CHAPTER 13

The Multi-Level Implementation of the Nagoya Protocol in the European Union

Christine Godt

The European Union and its 28 member states are preparing to implement the "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization" (hereinafter referred to as the "Nagoya Protocol"),[1] the second protocol[2] to the Convention on Biological Diversity (CBD) of 1992. Whereas a few member states hurried ahead,[3] most of them awaited the implementation concept of the EU, which was adopted by the Council on 14 April 2014 (hereinafter referred to as the EU Regulation on ABS).[4] The Nagoya Protocol entered into force on October 12, 2014, 90 days after the deposition of 50th document (ratification) was submitted to the secretariat.[5] Since the European Union did not wish to be the last in line to deposit a document, it was eager to finalize the legislative process before the entry into force. The Nagoya Protocol concretizes Article 15 of the CBD, which stipulates that

> each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing (ABS) legislation or regulatory requirements of the other Party.

* Part 3 of this contribution is based on an expert consultation commissioned jointly to the author and Franziska Wolff (senior consultant with the Ökoinstitut e.V., Berlin) by the German Federal Government, Ministry of the Environment, delivered in two separate papers: Christine Godt, Davor Šušnjar, Franziska Wolff, Umsetzung des Nagoya-Protokolls ins Deutsche Recht (Study I, submitted 9.3.2012), and Christine Godt, Tim Torsten Schwithal, Franziska Wolff, Umsetzung des Nagoya-Protokolls ins Deutsche Recht (Study II, submitted 29.6.2012).

1 Adopted on 29 October 2010 in Nagoya, Japan, as the Second Protocol to the Convention on Biological Diversity of 1992.

2 The first one is the Cartagena Protocol on Biosafety of 2000, in force since 11 September 2003 (ILM [2000] 1027).

3 See Norway (Norwegian Nature Diversity Act of 2009) and Denmark; [For an in-depth discussion on ABS in Denmark and Norway, see contributions to this volume by Koester (Chapter 2) and Tvedt (Chapter 7).]

4 Regulation No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

5 Nagoya Protocol Article 33 Sec. 1

 | DOI 10.1163/9789004293212_015

The EU Regulation on ABS relies on a concept of centralized regulation and de-centralized enforcement. In its initial proposal, the European Commission opted for the technical instrument of a regulation, rather than a directive. The focus of the Regulation is on user measures, and prudently leaves the regulation of access to EU-genetic resources to the member states. Its concept rests on the duty to exercise due diligence to ascertain that genetic resources and associated traditional knowledge are accessed in accordance with applicable ABS legislation. I argue that the EU approach camouflages a simplistic understanding of how the uses of genetic resources are regulated in detail. The approach relies on a narrow understanding of applicability and scope, has broad exceptions, and grants overbroad privileges to the research community. Most importantly, it ignores the administrative set-up of various pre-existing procedures, which fine-tune in many ways, the quality control of research and production. The approach wilfully downplays the difficulties of the information flow, and gives broad leeway to circumvention. Moreover, it does not install self-regulatory measures that deserve the label of due diligence so as to cushion the information problem. Thus, the draft as a user measure is not ambitious enough to complement existing and future provider measures. The analysis imposes that the EU wilfully slows down the ABS process for the sake of its research community and its industry.

This chapter substantiates this critique as follows. It will first solidify the content of the Nagoya Protocol by analysing its ambitions and shortcomings, comparing it to the Bonn Guidelines I. It will describe the concept of due diligence on which the EU Regulation on ABS is based II. It follows a counter-proposition labelled as "integrative" or "piggy-back," which cushions the duty to ascertain Nagoya Protocol-compliance within existing procedures III. A reflection on the respective information paradigm concludes the Chapter IV.

I The 2010 Nagoya Protocol and the 2001 Bonn Guidelines Compared

Various dissenting points made the Nagoya Protocol negotiations dreadful. Consensus has remained fragile about central questions as to if the Nagoya Protocol applies to material stored in collections after 1992 (or only

after 2014),[6] if it applies to derivatives,[7] and what the status of "privileged collections"[8] might be. The trade-off for making the ABS Regime internationally binding is that documents under international law only bind the treaty parties, *i.e.* member states rather than the private sector. The interesting feature about the (non-binding) predecessor, the Bonn Guidelines of 2001, was that those stipulated the transnational duties of private corporations directly.[9] But since the Bonn Guidelines remained largely ignored, the Conference of Parties to the CBD had to step back to classic international legal language and formulate the duties of states, thus disrupting the immediate bilateral approach of a relationship of "the provider" and "the user."[10] Evidently, it is far beyond

6 Greiber and Moneno distinguish between accessions made after the Nagoya Protocol came into force (Nagoya-ABS) and those accessions made between the entry into force of the CBD in 1992 and the entry into force of the Nagoya Protocol (CBD-ABS-regime). See Thomas Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing* (Gland, Switzerland: IUCN, 2012); Gerd Winter and Evanson C. Kamau, "Von Biopiraterie zu Austausch und Kooperation: Das Protokoll von Nagoya über Zugang zu genetischen Ressourcen und gerechtem Vorteilsausgleich," *Archiv des Völkerrechts* 49 (2011): 373–398; Michael Frein and Hartmut Meyer, *Wer kriegt was? Das Nagoya Protokoll gegen Biopiraterie. Eine politische Analyse* (Bonn: Evangelischer Entwicklungsdienst e.V. (EED), 2012): 13 argue that the trigger for the Nagoya Protocol is not the former accession of a sample, but the actual "access" to the sample. Hartmut Meyer *et al.*, *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization: Background and Analysis* (Berne Declaration (BD), Brot für die Welt, ECOROPA, TEBTEBBA and TWN, 2013): 57, document that drafters of the Nagoya Protocol conceived the temporal scope of the Nagoya Protocol to be identical to the CBD scope; "Retroactivity"(applicability of the CBD to pre-CBD-material) is strongly opposed by Matthias Buck and Claire Hamilton, "The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity," *Review of European Community & International Environmental Law* [*RECIEL*] (2011): 57. Whereas this question will become central for benefit sharing, access requirements are already broadly met, since most collections treat pre- and post CBD-material alike, see Christine Godt, "Networks of *Ex Situ* Collections in Genetic Resources," in *Common Pools of Genetic Resources*, ed. Gerd Winter and Evanson C. Kamau (Abingdon/Oxon: Routledge, 2013): 246–267.

7 Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol,* 28; Hartmut Meyer *et al.*, *Nagoya Protocol*, 35.

8 How big are options for circumvention, see Godt, "*Ex situ* collections," 261.

9 Christine Godt, "Biopiraterie zum Biodiversitätsregime – Die sog. Bonner Leitlinien als Zwischenschritt zu einem CBD-Regime über Zugang und Vorteilsausgleich," *Zeitschrift für Umweltrecht* (*ZUR*) (2004): 202–212.

10 Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol*, 13.

the capacities of international negotiations to find a common ground on the internal implementation of duties.

The most important short-coming, however, is the novel and restrictive definition of "utilization" in Article 2 of the Nagoya Protocol. The term is important as Article 15 of the CBD links ABS duties to utilization. However, whereas Article 6 of the Nagoya Protocol requires prior informed consent only for "access" in utilization cases, Article 5 is compliant with Article 15 Sec. 7 of the Convention, which requires that "[...] benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared [...]."[11] Thus, the Nagoya Protocol creates a double distinction (access/benefit-sharing and commercial/non-commercial) and it submits ABS to different rules. "Access for their utilization" (*i.e.* research and development, R&D) is only submitted to prior informed consent; benefits are to be shared which arise from "utilization of genetic resources" (*sic* R&D) *and* commercialization. Commentators focus on the indeterminacy (and the omission of the initially proposed list),[12] and on consequences for the later procedures of market approval.[13] More important, the re-definition of utilization creates a distinct situation for access and benefit-sharing. It implements the normative idea that the person who accesses the resource is not necessarily the same who owes the sharing of benefits. Thus, a time lap is created and duties become differential. As long as the normative idea prevails that the conditions for ABS are identical, the scope of duties to be met by those who access a resource ("accessors") and users are identical. The Nagoya Protocol bows to reality, which is that bio-prospectors, be they scientists or contractors, seldom generate "profits" from commercial utilization. Bio-prospectors either add value to the resource by accumulating information of it, or sell it. The split redistributes responsibilities. Accessors are *primarily* responsible for assuring that access requirements are met, and *not* for securing the sharing of benefits. Utilizers become *primarily* responsible for sharing benefits, and *not* for securing that access conditions were met. The normative split has two consequences.

11 CBD Article 15 Sec. 7, which reads: "Each Contracting Party shall take [...] measures [...] with the aim of sharing in a fair and equitable way the results of research and development *and* the benefits arising from the commercial *and* other utilization of genetic resources with the Contracting Party providing such resources [...]."

12 Greiber *et al.*, *An Explanatory Guide to the Nagoya Protocol,* 63; Hartmut Meyer *et al.*, *Nagoya Protocol*, 33.

13 Most contestable, Buck and Hamilton, "The Nagoya Protocol," 52 argue that approval procedure were excluded from the term "utilization" (against this interpretation: Godt, Šušnjar and Wolff, "NP-Umsetzung," 32 et seq.)

The accessors' (primarily scientists) burden to share benefits is reduced to share those benefits which he/she generated (regularly non-monetary benefits); the later utilizer is relieved from access compliance. (2) The split of duties creates an "information delta" with the risk that information gets lost (without the need to be retrieved). The unitary duty to secure ABS is dissolved into two separate duties which follow each other in time. This creates a novel need to secure the transfer of information and record tracking in both directions. The utilizer (in order to fulfil his sharing duty) needs to know which ABS requirements were negotiated when the resource was accessed. The provider needs to know *who* (finally) utilizes and commercializes the resource. The split re-nationalizes the duties: access regulation becomes a responsibility of provider states, whereas benefit-sharing becomes a responsibility of user states. This way, the idea that providers must have the option to decide about ABS (access *and* benefit-sharing) is diluted into differentiated member state implementation duties. User countries may focus on the implementation of benefit-sharing duties ("user measures"), but are not responsible for securing claims of providers ("access regulation"; realization of provider claims: tracking and enforcement).

II The EU Regulation on ABS

The EU Regulation on ABS is based on Art. 192 TFEU, and implements a concept of due diligence: "Users shall exercise due diligence to ascertain that genetic resources [...] were accessed [legally] and that [...] benefits [...] are shared [...]."[14] It uses the term "users," not "utilization." "Users" have to "exercise due diligence" to ascertain ABS. In contrast to the Nagoya Protocol, the draft refrains from regulating ABS in two separate articles. "Due diligence" alludes to a concept used in prior regulations for the tracking of "blood" diamonds[15] and uncertified (illegal) tropical timber.[16] In those two regulations, due diligence referred to a self-regulatory scheme, in which monitoring was delegated to private

14 EU Regulation on ABS Article 4 Sec. 1.

15 EC Regulation 2368/2002, Off. J. L 358/28 of 31 December 2002, implementing the so called Kimberley-Process into EC law, Joost Pauwelyn, "Non-Traditional Patterns of Global Regulation: Is the WTO 'Missing the Boat'?" in *Constitutionalism, Multilevel Trade Governance and International Economic Law,* eds. Christian Joerges and Ernst-U. Petersmann (Cambridge: Hart Publ., 2006): 199.

16 EC Regulation 995/201, Off. J. L 295/23 of 12 November 2000. [See also contribution by Oliva (Chapter 12) to this volume.]

organizations.[17] However, the EU Regulation is silent about the private monitoring scheme; it only refers to "associations of users" for the establishment of "best practices."[18] It only grants leeway to existing (self-regulated) *sui generis* regimes (as provided for in Article 4 Sec. 2 Nagoya Protocol) as "Union trusted collections"[19] by granting them special treatment and reversing the burden of proof for acquisition therefrom.[20] Regarding implementation, the Regulation contents itself with commanding member states to designate competent authorities.[21] The European Commission will designate a "focal point."[22] The national authorities will transmit the information received to the European Commission.[23]

The Regulation on ABS departs from its predecessors in various ways. It does not install a straight forward prohibition to use illegal material.[24] In contrast, it installs a duty to "exercise due diligence to ascertain that [resources and knowledge...] were accessed in accordance to access and benefit legislation [...]."[25] Thus, the due diligence duty is different from its predecessors in two distinct ways. First, due diligence does not refer to a self-monitoring scheme. Only Article 8 of the EU Regulation mentions a private association of users. It may submit "best practices" to the Commission, which might be recognized and then considered the standard of care. A self-regulatory supervising organization is neither stipulated nor prohibited. Thus, due diligence is a flexibility mechanism for the duty of care. The duty of care is to ascertain that resources and knowledge were accessed in accordance to access and benefit legislation. Article 4 Sec. 3 of the Regulation stipulates that "users shall seek, keep, and transfer to subsequent users" information relevant for ABS. The stipulated duty is not a (normative negative) prohibition ("Don't do!"), but a (positive) obligation to "seek, keep, and transfer information," thus record keeping.

17 EC Regulation 995/2010 Article 8 and EC Regulation 2368/2002 Article 17.

18 EU Regulation on ABS Article 8. For a thorough analysis of concepts labeled as "due diligence," see Christine Godt, "Due Diligence – Modernes Umweltmanagement oder Regulierungsverweigerung?" in *Der Rechtsstaat zwischen Ökonomie und Ökologie – Festschrift Götz Frank,* eds. Rainer Wolf and Ulrich Meyerholt (Tübingen: Mohr Siebeck, 2014) (forthcoming).

19 EU Regulation on ABS Article 5.

20 EU Regulation on ABS Article 4 Sec. 7.

21 EU Regulation on ABS Article 6 Sec. 1.

22 EU Regulation on ABS Article 6 Sec. 3.

23 EU Regulation on ABS Article 7 Sec. 3.

24 Regulation 995/2010 Article 4 and Regulation 2368/2002 Article 3 and 11.

25 EU Regulation on ABS Article 4 Sec. 1. Arguably, because the primary "duty to obey the law" is owed to the provider state, the conceived user state duty is adjacent, self-standing and monitoring in nature.

The monitoring concept of the EU Regulation is not one of self-regulation, but rests on two pillars of administrative control ("check-points").[26] Recipients of public research funding are submitted to the duty to declare *ex ante* to have exercised due diligence.[27] *Ex post* duties are not installed.[28] The respective agency is not explicitly named. The text only obliges "member states and the Commission [to] request [...] that [the recipients of public research funding] will exercise due diligence." All other users are submitted to a duty to declare *ex post*. Article 7 Sec. 2 demands that they "declare to the competent authorities established under Art. 6(1) that they have fulfilled the obligation under Article 4" on the occasion of requesting market approval for a product or at the time of commercialization where market approval is not required.[29] Article 7 is complemented by Article 9 which provides for checks on user compliance by the competent authorities.[30]

This due diligence concept for the EU Regulation is questionable for the following four reasons.

(1) The scope of the duty of care is not clear enough. The "duty to exercise due diligence to ascertain" has two elements, the "duty to ascertain" and "the exercise of due diligence" (standard of care). At the outset, the "duty to ascertain" requires clarification. It was criticized that the initial draft of the Regulation refrained from a general prohibition of illegal use (following its predecessors).[31] Although the respective penalty may extend to the "suspension of use activities,"[32] the duty itself refers to three specific *information* duties "seek, keep, transfer,"[33] and a duty to remedy a situation "where is appears that

26 Thus, it mixes two approaches that were earlier labeled in an assessment report as "upstream focus" and "downstream focus." IEEP, Ecologic and GHK, *Study to analyze legal and economic aspects of implementing the Nagoya Protocol on ABS in the European Union* (Brussels/London, 2012).

27 EU Regulation on ABS Article 7 Sec. 1.

28 This concept seems to be a constitutionally-demanded privilege of science, and approved by member states (*e.g.* for Germany cf. the answer from the German federal government to a parliamentary questionnaire [27 June 2013], Drs. 17/14245 [p. 6]).

29 A formulation was proposed for tightening by the European Parliament´s Committee on Development (30 May 2013, PE 508.195v03-00) as novel Article 7 Sec. 2 "users shall declare that they have complied with."

30 checking on their due diligence, EU Regulation on ABS Article 9 Sec. 4.

31 WWF, *Recommendation on amendments for ENVI vote on Regulation on Access to Genetic Ressources and Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*, of 1 July 2013 (on file with the author); Report of the European Parliament, new proposal Recital 8a, (PE 508.195v03-00 of 16 July 2013), 10.

32 Initial proposal for a Regulation by the European Commission, Article 11 Sec. 2.

33 EU Regulation on ABS Article 4 Sec. 3 lit. a and b.

access was not in accordance with applicable ABS legislation [...]." Thus, the EU law defines positive duties of behaviour with a focus on information. It is not a straightforward prohibition of utilization of illegal material, as defined by the provider state's laws. This is a conceptually important difference; it creates a self-standing domestic duty of care and refrains from directly linking domestic legal consequences to a violation of a foreign country's laws. With regard to the principle of common but differentiated responsibilities under international environmental law,[34] is the resistance to connect domestic legal consequences directly to a violation of foreign laws still timely?[35] I argued earlier that conflicts of laws[36] allow and the underlying international law principle requires a closer collaboration of provider and user states. Parties to Multilateral Environmental Agreements bear complementary (differentiated but related) duties, requiring recognition of extraterritorial effects.[37] However, the implementation process has to respect the contested negotiation history of the Nagoya Protocol. Industrialized countries strongly opposed the so-called "tripod", requiring user states to make domestic users disclose the country of origin, the compliance with access rules, and the negotiated contractual agreement.[38] The legal implementation of a self-standing duty, rather than a prohibition linked to foreign law, mirrors the rejection of the "tripod" rule. The Nagoya Protocol does not demand a broad prohibition of illegal use.[39] Therefore, if the European Union now implements the duty variant (instead of the straightforward prohibition), I argue that the legislative decision commands respect, even if one may criticize it for not being ambitious enough. As

34 Though not recognized as a rule yet, but only as a principle, Ellen Hey, "Common but differentiated responsibilities," *Max Planck Encyclopedia of Public International Law*: MPEPIL (Oxford: Oxford Univ. Press, 2012) (last update February 2011): (447); T. Honkonen, *The Common But Differentiated Responsibility Principle in Multilateral Environmental Agreements – Regulatory and Policy Aspects* (Alphen aan den Rijn: Kluwer Law Int'l, 2009).

35 However, there are precedents which link the domestic prohibition to a violation of foreign laws, the diamonds regime and the timber regime, *cf.* Godt, "Due Diligence."

36 C. Godt, "Enforcement of Benefit Sharing Duties in User Countries Courts," in *Genetic Resources, Traditional Knowledge & the Law – Solutions for Access & Benefit Sharing*, eds. E. Kamau and G. Winter (London/Lifting V.A.: Earthscan, 2009): 419–438.

37 C. Godt, *IPRs and Environmental Protection after Cancún* (paper presented at the International Confernce 'Moving forward from Cancún – The Global Governance of Trade, Environment and Sustainable Development,' Berlin, Germany, October 30–31 2003). Available online: http://ecologic-events.eu/Cat-E/en/documents/Godt.pdf (Nov. 2003).

38 For a detailed in depth analysis *cf.* Christine Godt, *Eigentum an Information* (Tübingen: Mohr Siebeck, 2007): 316.

39 Nagoya Protocol Article 5 Sec. 2: "Each party shall take [...] measures, as appropriate, with the aim of ensuring that benefits arising from the utilization [...] are shared [...]."

a matter of practice, one may wonder about the real life implications. Under the EU Regulation, users are under the duty to inquire, keep records, and transfer information. Article 4 Sec. 3 of the Regulation neatly specifies the information to be recorded: date and place of access, the description, the source, rights and obligations, and mutually agreed terms. If the use of illegal material is detected, the burden of proof shifts to the holder of the resource to show that he/she could not know, a difficult task in most cases. As much as a prohibition, the documentation duty exerts preventive effects, and triggers the industry to secure compliance along the production chain, also in provider states.[40] The "duty to ascertain" compared to a broad prohibition makes only a difference to enforcement agencies. Other agencies not being "the ABS entrusted agency," like permit approval agencies, cannot examine "illegal use" (enforcing the prohibition). I argue that this lower standard is acceptable although second best. The transposition as domestic legal duty is consistent with the concept of state sovereignty.

More problematic is the second element, the standard of care. "Due diligence" refers here to a negligence standard, which refers to the individual duty of care in a given situation. This concept is a tort concept, and deviates from the standard regime of administrative offenses of which the duty is the same to everybody (phrased as a prohibition, *e.g.* to use illegal material). Adherence to best practices will, as a general rule, satisfy the standard of care.[41] Thus, where information is not available with due diligence, the access permit cannot be obtained and mutual agreed terms not be established, Art. 4 sec. 5 of the Reguation now commands the utilisation to be discontinued.

(2) In the case of the EU Regulation on ABS, the due diligence monitoring system rests on two pillars, on the declaration duties of users and on checks by the competent authority.[42] The responsible agency to which the user has to declare is not the agency responsible for market approval, but the (separate) national ABS authority (most probable the nature conservation agency).[43] The applicant will face a double administrative burden. The EU Regulation does not make the documentation of the declaration to the competent ABS agency a constitutive part of the approval file. There is no legal base for a

40 On the legal implications of "duties" and the dialectic function of the standard of care and burden of proof, Gert Brüggemeier, "Organisationshaftung – Deliktische Aspekte innerorganisatorischer Funktionsdifferenzierung," *Archiv civilistischer Praxis* (*AcP*) 191 (1991): 33; transferred to the context of environmental liability: Christine Godt, *Haftung für Ökologische Schäden* (Berlin: Duncker & Humblot, 1997): 188 et seq.

41 EU Regulation on ABS Article 8 Sec. 4, also Godt, *Haftung für Ökologische Schäden.*

42 EU Regulation on ABS Article 9 Sec. 1.

43 EU Regulation on ABS Article 7 Sec. 2.

denial of the market approval. Since the duty is not formulated as a prohibition to use illegal material, a denial would even not be possible in exceptional cases where the law requires the examination of *all* public duties.[44] The declaration that due diligence is exercised[45] is a self-standing duty, penalized on its own merits according to Article 11 of the Regulation. The enforcement of the "declaration duty" and the "duty to ascertain" information about ABS compliance are restricted to administrative penalties established under Article 11. These might finally be severe (*e.g.* fines, immediate suspension of use activities, confiscation of illegally acquired material), but are not directed at remedying any illegal situation.[46] The competent agencies face several problems: Since the Regulation does not require the permit approving agency to ask for the declaration (the duty "shall declare" is one to the competent ABS agency),[47] it is unclear how the information about an application for product approval will be conveyed to the competent agency. The EU Regulation on ABS is silent on how to structure the information transfer between agencies. This is a severe lacuna, since most product approvals with relevance to ABS compliance are regulated on the EU level. It is an open question how the communication between product regulation agencies and ABS agencies shall be installed. In practice, it is quite dubious how competent ABS agencies shall know about possible violations of duties both, under Article 4 and Article 7 Sec. 2 of the Regulation. Commercialized products do not reveal in themselves the illegal use of genetic resources in either the R&D or the production process. The monitoring will depend on inspections of firm labs which require highly specialized expertise to detect possible violations of ABS ascertainment duties.[48]

(3) In cases where a market approval is not required, it is unclear which exact point in time is determined as "the stage of final development." Is it the

44 We found one single example in German law which is open enough to take prohibitions of adjacent laws on board (allowing the denial of a permit based on the non-declaration or inconsistent declaration or documentation of prior ABS-compliance): § 11 Sec. 1 No. 6 German Biotechnology Act (Gentechnikgesetz) demands that other norms do not stand against approval. It applies to labs of safety level 3 and 4 (which are submitted to ex ante approval). It reads: The approval is to be granted, if „andere öffentlich-rechtliche Vorschriften und Belange des Arbeitsschutzes der Errichtung und dem Betrieb der gentechnischen Anlage nicht entgegenstehen".

45 EU Regulation on ABS Article 7 referring to Article 4 Sec. 1.

46 Even penalty fines (in German 'Zwangsgelder') aimed at enforcing a positive behavior (not the omission) do not help to achieve the goal since the duty is confined to ascertainment (not ABS-compliance).

47 EU Regulation on ABS Article 7 Sec. 2.

48 EU Regulation on ABS Article 9.

first market placing of a product in the sense of the IP-exhaustion principle, or does it start with the application for a patent, as the European Court of Justice adjudicated when interpreting Article 6 Sec. 2 lit.c of Directive 98/44/EC?[49] Even the European Parliament has called for a better information exchange with the European Patent Office.[50] The central problem with enforcing the EU Regulation is its design of information flow. Agencies will not know *who* utilizes genetic resources in the first place. The draft is narrowly focused on (self)-declaration duties and on the detection of violations by public administration. No technical scheme of information transfer between agencies is put in place. It remains unclear on which data the "periodically reviewed plans following a risk-based approach" can be based.[51] Providers, private users or consumers have no access to information. Most probable, little information will be communicated, and the ABS user compliance for the territory of the 28 EU member states is not secured.

(4) Due to the exacerbated split between access in provider states and benefits generated in user states, the pursuit of provider claims for benefit-sharing will be cumbersome – not only for legal,[52] but already for factual reasons. The EU Regulation on ABS only requires users to "exercise due diligence to ascertain that genetic resources [...] were accessed in accordance with access and benefit-sharing [regulations...]."[53] The information is to be reported "at the stage of final development [...] to the competent authorities."[54] The competent agency will report to the Commission and the ABS Clearing House.[55] The declarations will not be made public. No safeguards are taken that information

49 Case 34/10, *Brüstle v Greenpeace*, [2011] ECR I-821, following the opinion of AG Bot. The decision is highly contested: Concurring: Ingrid Schneider, "Das EuGH-Urteil 'Brüstle versus Greenpeace': Bedeutung und Implikationen für Europa," *Zeitschrift für geistiges Eigentum/ Intellectual Property Journal* 3 (2011) 475; Rejecting: Jochen Taupitz, "Menschenwürde von Embryonen – europäisch-patentrechtlich betrachtet," *GRUR* 114 (2012) 1; Aurora Plomer, "After Brüstle: EU accession to the ECHR and the future of European patent law," *Queen Mary J IP* 2 (2012): 110; prior to the ECJ judgment, supporting the plaintiffs position: Joseph Straus, "Zur Patentierung humaner embryonaler Stammzellen in Europa. Verwendet die Stammzellenforschung menschliche Embryonen für industrielle oder kommerzielle Zwecke?" *GRURInt* 59 (2010): 911.

50 Opinion of the European Parliament's Committee on Agriculture and Rural Development (published as part of the Report of the European Parliament, *supra* note 5), 22.

51 EU Regulation on ABS Article 9 Sec. 3a.

52 Godt, "Enforcement of Benefit Sharing."

53 EU Regulation on ABS Article 4 Sec. 1.

54 EU Regulation on ABS Article 7 Sec. 2.

55 EU Regulation on ABS Article 7 Sec. 3.

about uses in user states is transparent and accessible.[56] Providers will depend on accidental discovery of use and commercialization. No means for structured monitoring and tracing of use allowances is put in place. The ABS Clearing House, which was installed to enhance the flow of information between provider and user states by Article 14 of the Nagoya Protocol, will primarily support users in tracking information about (provider state) legislation and about restrictions in access permits. Since transparent information about uses is not required by the Nagoya Protocol, the ABS clearing house will do little to respond to the information needs of providers. Yet, the underlying idea of the ABS mechanism rests on the back-flow of benefits from user states to provider states as an incentive mechanism for nature preservation. It is a common misunderstanding to conceive the duty to share benefits as a source of income for provider states to their free disposition, in their own interest. Benefit-sharing is primarily in the common interest of biodiversity protection of all Parties to the CBD. Therefore, it is sensible to earmark funds raised for the preservation of biodiversity. This is also true, if claims are raised by a state, and then resemble a transnational tax which a private entity owes to a foreign state.

III The Alternative: "Piggy-Back"-Procedures

The better alternative to the implementation approach taken by EU Commission is the integration of the duty to disclose information about ABS compliance into existing procedures, in which genetic resources and products based or derived from genetic resources are accessed, stored, analysed, developed, and make their way up to market commercialization, *coupled* with general rules which allow providers to seek judicial redress.[57] This idea departs from a different regulatory concept. Neither is it reduced to documentation duties of the utilizers, nor is the "illegal use" made the center of the user country's Nagoya Protocol-measure. It aims at facilitating the enforcement of legitimate claims by providers in user countries, regardless whether they are states, private entities or communities. This approach would complement the provider state measures by user state transparency rules.

56 A mechanism, however, could be the searchable patent data banks.

57 The analysis is based on a one year expert consultation of the authors commissioned by the German federal government, prior to the publication of the EU Regulation (*cf. supra* note 1). The task was to identify implementation schemes for the Nagoya Protocol which could comply with the European multilevel governance scheme and take residual national competences on board. The central findings are in the process of publication (2014).

States already control the use of biological and genetic resources by various procedures, although for different purposes. States record patents for innovation purposes; for security reasons they control dangerous behaviour and dangerous substances; for reasons of fostering research and economic growth, states subsidize research and industrial projects.

The central idea of the "piggy-back" approach is to utilize the existing procedures for more transparency, thus enabling providers to pursue their claims and, by employing these, to keep products off the market which were developed based on illegally acquired material. Research funding grants and IP granting procedures make the (potential) use of a resource public at a very early point in time. Later product approval procedures signal the market entry of a resource. Research funding and public procurement procedures can be utilized to submit applicants to documentation duties, thus enhancing information distribution, and could require that mutual agreed terms are stipulated which ensure that future benefits will either be invested in biodiversity protection or at least benefit biodiversity long-term.[58]

Therefore, the central idea of the "piggy-back" concept is to enable the pursuit of legitimate provider claims. However, the availability of this information about the granted access and benefit conditions is also in the interests of users along the production chain who utilize genetic resources commercially. It is in their interest to avoid biopiracy, and that is only possible if they have appropriate information. If disclosure were required in patent and in market approval procedures, the exploitation of genetic resources in the R&D-process and in testing would be made public in most instances.[59]

It is a different question whether these disclosure duties are to be complemented by a "general duty to comply," since many uses do not come in contact with any administrative procedure. Both concepts do not exclude each other; they can be combined. A good reason to do so is to avoid lacunae in the control of uses, and to submit all users to "the same" duty. It also might be in the interest of the user state to transpose, as an own sovereign act, the duty to comply with a foreign state´s rule into a domestic duty (*supra*).

In an earlier expertise, the author examined, whether amendments requiring the disclosure of information on benefit-sharing compliance (justified by environmental policy goals) can be implemented into existing regulations based on

58 Respective requirement could be modeled on ´equitable licensing´, *cf.* Christine Godt, "Equitable Licenses – Conceptualizing a New Model – Resolving Some Early Legal Problems," *GRUR Int.* (2011): 377–385.

59 This scheme risks utilizations protected by a business secret to remain undetected.

other competences rules than environmental protection.[60] The conclusion was that amendments can be installed to rules which pursue product safety or the promotion of innovation due to the integration clause for environmental protection.[61] With regard to consumer products, legislative competences for consumer protection and environmental protection do not differ in scope. We found only one single exception in which an amendment is not possible due to the specific (German) regulatory set-up of public procurement of pharmaceuticals under German social security rules (*Sozialgesetzbuch*-V).[62] The declaration duties integrated in product permit procedures should be complemented by a general prohibition of illegal use, stipulated either in existing nature protection laws or in self-standing ABS rules. It forms the legal base for subsequent declaration duties. The reference to foreign law is legitimized by the accession to the Nagoya Protocol, which rests on the principle of joint but differential duties of contract parties. A system which resorts to complementarity rests on the reference to the other system (of which legitimacy can still be independently controlled by the user state). In addition, procedural rules are to be clarified with regard to the standing of providers with regard to benefit-sharing claims. Due to the questionable public-private nature of financial claims raised by states, civil procedure rules need to clarify their legitimacy in advance.[63]

Where legally possible, the "piggy-back"-implementation is conceptually preferable for several reasons: it is advantageous for users and providers alike, and creates a robust implementation scheme for ABS compliance. However, it also encounters some limits.

(1) The "piggy-back"-implementation reduces costs for users, since they need to communicate with only one agency. The declaration can to be delivered at the occasion of approval application. Approvals granted have to be made public referring to the declaration. For providers, this installs a regular and reliable scheme for information disclosure which makes information available in a structured, transparent way. Patent information is structured by IPC codes mirroring technological sectors. Documentation in product approval procedures would guide inquiries into respective industry sectors

60 Godt, Šušnjar and Wolff, *NP-Umsetzung* (*Study I*).

61 TFEU Article 11. Explicitly European Court of Justice with regard to the European competition law framework of national public procurement in C-513/99, decision of 17 September 2002, ECR 2002 I-7213 – *Concordia Buses Finland.*

62 The supply with pharmaceuticals in the German system is based on a public social insurance model which provides for strong patient protection, which eventually prompts environmental protection, Godt, Šušnjar and Wolff, *NP-Umsetzung* (*Study I*), 117.

63 Godt, Šušnjar and Wolff, *NP-Umsetzung* (*Study I*), 139.

(pharmaceuticals, food ingredients and additives, chemicals and cosmetics). Complemented by funding organizations and *ex situ* collections,[64] a transparent data record would be built up.[65]

(2) It makes implementation more robust, as it slims down the ABS administration apparatus, sets true compliance incentives, and redirects the implementation focus. Although the legislative burden to implement documentation duties of ABS compliance in each procedure is high in the short term, it will reduce administrative operation costs in the long term. The national competent agency would not be flooded with declarations of legal use (by users), regulatory agencies would either report to the ABS competent agency where illegal use is detected,[66] (or report to it in a structured way: legal use *vs.* illegal use). In addition, since the permit could be withheld unless information is produced, a sincere incentive for users to comply is created. This is at least possible in pharmaceuticals and food additives regulations, as well as for permits which allow experiments with pesticides[67] and biocides,[68] as these are concrete, individual decisions and allow for declarations as to the origin/source of genetic resources as "raw material" and to use restrictions.[69] It is not cogent to finally deny the permit where information is *not* available. Various possibilities are conceivable to bridge the information delta. The central national focal point could convey information to the provider state, self-declarations could be accepted as substitution in case of credible affirmation that formal access requirements *could not* be met, and the payment of lump sums could be required to the biodiversity fund. Such a transnational information scheme would make the intergovernmental communication as required by the Nagoya Protocol operational.[70] More importantly, the administrative impulse would be

64 On collections see Godt, Šušnjar and Wolff, *NP-Umsetzung* (*Study I*), 117 et seq; Godt, "Ex Situ Collections."

65 We advised clear legal wording which submits *ex situ* collections to ABS-rules (notwithstanding to privileged "trusted ones"), and (often privately organized) funding organizations (not only "public" research funding); and not only duties to declare of recipients – as in the EU Regulation on ABS.

66 Godt, Šušnjar and Wolff, *NP-Umsetzung* (*Study I*), 5.

67 EU Regulation 07/2009 Article 54, Off. J. L 309/1 of 24 November 2009.

68 EU Directive 98/8/EC Article 17, Off. J. L 123/1 of 24 April 1998.

69 This is in contrast to general-abstract lists of approvals (as with the cosmetics, biocides, pesticides, chemicals). The violation of a use restriction of a general-abstract list registration does not allow for a recall of a substance from the list. However, the documentary value of the ABS-information would helpful. If the restriction is too narrow, the information might trigger re-negotiations with the provider state. Individual violations can be sanctioned with fines, Godt, Šušnjar and Wolff, *NP-Umsetzung* (*Study I*), Annex 27.

70 Godt, Šušnjar and Wolff, *NP-Umsetzung* (*Study I*), 48.

different. The focus of the national competent ABS agency would neither be the documentation of voluntary declarations, nor costly (since expert skills are required) inquisitorial inquiries in firm labs,[71] nor would agencies be stuck with the a possible blind documentation of resource use (which is already possible *de lege lata*,[72] and to which states would already be obliged by the Nagoya Protocol) without ABS focus.[73] The agency could focus on remedying the lacking consent and negotiations with providers – in contrast to the fuzzy penalization of declaration and documentation duties. It could re-direct administrative activity to providing information to users on how they can get (also *ex post*) proper ABS certificates (documenting ABS compliance). The regular declarations (recorded by regular civil servants) can still be recorded by the ABS agency. It should be noted, however, that the primary regulatory aim of approval procedures is product safety (enforced by prohibitions and limits). Therefore, many genetic resources enter the market place without procedural control. This, in turn, clarifies the nature of ABS requirements in product approval procedures. It is a check-point enabling transparency and enforcement where necessary. It cannot be the primary (and only) instrument of enforcement. The implementation scheme should equally take patent procedures and research control on board.

(3) An installed EU system would utilize the existing dynamics of the European multi-level governance system. That is to say, that the existing structures of strong product regulation on the EC level should be used without neglecting the opportunities for a sensible ABS management "above," "below" and "across" the EU level in respect of the national and private sovereignties. "Above" the EU level, member states and the EU should engage in negotiating amendments to the (intergovernmental) European Patent Convention.[74] The patent registries are a central source of technical data to which ABS information can be added. "Below" the central EU level, national governments should implement ABS user measures in areas of their own jurisdiction, in order to install experimental legislation on which future regulation could draw.[75] In our study of 2012, we identified several areas which have remained sovereign areas of

71 EU Regulation on ABS Article 9 Sec. 3b.

72 Godt, Šušnjar and Wolff, *NP-Umsetzung* (*Study I*) (documented for several areas of laws).

73 Since the agency would not be allowed to inquire about the country of origin and not request evidence for legal access and mutual agreed terms.

74 Which not even includes a voluntary disclosure rule similar to § 34a German Patent Act. This is in need of reform (see *supra* notes 27 and 28 for respective critiques of the EP-Agricultural Committee and NGOs).

75 Therefore, I support the EU Regulation on ABS in that it refrained from a pure central implementation scheme.

national law making (notwithstanding overarching EU law): national patent law, animal protection, research funding, residuary areas in biotechnology, public procurement, international development assistance, corporate governance codices, and civil procedure.[76] Yet within the EU realm, regulatory structures are not neatly separated; three structural types of procedures are distinguished:

(1) pure EU procedures (EU law *and* EU implementation, examples: biotech, pharmaceuticals, EU research funding);
(2) mixed multi-level procedures qualified by EU law with national implementation (example: food control); and
(3) mixed multi-level procedures with complementary legislation (example: biocides). Cross-cutting are (private) managerial schemes like corporate social responsibility.[77]

Whereas this article is not the right place to fully present the possible amendment to existing procedures, market approvals are of special concern for eventual benefits generated by the utilization of genetic resources and associated traditional knowledge. Three product sectors are of special interest: pharmaceuticals, foods, and the chemical sector in the broad sense (including inter alia pesticides and cosmetics). Relevant are the following regulations and directives:

(a) for the pharmaceuticals sector (providing for central procedure with European Medical Agency,[78] and for de-centralized, but orchestrated procedures[79]);
(b) food production (five regulations, one directive);[80]
(c) chemical industry.[81]

76 Godt, Šušnjar and Wolff, *NP-Umsetzung* (*Study I*).

77 For a concise overview: Godt, Šušnjar and Wolff, *NP-Umsetzung* (*Study I*), 148–155.

78 EU Regulation 726/2004, Off. J. L 136/1 of 30 April 2004.

79 EU Directiv 2001/83/EC Pharmaceuticals for human use, Off. J. L 3011/67 of 28 November 2001; EU Directive 2001/82/EG Veterinary medicinal products, Off. J. L 3011/1 of 28 November 2001.

80 EC Regulation No. 178/2002on general principles, Off. J. L 31/1 of 1 February 2002, revised by EC-Reg. No. 575/2006 (contaminants in foodstuffs), Off. J. L 100/3 of 20 December 2006; EC Regulation No. 1333/2008 on food additives, Off. J. L 354/16 of 31 December 2008, revised by EU-Reg. No. 238/2010, Off J. L 75/17 of 23 March 2010; EC Regulation No. 258/97 on novel foods, Off. J. L 43/1 of 14 February 1997; EC Regulation 1332/2008 on enzymes, Off. J. L 354/7 of 31 December 2008; and Directive 2002/46/EC on food supplements, Off. J. L 183/51 of 12 July 2002.

81 REACH Reg. 1907/2006 on chemicals, Off. J. L 396/1 of 30 December 2006; Dir. 76/768/EC on cosmetics, Off. J. L 262/169 of 27 November 1976; Dir. 98/8/EC on biocides, Off. J. L 123/1 of 24 April 1998; Reg. 1107/2009 on pesticides, Off. J. L 309/1 of 24 November 2009; Dir. 2009/41/EC on contained use of genetically modified organisms, Off. J. L 125/75 of 21 May 2009; Dir. 2001/18/EC on deliberate release of genetically modified organisms, Off. J. L 106/1 of 17 April 2001; and again EC Reg. No. 258/97 on novel foods, Off. J. L 43/1 of 14 February 1997.

As noted earlier, only permits for pharmaceuticals, food additives and research experiments can be retained for not producing evidence of ABS compliance. The other product approval procedures can only serve as depository of information with regard to the country of origin and eventual use restrictions, thus making the utilization of genetic resources and associated traditional knowledge more transparent and enabling providers to pursue given claims.

Considering the transparency advantages of the "piggy-back" approach, one could argue that its disadvantage is its focus on the "extremity" of the genetic resource use chain. This argument caters to the criticism that benefit-sharing comes too late and should not be limited to financial benefits. However, neither does the "piggy-back" approach limit the sharing duty to financial benefits, nor is it limited to financial flows attributed to speculative royalties of some lucrative end products sometime in the future. Already the sale of a given substance as a diagnostic kit would be covered in most cases. The simple use of a substance *in the process* could be detected if it were subject of a patent claim. Otherwise, the (illegal) use of resources in processes would only be detectable once the end product becomes marketed. Since disclosure rules do not focus on the end product itself, but on the "utilization of genetic resources" (including the production chain), they embrace processes as well as products, even if genetic resources are not part of the end product.

IV Conclusion

The biggest challenge to the implementation of Nagoya Protocol-compliant user measures is transparency which allows the pursuit of claims by providers. The EU Regulation on ABS is too narrowly focused on declaration duties and on the detection of violations by public administration. In contrast, an intelligent and transparent flow of information primarily between users along the production chain, and additionally between agencies is essential. A well-designed information system is not only in the interest of providers, but it is also in the interest of commerce as a protection against unsubstantiated accusations of biopiracy, and in the public interest of biodiversity protection as such, considering that the ABS mechanism was put in place as a means for preservation, not as a goal in itself. Since the Nagoya Protocol installs a truly

novel instrument, it is evident that there are high risks for the Nagoya Protocol to be misused as an impediment to innovation, to stifle entrepreneurial development, and as an undue source of income. However, the whole idea was to install a financial mechanism to transfer benefits, thus, some sort of transnational (earmarked) tax. The underlying idea is that a more fair and equitable distribution of wealth will hold the further depletion of biodiversity. It would certainly raise adherence of users could they trust that money which is transnationally transferred is benefiting biodiversity protection. The instrument to achieve this goal is not only provider states' regulation (and safeguards against corruption), but also mutually agreed terms which are interested in the way benefits are invested. Parties to the Nagoya Protocol *and* corporate governance remain under pressure to develop the Nagoya Protocol into this direction. The engagement of corporate governance to install functional ABS schemes would help. Workable EU-user measures are one brick in the whole edifice of employing ABS as a means for biodiversity protection.

CHAPTER 14

Collecting Plant Genetic Resources in Europe: A Survey of Legal Requirements and Practical Experiences

Lorenzo Maggioni, Isabel López Noriega, Isabel Lapeña, Vojtech Holubec and Johannes M.M. Engels

I Rationale for a Survey on Collecting Plant Genetic Resources in Europe

Collecting plant germplasm from the wild and farmers' fields is an essential task for the acquisition of genetic resources for conservation and use. Until recently, this activity has been carried out within and across countries in a largely unregulated fashion. We have focused our study on understanding how the current regulatory framework is affecting germplasm collecting in Europe.

Most of the studies around Access and Benefit-sharing (ABS) regulations and their effect on research and development activities have focused on developing countries. Very few works provide a comprehensive account of policies and laws regulating the conservation and use of genetic resources in Europe,[1]

* The authors wish to thank all the people who contributed data and information: Albania: Belul Gixhari; Armenia: Margarita Harutyunyan and Gayane Melyan; Austria: Paul Freudenthaler; Azerbaijan: Afig Mammadov and Zeynal Akparov; Belarus: Iryna Matys; Belgium: Marc Lateur; Bosnia and Herzegovina: Gordana Đurić and Fuad Gasi; Bulgaria: Liliya Krasteva†; Cyprus: Angelos Kyratzis; Estonia: Külli Annamaa; Finland: Elina Kiviharju; France: Audrey Didier, Francois Balfourier, Marie-Christine Daunay and Emmanuel Geoffriau; Georgia: Tamar Jinjikhadze; Germany: Ulrike Lohwasser, Magda-Viola Hanke, Evelin Willner, Frank Begemann, Matthias Ziegler and Sarah Sensen; Greece: Parthenopi Ralli; Hungary: Attila Simon; Israel: Lea Mazor, Rivka Hadas and Raul Klinerman; Italy: Gaetano Laghetti and Carlo Fideghelli; Latvia: Anita Gaile; Macedonia (FYR): Suzana Kratovalieva; Montenegro: Zoran Jovovic; The Netherlands: Chris Kik and Bert Visser; Norway: Åsmund Asdal; Poland: Zofia Bulińska-Radomska; Portugal: Ana Maria Barata, Filomena Rocha and Eliseu Bettencourt; Romania: Silvia Strãjeru; Russian Federation: Sergey Alexanian†; Serbia: Sreten Terzic, Miodrag Dimitrijević and Milena Savić-Ivanov; Slovakia: Daniela Benediková; Slovenia: Vladimir Meglič; Spain: Fernando Latorre; Sweden: Jens Weibull; Switzerland: Beate Schierscher Viret; Turkey: Ayfer Tan; United Kingdom: Mike Ambrose and Julian Jackson. The authors also thank Marie-Lara Hubert Chartier for her review of laws and literature on access and benefit-sharing in Europe, and Michael Halewood for his comments on an earlier version of this chapter.

1 D. Lange, *Europe's medicinal and aromatic plants: their use, trade and conservation* (Cambridge (UK): TRAFFIC International, 1998); Thomas Geburek, and Jozef Turok, eds., *Conservation*

 | DOI 10.1163/9789004293212_016

Legal Studies on Access and Benefit-Sharing

Series Editors

Elisa Morgera
Matthias Buck
Elsa Tsioumani

VOLUME 3

The titles published in this series are listed at *brill.com/labs*

Implementing the Nagoya Protocol

Comparing Access and Benefit-Sharing Regimes in Europe

Edited by

Brendan Coolsaet
Fulya Batur
Arianna Broggiato
John Pitseys
Tom Dedeurwaerdere

BRILL
NIJHOFF

LEIDEN | BOSTON

Library of Congress Cataloging-in-Publication Data

Implementing the Nagoya Protocol : comparing Access and Benefit-Sharing regimes in Europe / edited by Brendan Coolsaet [and four others].
pages cm. -- (Legal studies on access and benefit-sharing series, ISSN 2213-493X ; v. 3)
Includes bibliographical references and index.
ISBN 978-90-04-29320-5 (hardback : alk. paper) -- ISBN 978-90-04-29321-2 (e-book) 1. Convention on Biological Diversity (1992 June 5). Protocols, etc. (2010 October 29) 2. Biodiversity conservation--Law and legislation--Europe. 3. Nature conservation--Law and legislation--Europe. 4. Renewable natural resources--Law and legislation--Europe. 5. Sustainable development--Law and legislation--Europe. 6. Germplasm resources conservation--Law and legislation--Europe. I. Coolsaet, Brendan, editor.

K3488.I47 2015
346.404'695--dc23

2015006492

This publication has been typeset in the multilingual "Brill" typeface. With over 5,100 characters covering Latin, IPA, Greek, and Cyrillic, this typeface is especially suitable for use in the humanities. For more information, please see http://www.brill.com

ISSN 2213-493X
ISBN 978-90-04-29320-5 (hardback)
ISBN 978-90-04-29321-2 (e-book)

This book is printed on acid-free paper.

MIX
Paper from responsible sources
FSC® C109576
FSC www.fsc.org

Printed by Printforce, the Netherlands

Contents

Foreword

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

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

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

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

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