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<p>The implementation of ‘Access and Benefit-sharing’ in five EU member states: the achievements and deficiencies of the Nagoya Protocol and the EU Regulation 511/2014</p>
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Abstract²

The Nagoya Protocol of 2010 on Access and Benefit-sharing and the related European Regulation 511/2014 provide an answer to the question how access to genetic resources may be ensured. However, the EU itself as well as several EU member states struggle with the implementation of the protocol (and the regulation). This article analyses the difficulties encountered at the European and the national level (in five member states) with the implementation of the Nagoya Protocol obligations. It concludes that, although the Nagoya Protocol is an important step forward for the protection of biodiversity and the fight against biopiracy, it clearly is a compromise text, with all the issues arising therefrom. Also Regulation 511/2014 drops a few stitches in the clear delineation of obligations. However, on the national level this does not lead to extremely discrepant national enforcement mechanisms, at least within the five reviewed member states.

Keywords

Access and Benefit-sharing – Nagoya Protocol – Regulation 511/2014 – Implementation in five EU member states – Enforcement and inspection tools

1. Introduction

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Research and utilization of genetic resources has increased significantly in recent decades. The importance of genetic resources for inter alia the pharmaceutical sector and food safety can hardly be overestimated. Increasingly often the question arises as to how access to genetic resources may be ensured (in the future). With the Nagoya Protocol (NP)³ the international community tried to provide an answer to this question, but the implementation of this compromise text raises several questions.

This contribution reflects on the implementation of the Nagoya Protocol and the related European Regulation 511/2014⁴ in five European member states (United Kingdom, the Netherlands, France, Germany and Belgium).

After an outline of the situation of the creation of the Nagoya Protocol and the main commitments and obligations arising from it, this contribution goes through the main articles of Regulation 511/2014. Subsequently, it looks more closely to the difficulties encountered at the European level with the implementation of the Nagoya Protocol obligations. This is done on the basis of several examples. We then discuss the difficulties that may arise, implementing these obligations at the national level by giving a general example on traditional knowledge. Finally, we zoom into the state of affairs on the national level in the five member states concerned.

2. Historical background of the Nagoya Protocol

It is widely accepted that biological diversity is of immeasurable intrinsic value and performs numerous functions that are critical to the quality of our living environment. Even so, biodiversity keeps declining strongly worldwide and it seems hard to stop this trend. In 1992 the Convention on Biological Diversity (CBD) was accepted and signed⁵. It is the first (and only) international instrument that deals with biodiversity in a comprehensive way. The objective of the CBD is threefold: firstly, the Convention aims to protect and preserve the

³ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, to the Convention on Biological Diversity, Nagoya 29 October 2010.

⁴ Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union *OJ L* 20 May 2014, Vol. 150, 59 and following (hereafter: Regulation 511/2014).

⁵ Convention on Biological Diversity, and its Annexes I and II, Rio de Janeiro, the 5th of June 1992.

existing biodiversity; secondly, it seeks to encourage the sustainable use of the components of biodiversity; and thirdly, it lays a foundation for the fair and equitable sharing of benefits arising from the use of genetic resources.

The third objective, which contains the principle of access and benefit-sharing (ABS), is the most controversial and progressive objective of the Convention. It derived from the consideration that benefit-sharing can be an important incentive for biodiversity conservation. Though the unequal geographical distribution of biological diversity and the lack of a distribution of the benefits from genetic resources, are also reasons that underpin it.

While the bulk of biological diversity is located in ‘developing’ countries (around the equator), the technology to use their components and to patent these are mainly settled in ‘developed’ countries. In this way, the advantages and benefits of biodiversity and genetic resources mainly end up in ‘developed’ countries, despite the fact that the burden to protect and preserve biodiversity rests for the greater part on the shoulders of ‘developing’ countries. In parallel with the increasing demand from the West to deal with biodiversity in a more sustainable way, the demand of ‘developing’ countries for more sovereignty over their genetic resources increased⁶. These concerns were reflected in the CBD. However, the implementation of this objective was long overdue.

In 2002 the Bonn Guidelines⁷ were established as a non-binding code of conduct aimed at guiding CBD parties and other stakeholders in the implementation of the ABS provisions of the CBD⁸. The guidelines were to assist parties, governments and other stakeholders in developing an overall ABS strategy and legal, administrative or policy measures, but fell short through their noncommittal character⁹. Yet, the Bonn Guidelines were useful. Until the adoption of the Nagoya Protocol, they were the only instrument to implement the ABS

⁶ S. Oberthür & G. K. Rosendal (eds), *Global governance of genetic resources, Access and benefit sharing after the Nagoya Protocol*, 2014, pp. 4-5.

⁷ Bonn Guidelines on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilization, UN Doc. UNEP/CBD/COP/6/20 (2002), sixth meeting of the Conference of the Parties to the Convention on Biodiversity, The Hague, 7th-19th of April 2002, available at: www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

⁸ www.cbd.int/abs/bonn/

⁹ www.cbd.int/abs/bonn/

provisions in the CBD¹⁰. Moreover, much of its content found its way into the Nagoya Protocol.

The Nagoya Protocol was eventually agreed upon in 2010, after another six years of negotiations. It offers a binding framework, within which parties should further elaborate the ABS system. By doing so, it responds to the dissatisfaction of supplier countries (biodiversity rich countries) about the increasing number of cases of biopiracy by users (mostly private companies from Western countries)¹¹. Additionally, the Nagoya Protocol provides an adequate solution for the lack of implementation of the third objective of the CBD.

3. Guiding principles of the Nagoya Protocol

The Nagoya Protocol provides a strong basis for more legal certainty and transparency between genetic resource-suppliers and users. Instead of establishing an ABS system, it obliges the state parties to elaborate one themselves¹². It therefore installs a framework that facilitates the use of genetic resources and associated traditional knowledge. By encouraging the use of genetic resources and traditional knowledge and enhancing the opportunities for fair and equitable sharing of benefits, the Nagoya Protocol aims to create incentives to preserve biodiversity, to use its components in a sustainable way and to increase the contribution of biodiversity to sustainable development and human well-being¹³.

As it is a crucial concept for the interpretation of the Nagoya Protocol, we briefly cite the definition of "utilization of genetic resources". According to article 2, c of the Nagoya Protocol "utilization of genetic resources" means *to conduct research and development on the*

¹⁰ M. Hufty, T. Schulz & M. Tschopp, The role of Switzerland in the Nagoya Protocol negotiations, in: S. Oberthür & G. K. Rosendal (eds), Global governance of genetic resources, Access and benefit sharing after the Nagoya Protocol, 2014, p. 104.

¹¹ K. Bavikatte & D. F. Robinson, Towards a People's History of the Law: Biocultural Jurisprudence and the Nagoya Protocol on Access and Benefit Sharing, LEAD Journal 2011 (7/1), pp. 35-51, available at: www.lead-journal.org/content/11035.pdf

¹² T. R. Young, An International Cooperation Perspective on the Implementation of the Nagoya Protocol, in: E. Morgera, M. Buck & E. Tsiumani, The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective, 2013, p. 457.

¹³ Introduction Nagoya Protocol: www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

*genetic and/or biochemical composition of genetic resources, including through the application of biotechnology (as defined in article 2 CBD)*¹⁴. We return to this at a later stage.

The provisions of the Protocol broadly can be divided into three pillars:

- provisions concerning the access to genetic resources and traditional knowledge;
- provisions concerning benefit-sharing; and
- provisions concerning compliance.

These will be briefly explained below, as an understanding of the main provisions of the Nagoya Protocol is necessary to fully understand the difficulties that arise in the implementation of the Protocol.

3.1 Access

The provisions concerning access can be found in the articles 6 (with regard to genetic resources) and 7 (with regard to traditional knowledge) of the Nagoya Protocol. Article 6 requires prior informed consent (PIC) of the supplier country¹⁵ for access to its genetic resources, unless that country decides otherwise. It obliges the parties to take legislative, administrative or policy measures that are necessary for this purpose, as (for example) provide information about how PIC can be requested and make the national ABS regulations clear and transparent¹⁶. In addition, parties shall take measures, as appropriate, to ensure that PIC or approval and involvement of indigenous and local communities, who have an established right to grant access to such genetic resources, has been established¹⁷.

Article 7 provides the same obligation for the parties, but regarding traditional knowledge associated to genetic resources. In addition, it states that mutually agreed terms (MAT) should be established with the indigenous and local communities involved.

3.2 Benefit-sharing

¹⁴ “Biotechnology” means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (art. 2 CBD).

¹⁵ That is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the CBD (art. 6.1 NP).

¹⁶ Art. 6.3 NP.

¹⁷ Art. 6.2 NP.

Concerning benefit-sharing, article 5 of the Nagoya Protocol dictates that the benefits arising from the utilization of genetic resources (and from successive applications and commercialization) shall be shared fairly and equitably and according to with the supplier country mutually agreed terms and conditions¹⁸. To this end, parties should take the necessary legal, administrative or policy measures¹⁹. They must also ensure that such benefits are shared in a fair and equitable manner and on the basis of MAT with the indigenous and local communities who possess these genetic resources, regarding the established rights of these indigenous and local communities over these genetic resources²⁰. The use of traditional knowledge also entails benefit-sharing (also on the basis of MAT) with the indigenous and local communities concerned²¹. In this respect, we would like to make a comment on the difference between benefit-sharing arising from the use of genetic resources (article 5.2) and benefit-sharing arising from the use of traditional knowledge (article 5.5). It is remarkable that the obligation to share benefits arising from the use of genetic resources is formulated quite more noncommittal than the obligation to share benefits arising from the use of traditional knowledge²².

As each use of genetic resources that generates benefits, gives rise to the obligation to share those benefits, we felt it important to have a look at the definition of “use of genetic resources”. As already mentioned above “use of genetic resources” means *to conduct research and development on the genetic and/or biochemical composition of genetic resources*²³. Although it was previously considered in the negotiations, the Nagoya Protocol does not contain a list of types of research and development that fall within this definition²⁴. However this could, even if it were only an illustrative list, prevent certain problems of interpretation. But more on that later.

¹⁸ This refers to both monetary and non-monetary benefits (art. 5.1 and 5.4 NP).

¹⁹ Art. 5.3 NP.

²⁰ Art. 5.2 NP.

²¹ Art. 5.5 NP.

²² This is demonstrated by the phrase “*in accordance with domestic legislation regarding the established rights of these indigenous and local communities*”, which is missing in art. 5.5, just as “*with the aim of ensuring...that benefits are shared*” (in art. 5.2) encompasses a weaker obligation than the “*in order that...*” (in art. 5.5).

²³ Art. 2, c NP.

²⁴ Access and Benefit Sharing, COP decision IX/12, Decision adopted by the Conference of the Parties to the Convention on Biological Diversity at its ninth meeting, UN Doc. UNEP/CBD/COP/DEC/IX/12 (2008)., Section B of Annex II and WG-ABS official document 7/2, Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches, UN Doc. UNEP/CBD/WG-ABS/7/2 (2008). See also: *E. C. Kamau & G. Winter*, An introduction to the international ABS regime and a comment on its transposition by the EU, LEAD Journal 2013 (9/2), p. 113.

3.3 Compliance

The core provisions on compliance are contained in article 15, 16 and 18 of the Nagoya Protocol. However, they are quite vague and their main task is therefore to oblige the parties to take effective and proportionate compliance measures to ensure that access to genetic resources and traditional knowledge could be obtained only on the basis of prior informed consent and after mutually agreed terms were established. While article 15 (on genetic resources) and article 16 (on traditional knowledge) basically say the same thing, article 18 adds to it that parties should ensure that their legal system can be invoked to settle possible disputes arising from MAT²⁵. In addition, parties should encourage users and suppliers of genetic resources and traditional knowledge to include provisions on dispute resolution in the MAT²⁶.

To support compliance, monitor the use of genetic resources and traditional knowledge and to increase transparency, article 17 of the Nagoya Protocol prescribes various monitoring provisions. For example: designating one or more checkpoints, in which the relevant information about PIC, MAT and the origin of the genetic resources is collected²⁷, but also creating a permit that comprises an international certificate of compliance. This certificate serves as evidence that access to the genetic resources in question was obtained with PIC and MAT have been established in accordance with the requirements of the supplier country²⁸. The international certificate of compliance must also be delivered to the ABS-Clearing House. Article 14 of the Nagoya Protocol provides for the establishment of the ABS Clearing House as an international platform for the distribution of information concerning access and benefit-sharing. Without prejudice to the protection of confidential information, each party should provide the necessary information to the ABS Clearing House²⁹. This information should

²⁵ Art. 18.2 NP.

²⁶ Art. 18.1 NP. This means amongst others: provisions regarding which law will be applicable, to which court they will submit a dispute, and possible alternative dispute resolution options.

²⁷ Art. 17.1, a) NP.

²⁸ Art. 17.2 and 17.3 NP. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential: the issuing authority, date of issuance, the provider, a unique identifier of the certificate, the person or entity to whom prior informed consent was granted, the subject-matter or genetic resources covered by the certificate, confirmation that mutually agreed terms were established, confirmation that prior informed consent was obtained; and whether it is for commercial and/or non-commercial use (art. 18.4 NP).

²⁹ Art. 14.2 NP. Additional information, if available and as appropriate, such as: relevant competent authorities of indigenous and local communities, model contractual clauses, methods and tools developed to monitor genetic resources; and codes of conduct and best practices, may be shared through the ABS-Clearing House (art. 14.3 NP).

include at least: the legal, administrative and policy measures concerning ABS; information on the national focal point and the competent national authorities; and permits that served as evidence for PIC and MAT at the time of access.

Less straightforward, but also relevant for the compliance is article 13 of the Nagoya Protocol, that obliges the parties to designate a national focal point and a competent authority. The national focal point is responsible for the communication with the Secretariat and to provide the necessary information (about the procedures to be followed to obtain PIC and MAT and about the competent national authorities, indigenous and local communities and stakeholders) to applicants³⁰. The competent national authority is responsible for granting access or, as applicable, provide written evidence that the access requirements are met. The competent authority also gives advice on the applicable procedures and requirements to obtain PIC and MAT³¹. These functions may be performed by one and the same entity³².

4. European Regulation 511/2014

In the European Union, Regulation (EU) no. 511/2014 implements the Nagoya Protocol. This Regulation entered partly into force on the 12th of October 2014, whilst some provisions (namely article 4, 7 and 9) only came into force one year later. In this section we will briefly examine the most important articles of the Regulation. Further we will have a look at some shortcomings of the Regulation on the basis of some examples.

4.1 Implementation of the Protocol by the Regulation

Article 4 contains the obligations of users of genetic resources and traditional knowledge. It prescribes users to exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation, and that benefits are fairly

³⁰ Art. 13.1 NP.

³¹ Art. 13.2 NP.

³² Art. 13.3 NP.

and equitably shared upon mutually agreed terms, in accordance with any applicable legislation³³.

To do so, users have to seek, keep (for 20 years after the end of the period of utilisation) and transfer to subsequent users the internationally-recognised certificate of compliance and information about the content of MAT which is relevant for subsequent users³⁴. If required by applicable legislation or regulatory requirements, genetic resources and traditional knowledge shall only be transferred and utilised in accordance with mutually agreed terms³⁵. When users possess insufficient information or when uncertainties about the legality of access and utilisation persist, they have to obtain an access permit or its equivalent and establish MAT, or discontinue utilisation³⁶.

There are several exceptions for: certain plant genetic resources for food and agriculture (PGRFA), genetic resources that are (likely) the causing pathogens of a present or imminent public health emergency of international concern, and genetic resources from registered collections within the EU³⁷.

Under the auspices of the European Commission a European register of collections (that meet certain criteria) will be established³⁸. The member states have to regularly verify that each collection or part of a collection under their jurisdiction included in the register meets the criteria. If that is not the case, the member state shall, in dialogue with the collection holder concerned, identify remedial actions or measures and inform the Commission. The Commission can remove the collection or the part of the collection concerned from the register³⁹.

³³ Art. 4.1 Regulation 511/2014.

³⁴ Art. 4.3 and 4.6 Regulation 511/2014. If there is no internationally-recognised certificate of compliance available, the following information and relevant documents should be kept: date and place of access of GR or TK; the description of GR or TK utilised; the source from which the GR or TK were directly obtained; information about subsequent users of GR or TK; the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation; access permits, where applicable; and MAT (art. 4.3 Regulation 511/2014).

³⁵ Art. 4.2 Regulation 511/2014.

³⁶ Art. 4.5 Regulation 511/2014.

³⁷ Art. 4.4, 4.7 and 4.8 Regulation 511/2014.

³⁸ Art. 5.1 and 5.3 Regulation 511/2014. Such collections should, for example, be able to apply standardised procedures for exchanging samples of genetic resources and related information with other collections and for supplying third persons, they should as well keep records of all samples supplied to third persons for their utilisation, etc.

³⁹ Art. 5.4 Regulation 511/2014.

According to article 6 of the Regulation 511/2014, each member state has to designate one or more competent authorities to be responsible for the application of the Regulation. When the Regulation came into force, member states had to inform the Commission of the name and address of the competent authority⁴⁰. The Commission designates a focal point on access and benefit-sharing that will be responsible for liaising with the Secretariat of the Convention⁴¹.

The monitoring of user compliance is regulated by article 7. It obliges the member states and the Commission to request all recipients of research funding involving the utilisation of genetic resources and traditional knowledge to declare that they exercise due diligence (as prescribed by article 4)⁴². Users have to make this declaration of due diligence at the stage of final development, together with the relevant information from the internationally-recognised certificate of compliance, to the competent authorities⁴³. The national authorities have to transmit this information to the ABS-Clearing House, taking into account the possible confidentiality of certain commercial or industrial information⁴⁴.

There is a rather sceptical attitude towards obliging users to declare to have exercised due diligence only at the end stage of product development⁴⁵. This is indeed quite late in the research and development chain to be reconcilable with the Nagoya Protocol and the political aim of the Regulation, namely to prevent that illegally obtained genetic resources and traditional knowledge would be used within the EU⁴⁶.

To ascertain that users comply with their obligations under articles 4 and 7 of the Regulation 511/2014, member states have to carry out checks⁴⁷. Such checks should be effective, proportionate, and dissuasive and should be conducted in accordance with a periodically

⁴⁰ Art. 6.1 Regulation 511/2014.

⁴¹ Art. 6.3 Regulation 511/2014.

⁴² Art. 7.1 Regulation 511/2014.

⁴³ Art. 7.2 Regulation 511/2014.

⁴⁴ Art. 7.3 and 7.5 Regulation 511/2014.

⁴⁵ *T. Burelli, L'Union Européenne et la mise en oeuvre du Protocole de Nagoya. Faut-il se réjouir de l'adoption du Règlement no. 511/2014?*, RJE 2015 (3), p. 461.

⁴⁶ Cons. 9, Regulation 511/2014. See also: Opinion of the European Economic and Social Committee of the 20th of March 2013 on the 'Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union' COM(2012) 576 final — 2012/0278 (COD), *OJ L*, 6th of June 2013, Vol. C 161, 76, no. 4.3.

⁴⁷ Art. 9.1 Regulation 511/2014.

reviewed plan developed using a risk-based approach⁴⁸. Where, following the checks, shortcomings have been detected, the competent authority shall issue a notice of remedial action or measures to be taken by the user. Depending on the nature of the shortcomings, member states may also take immediate interim measures⁴⁹.

At last, member states have to lay down effective, proportionate and dissuasive sanctions applicable to the infringements of articles 4 and 7 and take all the measures necessary to ensure that they are applied⁵⁰.

4.2 Difficulties

Without denying that Regulation 511/2014 is an important step towards an efficient –and within the EU relatively harmonized- ABS system, its potency could nevertheless use a sense of proportion. As the Regulation is obviously written by and for user states, it might not surprise that it misses some vigorousness. While clarifying some of the issues the Nagoya Protocol left undefined or vague, the Regulation fails to provide a satisfying answer to certain other questions.

One of those issues is the exception in article 4 §4 of the Regulation concerning plant genetic resources for food and agriculture (PGRFA). In general the Nagoya Protocol makes an exception for genetic resources that fall under specialized agreements. Hence, the PGRFA that fall under the multilateral sharing system of ITPGRFA⁵¹ are automatically banned from

⁴⁸ Art. 9.2 and 9.3 Regulation 511/2014: Also when a competent authority is in possession of relevant information, including on the basis of substantiated concerns provided by third parties, regarding a user's non-compliance, checks shall be conducted.

⁴⁹ Art. 9.6 Regulation 511/2014.

⁵⁰ Art. 11.1 and 11.2 Regulation 511/2014. No later than the 11th of June 2015, member states must notify the Commission of their sanction regime (art. 11.3).

⁵¹ These are all the PGRFA from the 64 listed crops from Annex I ITPGRFA that are “in the public domain” and “under the management and control” of the national authorities. The multilateral sharing system under the ITPGRFA allows parties to use the PGRFA that it holds for free (or against minimal transaction costs). Unlike the Nagoya Protocol (which creates a bilateral system) it is multilateral, meaning it is less tailored to the individual cases, but also there's less administrative follow-up work. Further, parties achieve no direct benefits for the PGRFA they bring into the system, instead, the advantage they benefit is the (free) access to all PGRFA in the system. This happens through the standard material transfer agreement (MTA), adopted by the ITPGRFA governing body (Resolution 1/2006, 16th of June 2006, available at: <ftp://ftp.fao.org/ag/agp/planttreaty/agreements/smta/SMTAe.pdf>). The MTA does not set the same minimal requirements as the international certificate of compliance (under the Nagoya Protocol). Also the enforcement mechanism addressing non-compliance under the ITPGRFA is, though more uniform, not as far-reaching (issuing a warning or publishing cases of non-compliance) as –possibly- under the Nagoya Protocol.

the scope of the Nagoya Protocol and Regulation 511/2014, since they are submitted to a specialized treaty⁵².

However, as a consequence of article 4 §4 regulation 511/2014, also PGRFA that are not included automatically in the ITPGRFA sharing system, will under certain conditions not be affected⁵³ by the Nagoya Protocol. This is the case if the party from where the PGRFA originate, states that these will be subjected to the standard material transfer agreement (MTA)⁵⁴, if the PGRFA concerned are under its management and control and in the public domain⁵⁵.

In other words, article 4 §4 allows member states to exclude, except from the PGRFA falling automatically under the multilateral sharing system, a number of other cases from the scope of the Nagoya Protocol and to instead subject those to the ITPGRFA sharing system. Given that the ITPGRFA sharing system is not as obligatory and comprehensive as the ABS system envisaged by the Nagoya Protocol, one could question the EU's compliance with the Nagoya Protocol.

In the original draft regulation the ITPGRFA was not even mentioned, but in consideration 10⁵⁶. Consequently the Commission noted that the exact relationship between the measures to implement the Nagoya Protocol and the utilization of genetic resources in accordance with the ITPGRFA was ambiguous. According to the Commission, member states could develop a differing policy on this point, which it considered unfavourable⁵⁷. While addition of the current §4 to article 4 of Regulation 511/2014 brings more clarity, it also raises questions about how far the Regulation should go in interpreting the Nagoya Protocol.

⁵² Art. 4, §4 Nagoya Protocol; Cons. 12 and art. 2, §2 Regulation 511/2014.

⁵³ In the sense that users shall be considered to have exercised due diligence (art. 4, §4 Regulation 511/2014).

⁵⁴ This is applicable to the PGRFA in the multilateral sharing system.

⁵⁵ It is however, not always clear whether or not a PGRFA is under national management and control and in the public domain. Even in collections under semi-public or national public universities, those boundaries are often vague.

⁵⁶ As a specialized instrument that may not be affected by the regulations implementing the Nagoya Protocol.

⁵⁷ Commission Staff working document: *Impact assessment, accompanying the document, Proposal for a Regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Part I*, 4th of October 2012, available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012SC0292&from=EN> (hereafter: SWD/2012/0292 final).

Another deficiency of Regulation 511/2014 is its restricted definition of traditional knowledge. Article 3.7 of the Regulation describes “traditional knowledge associated with genetic resources” as *traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources*.

Therefore, Regulation 511/2014 only covers traditional knowledge to the extent that it falls under the same contract (MAT) as the genetic resources to which it relates. It is however not unthinkable that access is sought to traditional knowledge separately from the genetic resource to which it relates. A broader approach, in which access and benefit-sharing with reference to traditional knowledge is made independent from access and benefit-sharing concerning the genetic resources to which this traditional knowledge is linked, is thus clearly needed. Yet to get there, several obstacles must be overcome.

First of all, the lack of an internationally recognized definition of traditional knowledge appears to be a major barrier⁵⁸. So far, nor in the Nagoya Protocol, nor in other international instruments a definition of traditional knowledge is agreed on⁵⁹. It is problematic that the Nagoya Protocol does not specify how and under which conditions knowledge in a particular case can be qualified as “traditional knowledge”. Since there is no procedure to protect knowledge as “traditional knowledge” under the Protocol, this qualification seems to be left to the parties and the indigenous and local communities⁶⁰.

⁵⁸ Cons. 20, Regulation 511/2014 and SWD/2012/0292 final.

⁵⁹ In the negotiations of the Nagoya Protocol, there were two views on whether or not to include a definition that clarifies traditional knowledge. The argument that the term, particularly in the light of Article 8 (j) CBD speaks for itself, was more decisive than the argument that a formal definition would better define the scope of the Protocol. Art. 8 (j) CBD: *Each contracting Party shall, as far as possible and as appropriate, subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge innovations and practices*.

On its last meeting the IGC on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore endeavoured to draft a definition: *Traditional knowledge [refers to]/[includes]/[means], for the purposes of this instrument, knowhow, skills, innovations, practices, teachings and learnings of [indigenous [peoples] and [local communities]]/[or a state or states]. [Traditional knowledge may be associated, in particular, with fields such as agriculture, the environment, healthcare and indigenous and traditional medical knowledge, biodiversity, traditional lifestyles and natural resources and genetic resources, and know-how of traditional architecture and construction technologies* (draft document, 28th Session, Geneva, 7th - 9th of July 2014, available at: www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_28/wipo_grtkf_ic_28_5.pdf).

⁶⁰ Thereby, reports from the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing and the Ad Hoc Open-ended Working Group on Art. 8(j) CBD may be a useful guidance.

According to the EU Commission, *it would create unacceptable legal uncertainties to base EU user-compliance measures on something not clearly defined in EU law but varying with the respective definition of this term found in the domestic laws of potentially more than 170 countries*⁶¹. Obviously, the Commission considers legal certainty very important and thinks to achieve this by making the ABS-system only applicable to traditional knowledge that is accessed in the same contract (MAT) as the genetic resource it is related to. With this in mind, it is surprising that the European Union does not seem to worry about the far too narrow scope of the Regulation concerning traditional knowledge. Though the Commission considers a broad interpretation of the term traditional knowledge to conflict most likely with ongoing negotiations of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore⁶², in our opinion such an interpretation is more than necessary to ensure compliance with the Nagoya Protocol. As the current negotiations do not offer the perspective of a rapid agreement about the definition, several authors rightly wonder to what extent Europe is sincerely interested in the expectations and needs of (its own) indigenous and local communities⁶³.

At last, it is remarkable that, although the EU considered legal certainty highly important when it comes to the interests of users of genetic resources, it did not extrapolate this view to the inspection and sanctioning system⁶⁴. As a consequence member states still have a broad margin of appreciation to install enforcement mechanisms to their own discretion. As discussed below, this does not lead to extremely discrepant national enforcement mechanisms, at least with regard to the five countries under review, but it will not enhance legal certainty and clarity either.

5. Implementation of the Nagoya Protocol and the Regulation 511/2014 on the national level

⁶¹ SWD/2012/0292 final, p. 28.

⁶² SWD/2012/0292 final, p. 28.

⁶³ See: *T. Burelli*, L'Union Européenne et la mise en oeuvre du Protocole de Nagoya. Faut-il se réjouir de l'adoption du Règlement no. 511/2014?, RJE 2015 (3), pp. 444-447; and *T. Brendan*, Biopiracy by law: European Union draft law threatens indigenous peoples' rights over their traditional knowledge and genetic resources, European Intellectual Property Review 2014, p. 126.

⁶⁴ See: *T. Burelli*, L'Union Européenne et la mise en oeuvre du Protocole de Nagoya. Faut-il se réjouir de l'adoption du Règlement no. 511/2014?, RJE 2015 (3), p. 461.

Since the Regulation 511/2014 fully came into force in October 2015, European member states are bound to implement its provisions in their national legislation. Now, one year later, it is interesting to see how several member states made the transposition and adapted their legislation, whilst others are playing a waiting game and are still discussing the competent authority or the format of the regulations.

In this section we will take a closer look at the implementation of Regulation 511/2014 in five EU member states. To this end, we will examine the enforcement and inspection tools that have been (or are being) created in the United Kingdom, the Netherlands, France, Germany and Belgium. Before giving more attention to some uncertainties arising from the text of the Nagoya Protocol and the Regulation 511/2014, we make a concise comparison of the approach and the introduced enforcement systems in the member states under review.

5.1 The implementation of the Nagoya Protocol and the Regulation 511/2014 in 5 EU member states

5.1.1 The United Kingdom

Initially it was the Department of Environment, Food and Rural Affairs (DEFRA) that was engaged with the implementation of the Regulation 511/2014 within the United Kingdom. However since, the National Measurement and Regulation Office (NMRO)⁶⁵ has been appointed as responsible for the implementation and the enforcement of the Regulation 511/2014⁶⁶.

Statutory Instrument No. 821 regulates the internal competence, as well as the rights of inspection and the administrative sanctions and measures⁶⁷. Articles 10 and 11 of the Statutory Instrument No. 821 contain the conditions and restrictions governing the rights of inspection. The right of access is defined quite accurately in article 10. Thus, an inspector may, on serving reasonable notice, enter premises at any reasonable hour for the purpose of

⁶⁵ This Office falls under DEFRA and the Department for Business Innovation and Skills. See: www.gov.uk/government/organisations/agencies-and-public-bodies for an overview of the existing departments, public bodies and agencies.

⁶⁶ See: www.gov.uk/guidance/abs#sthash.7MazvFSs.dpuf

⁶⁷ Statutory Instrument No. 821, Environmental Protection, The Nagoya Protocol (Compliance) Regulations 2015, made 17 March 2015, laid before the parliament 23 March 2015, available at: www.legislation.gov.uk/uksi/2015/821/pdfs/uksi_20150821_en.pdf? (hereafter: Statutory Instrument No. 821).

enforcing the Regulation 511/2014, except premises used wholly or mainly as a private dwelling house. The requirement to serve a notice does not apply where reasonable efforts to agree an appointment have failed; where an inspector reasonably believes that serving a notice would defeat the object of the entry; where an inspector has a reasonable suspicion that an offence has been committed and in case of an emergency⁶⁸.

The justice of peace may by signed warrant permit an inspector to enter premises, if necessary by reasonable force⁶⁹. This may only when the justice on sworn information in writing, is satisfied that there are reasonable grounds for an inspector to enter those premises for the purpose of enforcing the Regulation 511/2014 and if one of the following conditions is met:

- entry to the premises without warrant has been refused or is likely to be refused, and notice of the intention to apply for a warrant has been served on the occupier;
- asking for admission to the premises, or serving notice of entry, would defeat the object of the entry;
- entry is urgently required; or
- the premises are unoccupied or the occupier is temporarily absent⁷⁰.

Further, an inspector may stop all vehicles that the inspector has reasonable grounds to believe are transporting evidence to check them⁷¹.

Article 11 defines the powers of inspection more in detail. It allows inspectors to inspect the premises and any products, goods or biological material found there; have access to, inspect and copy documents, records or other information, in whatever form they are held, and remove them to enable them to be copied; take samples of products, goods or biological material; carry out any examination, investigation or test; and take photographs, measurements or recordings⁷².

⁶⁸ Inspectors may be assisted by the persons and use the equipment they consider necessary. Art. 10.2 and 10.9 Statutory Instrument No. 821.

⁶⁹ This does not extend to premises used wholly or mainly as a dwelling house. Art. 10.5 and 10.7 Statutory Instrument No. 821.

⁷⁰ Art. 10.6 Statutory Instrument No. 821.

⁷¹ Art. 10.11 Statutory Instrument No. 821.

⁷² An inspector may even require computer records to be produced in a form in which they may be easily accessed and taken away by the inspector. Art. 11.1 Statutory Instrument No. 821.

As regards the sanction policy, in the United Kingdom an infringement of the due diligence obligation will in the first place be sanctioned with civil sanctions⁷³. A civil sanction may be imposed for infringements of the following obligations: the obligation to exercise due diligence, the obligation to seek, keep and transfer information and documentation to subsequent users, and the obligation to make a declaration of due diligence⁷⁴.

An important example of such civil sanctions, is the variable monetary penalty. The Secretary of State (from DEFRA or the Department for Business Innovation and Skills) may by notice impose a variable monetary penalty on any person that: fails to comply with article 4.1, 4.3 or 7.2 of the Regulation 511/2014, fails to keep the necessary information for 20 years after utilisation or intentionally obstructs an inspector⁷⁵. Before doing so, the Secretary of State must be satisfied beyond reasonable doubt that the person has failed to comply with the provision or committed the offence⁷⁶. There is no arbitrary cap on the variable monetary penalty in order not to undermine the approach of linking the level of the fine with the financial benefits obtained by users. The idea behind this was that the aim of financial penalties should be to remove the financial incentive of non-compliance⁷⁷. The variable monetary penalty may be imposed only once in relation to the same act or omission and before serving the notice relating to a variable monetary penalty, the Secretary of State may require the user to provide such information as is reasonable to establish the amount of any financial benefit arising as a result of the non-compliance⁷⁸.

Penalties would only be imposed when civil sanctions are trampled down, and users fail to comply with for instance a stop notice⁷⁹ or a compliance notice⁸⁰. This approach should

⁷³ *Department for Environment & Rural Affairs*, Consultation on implementing the Nagoya Protocol in the UK, A summary of responses and the government reply, March 2015, pp. 7-8 available at: www.gov.uk/government/uploads/system/uploads/attachment_data/file/415474/nagoya-consult-sum-resp.pdf (hereafter: *DEFRA*, Consultation on implementing the Nagoya Protocol in the UK, A summary of responses and the government reply). The term 'civil sanctions' is the term used in the Statutory Instrument No. 821. In other countries, such as Belgium, the term 'administrative sanctions' would be used.

⁷⁴ Art. 8.1 Statutory Instrument No. 821.

⁷⁵ Art. 2.1 (Schedule Civil Sanctions: Part 1) Statutory Instrument No. 821.

⁷⁶ Art. 2.2 (Schedule Civil Sanctions: Part 1) Statutory Instrument No. 821.

⁷⁷ Initially, a cap of £250.000 was envisaged, but the possibility that benefits arising from non-compliance could (in extreme cases) be higher than this amount, while in most of the cases those financial benefits will be lower, led to the conclusion to omit the maximum amount, as it would be too arbitrary. *DEFRA*, Consultation on implementing the Nagoya Protocol in the UK, A summary of responses and the government reply, p. 9.

⁷⁸ Art. 2.1 (Schedule Civil Sanctions: Part 1) Statutory Instrument No. 821.

⁷⁹ A 'stop notice' may be imposed on any (natural or legal) person that does not comply with the obligations arising from the Regulation 511/2014. It is a prohibition to continue to act until the necessary proceedings (mentioned in the notice) to comply are taken.

reduce the uncertainties about compliance with unclear provisions of the Nagoya Protocol and the Regulation 511/2014. In a compliance notice for example, the issuing authority has to describe clearly what the user is expected of and which specific steps he must take to comply with the regulations.

For certain situations of non-compliance however, a direct criminal sanction is preferable⁸¹. This is the case for infringements that undermine the enforcement of the regulation, in particular the intentional obstruction of an inspector, the failure to give an inspector any information or assistance, or the knowingly falsification of information⁸².

5.1.2 The Netherlands

At the end of September 2015, a law imposing the Nagoya Protocol was approved in the Netherlands⁸³. Not long after, a clear and user-friendly ABS-counter with, amongst others, points of contact, FAQs and guidelines for users, came online⁸⁴.

The Law implementing the Nagoya Protocol offers a plain framework with a number of specific rules, while assigning some important powers to the executive power. The Ministry of Economic Affairs is, for instance, responsible for designating a national contact point and a competent national authority. But also the implementation of the parts of the European Regulations concerning genetic resources that leave no discretion or that relate to the way in which applications and documents are submitted, should be laid down by Ministerial Decree⁸⁵.

The monitoring of compliance with the provisions in question is allocated to the Dutch Food and Goods Authority (NVWA), because this authority already inspects a great deal of the

⁸⁰ A 'compliance notice' may be served when it is proven that a (natural or legal) person does not comply with the regulations. It contains evidence of the non-compliance and the concrete steps that should be taken to comply.

⁸¹ DEFRA, Consultation on implementing the Nagoya Protocol in the UK, A summary of responses and the government reply, p. 8.

⁸² Art. 14 Statutory Instrument No. 821.

⁸³ Law of the 30th of September 2015, concerning the rules to implement the Nagoya Protocol, *Staatsblad van het Koninkrijk der Nederlanden*, 3th of November 2015, p. 388 (hereafter: Law implementing the Nagoya Protocol).

⁸⁴ www.wageningenur.nl/nl/Expertises-Dienstverlening/Wettelijke-Onderzoekstaken/Centrum-voor-Genetische-Bronnen-Nederland-1/ABS-loket-Nederland.htm

⁸⁵ See art. 2 to 7 Law implementing the Nagoya Protocol.

relevant sectors (plant breeders, food industry, pharmaceutical industry, breeders and owners of collections such as zoos and botanical gardens)⁸⁶. Moreover, the NVWA has experience in due diligence requirements⁸⁷ and its officials can rely on the necessary powers to detect infringements of regulations to implement the user obligations under the Nagoya Protocol and the Regulation 511/2014.

In the compliance section, behaviour contrary to the rules concerned is categorized as an economic offense⁸⁸. Consequently, such forms of non-compliance fall under criminal law. A distinction is made between a crime and an administrative offense. For a crime a prison sentence of up to six years, community service or a fine of max. € 81.000 (for individuals) or € 810.000 (for legal entities) may be imposed. While the judge may impose imprisonment of a period not exceeding one year, community service or a fine of max. € 20.250 (for individuals) or € 81.000 (for legal persons) for an administrative offense⁸⁹.

For smaller administrative offenses, for which no use of investigative powers is required, an administrative penalty (of max. € 405 per offense, or € 4.050 if the offender is a legal person or company) may be imposed⁹⁰. This is consistent with the criminal penalties that are generally applicable to this type of economic crimes of an administrative nature. This allows relatively simple cases to be settled swifter through rapid reaction so that less burden is posed on the public prosecutor. However, as such crimes also remain an economic offense, the matter can be passed to the public prosecutor in situations in which the nature of the offense is so serious that criminal prosecution seems to be appropriate⁹¹.

⁸⁶ Explanatory Memorandum to the Proposed Law implementing the Nagoya Protocol, 2nd of February 2015, Parliamentary Paper 34142 No. 3, p. 16.

⁸⁷ The experience with due diligence requirements arises from the obligations arising from the European Timber Regulation (Regulation No.995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market, *OJ L* 12th of November 2010 Vol. 295, p. 23). Explanatory Memorandum to the Proposed Law implementing the Nagoya Protocol, 2nd of February 2015, Parliamentary Paper 34142 No. 5.

⁸⁸ Art. 8 Law implementing the Nagoya Protocol.

⁸⁹ Explanatory Memorandum to the Proposed Law implementing the Nagoya Protocol, 2nd of February 2015, Parliamentary Paper 34142 No. 3, pp. 16-17.

⁹⁰ Art. 7.2 and 7.4 Law implementing the Nagoya Protocol, 2nd of February 2015, Parliamentary Paper 34142 No. 2. For your information: on the 10th of September 2015 this law was passed in the Parliament as a “*hamerstuk*” (a “*hamerstuk*” is a draft law that no one wishes to discuss at plenary meeting and that is accepted without voting).

⁹¹ Explanatory Memorandum to the Proposed Law implementing the Nagoya Protocol, 2nd of February 2015, Parliamentary Paper 34142 No. 3.

Besides that the Minister of Economic Affairs may impose an enforcement action or a penalty as a remedial measure and the NVWA is mandated to immediately impose the following temporary measures⁹²:

- a. put genetic resources and derived products into custody;
- b. prohibit transporting, processing or bringing into circulation of genetic resources or derivatives;
- c. ban the further use of genetic resources or derivatives;
- d. oblige the temporary storage of genetic resources or derivatives;
- e. inform holders, or probable holders of genetic resources or derivatives promptly and effectively of the fact that these resources are not acquired legally;
- f. oblige the return of the genetic resources or derivatives to the country that supplied them;
- g. oblige the retrieval or central storage of genetic resources or derivatives that were released for circulation;
- h. oblige the identification and registration of the genetic resources or derivatives.

These measures correspond to the measures that may be imposed in respect of timber or timber products imported or marketed in breach of the European Timber Regulation. The costs are borne by the owner, transporter, importer or his agent, and can be recovered through a writ of execution if necessary⁹³.

5.1.3 Germany

For Germany the draft law of April 29th, 2015 constitutes an important step towards the implementation of the obligations arising from the Nagoya Protocol and the Regulation 511/2014⁹⁴. The 25th of November 2015 this draft law (completed with two new articles) was accepted in its entirety by the *Bundestag*⁹⁵. It is a concise law, but it empowers the Minister of Environment, Nature conservation, Construction and Nuclear Safety (in agreement with the

⁹² Art. 6.1 Law implementing the Nagoya Protocol, 2nd of February 2015, Parliamentary Paper 34142 No. 2.

⁹³ Art. 6.2 Law implementing the Nagoya Protocol, 2nd of February 2015, Parliamentary Paper 34142 No. 2.

⁹⁴ Draft Law nr. 5321, April 29th, 2015 from the Federal State (*Bundesregierung*) on the implementation of the commitments under the Nagoya Protocol and the implementation of Regulation No. 511/2014 (EU) and amending the Patent Law, available at: <http://dip21.bundestag.de/dip21/btd/18/053/1805321.pdf>

⁹⁵ Law of November 25th, 2015 on the implementation of the commitments under the Nagoya Protocol and the implementation of Regulation No. 511/2014 (EU) and amending the Patent Law and the Environmental Audit Act (*Umweltauditgesetz*), *Bundesgesetzblatt I*, No. 47, 2nd of December 2015 (hereafter: Law of November 25th, 2015).

Ministries of Health, Food and Agriculture, Education and Research and Economy and Energy) to regulate amongst others the following issues more in detail, as far as this is necessary for the implementation of the Regulation 511/2014 (or its executive decrees)⁹⁶:

- the conduction of inspections including sampling and the details of tolerance-, assistance- and reporting requirements;
- the details of the obligation to declare due diligence (article 7, §1 Regulation 511/2014); and
- the details of the obligation to submit the international certificate of compliance, or certain information, in the last stage of development (article 7, §2 Regulation 511/2014).

The largest part of this law entered into force the 1st of July 2016⁹⁷. Only article 3, that introduces the amendments to the *Umweltauditgesetz* entered into force on the 3rd of December 2015 (the day after its publication)⁹⁸.

The Law of November 25th, 2015 assigns the Federal Agency for Nature Conservation (BfN)⁹⁹ as the competent authority under article 6.1 of the Regulation 511/2014. An amendment to the Patent law (*Patentgesetzes*) obliges the German Patent and Trademark Office to inform the BfN if a patent application contains information on the geographical origin of biologic material (as far as the invention/application concerned uses or contains biological material of plant or animal origin)¹⁰⁰.

As regards the inspection, the by the Federal Agency for Nature Conservation appointed inspectors have the right to consult documents and to take copies thereof, to do tests (including sampling) and to enter and examine the operational and administrative premises and land (during the operational hours)¹⁰¹. Alongside this, the inspectors are duty-bound to treat trade and business secrets confidentially¹⁰². Users are obliged to assist the inspectors if

⁹⁶ Art. 1, §3 Law of November 25th, 2015.

⁹⁷ Art. 4.1 Law of November 25th, 2015.

⁹⁸ Art. 4.2 Law of November 25th, 2015. It is a small, predominantly administrative amendment in the field of standardization (available at: www.buzer.de/gesetz/4869/al52078-0.htm).

⁹⁹ Abbreviation of: *Bundesamt für Naturschutz*.

¹⁰⁰ Art. 2 Law of November 25th, 2015 read in conjunction with §34 a) Patent Law, as published on the 16th of December 1980 (*Bundesgesetzblatt 1981 I*, S. 1) and last amended by art. 204 of the Regulation of August 31st, 2015 (*Bundesgesetzblatt I*, S. 1474).

¹⁰¹ Art. 1, §1, lid 3 Law of November 25th, 2015.

¹⁰² Art. 1, §1, lid 5 Law of November 25th, 2015.

they are requested to do so and to submit the necessary documents and samples of genetic resources¹⁰³. However, they may refuse to answer questions, if this would expose themselves or one of their family members at risk of prosecution for committing a crime or misdemeanour¹⁰⁴.

Article 1, §4 of the Law of November 25th, 2015 lists a number of offenses that are to be dealt with by the Federal Agency for Nature Conservation. This involves offenses committed intentionally or negligently and in breach of Article 4, §3 (to not seek or keep the required information -from the beginning of use- or to not transfer this information –timely- to subsequent users) and §6 (to not keep the information relevant to ABS for 20 years after the end of the period of utilisation) and article 7, §2 (to make the declaration of due diligence incomplete, not at all, or not within four weeks after the completion of use, or not provide the international certificate of compliance, or in lack thereof the by article 4, §3, b) and i) to v) and in article 4, §5 of the Regulation 511/2014 required related information, or, at the request of the competent authorities¹⁰⁵, provide no further evidence).

In addition, the following acts (either intentionally or negligently) are regarded as a breach of the law¹⁰⁶:

1. providing false information or provide the competent authorities not, incomplete or late with the information necessary for the implementation of Regulation 511/2014, the relating executive decrees or this law¹⁰⁷;
2. failing to provide assistance at the request of an inspector with sampling and testing or not, not timely or incomplete delivery of the required samples or submitting false samples¹⁰⁸;
3. acting in violation of a seizure (of illegally used genetic resources) or an operating ban¹⁰⁹;
4. acting contrary to an ordonnance of the Ministry of Environment, Nature Conservation, Construction and Nuclear Safety, that gives effect to the Regulation or

¹⁰³ Art. 1, §1, lid 2 and 3 Law of November 25th, 2015.

¹⁰⁴ Art. 1, §1, lid 4 Law of November 25th, 2015.

¹⁰⁵ For Germany: the Federal Agency for Nature Conservation.

¹⁰⁶ Art. 1, §4.1 Law of November 25th, 2015.

¹⁰⁷ In contravention of art. 1, §1.2 Law of November 25th, 2015.

¹⁰⁸ In contravention of art. 1, §1.3 Law of November 25th, 2015.

¹⁰⁹ In contravention of art. 1, §2.2 Law of November 25th, 2015.

one of its executive decrees and regulates certain issues more in detail¹¹⁰, such as the obligation to declare due diligence, the obligation to submit the international certificate of compliance or certain information in the final stages of development, the implementation of inspections, including sampling, the obligation for users to allow inspections, to give assistance on request of the inspector and to submit the required samples or information¹¹¹.

The administrative fine is minimum € 5 and can, in principle, amount up to maximum € 50,000 for an offense committed intentionally¹¹² and € 25,000 for an offense of negligence¹¹³. However, according to article 17, §4 of the Code of Administrative Offences this limit may be exceeded if the financial benefit of non-compliance is higher. The underlying idea is that, to have a warning and a punitive effect, the fine should be higher than the economic benefit resulting from the violation. The severity of the administrative offense and the charge form the basis for the assessment of the administrative fine. Account should also be taken of the financial situation of the offender, except in cases of negligible administrative offenses¹¹⁴.

In addition, article 1, §2 of the Law of November 25th, 2015 provides the Federal Agency for Nature Conservation with the ability to issue orders, to take illegally used genetic resources into custody, to take remedial measures and to prohibit certain actions or stop the exploitation. Such measures should be suspended when the user complies¹¹⁵. The resulting costs are to be borne by the violator¹¹⁶.

5.1.4 France

The Law of 8 August 2016 for the Restoration of Biodiversity, Nature and Landscapes (hereafter: Biodiversity Law) has come a long way. It was submitted on March 26th of 2014

¹¹⁰ This gives the opportunity to further define violations, once the executive decrees based on art. 5, §5, 7, §6 and §7 and 8 Regulation 511/2014 are available.

¹¹¹ Art. 1, §3 Law of November 25th, 2015.

¹¹² Art. 1, §4.3 Law of November 25th, 2015.

¹¹³ Art. 17, §2 Code of Administrative Offences (Gesetz über Ordnungswidrigkeiten) as published on February 19th, 1987, *Bundesgesetzblatt I*, 602, last amended by art. 4 of the Law of May 13th, 2015, *Bundesgesetzblatt I*, 706 (hereafter: Code of Administrative Offences). Art. 17, §2 states that if the law prescribes an administrative fine without distinguishing whether an offense was committed intentionally or by negligence, the fine for the offense by negligence may not exceed half of the prescribed penalty.

¹¹⁴ Art. 17, §1 Code of Administrative Offences.

¹¹⁵ Art. 1, §2.3 Law of November 25th, 2015.

¹¹⁶ *Id.*

and read and discussed twice both in the Parliament and in the Senate. It was modified by committees, and finally adopted on 8 August 2016¹¹⁷. The Law is much broader than just the scope of the Nagoya Protocol and the Regulation 511/2014 and contains mainly amendments and additions to the Environmental Code (*code de l'environnement*), the Civil Code (*code civil*), the Tax Code (*code général des impôts*), the General Code of Local Authorities (*code général des collectivités territoriales*), the Town Planning Code (*code de l'urbanisme*), the Rural and Maritime Fishing Code (*code rural et de la pêche maritime*), the Forestry Code (*code forestier*) and several other relevant legislation. Given the detailed nature of the Biodiversity Law, we will limit this article to Title V, which regulates the access to genetic resources and the fair and equitable sharing of benefits. It mainly amends the Environmental Code.

To regulate the access to genetic resources, a declaration and permit system is proposed in France¹¹⁸. A distinction is made between commercial use of genetic resources, commercial use of traditional knowledge and use to preserve collections, to increase knowledge about biodiversity or valorisation without direct commercial purpose.

To use genetic resources for commercial purposes, it is necessary to obtain a permit from the competent authority prior to the utilisation (such a permit should be delivered within two months after the deposit of the MAT)¹¹⁹. The permit may be refused, as far as it is motivated, if:

- the competent authority and the applicant (where appropriate after conciliation) do not agree on the distribution of benefits;
- the proposal for the distribution of benefits from the applicant clearly does not correspond to his potential (financial and technical); or
- the activity or its potential applications risk to affect biodiversity in a significant way by limiting the sustainable use of genetic resources or by exhausting the genetic resources¹²⁰.

¹¹⁷ For an overview of the legislative procedure and documents see: www.senat.fr/dossier-legislatif/pjl14-359.html#block-timeline.

¹¹⁸ Art. 37 (amending L.412-7 and following) Biodiversity Law.

¹¹⁹ Art. 37 (amending L. 412-8) Biodiversity Law.

¹²⁰ Art. 37 (amending L. 412-8, IV) Biodiversity Law.

A permit to use traditional knowledge related to genetic resources can only be obtained in accordance with the procedure laid down in article 37 (L. 412-10 to L. 412-14) Biodiversity Law¹²¹. This procedure intends to ensure the knowledgeable prior informed consent (PIC) of the communities concerned, by appointing a legal entity of public law in every indigenous community. This entity is, among other things, responsible for the organization of the public consultation and the negotiation and signing of the contract for the distribution of benefits (and -if necessary- to manage the issues obtained on the basis of the contract)¹²².

A simple declaration suffices for the use of genetic resources or related traditional knowledge with the purpose of conserving biodiversity in collections, increasing knowledge about biodiversity, or valorisation without direct commercial purpose¹²³. The same applies to the use of genetic resources in case of an emergency in which human-, plant- or animal health is at stake.

No specific inspectorate is designated to monitor the compliance with Regulation 511/2014. Instead, all officials who may come into contact with this matter in the effectuation of their research and investigative missions, are designated as competent to investigate breaches of the legislation implementing the Nagoya Protocol and the Regulation 511/2014¹²⁴. Thus, inter alia, the customs officers, the sworn inspectors of regional nature parks and the coast guard, but also the sworn officers appointed by the Minister of Defence are competent.

In terms of sanctions, the Biodiversity Law is developed remarkably detailed. Failing to seek, keep or transfer information on access and benefit-sharing of genetic resources/traditional knowledge to subsequent users is punishable with one year imprisonment and € 150.000 fine¹²⁵.

The same sanction applies to the use of genetic resources/traditional knowledge without submitting the (by article 4.3 of the Regulation 511/2014) required documents, except for commercial use, in that case the fine is increased to € 1.000.000¹²⁶. The physical or legal persons who commit such offenses may -as additional sanction- be banned to submit a permit

¹²¹ Art. 37 (amending L. 412-9) Biodiversity Law.

¹²² Art. 37 (amending L. 412-10) Biodiversity Law.

¹²³ Art. 37 (amending L. 412-7) Biodiversity Law.

¹²⁴ Art. 38 (amending L. 415-1) Biodiversity Law.

¹²⁵ Art. 39 (amending L. 415-3-1, I) Biodiversity Law.

¹²⁶ Art. 39 (amending L. 415-3-1, I) Biodiversity Law.

application for access to genetic resources (or certain categories thereof) and traditional knowledge with a commercial purpose¹²⁷. This applies for a maximum period of 5 years¹²⁸.

A prison sentence of two years and a fine of € 100.000 are set¹²⁹ for the illegal continuation of an activity, the exploitation of an installation or the realization of works for which a permit or a notification is required or for which a derogation regime applies (as provided in L. 412-1 and L. 412-7 to 412-16) without complying with the notice of default or the order for regularization of the competent administrative authority within the time limit set by this authority¹³⁰. If, at the end of this term, a user still has not complied with the order, the competent authorities may¹³¹:

1. oblige him to pay a sum -equal to the costs of the preconceived works- that will be returned if and as far as those works are carried out (appeal against this measure does not suspend it);
2. carry out the imposed measures on behalf of the user and at his expense (the paid sum may be used for this purpose);
3. close down works or activities until the imposed conditions are met and take conservation measures at the expense of the user;
4. impose an additional fine of € 15.000 as well as a penalty of € 1.500 per day, counting from the day of notification until the imposed conditions are met.

The fines and penalties should be proportionate to the seriousness of the infringement and, inter alia, take into account the extent to which the environment might be disturbed by the infringement. The sanctions cannot be imposed more than one year after the determination of the infringement and only after the person concerned was informed that he (within a certain period) may submit his findings¹³².

In addition, the closure or suspension of facilities or activities, the permanent shutdown of activities and the recovery in the original condition may be ordered¹³³. In emergency

¹²⁷ Art. 39 (amending art. L. 415-3-1, II) Biodiversity Law.

¹²⁸ *Id.*

¹²⁹ Art. 40 (amending art. L. 173-2, II) Biodiversity Law.

¹³⁰ In the application of art. L. 171-7 or L. 171-8 Environmental Code, last amended on the 23th of April 2016, available at: www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074220

¹³¹ Art. L. 171-8, II Environmental Code.

¹³² *Id.*

¹³³ Art. L. 171-7 Environmental Code.

situations, the competent authority may take the necessary measures to prevent major risks to health, public safety or the environment¹³⁴.

5.1.5 Belgium

As it comes to Belgium, it is not coincidentally the fifth and last country to be discussed in this article. A look at the state of affairs in neighbouring member states reveals that Belgium is lagging behind. While Regulation 511/2014 is directly applicable in Belgium since October 2015, no official steps have been taken to provide for its implementation. The Royal Belgian Institute of Natural Sciences has been appointed as national focal point¹³⁵, but as regards the competent national authority¹³⁶ it remains -up to now- conspicuously silent.

It may be clear that the transposition of the obligations under the Nagoya Protocol and the Regulation 511/2014 in Belgium, gives rise to a number of questions. The most important thereof is undoubtedly: Which is the competent authority? And thus: Who will implement the Nagoya Protocol and the Regulation 511/2014 at the domestic level?

As a consequence of the jurisdictional federalism¹³⁷, the demarcation of competences (in competence overlapping issues) in Belgium is often a thorny issue¹³⁸. The question whether the federal state or the regional authorities (communities or regions) are competent, seems to be more prominent than in Germany, where functional federalism assigns the legislative power to the federal state, whereas the regions are competent for the execution(al legislation) at the regional level¹³⁹.

¹³⁴ Art. L. 171-8, I Environmental Code.

¹³⁵ www.cbd.int/doc/lists/nfp-abs.pdf

¹³⁶ Prescribed by art. 13.2 NP.

¹³⁷ This means that the competences are divided into packets and contain both the competence to issue regulations and the competence to implement and enforce these regulations. The reason behind this is to ensure maximum independence between the different authorities. See: *H. Matthijs & M. T. Jans*, Bestuurswetenschappen, de overheid: instellingen en beleid, 2005, pp. 108-109.

¹³⁸ With around twenty cases per year, the litigation regarding distribution of powers forms at present only a small proportion of the decisions of the Constitutional Court. See: *R. Moerenhout*, De rechtspraak van het Arbitragehof in 1998. Bevoegdheid en rechtspleging, TBP 1999, p. 46; *A. Alen*, Twintig jaar rechtspraak van het Arbitragehof, TBP 2005, pp. 209-226; *R. Moerenhout*, Rechtspraakoverzicht Grondwettelijk Hof 2008, Bevoegdheid en rechtspleging, TBP 2009, p. 515; *R. Moerenhout*, Rechtspraakoverzicht Grondwettelijk Hof 2012, Bevoegdheid en rechtspleging, TBP 2014, p. 69.

¹³⁹ *H. Matthijs & M. T. Jans*, Bestuurswetenschappen, de overheid: instellingen en beleid, 2005, pp. 108-109.

Given that the Nagoya Protocol touches upon several diverging matters, it may not be surprising that the competent authorities for each of these matters (nature-science-economy-agriculture-...), claim the right to regulate the issue. The use of genetic resources is indeed widespread in various sectors: from applications in the pharmaceutical industry to, among others, biotechnology, food and cosmetics. Because the competences over these sectors are divided among the federal state (responsible for science and economy), the regions (responsible for nature, agriculture and environment) and the communities (responsible for scientific research and education), this easily leads to a temporary impasse with retardation as a consequence. And in fact the tangle is twofold. Not only is there disagreement possible about which is the competent authority (federal vs regional) but also within the authorities it remains unclear which are the competent policy areas (nature vs agriculture)¹⁴⁰.

In order to determine in the competences *in casu* we need in the first place to look at the Nagoya Protocol and by extension at the CBD. As the objectives set out in the Protocol determine the internal distribution of competences. As its name says, the objective of the Nagoya Protocol is the fair and equitable sharing of benefits arising from the use of genetic resources. In the introduction we already stressed that this fits within the framework of the protection and conservation of biodiversity, since the protocol is the implementation of the third objective of the CBD¹⁴¹. Moreover, the Protocol was negotiated and approved by the Flemish Minister for Nature and Environment (and co-approved by the Flemish Minister-President). The Regulation 511/2014 has its legal basis in article 192, §1 TFEU¹⁴², which includes the environmental competence of the European Union. Taking this into account, it is rather logical that the subject matter falls within the competence of the Minister of Nature.

We may therefore assume that the Regions, based on their competence for nature protection and conservation (article 6, §1, III, 2° BWHI¹⁴³), are competent to promulgate regulations to implement the Nagoya Protocol and the Regulation 511/2014. However, an important comment needs to be made. This legislation will after all, and even mainly, have an impact on other policy areas. Scientific research on genetic resources or that makes use of genetic

¹⁴⁰ As both the Department of Agriculture and the Department of Nature claim to be the competent authority on the regional level.

¹⁴¹ See No. 3.

¹⁴² Treaty on the Functioning of the European Union.

¹⁴³ Abbreviation of “Bijzondere Wet Hervorming Instellingen”: Special Law of August 8th, 1980 on institutional reform, BS 15th of August 1980.

resources will for example be affected by this legislation, but also the production of medicines or cosmetics based on genetic resources will be affected by the new regulations.

It would lead us too far to discuss the Belgian division of competences for this matter thoroughly. Instead we would like to put emphasis on a possible solution.

Though several scenarios are possible, a cooperation agreement seems to be the most appropriate solution, seen the complex interconnectedness. In such a cooperation agreement the regions, the communities and the federal state may clearly define their competences and agree on a common policy. Existing cooperation agreements on other issues could serve as an example for an ABS-cooperation agreement. Depending on the priorities, the cooperation agreement on the transit of waste¹⁴⁴, or the REACH¹⁴⁵ and Seveso III¹⁴⁶ cooperation agreements would be more suitable. The first one assures more uniformity and efficiency as it gives more responsibility to the federal state and less discretionary power to the regional level (consequently, less administration and coordination will be necessary). Whilst the other two leave more discretionary power to the regional authorities (to install their own inspection and sanctioning system), guaranteeing that the division of competences is respected. As a consequence, the REACH and Seveso III cooperation agreements require more coordination and conflicts of competences cannot be ruled out. Though, the superordinate consultation bodies¹⁴⁷ these establish, are likely to give an adequate answer to this problem.

5.2 Comparative law

As regards the competent authority, we see that the transposition of Regulation 511/2014 in the United Kingdom is done by DEFRA (the Department of Environment, Food and Rural Affairs) and NMRO (the National Measurement and Regulation Office). While in France, the

¹⁴⁴ Cooperation Agreement of the 26th of October between the Federal State, the Region of Flanders, the Region of Wallonia and the Brussels Capital Region, concerning the coordination of the policy on import, export and transit of waste, *BS* 13th of December 1995.

¹⁴⁵ Cooperation Agreement of the 17th of October 2011 between the Federal State, the Region of Flanders, the Region of Wallonia and the Brussels Capital Region, concerning the registration, evaluation, authorisation and restrictions with respect to chemicals, *BS* 14th of March 2012 (hereafter: REACH cooperation agreement).

¹⁴⁶ Cooperation Agreement of the 5th of June 2015 between the Federal State, the Region of Flanders, the Region of Wallonia and the Brussels Capital Region, concerning the control of hazards caused by major accidents involving dangerous substances, *BS* 20th of August 2015 (hereafter: Seveso III cooperation agreement).

¹⁴⁷ For the REACH cooperation agreement the Committee REACH and the Forum National REACH may serve as superordinate consultation bodies, whereas for the Seveso III cooperation agreement this function is performed by the Cooperation Committee Seveso Helsinki.

Ministry of Ecology, Sustainable Development and Energy is responsible for the implementation and in Germany it is the Ministry of Environment, Nature Conservation, Building and Nuclear Safety (BMUB). In the Netherlands, by way of contrast, the Ministry of Economy is appointed as the competent authority in this matter.

Most of the countries under review introduced a relatively brief law to implement the Regulation 511/2014 and left it to the regional level or the Ministry to further work out the details in a decree or a ministerial decision. In France however, both the scope and the sanctions are fully delineated and defined in the law.

The Netherlands and Germany appointed one inspectorate for the supervision of the compliance with the implementation of Regulation 511/2014. The United Kingdom did not yet officially designate a competent supervisory authority. France, on the other hand, chose to empower all the inspectors that potentially come into contact with the use of genetic resources as the competent supervisory authority.

The advantage of the French approach is that the extra workload (caused by the extra inspections to supervise compliance with the Nagoya Protocol) is spread. Because inspections are carried out in several sectors and by more inspectors. Indeed, it seems logical and efficient to use the already existing checkpoints (for monitoring compliance with other regulations) that are likely to come into contact with genetic resources and/or traditional knowledge about these resources, and to effectively involve these checkpoints in the control chain.

On the other hand, this way of working requires more coordination, which makes it more difficult to control as in one plan drawn up on the basis of a risk-based approach. Moreover, such a system may lead to less specialization (about this matter) within the inspectorate and allow for a difference in the carrying out of the inspections. While, a (more) uniform method of inspecting, by one and the same inspectorate, allows a higher level of specialization and probably creates more legal certainty. For those reasons giving the responsibility to one inspectorate might be desirable.

Remarkably, France is the only state (of the five reviewed member states) that introduces a licensing system. This system allows a far-reaching control over the commercial use of genetic resources and traditional knowledge, and provides the government more leverage to

negotiate a fair distribution of benefits. A possible disadvantage of the licensing system is that it will render the use of genetic resources cumbersome for the users. As they shall, instead of having to make a simple declaration, have to apply for authorisation, which will likely be more time-consuming.

Concerning the sanctioning system, the emphasis in each of the five member states is different. The United Kingdom and Germany tackle situations of non-compliance mainly administrative, while the Netherlands and France regard criminal enforcement as the line to follow. It is striking that the German Law of the 25th of November 2015 even only requires administrative penalties, including for acts such as falsifying information or failure to provide assistance at the request of an inspector. This is quite far-reaching compared to the other member states, where certain behaviours (such as obstruction of inspectors and falsifying information) are generally made punishable.

A brief comparison between the types of sanctions and enforcement measures in the member states concerned learns us that there is not so much difference in this field. About each of them applies a fine and/or imprisonment to non-compliance with the rules implementing the Regulation 511/2014. Those sanctions are regularly supplemented with the possibility to deprive benefits arising from the noncompliance or to impose remedial action or compensation, and often the ability to impose a penalty is established.

However, there are some unique sanctions, which are inherent to the legal order of member states. One of these is the French prohibition to apply for a license in the light of commercial use of (certain categories of) genetic resources and associated traditional knowledge for a maximum period of 5 years¹⁴⁸. Another example is the compliance notice in the UK¹⁴⁹. The compliance notice offers an interesting tool in the sense that it creates certainty for users in what they are expected to do.

Having a look at the scale of the sanctions, a comparison is hard to make as some member states classify a certain conduct as a crime, while others classify the same conduct as an administrative offense. While in some member states there's no agreement upon any sanctioning system yet. However, it is interesting to see that in the Netherlands for example, a

¹⁴⁸ Art. 20 (art. L. 415-3-1, II) Biodiversity Law.

¹⁴⁹ Civil sanctions, part 1, Statutory Instrument No. 821.

different amount of fines is set, depending on whether the accused is a natural or a legal person¹⁵⁰. And in France no margin of appreciation is left to the judge, as a very detailed legislation defines fixed amounts of fines for specific infringements¹⁵¹.

5.3 Issues arising from the implementation

As mentioned above briefly, parties to the Nagoya Protocol encounter a lot of ambiguities when transposing the Nagoya Protocol into national law. An important part thereof stems from inadequate or incomplete definitions of key concepts. For example, “traditional knowledge related to genetic resources” is a concept that appears in almost every core provision of the Protocol, yet the Protocol, nor the CBD includes a definition of it¹⁵². The same is true for the notion “sovereignty”, which reserves both in the Nagoya Protocol and in the Regulation 511/2014 a broad regulatory competence for the parties. The absence of an internationally recognized definition of those concepts, renders it almost impossible for state parties to delineate and fulfil their obligations under the Nagoya Protocol and Regulation 511/2014.

Further, wordings as “as appropriate” and “in accordance with domestic law” give more discretionary power to the parties and render the obligations less clearly defined. Which in turn can lead to less legal certainty.

It also remains vague from which date the protocol applies. Especially the situation in which access to genetic resources or traditional knowledge was obtained after the entry into force of the CBD, but before the entry into force of the Nagoya Protocol, creates confusion. On the one hand it could be argued that access that took place before the entry into force of the Nagoya Protocol, constitutes an act or a situation that ceased to exist before the entry into force of the Protocol and consequently does not fall within the temporal scope of the protocol. On the other hand, article 3 of the Nagoya Protocol, which determines the scope of the Nagoya Protocol, applies to genetic resources that fall within the scope of Article 15 CBD¹⁵³. This article requires since 1993 PIC for access (with the purpose of utilisation) to genetic

¹⁵⁰ See No. 46 and 47.

¹⁵¹ See No. 61 and 62.

¹⁵² See No. 28-30.

¹⁵³ IUCN, An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing, 2012, p. 72.

resources, it also requires benefits, arising from research and development, commercial and other uses of genetic resources, to be shared¹⁵⁴.

Usually it is assumed that, with regard to “access”, the Nagoya Protocol applies to genetic resources and traditional knowledge to which access was sought after its entry into force. This often leads to the conclusion that the same is true as regards “benefit-sharing”¹⁵⁵. This is, however, not necessarily the case. More precisely, it is possible that genetic resources or traditional knowledge to which access was obtained before the entry into force of the Nagoya Protocol, are continued to be used after its entry into force. And such situations cannot be excluded from the conditions set out in article 5¹⁵⁶. The Protocol is, for example, not applicable to existing patents that are based on traditional knowledge, but as soon as these patents expire, the Nagoya Protocol requires PIC or involvement and consent from the indigenous and local communities concerned, if the traditional knowledge on which the patent was based would continue to be used.

In contrast to the Protocol, the scope of the Regulation 511/2014 is clearly defined. Article 2.1 states explicitly that the Regulation only applies to genetic resources and traditional knowledge to which access was obtained after its entry into force. Yet, it is questionable whether this narrow scope is consistent with the Nagoya Protocol.

6. Conclusion

Although the Nagoya Protocol is an important step forward for the protection of biodiversity and the fight against biopiracy, it may be clear that it is a compromise text, with all the issues arising therefrom. The lack of a clear definition and the high level of discretionary powers afforded to the state parties, obstructs a uniform and efficient implementation.

For the European Union, Regulation 511/2014 picks up the pieces as regards uniformity by imposing the same user obligations for all the member states and by establishing a common monitoring system. But also Regulation 511/2014 drops a few stitches in the clear delineation

¹⁵⁴ Art. 15.5 and 15.7 CBD.

¹⁵⁵ *M. Buck & C. 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, 2011, p. 57.

¹⁵⁶ *IUCN*, An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing, 2012, p. 90.

of obligations. Moreover, the Regulation is clearly written by a majority of user states, which has found its resonance in some too lax or too limited provisions. Furthermore, it is remarkable that although the EU considered legal certainty highly important, it afforded a broad margin of appreciation to the member states as regards the enforcement mechanisms.

On the national level however, we see that this does not lead to extremely discrepant national enforcement mechanisms, at least with regard to the five member states under review. Broadly similar inspection and sanctioning systems apply in those member states: the Netherlands and Germany appointed one inspectorate, whereas France chose to empower all the inspectors that potentially come into contact with the use of genetic resources as the competent supervisory authority. Though the emphasis, concerning the sanctioning system, is different in each of the five member states (Germany and the United Kingdom tackle situations of non-compliance mainly administrative, whereas France and the Netherlands put the emphasis on criminal sanctioning), the types of sanctions and enforcement measures appear to be quite similar. Obviously, each of these approaches has its own advantages and disadvantages.

In implementing the obligations arising from the Nagoya Protocol, state parties may encounter several uncertainties. The most important being inadequate or incomplete definitions of key concepts, wordings as “as appropriate” and “in accordance with domestic law” (as these give more discretionary power to the parties and render the obligations less clearly defined) and the pending discussion about from which date the Protocol applies.

Compared to the other member states under review, it is striking how much Belgium lags behind. Much can be said about the limitations and ambiguities of the Nagoya Protocol and Regulation 511/2014, but in the Netherlands, Germany, France and England a law to implement the obligations under the Nagoya Protocol and the Regulation has been approved. While Regulation 511/2014 has been directly applicable since October 2015, in Belgium no specific legislative steps have been taken to meet the obligations arising from it.