

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 2014.¹ 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

¹ 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,² 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.³ About half of the world largest cosmetics companies are located in Western-Europe,⁴ 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,⁵ which keep over 50% of the world living plant accessions.⁶ In more than 500 culture collections and gene banks, these countries also possess 30% of all cultures of microorganisms⁷ and between 10 and 15% of the total accessions of germplasm for food and agriculture in the world.⁸

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;⁹
- 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;¹⁰

- 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;¹¹
- 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);¹²
- The use of *Artemisia Judaica*, a Lybian medicinal plant, and its associated traditional knowledge for the treatment of diabetes by Phytopharm (UK);¹³
- 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);¹⁴
- Research on a new cancer treatment at the University of Bradford (UK), derived from a native British flower *Colchicum Autumnale*.¹⁵

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,¹⁶ 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.¹⁷ 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

¹⁶ Convention on Biological Diversity Article 2.

¹⁷ 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.¹⁸

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. Tvedt¹⁹ 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.”²⁰ 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

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.”²¹ 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.²²

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

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,²³ 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 potential²⁴ 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;

²³ Nagoya Protocol Article 2.

²⁴ 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 “*allemansretten*” 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.²⁵ 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.

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.*,²⁶ 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.²⁷ 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.²⁸

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,²⁹ the lack of measures adopting ABS rules by user countries has led to the establishment of restrictive conditions for access

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.”³⁰ 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

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.³¹

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).³²

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.³³ However, the implementation of access and benefit-sharing in Europe has largely taken the shape of a strongly decentralized approach.³⁴ 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-Mueller³⁵ 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.³⁶ 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.

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.³⁷

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.³⁸

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),³⁹ 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.⁴⁰ 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.”⁴¹ 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.⁴² 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.⁴³ 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

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, Godt⁴⁴ 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.⁴⁵ 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.⁴⁶

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.⁴⁷ 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,”⁴⁸ 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

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.⁴⁹ 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.⁵⁰ 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.⁵¹ 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.⁵² 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.⁵³

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

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 (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.⁵⁴ In other words, “[w]here there is no contract for access to traditional knowledge, [...] European law would therefore provide no protection against biopiracy.”⁵⁵

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.”⁵⁶ 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.”⁵⁷ 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.”⁵⁸ 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.”⁵⁹ 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.”⁶⁰ 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).⁶¹

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,⁶² 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.⁶³

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.”⁶⁴ 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.⁶⁵ However, questions remain as to how successful and effective voluntarily measures will be in the ABS context. Without an overarching institutionalisation of

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,⁶⁶ without at least agreeing on the underlying principles governing the responsibilities of the private actors,⁶⁷ 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.*,⁶⁸ 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

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.⁶⁹ 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.

69 European Directive on the Legal Protection of Biotechnological Inventions (Directive 98/44/EC).