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

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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." 1

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.² 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.³ According to its own figures, the

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ı CBD Article 1.

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

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 ABSrelated 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 biophysical 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 1970.⁴ 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

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. The Federal State does not have any pre-eminence on the federated collectivities. The implementation of the Nagoya Protocol, as a "mixed treaty," 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. 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. 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

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.

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. 9 In the Walloon Region, however, permit delivery is regulated by the regional Code for urban and land-use planning, 10 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. 11 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.¹² 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 Nagova Protocol.¹³

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

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.

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.

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.

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.¹⁴ 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).¹⁵ 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.16

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

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 Criekemans, *Een vergelijkend onderzoek naar en bestedingsanalyze 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 Nagova Protocol is thus treated as a double "mixed treaty" by the Belgian Interministerial Conference on Foreign Policy, i.e. one which requires consent form 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, 17 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. 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.19

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.

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 Law²⁰ 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.²¹ 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.²² 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.

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.

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 subjectspecific 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.²³ 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.²⁴ 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.²⁵

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.²⁶ It therefore implies the preliminary recognition of a crime and could only be

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.²⁷ This provision could for instance be applied in an ABS context with regard to the exceptions that ought to be provided for research purposes,²⁸ 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.²⁹ However, protection tools which constitute designations of origin with a regional or local character fall under regional competence.³⁰ 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." Furthermore, "a biological

²⁷ Criminal Code of the Kingdom of Belgium Article 491.

²⁸ Nagoya Protocol Article 8a.

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 &}quot;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"³²: 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."³³ Scientific purposes should in this regard be understood in a large sense.³⁴ 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.³⁵ 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.³⁶

[&]quot;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).

[&]quot;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.

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.

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,³⁷ the production, reproduction, conditioning for the purpose of propagation, sale, marketing, import, export or stocking of this variety would need the authorization of the breeder³⁸ 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.³⁹

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

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. 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

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, 41 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. 42 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 Aïchi 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 2004-2008⁴³ and calls for a coherent national position on access and benefitsharing. 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).⁴⁴ 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. 45 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, 46 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,⁴⁷ 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

[&]quot;Biodiversity: an essential partner in development," Belgian Development Cooperation, accessed 2012, http://www.biodiv.be/infoo4o5/activities.

^{45 &}quot;Belgian Development Cooperation," Royal Museum for Central Africa, accessed 2012, http://www.africamuseum.be/museum/about-us/cooperation/index_html.

^{46 &}quot;tematea," accessed 2012, http://www.tematea.org.

^{47 &}quot;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. 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. 49

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,⁵⁰ 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 &}quot;PLANTCOL: Belgian Living Plant Collections," accessed 2012, http://www.plantcol.be.

^{49 &}quot;Belgian Biodiversity Platform: give wings to your research," accessed 2012, http://www.biodiversity.be.

^{50 &}quot;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,⁵¹ 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.⁵² 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.⁵³ Second,

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

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."

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. ⁵⁴ 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.⁵⁵ 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, 56 it ratified the 1965 Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters.⁵⁷

^{54 &}quot;GEF benefits index for biodiversity," The World Bank, accessed on March 12, 2014, http://data.worldbank.org/indicator/ER.BDV.TOTL.XQ.

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.

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,⁵⁸ 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 interand 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

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.