treaty and the Nagoya Protocol, can be effectively achieved in European countries.

Our first recommendation is that those European countries that decide to request prior informed consent and mutually agreed terms stick to the principles behind Article 3 of the Nagoya Protocol, which calls for certain and easy procedures. We also encourage European countries to put in place the necessary mechanisms to effectively implement the Treaty's multilateral system of access and benefit-sharing. Even if the implementation of this system has proven to be challenging, it represents a huge step forward in facilitating the access to plant genetic resources for breeding, research and conservation purposes and the sharing of the benefits arising from its use. For the transfer of *in situ* genetic resources that are included in the Treaty's multilateral system, we recommend that European countries use the standard material transfer agreement designed to facilitate and regulate the access to material within such system. Besides definitively clarifying the access rules to be applied to multilateral system material found *in situ*, the prescribed use of the SMTA for such material would allow providers, collectors and further users in Europe to certify compliance with national ABS requirements under the Nagoya Protocol and the EU Regulation on ABS. Those countries which do not regulate the access to genetic resources that are not otherwise protected should find an alternative solution to waive the collectors from the burden of proving compliance.

Plant collecting missions would greatly benefit if European countries adopted harmonized approaches to monitor plant collecting, within and beyond the ABS sphere. The EU Regulation evidences that the European Commission is not perceived by the member countries as the appropriate forum to share their experiences. European countries within and outside the EU could consider other fora or organizations which could possibly host technical and intergovernmental dialogues oriented to identify best practices and eventually develop standards for facilitating and monitoring plant collecting in Europe. An international dialogue on plant collecting rules should be relatively easy to put in place in Europe, where inter-country connections for technical and policy work on plant genetic resources are already very strong. The Europe Regional Group within the Treaty could provide the necessary platform for such dialogue, and the ECPGR could back up the activities of the platform with technical advice. Such an initiative would be particularly useful once European countries ratify the Nagoya Protocol and once the Protocol enters into force, as the users' obligations under the Protocol will most likely increase the pressure on European national authorities to provide clear evidences of collectors' compliance with national ABS rules or with the legality of collecting activities in the absence of such rules.

In addition to these general recommendations, we can suggest two very concrete and practical measures that would improve the current situation considerably, without requiring countries to make big changes in their approaches to ABS and their collecting rules:

- In the majority of European countries, competences and responsibilities of authorities within countries could be more clearly defined and communicated through dedicated web sites;
- Considering that, in most cases, competences will remain distributed among different authorities within each country, it would be ideal if each country could establish one single entry point (contact point), who could guide and help the prospective collectors of PGRFA to meet all the requirements within a reasonable time frame.

# Conclusion. Comparing Access and Benefit-Sharing in Europe

*Brendan Coolsaet*

The concept of access and benefit-sharing (ABS) grew out of the emergence of the global governance of genetic resources during the second half of the twentieth century. The evolution of environmental ethics, of international environmental law, of North–South relations, and of international cooperation for scientific research all nourished an international regime, which eventually led to the Nagoya Protocol. The Protocol thus is the product of a series of international legal doctrines, as exposed in the introduction of this book. Likewise, the implementation of the Protocol will need to build on a series of existing legal principles and rules, which are currently governing issues related to access and benefit-sharing. As illustrated throughout the chapters in the first part of the book, these issues are numerous and differ from country to country, including *inter alia* property regimes, market regulation and access, industrial policy, health, international development, legislation related to environmental matters and nature conservation, agriculture, research & development, traditional knowledge, administrative laws, and private international law. In addition, the implementation will have to complement and/or further a plethora of quasi-legal instruments, best practices and private standards, all of which may or may not have been designed with ABS or the Nagoya Protocol in mind. Finally, European ABS instruments will also converge at the European level, where an EU-harmonised approach on compliance measures for users from the Nagoya Protocol was adopted in April 2014.<sup>1</sup> The story of the Nagoya Protocol thus can be said to be one of legal confluence: born out of a union of legal doctrines, it gathers a large range of legal fields extending far beyond environmental law only, and combines (or will need to combine) existing legal regimes, numerous actors, both public and private, and a multitude of policy and private initiatives.

The confluence of these different streams into a functional ABS regime is of paramount importance for the EU, in particular for its biotechnology sector and its non-commercial biodiversity research sectors. Although being only

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<sup>1</sup> Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

second to North America in terms of pharmaceutical sales,<sup>2</sup> Europe dominates the world pharmaceutical manufacturing sector. For instance, 11 EU countries and Switzerland together account for over 70% of the world exports of medicinal and pharmaceutical products, and medicaments.<sup>3</sup> About half of the world largest cosmetics companies are located in Western-Europe,<sup>4</sup> the largest by sales being France-based l'Oreal with 22.5 billion euros of sales in 2012. Moreover, through its extensive *ex situ* network of botanical gardens, culture collections and gene banks, Europe hosts a considerable amount of the world genetic material, be it endemic or non-endemic. Together with Switzerland and Norway, the EU member states approximately host a quarter of all botanical gardens worldwide,<sup>5</sup> which keep over 50% of the world living plant accessions.<sup>6</sup> In more than 500 culture collections and gene banks, these countries also possess 30% of all cultures of microorganisms<sup>7</sup> and between 10 and 15% of the total accessions of germplasm for food and agriculture in the world.<sup>8</sup>

More specifically, while not necessarily mentioned in this book, numerous examples of European research and development activities involving genetic resources and traditional knowledge can be found in the literature. Among many others, examples include:

- The development of *Vernonia Galamensis*, the oil of which is used in plastic formation and coating, by the British company Vernique Biotech;<sup>9</sup>
- The development of new tomato genotypes through the European EU-SOL project, by the Dutch breeding companies Enza Zaden B.V. (higher-yielding

2 EFPIA, *The Pharmaceutical Industry in Figures* (European Federation of Pharmaceutical Industries and Associations, 2013).

3 Figures from UN Commodity Trade Statistics Database, *Medicinal and Pharmaceutical Products, Other than Medicament (SITC 541) and Medicaments (including veterinary medicaments) (SITC 542)* (New York, 2011), Available at <http://comtrade.un.org/>.

4 Chang Hoon Oh, Alan M. Rugman, "Regional Sales of Multinationals in the World Cosmetics Industry," *European Management Journal*, Volume 24 (2006): 163–173.

5 BGCI, Global Distribution of Botanic Gardens: <http://www.bgci.org/map.php>, accessed on 20 January 2014.

6 European Commission, *Impact Assessment Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*, SWD(2012) 292 final.

7 WFCC, World Data Center for Microorganisms: <http://www.wfcc.info/ccinfo/statistics/>, accessed on 20 January 2014.

8 Approximate figure based on FAO, *The Second Report on the State of the World's Plant Genetic Resources for Food and Agriculture and Accompanying Country Studies* (Rome: FAO, 2010).

9 R. Feyissa, "Farmers' Rights in Ethiopia. A Case Study," *FNI Report 7* (2006).

tomato plants) and Western Seeds International (seedless tomatoes), with tomato wild relatives from Ecuador and Peru;<sup>10</sup>

- The extraction of *Prunus Africana* bark in Cameroon by Plantecam, a subsidiary of the French company Groupe Fournier, to be sold in Europe as a treatment for benign prostatic hyperplasia;<sup>11</sup>
- The use of a Kenyan bacteria strain for the development of an “alpha glucosidase inhibitor,” a drug regulating absorption of glucose for type 2 diabetes patients, by Bayer (Germany);<sup>12</sup>
- The use of *Artemisia Judaica*, a Lybian medicinal plant, and its associated traditional knowledge for the treatment of diabetes by Phytopharm (UK);<sup>13</sup>
- The use of Moroccan argan tree (*Argania spinosa*) products in the cosmetics, skin and hair care industry, in particular by BASF (Germany) and l’Oreal (France);<sup>14</sup>
- Research on a new cancer treatment at the University of Bradford (UK), derived from a native British flower *Colchicum Autumnale*.<sup>15</sup>

This chapter takes stock of the regulatory contexts in which the above examples take place. It does so by comparing the provisions detailed in the country case studies of this book (chapters 1 to 10). Alongside the 8 selected EU countries, Norway and Turkey have been included in the comparative analysis. Readers are invited to consult the separate case studies for more in-depth analysis, as this chapter only provides a comparative summary of the case-studies.

As a conclusion to this book, this chapter then builds on the comparative analysis to discuss some of the future challenges and opportunities to implementing the Nagoya Protocol in the EU. It does so by discussing the provisions of the EU Regulation on ABS, in light of the input provided by the chapters of the second part of this book (chapters 11 to 14).

10 Edward Hammond, *Biopiracy Watch. A Compilation of Some Recent Cases* (Penang, Malaysia: Third World Network, 2013).

11 Charles Zerner, *People, Plants, and Justice: The Politics of Nature Conservation* (New York/ West Sussex: Columbia University Press, 2013).

12 Jay McGown, *Out of Africa: Mysteries of Access and Benefit Sharing* (Washington, USA: Edmonds Institute/ African Centre for Biosafety, 2006).

13 *Ibid.*

14 Daniel F. Robinson, *Biodiversity, Access and Benefit-sharing. Global Case Studies* (London/ New York: Routledge, 2015).

15 Battison, L., “British Flowers are the Source of a New Cancer Drug,” BBC News, Science & Environment, 12 September 2011; [See contribution by Smith to this volume (Chapter 8)].

## I Comparing ABS Regimes in Selected European Countries

While all EU member states and the Union itself are Party to the Convention on Biological Diversity, it must be acknowledged that, since the entry into force of the CBD, little was done to implement ABS obligations embedded in Articles 15 and 8(j) of the Convention. Specific regulation for the utilization of genetic resources and associated traditional knowledge is rather scarce, with important differences existing among countries.

This section compares the different regulations in place in selected European countries, according to the thematic division of the research questions described in the introduction of this book. Consecutively, this section summarizes and discusses provisions related to:

- (1) the legal status of genetic resources and traditional knowledge;
- (2) access to domestic genetic resources and traditional knowledge;
- (3) benefit-sharing mechanisms;
- (4) compliance mechanisms; and
- (5) the distribution of ABS-related competences.

### 1 *The Legal Status of Genetic Resources and Traditional Knowledge*

To determine the applicable rules for access and utilization of genetic resources and traditional knowledge, one needs to consider the current legal status of these resources and/or knowledge first. The legal status of genetic resources refers to the way these resources are covered by national and sub-national law, including property regimes, administrative law and legislation for the protection of natural areas and/or plant and animal species.

Although rarely explicitly specified, and although a distinction is being made by the CBD,<sup>16</sup> the ownership of genetic resources in our selected European countries is generally derived from the ownership of biological resources and/or land, which is defined either by the Constitution or the civil code.<sup>17</sup> This means that when genetic resources occur in *in situ* conditions and are not (indirectly) covered by specific legal rules (see below), landowners can manage their biological resources as they see fit, and reap the potential benefits arising from their use. In our subset of countries, only Norway (and potentially France in the near future) specifically indicates that genetic resources are

<sup>16</sup> Convention on Biological Diversity Article 2.

<sup>17</sup> CBD, "Report on the Legal Status of Genetic Resources in National Law. Including Property Law, where applicable, in a Selection of Countries," (2007) UN Doc UNEP/CBD/WG-ABS/5/1.

considered a common resource belonging to society as a whole, even if that does not preclude the application of (intellectual) property law and other relevant legislation. It should also be noted that citizens in most of our studied countries enjoy a constitutional right to a healthy and sustainable environment, in some form or the other. In Greece, for instance, the constitutional right to “the protection of the environment,” to “the development of the human personality,” and to “the protection of the value of the human being” extends to the protection and use of environmental goods such as wild flora and fauna, and biodiversity.<sup>18</sup>

In most countries, the ownership of land or of an organism extends to the fruits and the products generated by it. Once the fruit or the product is collected or extracted, thus becoming movable property, a different property regime may apply. As such, in our studied countries, immovable property extends to the essential components of a thing as long as they are united, attached and/or incorporated to it. Once collected, these products become movable property for which the buyer or recipient automatically obtains ownership over the exchanged good and its genetic resources. Likewise, plants kept in *ex situ* conditions for temporary purposes (*e.g.* nurseries for public selling) may be considered as movable property.

Some countries provide exceptions to these ownership rules for specific cases. As such, in Greece, for trees located at boundaries of immovable properties a separate ownership is established. In Norway, private ownership over biological material may end when this material stops being excludable. Tvedt<sup>19</sup> uses the example of an escaped farmed salmon, which, if not re-captured by its legitimate owner and not protected by IPR, can be used by anyone who finds it. These examples of special situations might serve as inspiration for the further regulation of the utilization of genetic resources accessed in “transboundary situations or for which it is not possible to grant or obtain prior informed consent.”<sup>20</sup> Independently of potential exceptions, all European countries dispose of a series of civil and/or criminal liability and redress options which may be suitable to address misappropriation of genetic resources (*e.g.* theft, concealment, breach of trust...).

While genetic resources can be considered biophysical entities, they also comprise an informational component (*i.e.* the genetic code, traditional knowledge, published data etc.). However, the above described property rules usually apply to genetic resources as biophysical goods, and the rules governing the

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18 See contribution by Maria and Limniou to this volume (Chapter 5).

19 See contribution by Tvedt to this volume (Chapter 7).

20 Nagoya Protocol Article 10.

ownership of associated information are rarely as clear and homogeneous. In some cases, authors have indicated that unless they are protected by exclusive rights (such as IPR), these informational components might constitute a *res communis*: “things owned by no one and subject to use by all.”<sup>21</sup> In such cases, the informational components may not be subject to existing liability and redress options for the enforcement of property rights, since they cannot be appropriated. However, some authors have argued that, under certain circumstances, property rights on a thing may encompass the associated informational components.<sup>22</sup>

Use rights over genetic resources and associated traditional knowledge may also be regulated through intellectual property rights. Different case studies in our book address this issue, with an unusual homogeneity. Broadly speaking, potential intellectual property rights applicable to genetic resources and traditional knowledge include patents, plant variety rights and geographical indications.

In all studied European countries, ownership and use of biological resources is limited in some way by nature conservation laws or by legislation on protected species, protected areas, forests and/or marine environments, some of which have a European origin. The level of protection can be contingent upon the type of resources, with several countries ranking their protected *fauna* and *flora* according to their protection level. In Greece and Turkey, additional distinctions are made between native and non-native species. This creates a lot of potential constraints which will need to be taken into account when establishing future ABS rules (see next sections). These limitations are not only reserved for protected areas in the strict sense of the word: in some regions, the use of natural resources found in “unprotected areas” is equally limited. In Flanders, Belgium, for instance, all acts that are not understood to include the normal maintenance of vegetation require a permit, including in commonly accessible green spaces such as parks and gardens.

As for the legal status of traditional knowledge, few of the studied countries have explicitly addressed the issue. There is currently no internationally-agreed definition of “traditional knowledge associated with genetic resources.” Moreover, some countries consider that traditional communities do not exist (anymore) or cannot be traced back, even though some (mainly agricultural) practices could be considered traditional knowledge. This has not kept some countries, like Spain, to define the concept of traditional knowledge, thereby attending to the definitional gap left by the CBD. France is the only country

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21 See for example contribution by Pitseys *et al.*, to this volume (Chapter 1).

22 See for example contribution by Koester to this volume (Chapter 2).



currently envisaging to specifically define both traditional knowledge associated with genetic resources and traditional communities. The latter, defined in the new draft Biodiversity Law in the broadest possible manner, are understood as being communities of inhabitants deriving their means of subsistence from the natural environment.

## 2 *Access to Domestic Genetic Resources and Traditional Knowledge*

The above described legal status of genetic resources and traditional knowledge in European countries has direct influence on the way these resources and knowledge can (or will) be accessed. When the legal status of genetic resources is derived from the ownership rules of the land or of an organism, the permission for collecting such resources needs to be agreed upon with the legal owner. However, access to and use of biological resources are generally the subject of a large body of existing rules, as defined by environmental, urban planning, nature conservation, forest, marine, water, agriculture and/or administrative laws. Access may also be regulated for certain types of (genetic) resources but not for others. This section therefore compares the different access provisions described in the country case-studies. While “access” and “use” here do not necessarily correspond to “access for utilization” as understood in the Nagoya Protocol,<sup>23</sup> they do cover acts which are likely to occur in the case of “access for utilization.” These include *inter alia* capturing, collecting, picking, cutting, uprooting, transferring, transplanting, transporting, purchasing, selling, exchanging and/or exporting the resources. Unless otherwise specified, the terms “access” and “use” in this section should thus be understood as referring to these acts and not to “access for utilization.”

Although most European countries have relatively low levels of biodiversity potential<sup>24</sup> and could therefore be more flexible on access to their domestic resources than biodiversity-rich countries, only the Netherlands and Denmark have implicitly or explicitly adopted a position of unrestrained access to their genetic resources. For access to unprotected biological and/or genetic resources, other countries and regions can be divided into three groups:

- Countries/regions having a restrictive approach towards access (*i.e.* strongly regulated access, with most acts requiring a permit/notification): *e.g.* Flanders (Belgium), France (draft Biodiversity Law), Greece, Turkey;

<sup>23</sup> Nagoya Protocol Article 2.

<sup>24</sup> See GEF, “Benefits index for biodiversity,” accessed March 2014, <http://data.worldbank.org/indicator/ER.BDV.TOTL.XQ>. See also contribution by Maggioni *et al.*, to this volume (Chapter 16).

- Countries/regions having an unrestrictive approach towards access (*i.e.* free access is allowed in non-protected areas and for non-protected species): *e.g.* Brussels (Belgium), France (current rules), Germany, Norway, the Netherlands;
- Countries/regions where access rules are undefined beyond the property law or other nature-related or administrative rules: *e.g.* Spain.

Through the “everyman’s right,” a right for the public to access privately owned land, Nordic countries provide a set of generalized exceptions to access biological resources found on private property. In Denmark, the “Danske Lov” includes a provision allowing for the collection of “nuts” by all, whether these are located on private ground or not. Nuts include biophysical entities containing units of heredity such as flowers, leaves, berries, fruits, fungi etc. In Norway, like in most other Nordic countries, the “*allemandsretten*” is a right of public access to privately owned land. While originally conceived for roaming, it also allows visitors to pick and collect biological material under certain conditions.

Access regulation in natural areas, whether protected or not, comes in all possible forms and flavors in Europe. This heterogeneity can lead to a complex maze of access and use rules across countries but also potentially within the same country. These may also be additional to the future requirements for “access for utilization.” The situation in Belgium is premonitory in this regard. As environmental management is a highly decentralized competence in the country, at least three different kinds of access rules for each category of biological resources (protected, cultivated, forest...) co-exist on its small territory. Each power level, moreover, provides its own set of specific exceptions to these access rules. Access rules can also be coupled with conditions of use, especially when related to genetic resources for food and agriculture. In Turkey, for instance, a technical committee regulates the amount of endemic seeds, bulbs or other parts of natural bulbous flowers that can be collected and imposes quotas for their production. Access restriction imposed by nature protection laws may also be limited in time, to prevent disturbance of breeding periods or in relation to hunting seasons. Whereas countries limit access to protect natural resources from a biological point of view, some also invoke cultural reasons for regulating access and thus see genetic resources as part of their national heritage.

Access for research, which is particularly relevant for ABS under the Protocol, is generally made possible through a multitude of exceptions in all studied countries. However, the way in which this is done varies considerably. While certain countries require a specific permit to be acquired for research-related

access, others simply impose a notification requirement. Some countries have tried differentiating access rules depending on the purpose of the research. Spain, for instance, specified different rules for commercial and non-commercial access, although authors in our case-study seem to be rather sceptical about the effectiveness of this distinction.<sup>25</sup> In Greece, different rules apply when the collected material is destined for export, as well as when the accessed material is a native landrace and/or a traditional variety.

In light of the above analysis, at the moment of this writing, none of the European countries, with the exception of Denmark, have currently regulated access to their genetic resources for utilization, as defined by the Nagoya Protocol. Nor have any of them introduced a formal PIC requirement for their domestic resources. Denmark has decided not to require PIC for its genetic resources, but is envisaging notification requirements for access to genetic resources of wild species. Norway and France are both on track to implement full-fledged Nagoya-compliant access legislation. The French Biodiversity Law contains different access-relevant aspects which are worth mentioning here, as they might inspire other countries. The French Biodiversity Law differentiates access rules by its stated purpose: non-commercial research and emergency situations only require notification to the competent authority, while other types of access require going through a specific access procedure. The Law also includes specific rules for access to traditional knowledge, whereby identification and consultation of the concerned communities, and the establishment of a benefit-sharing agreement with them, are mandatory steps in the access procedure. Finally, the Law envisages a broader temporal scope than the Nagoya Protocol, with the current proposal covering all new uses. In such a case, ABS provisions would be triggered for all new R&D activities not previously pursued by the same user, independently of how and when the original material was accessed.

### 3 *Benefit-Sharing Mechanisms*

While the role of Europe as a provider of genetic resources and/or traditional knowledge is a debatable matter, its position as a major user of global genetic resources is a settled fact. 20 years after the introduction of the CBD, the question arises as to whether European users share or have shared benefits for genetic resources and/or traditional knowledge they utilize. And if so, whether the benefit-sharing arrangements are regulated by applicable law in European countries, or by private mechanisms? This section takes stock of benefit-sharing arrangements which might have been concluded by users of our studied countries, as well as the regulatory contexts, if any.

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25 See contribution by Silvestri and Lago Candeira to this volume (Chapter 9).

A first example is the benefit-sharing arrangement concluded in 2005 between the Dutch company Healthand Performance Food International (HPFI) and the Ethiopian Institute of Biodiversity Conservation (IBC), mentioned by Visser *et al.*,<sup>26</sup> The agreement gave HPFI access to teff varieties in Ethiopia, and allowed the company to utilize them for the development and commercialization of food and beverages. Access to and use of associated traditional knowledge was prohibited. In exchange, both monetary and non-monetary benefits were agreed upon, including a lump sum of profits arising from use of tef genetic resources, royalties on the net profit of the sale of teff seeds, license fees, contributions to a local fund to improve living conditions of farmers and research related provisions such as cooperation and the sharing of results.<sup>27</sup> However, while considered an example of an ideal ABS agreement at the time, various problems including an over-estimation of potential benefits, a controversial patent claim, distrust between HPFI and IBC, irregularities in the management and the eventual bankruptcy of HPFI, and the lack of user-measures in the Netherlands led to the failure of the agreement.<sup>28</sup>

Another, more successful, example of benefit-sharing by a European user is the cooperation agreement concluded between the German Research Foundation and several Ecuadorian universities. This project is a clear example of non-monetary benefit-sharing, coupled with environmental objectives. The project included the establishment of joint graduate programs, funded post-graduate and PhD students, research facilities and equipment as well as broader structural benefits such as the improvement transport and energy systems.

However, examples of benefit-sharing arrangements are rare in our case studies. It is unclear whether the availability of such a small amount of agreements is due to potential confidentiality issues or to their non-existence. While the reasons behind the absence of such agreements are potentially numerous, the responsibility of the user countries mainly resides in their inability to fill the current legal vacuum surrounding the utilization of genetic-resources and the absence of binding benefit-sharing rules. As the European Commission itself acknowledges,<sup>29</sup> the lack of measures adopting ABS rules by user countries has led to the establishment of restrictive conditions for access

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26 See contribution by Visser *et al.*, to this volume (Chapter 6).

27 Sarah Laird and Rachel Wynberg, "Access and Benefit-sharing in Practice: Trends in Partnerships across Sectors," Technical Series No. 38 (Montreal: Secretariat of the Convention on Biological Diversity, 2008), 140 pages.

28 Regine Andersen and Tone Winge, "The Access and Benefit-sharing Agreement on teff Genetic Resources, Facts and Lessons," *FNI Report 6* (2012). Oslo, Norway.

29 European Commission, "Impact Assessment."

to genetic resources and/or traditional knowledge in provider countries. Failing to access global genetic resources would strongly affect the activities of a wide range of European economic and environmental stakeholders in the future, including botanic gardens, culture collections, gene banks, academic research institutions, biotechnology companies and the food and beverages industry.

Even when European countries have ABS-related instruments in place, these rarely include provisions that go beyond stating that benefit-sharing is a desirable objective to be achieved. Denmark, for instance, adopted an ABS Act titled “Act on Sharing of Benefits arising from the Utilization of Genetic Resources,” but it contains no provisions ensuring that benefits are truly shared with providers. Moreover, the Act excludes benefit-sharing for the utilization of traditional knowledge, as its definition for utilization does not encompass traditional knowledge.

Countries which regulate access to their own domestic genetic resources have not always established clear benefit-sharing rules either. In Greece, for instance, access to genetic resources is subject to a permit delivered by the competent national authorities, but these permits contain no benefit-sharing provisions, be it for utilization or trade of the resources. Likewise, the Norwegian Nature Diversity Act only includes the possibility to require benefit-sharing for the utilization of Norwegian genetic resources, without making it mandatory. This absence explains why the sharing of benefits for the exchange or the utilization of genetic resources currently tends to be self-regulated by the sector, for better or for worse.

#### 4 *Compliance Mechanisms*

Currently available compliance mechanisms appear as the weak spot of the ABS regimes throughout the studied European countries. The adoption of a common EU Regulation focusing mainly on user-measures is therefore a welcomed (and overdue) step in the right direction.

Some exceptions nonetheless exist. Denmark and Norway have both developed extensive user-measures, albeit with differing approaches. The import of genetic resources for utilisation in Norway from countries requiring access consent is only allowed in accordance with this consent. The country also has taken a strong position in favour of the enforcement of the conditions set out in such consents, by empowering the State to bring legal action on behalf of the provider. The Norwegian Nature Diversity Act further imposes a series of information requirements for users of genetic material, which bear some resemblance to the due diligence approach of the EU Regulation on ABS. Users have to keep information regarding the provider, the country of origin, and the access consent, if relevant. Unlike in Norway, which prohibits the *import* of

illegal material, Denmark prohibits the use of illegally acquired genetic resources and/or traditional knowledge. Illegal material, in this case, is material acquired “in contravention of the legislation on access to genetic resources of the country from which they originate.”<sup>30</sup> Interestingly enough, the choice of words in this citation may point to an expansive interpretation of Article 15 of the Nagoya Protocol. Indeed, unlike Article 15 which refers to the “regulatory requirements of the other Party” (*i.e.* the provider country), the Danish ABS Act refers to the alleged country of origin. Finally, both countries regulate the use of genetic resources originating from countries which have established ABS-relevant legislation or which are Parties to the Protocol. What position they adopt vis-à-vis non-Parties to the Protocol remains unclear at this stage.

As indicated earlier, the main ABS-related implementation measure taken by European countries is the transposition of EU Directive 98/44/EC, the European Biotechnology Directive. In its recital 27, the Directive calls for the inclusion of information on the country of origin in patent application using biological resources. As a direct consequence of the adoption of this Directive, Belgium, Denmark, Germany and Norway have introduced a disclosure requirement in their respective patent systems, requiring the patent application using biological material to indicate the country of origin, if known. Norway also requires the application to mention whether Prior Informed Consent was required by the country of origin, and has extended both requirements to apply to applications for Plant Variety Protection. However, non-compliance with this disclosure requirement is unlikely to be sanctioned, as the opportunity is generally provided to circumvent the requirement by declaring the country of origin to be unknown. It should also be noted that, although extensively discussed and then finally dropped in the negotiations, the information disclosure is not included in the Protocol. Nonetheless, for countries that do have the requirement in place, it may be used as an easily implementable and low-cost element of a broader Nagoya-compliant monitoring system.

The absence of user-compliance measures has not kept some users of genetic resources and traditional knowledge to take the lead in establishing self-regulated compliance measures. In Belgium, the Belgian Coordinated Collection of Micro-organisms (BCCM) uses a voluntary code of conduct and a standardized Material Transfer Agreement (MTA). Both these instruments are kept in line with the CBD, the TRIPS Agreement and other applicable national and international laws. To access resources held by the BCCM, users

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30 Danish ABS Act, Sections 3 and 4. For an in-depth overview of the Danish ABS Act see contribution by Koester to this volume (Chapter 2).

have to obtain consent and agree on the terms of use with the rightful owners, prior to starting using the resources.<sup>31</sup>

In numerous European countries, botanical gardens have joined the International Plant Exchange Network (IPEN), a network of botanic gardens that organizes the exchange of living plant specimens. IPEN's members have adopted a code of conduct regarding access to genetic resources and benefit-sharing. In line with the code, the gardens only accept plant material that has been acquired in accordance with the provisions of the CBD. Material can only be supplied on the same terms under which it was acquired, unless an "agreement on the supply of living plant material for non-commercial purposes leaving the International Plant Exchange Network" is signed by authorized staff. Some private biotechnology companies also provide bioprospecting guidelines, such as BIO, the world's largest biotechnology association, and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).<sup>32</sup>

### 5 *The Distribution of ABS-Related Competences in European Countries*

It can be argued that recent evolutions in international environmental law have reinforced the national enclosure of natural commons governed by state sovereignty.<sup>33</sup> However, the implementation of access and benefit-sharing in Europe has largely taken the shape of a strongly decentralized approach.<sup>34</sup> Power and competences are distributed on a territorial scale, allowing for national, sub-national and local power-levels to co-govern genetic resources and traditional knowledge. This power is also shared between public and private actors, with the transnational exchange of genetic resources being generally self-regulated by private actors, and with the ambition of strengthening the rights of indigenous and local communities to determine the terms of access to their traditional knowledge. Moreover, alongside this vertical division of powers, there is also a horizontal division: ABS encompasses a large range of issues extending far beyond sole environmental matters, including market regulation and access, international trade, industrial policy, agriculture, health, development cooperation, research &

31 See contribution by Pitseys *et al.*, to this volume (Chapter 1).

32 For more examples see contribution by Oliva to this volume (Chapter 12).

33 Peter H. Sand, "Sovereignty Bounded: Public Trusteeship for Common Pool Resources?" *Global Environmental Politics* 4(2004): 47–71.

34 Coolsaet, Brendan; Dedeurwaerdere, Tom; Pitseys, John. 2013. "The Challenges for Implementing the Nagoya Protocol in a Multi-Level Governance Context: Lessons from the Belgian Case." *Resources* 2, no. 4: 555–580.

development and innovation. This section compares the different institutional contexts of European Member States, in which the Nagoya Protocol will be implemented.

Two of our case studies are *de jure* federal states: Belgium and Germany. In both these countries, the implementation of the Nagoya Protocol will fall under the competences of both the federal and federated entities (in Belgium: Regions and/or Communities; in Germany: Länder). Nonetheless, the division of ABS-related competences is different. In Germany, both the federal Government and the Länder possess concurrent nature conservation acts, which regulate access to and use of natural resources. In Belgium, the Regions have full competences on overall environmental policy, with the exception of some matters that have been reserved for the federal government and residual matters. Flowing from this, the positions both countries take with regard to the competent national authority (CNA) under the Nagoya Protocol also differs. Rodríguez and Holm-Mueller<sup>35</sup> assume that Germany will establish a single CNA, while the Belgian authorities rather envisage four different authorities, albeit possibly with a common access point for users.<sup>36</sup> Moreover, Belgium, unlike Germany, has an additional layer of competences held by the language Communities: the Flemish Community, the German speaking Community and the Wallonia-Brussels Federation. These Communities possess competences on fundamental research and higher education in Belgium, as well as the regulation of researchers' funding and the management of research institutions, all key aspects of ABS. This is further complexified by the fact that the Regions and the federal government stay competent for research matters related to the exercise of their own competences.

Most of the others studied countries are unitary states, with more or less devolution to some sub-national entities. Spain forms a special case, and could be seen as a *de facto* federal state when it comes to environmental protection. While the Spanish Constitution grants exclusive competence on environmental protection to the national Government, this is increasingly being challenged by the Autonomous Communities of the country. As such, in 2004, these Communities were devolved full competence over the management of National Parks found on their territories. The specific implementation of ABS and the choice of introducing PIC and MAT in Spain, however, have to be taken through a Royal Decree, which can only be enacted by the national Government.

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35 See contribution by Rodríguez, Dross, and Holm-Mueller to this volume (Chapter 4).

36 Coolsaet Brendan, Dedeurwaerdere Tom, Pitseys John, and Batur Fulya (2013), Study for the implementation in Belgium of the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity. Final Report, 21st of March 2013.



In all our studied countries, a strong horizontal division of competences can be observed. ABS-relevant competences are distributed among many different relevant administrative sectors, which do not necessarily coincide across countries. In Greece, the management of access to biological material for research purposes, for instance, is different depending on the subject of the research. Hence, the competent authority in charge of granting permits might be different from one access to the other, even when concerning the same resources. France also envisages having different competent authorities, but differentiates the procedures by the type of resources being accessed. According to the new Biodiversity Law, the Ministry of Agriculture, Agrifood, and Forestry, the Ministry of Ecology, Sustainable Development and Energy, and the Ministry of Social Services and Health will all be responsible in the near future for access to genetic resources under the Nagoya Protocol. In the Netherlands, it is the Ministry of Economic Affairs which co-ordinates the implementation of the Convention on Biological Diversity and the Nagoya Protocol. The Ministry also assumes the role of Competent National Authority on ABS. Turkey has recently split its potential competent national authorities on ABS, with the Ministry of Environment managing the country's protected areas and the Ministry of Forestry and Water Affairs hosting the national focal point to the CBD. A similar situation can be found in Norway, where the Ministry of the Environment ensures the function of national focal point on ABS, but shares responsibility of the management of a new ABS permit system with the Fisheries Ministry (hosted by the Ministry of Commerce).

Some of the EU Member States in our subset of countries encompass overseas territories, (some of which are not part of the EU) and have varying legal status, autonomy and potential ABS rules. The Danish Realm, for instance, consists of Denmark, the Faroe Islands and Greenland (the two latter are not part of the Danish membership to the European Union). The Constitution applies to all three parts of the Realm, but they have different approaches to implementing ABS. As indicated earlier, Denmark has chosen not to require PIC but adopted user legislation. Greenland has done the exact opposite (PIC, but no user legislation), while the Faroe Islands have no legislation whatsoever regarding ABS. France also has a considerable amount of overseas territories with diverging rules. These territories are divided into overseas departments and regions (DROM), on the one hand, and overseas collectivities and territories (COM), including Clipperton Island, the French Southern and Antarctic Lands and New Caledonia, on the other. The former are subject to French law and are part of the EU. They will thus be subject to the same legislative framework on ABS as metropolitan France (*i.e.* the EU Regulation on ABS and the French Biodiversity Law). The latter, with a whole set of possible exceptions, will not.

It should be noted that some (parts) of these overseas territories, both DROM and COM, already have local ABS regulation in place.<sup>37</sup>

## II The Future of ABS in Europe

### 1 *The EU Regulation on ABS*

On April 16, 2014, following an extensive dialogue with the European Commission and the European Parliament, the Council adopted “Regulation N° 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union” (hereafter, the “EU Regulation on ABS”).

As the title indicates, the EU Regulation focuses primarily on user-compliance measures. In the explanatory memorandum of its 2012 proposal for a regulation, the European Commission justifies this approach by stating that

[harmonizing user compliance] avoids negative effects on the internal market in nature-based products and services that would result from a fragmentation of user-compliance systems in the Member States and also has the best performance as regards the creation of an enabling context for research and development on genetic resources with benefits for the conservation and sustainable use of biological diversity worldwide.<sup>38</sup>

In doing so, the European Commission seems to consider the regulation as an instrument for the strengthening of the internal market and for the facilitation of R&D, thereby appearing at odds with its own claim of legislative competence on the basis of Article 192(1) of the Treaty on the Functioning of the European Union (the Union’s environment policy competence). This approach is further reinforced by the EU Regulation which, with the exception of its Article 13(2),<sup>39</sup> contains no provisions for conservation and sustainable use of

37 For an example of ABS regulations in place in a French overseas territory, see contribution by Karpe *et al.*, to this volume (Chapter 11).

38 European Commission, proposal for a regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, explanatory memorandum, p. 7 (COM(2012)0576-2012).

39 “The Commission and Member States shall, as appropriate, encourage users and providers to direct benefits from the utilisation of genetic resources towards the conservation of

biodiversity. However, this first step does not pre-empt the Commission to take additional legal measures for harmonization in later stages of implementation of the Protocol if this would be deemed appropriate and necessary.

The Regulation applies to genetic resources over which States exercise sovereign rights and to associated traditional knowledge that are accessed after the entry into force of the Nagoya Protocol.<sup>40</sup> It thus only considers claims within this narrow temporal scope, while the Protocol more generally, through its Article 3, applies to genetic resources within the scope of Article 15 of the Convention and to associated traditional knowledge within the scope of the CBD. In other words, the Regulation does not fill the legal vacuum surrounding the utilization of resources and knowledge acquired before the entry into force of the Protocol.

In this context, the main provision of the Regulation is its “obligations for users.”<sup>41</sup> It requires users to exercise “due-diligence,” with the aim of ensuring that genetic resources and associated traditional knowledge have been accessed and are being utilized in accordance with regulatory requirements and mutually agreed terms. Exercising due diligence has to be understood as seeking, keeping and transferring the “internationally recognized certificate of compliance” to subsequent users. The international certificate is an access permit delivered by the provider country, providing evidence that genetic resources have been accessed through prior informed consent and that mutually agreed terms have been established for their utilization.<sup>42</sup> In case such a certificate does not exist, the Regulation lists a series of information and relevant documents to be sought, kept and transferred by users, including the date and place of initial access, the description of the resources, the source of access and the previous users, the relevant ABS-related rules, the access permit and the mutually agreed terms.

With regard to monitoring of user compliance, the EU Regulation establishes two checkpoints: the reception of research funding and the “stage of final development” of a product before commercialisation.<sup>43</sup> The Regulation requires users to declare that they have fulfilled the user obligations and contacted the competent authorities to collect these declarations. It is important to note that the competent authorities referred to here are not the research

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biological diversity and the sustainable use of its components in accordance with the provisions of the Convention.”

40 EU Regulation on ABS, Article 2.

41 EU Regulation on ABS, Article 4.

42 EU Regulation on ABS, Article 3(11).

43 EU Regulation on ABS, Article 7. The stage of final development is described in Recital 25.

funding authorities or the market approval authorities, for instance, but the national competent ABS authorities under the Protocol, as described above. As these measures come on top of other administrative measures along the development chain, users may face a double administrative burden. In this book, Godt<sup>44</sup> argues this is a missed opportunity to adopt an integrative approach to ABS, whereby ABS measures are included within existing procedures along the development chain. Not only would this lower the administrative burden of both users and the state, it would also strongly improve transparency of the flow of genetic resources and/or traditional knowledge in the development of a product. Moreover, such an integrative approach would also help to avoid a scenario where due diligence is only monitored at a very advanced stage of the development chain (*e.g.* before commercialisation). Putting the burden of proof at the end of the development chain does not encourage early users (whose products never make it to the commercialization stage) to acquire genetic resources legally, increasing the legal uncertainty of end users.<sup>45</sup> Although only superficially addressing ABS measures, a limited example of such an integrative approach can be found in Belgium. Alongside the development of a self-standing biodiversity strategy, a plan of sectorial integration of biodiversity was adopted in 2010. The plan lists a number of actions to integrate biodiversity measures in existing policy sectors such as the economy, the development cooperation, the science policy and the transport sector.<sup>46</sup>

Following the wording of the Nagoya Protocol, the term “monitoring” is somewhat misleading here. The accuracy of these declarations is not checked by the competent authority. Monitoring has to be understood as keeping record of information related to the utilization of genetic resources and/or associated traditional knowledge.<sup>47</sup> Checks are however regulated by Article 9 of the Regulation. Competent authorities will verify user compliance when possessing information regarding user’s non-compliance, following a periodically reviewed plan, and/or through on on-the-spot checks. However, with the exception of the first scenario, competent authorities “will not know who utilizes genetic resources in the first place,”<sup>48</sup> given that no information transfer are established between relevant ABS and non-ABS authorities. This is a significant difference from existing due diligence processes in the EU, which

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44 See contribution by Godt to this volume (Chapter 13).

45 IEEP, Ecologic and GHK, *Study to Analyze Legal and Economic Aspects of Implementing the Nagoya Protocol on ABS in the European Union* (Brussels/London, 2012).

46 See contribution by Pitseys *et al.*, to this volume (Chapter 1).

47 EU Regulation on ABS, Article 7.

48 See contribution by Godt to this volume (Chapter 13).

include genuine monitoring and/or certification schemes.<sup>49</sup> In the regulation of timber, for instance, third-party monitoring organization are created to verify proper use of the due diligence system and to identify cases of non-compliance. These organizations can trace the use of timber product along the supply chain and keep illegally harvested timber from entering it.<sup>50</sup> With its focus on downstream use, the EU Regulation on ABS does not allow doing this for the utilization of genetic resources, nor does it envisage the creation of independent third-party verification.

The patenting stage of development as a possible checkpoint is notably absent in the Regulation, as it could have been an opportunity to extend the scope of EU Directive 98/44/EC on biotechnological inventions and make the disclosure requirement binding and compliant with the Nagoya Protocol. EU Directive 98/44/EC calls upon Member States to include information on the geographical origin of biological material used in patent application.<sup>51</sup> It would also have been consistent with the EU position at WIPO, where it initially supported binding disclosure requirements of the country of origin of genetic resources and associated traditional knowledge in patent applications.<sup>52</sup> The absence of the patent stage as a potential checkpoint is also problematic in light of recent research showing a steadily increasing trend of patent activity involving genetic resources and associated traditional knowledge.<sup>53</sup>

The issue of traditional knowledge associated with genetic resources is barely addressed in the Regulation. The Regulation does not attend to the definitional gap on traditional knowledge, but circumvents the issues by stating that traditional knowledge associated with genetic resources is to be defined in the mutually agreed terms. This approach is problematic for different reasons. First, the definition of TKaGR will depend upon the content of each individual

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49 See contributions by Oliva to this volume (Chapter 12).

50 *Ibid.*

51 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

52 See the letter dated 11 May 2005 by the Permanent Delegation of the European Commission to the International Organizations in Geneva addressed to WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO/GRTKF/IC/8/11). World Intellectual Property Organization: Geneva, Switzerland, 2005. Available online: [http://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_8/wipo\\_grtkf\\_ic\\_8\\_11.pdf](http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_8/wipo_grtkf_ic_8_11.pdf) (accessed on 15 June 2013).

53 Paul Oldham, Stephen Hall and Oscar Forero, "Biological Diversity in the Patent System," *PLoS ONE* 8(2013); Paul Oldham, Colin Barnes and Stephen Hall, "A Review of UK Patent Activity for Genetic Resources and associated Traditional Knowledge," *One World Analytics* (2013).

benefit-sharing agreement and will thus be different from one agreement to the other. Accessing the same traditional knowledge at different points in time, or through different providers, may thus possibly produce a changing definition, a solution which will hardly improve legal certainty. Yet, in its recitals, the Regulation nonetheless indicates that relying on such a dynamic approach allows ensuring flexibility and legal certainty for providers and users. Second, this approach *de facto* excludes traditional knowledge which has been accessed without a benefit-sharing agreement. This can be the case, for example, for “publicly available traditional knowledge,” which was acquired before the entry into force of the CBD and the Nagoya Protocol.<sup>54</sup> In other words, “[w]here there is no contract for access to traditional knowledge, [...] European law would therefore provide no protection against biopiracy.”<sup>55</sup>

This problem is further amplified by the fact that, at various occasions, the Regulation seems to envisage situations where the mutually agreed terms (or its provisions) related to genetic resources may be unnecessary or even “irrelevant.”<sup>56</sup> Examples are Article 4.2 and Article 5.3(c). The former indicates that genetic resources and traditional knowledge may only be utilized in accordance with MAT “if they are required by applicable legislation.”<sup>57</sup> The latter states that registered collections must provide genetic resources for their utilization only with evidence of lawful acquisition and, “where relevant, with mutually agreed terms.”<sup>58</sup> However, having regard to Article 5.1 of the Nagoya Protocol, for Parties to the Protocol, it is unclear under which circumstances mutually agreed terms would not be required or prove to be irrelevant. Unlike other provisions of the Protocol, Article 5.1 does not contain the usual debilitating qualifiers (*e.g.* “where applicable”) and thus constitutes a clear “obligation of means.”<sup>59</sup> Such a provision requires “the adoption of a particular course of conduct” (*i.e.* benefit-sharing upon MAT) which is “not characterized by its

54 Susette Biber-Klemm, Kate Davis, Laurent Gautier, and Sylvia I. Martinez, “Governance Options for ex-situ Collections in Academic Research,” in *Global Governance of Genetic Resources. Access and benefit sharing after the Nagoya Protocol*, edited by Sebastian Oberthür and G. Kristin Rosendal. New York and London: Routledge, 2014.

55 Brendan Tobin, “Biopiracy by Law: European Union Draft Law Threatens Indigenous Peoples’ Rights over their Traditional Knowledge and Genetic Resources,” *European Intellectual Property Review* 36 (2) (2014): 127.

56 EU Regulation on ABS Articles 4.2 and 5.3(c).

57 EU Regulation on ABS Article 4.2, emphasis added.

58 EU Regulation on ABS Article 5.3(c), emphasis added.

59 Pierre-Marie Dupuy, “Reviewing the Difficulties of Codification: On Ago’s Classification of Obligations of Means and Obligations of Result in Relation to State Responsibility,” *European Journal of International Law* 10 (1999): 371–385.

flexibility but, on the contrary, by the strict legal determination of its content.”<sup>60</sup> In other words, for the utilization of genetic resources accessed after the entry into force of the Protocol, benefit-sharing upon mutually agreed terms will *always* be relevant. This obligation is further reinforced by Article 5.3 of the Protocol, which stresses that “*each Party* shall take legislative, administrative or policy measures” to implement benefit-sharing upon MAT. Hence the obligation “extends not only to countries providing access to genetic resources but also to [Parties to the Protocol] where biodiversity-based research, development, and commercialization usually take place” (*i.e.* user countries).<sup>61</sup>

Finally, it is important to note that the Regulation does not encompass specific sanctions or penalties related to non-compliance with the obligations of users and the monitoring requirements. Both the initial proposal by the European Commission and the amended version by the Environmental Committee of the European Parliament included examples of penalties such as fines, suspension of utilization and confiscation of illegally acquired genetic resources,<sup>62</sup> but these were not sustained in the final version. The EU thus leaves the responsibility of sanctioning non-compliance to the Member-States. As in the Nagoya Protocol, it only calls upon Member States to establish “effective, proportionate and dissuasive” penalties applicable to infringements.<sup>63</sup>

## 2      *The Role of Non-State Actors*

Important responsibility is left by the EU Regulation on ABS to non-state actors, through self-regulation and voluntary provisions, especially on the provider side. As such, the Regulation aims to establish a list of registered *ex situ* collections which restrict “the supply of samples of genetic resources to third persons with documentation providing evidence of legal access.”<sup>64</sup> The objective of this measure is to reduce the risk of the utilization of illegally acquired genetic resources in the Union. Users accessing genetic resources from a registered collection will be considered to have exercised due diligence, a measure which is likely to lower the administrative burden. However, it is unlikely that all the collections will have the capacities (and/or funds) to joining the list.

60    *Ibid.*

61    Thomas Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing* (Gland, Switzerland: IUCN, 2012): 87.

62    See Article 11 of the initial proposal COM(2012) 576 and Amendments 62 and 63 in the Draft Report by the Committee on the Environment, Public Health and Food Safety on the proposal for a regulation, published on May 6, 2013.

63    EU Regulation on ABS Article 11. The Regulation does not define the terms “effective, proportionate and dissuasive.”

64    EU Regulation on ABS, recital (28).

Moreover, as stressed previously, the Regulation does not provide a solution for the utilization of the numerous resources acquired by European collections (which will potentially become registered collections) before the entry into force of the Protocol. Will a user be allowed to utilize pre-Nagoya resources provided by a collection? Will the acquisition of such resources from a registered collection be considered as exercising due diligence? What are the rules surrounding the utilization of genetic resources for which a registered collection has no information and relevant documents on PIC and MAT? And what happens with resources which have been accessed long before the entry into force of the CBD? All these questions remain unanswered with the Regulation, thereby creating legal uncertainty for users and collections alike.

Non-state actors are also solicited for the development of codes of conduct and best practices, as called for in Article 20 of the Nagoya Protocol. To this effect, the Regulation introduces the concept of “associations of users.” They represent the interests of users and are responsible for developing and overseeing best practices. These practices are defined as a combination of procedures, tools and/or mechanisms enabling users to comply with the EU Regulation, which are to be recognized by the European Commission. It is an opportunity to build upon practices which are already being used by European actors, especially by *ex situ* collections. Throughout the chapters of the book, authors have stressed the importance of existing instruments. In most of the studied countries, semi-public or private *ex situ* collections rely upon some form of standardization of contractual clauses and procedures for collecting, accessing and exchanging genetic resources, which are compliant with the provisions of the Protocol. Examples in this book include the International Plant Exchange Network (IPEN), the international Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC), the UK Royal Botanic Gardens (Kew) ABS Toolkit, and the MTA developed by the European Culture Collection Organisation (ECCO).

Officially recognizing these instruments as best practices will hopefully allow addressing the strong heterogeneity of uses and interests with the Nagoya Protocol among non-state actors. And voluntary norms have proved useful to improve, strengthen and complement existing procedures and public policy in other sustainability sectors such as pollution control, food quality monitoring, natural resources management and the reduction of carbon emissions.<sup>65</sup> However, questions remain as to how successful and effective voluntarily measures will be in the ABS context. Without an overarching institutionalisation of

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65 For a more in-depth overview of private norms in environmental governance see contribution by Oliva to this volume (Chapter 12).



the objectives to be met through the implementation of the Nagoya Protocol,<sup>66</sup> without at least agreeing on the underlying principles governing the responsibilities of the private actors,<sup>67</sup> and without an effective follow-up and monitoring system, voluntary measures may not be sufficient to generate convergence of the interests of the different actors involved in the transaction. Moreover, as noted by Maggioni *et al.*,<sup>68</sup> due to the scope of the EU Regulation on ABS, potential recognition of best practices under Regulation would only apply to the utilization activities of *ex situ* collections. Collecting mission and access procedures will be left to the discretion of member states, and are thus unlikely to be simplified and/or standardized any time soon, despite what the above mentioned initiatives have been trying to achieve.

### III Conclusions

In 2010, 17 years after the entry into force of the CBD, the Nagoya Protocol was adopted by the 10th Conference of the Parties to the CBD. The Protocol provides a long overdue legal framework to protect the sovereign rights of countries on their genetic resources and the rights of indigenous and local communities over their traditional knowledge, as instituted by the CBD. Between 1993 and 2010, some Parties to the CBD have established ABS-related rules in their legal systems. The EU, however, although being one of the major users of genetic resources and traditional knowledge in the world, was lagging behind.

With the adoption of the EU Regulation on ABS in 2014, and the decision to ratify the Nagoya Protocol, the EU has set a decisive step in the right direction towards taking its responsibility on ABS. This Regulation closes a chapter of the ABS saga, and starts a new one. As we have seen in this book, much remains to be done for Europe to have a functioning, effective and stable ABS regime. Tellingly, with the exception of Denmark, the most advanced ABS framework in Western-Europe addressed in this book, is found in a country which is not a EU member state (Norway). On user measures, as if they had been waiting for initiatives coming from the European Union, member states' action on ABS has been broadly limited to the transposition of the European Biotechnology

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66 Brendan Coolsaet, Tom Dedeurwaerdere and John Pitseys, "The Challenges for Implementing the Nagoya Protocol in a Multi-Level Governance Context: Lessons from the Belgian Case," *Resources* 2 (2013): 555–580.

67 Susette Biber-Klemm *et al.*, "Governance Options for ex-situ Collections in Academic Research."

68 See contribution by Maggioni *et al.*, to this volume (Chapter 14).

Directive.<sup>69</sup> On the access side, Denmark and the Netherlands are the only EU countries having specified the conditions for access to their genetic resources. While the EU has laid the groundwork for an EU-harmonized approach on (user-measures for) ABS, which is to be complemented with existing measures, this book illustrates that currently existing rules, both public and private, strongly differ in terms of depth, scope and effectiveness as well as across different types of users. Furthermore, we have seen that access and utilization of genetic material is already (directly or indirectly) regulated by private and public law provisions—if not by specific ABS laws. This is not to say that these existing rules are compliant with access and utilization under the Nagoya Protocol, nor that they will be sufficient for an effective implementation of the Protocol. These existing instruments will, however, impact or be impacted by a harmonization at EU level. This situation is further complicated by the plurality of political structures and the very broad division of competences within member states, as well as by their different interests with the Nagoya Protocol (user, provider or both).

Different legal processes are currently under way in Europe, and will give rise to national Nagoya-compliant ABS regimes. However, the minimal approach adopted by the EU Regulation already generates very different interpretations and implementation approaches in Europe. Moreover, as it stands today, the due diligence approach of the EU is lacking some basic features to guarantee its effectiveness. Examples discussed in this book include the ambiguities concerning the temporal scope, the lack of independent monitoring provisions, the positioning of the main burden of proof at the end of the development chain, the heavy reliance on private standards and voluntary measures, the absence of information exchange between existing product development processes and future ABS authorities, the weak language with regard to the applicability of the mutually agreed terms and the inability to effectively protect the traditional knowledge of indigenous peoples.

An effective ABS regime is one that prevents illegal use of genetic resources and traditional knowledge and ensures genuine benefit-sharing arrangements. Failing to implement such a regime in Europe will generate restrictive conditions for access to genetic resources and/or associated traditional knowledge in provider countries. This would not only have important consequences for the European biotechnology sector, but would also threaten the international environmental justice objectives instituted by the Nagoya Protocol. It would also undermine the global efforts to conserve and sustainably use biodiversity, the first two objectives of the CBD, thereby jeopardizing the legitimacy of the European Union as a global environmental leader.

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69 European Directive on the Legal Protection of Biotechnological Inventions (Directive 98/44/EC).

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