CHAPTER 13
The Multi-Level Implementation of the Nagoya Protocol in the European Union

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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"), the second protocol to the Convention on Biological Diversity (CBD) of 1992. Whereas a few member states hurried ahead, most of them awaited the implementation concept of the EU, which was adopted by the Council on 24 April 2014 (hereinafter referred to as the EU Regulation on ABS). The Nagoya Protocol entered into force on October 12, 2014, 90 days after the deposition of the document (ratification) was submitted to the secretariat. 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 accession in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing (ABS) legislation or regulatory requirements of the other Party.

The EU Regulation on ABS relies on a concept of centralized regulation and de-centralized enforcement. In its initial proposal, the European Commission opted for the technical instrument of a regulation, rather than a directive. The focus of the Regulation is on user measures, and prudently leaves the regulation of access to EU-genetic resources to the member states. Its concept rests on the duty to exercise due diligence to ascertain that genetic resources and associated traditional knowledge are accessed in accordance with applicable ABS legislation. I argue that the EU approach camouflages a simplistic understanding of how the uses of genetic resources are regulated in detail. The approach relies on a narrow understanding of applicability and scope, has broad exceptions, and grants broadband 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 willfully 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 willfully 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.

1 Adopted on 29 October 2010 in Nagoya, Japan, as the Second Protocol to the Convention on Biological Diversity of 1992.
3 See Norway (Norwegian Nature Diversity Act of 2005) and Denmark [For an in-depth discussion on ABS in Denmark and Norway, see contributions to this volume by Koersel (Chapter 2) and Teets (Chapter 7)].
5 Nagoya Protocol Article 15 Sec. 1.
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 15 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 [...]". 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), and on consequences for the later procedures of market approval. 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 lapse is created and duties become different. 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 bowers to reality, which is that bio-prospects, be they scientists or contractors, seldom generate "profits" from commercial utilization. Bio-prospects 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.


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,' 26.


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 utilisation of genetic resources with the Contracting Party providing such resources [...]".


13 Most contestable, Bück and Hamilton. "The Nagoya Protocol," 52 argues that approval procedure were excluded from the term "utilization" (against this interpretation: Godt; Subaş and Well, "NP-Umsetzung." 52 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 fulfill 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. 193 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 [...]". 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 and uncertified (illegal) tropical timber. In those two regulations, due diligence referred to a self-regulatory scheme, in which monitoring was delegated to private organizations. However, the EU Regulation is silent about the private monitoring scheme; it only refers to "associations of users" for the establishment of "best practices." 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" by granting them special treatment and reversing the burden of proof for acquisition therefrom. Regarding implementation, the Regulation contains itself with commanding member states to designate competent authorities. The European Commission will designate a "local point." The national authorities will transmit the information received to the European Commission.

The Regulation on ABS departs from its predecessors in various ways. It does not install a strict forward prohibition to use illegal material. 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 [...]". 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.

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14 EU Regulation on ABS Article 4 Sec. 1.
16 EC Regulation 355/2001, Off. J. L 125/25 of 22 November 2001. [See also contribution by Oliva (Chapter 19) in this volume.]
The monitoring concept of the EU Regulation is not one of self-regulation, but rests on two pillars of administrative control ("checkpoints").27 Recipients of public research funding are submitted to the duty to declare ex ante to have exercised due diligence.28 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).20 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 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 the resistance to connect domestic legal consequences directly to a violation of foreign laws still timely.35 I argued earlier that conflicts of laws36 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

26 Thus, it misses two approaches that were earlier labeled in an assessment report as "upstream focus" and "downstream focus." 27 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]. 28 EU Regulation on ABS Article 7 Sec. 1. 29 This concept seems to be a constitutionally-demanded privilege of science, and approved by member states (e.g. for Germany: the answer from the German federal government to a parliamentary questionnaire [27 June 2013], Drs. 17/14459 [p. 6]). 30 A formulation was proposed for tightening by the European Parliament’s Committee on Development (30 May 2013, PE 508.092/2013-00) as novel Article 7 Sec. 2. "Users shall declare that they have complied with:" 31 checking on their due diligence, EU Regulation on ABS Article 9 Sec. a. 32 WWF, Recommendation on amendments for ENVI vote on Regulation on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, of 1 July 2013 (on file with the author); Report of the European Parliament, new proposal Recital 8a, (PE 508.092/2013-00 of 27 July 2013), nn. 33 Initial proposal for a Regulation by the European Commission, Article 11 Sec. a. 34 EU Regulation on ABS Article 4 Sec. 3 liis. a and b. 35 Though not recognized as a rule yet, but only as a principle. 36 Ellen Hey, "Common but differentiated responsibilities," Max Planck Encyclopedia of Public International Law: MPEPIL (Oxford: Oxford Univ. Press, 2012) (last update February 2012) ([447]); T. Hönken, The Common But Differentiated Responsibility Principle in Multilateral Environmental Agreements - Regulatory and Policy Aspects (Alphen aan den Rijn: Kluwer Law Int L, 2009). 37 However, there are precedents which link the domestic prohibition to a violation of foreign laws, the diamond regime and the timber regime. cf. Godt, "Due Diligence." 38 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. Kamanu and G. Winter (London/Lifning U.A.: Earthscan, 2003) 409-458. 39 C. Godt, IPIs and Environmental Protection after Cancún (paper presented at the International Conference ‘Moving forward from Cancun – The Global Governance of Trade, Environment and Sustainable Development,’ Berlin, Germany, October 29–31, 2009). Available online: http://ecologic-events.eu/En/Eu/documents/Godt.pdf (Nov 2013). 40 For a detailed in depth analysis cf. Christine Godt, Eigentum an information (Tübingen: Mohr Siebeck, 2007): 384. 41 Nagoya Protocol Article 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.44 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 of 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.45 Thus, where information is not available with due diligence, the access permit cannot be obtained and mutual agreed terms will not be established, Art. 4 Sec. 5 of the Regulation now commands the utilisation to be discontinued.

(2) In the case of the EU Regulation on ABS, the due diligence monitoring system rests on two pillars, on the declaration duties of users and on checks by the competent authority.46 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).47 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 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.48 The declaration that due diligence is exercised49 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.50 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),51 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. 5 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.52

(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

45 EU Regulation on ABS Article 8 Sec. 4, also Goett, Haftung für Ökologische Schäden.
46 EU Regulation on ABS Article 3 Sec. 1.
47 EU Regulation on ABS Article 7 Sec. 2.
48 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): § 12 Sec. 1 No. 6 German Biotechnology Act (Genetikgesetz) 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 and only if and inceptive-echtliche Vorschriften and Belange des Arbeitsschutzes der Erreichung und dem Betrieb der genetischen Anlage nicht entgegenstehen.
49 EU Regulation on ABS Article 7, referring to Article 4 Sec. 5.
50 EU Regulation on ABS Article 7 Sec. 5.
51 Even penalty fines (in German "Zwangs geld") aimed at enforcing a positive behavior (not the omission) do not help to achieve the goal since the duty is confined to ascertain (not ABS-compliance).
52 EU Regulation on ABS Article 7 Sec. 5.
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. a lit.c of Directive 98/44/EC249
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 uti-

izes 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 com-
municated, and the ABS user compliance for the territory of the ABS member
states is not secured.

(a) Due to the exacerbated split between access in provider states and ben-
efits 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 ascer-
tain 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 decla-

rations will not be made public. No safeguards are taken that information

49 Case 34/09, Brüstle v Greenpeace, [2011] ECR 1-Bis, following the opinion of AG Rent. The
decision is highly contested: Concurring: Ingrid Schneider, "Das EU-URteil 'Brüstle ver-
sus Greenpeace': Bedeutung und Implikationen für Europa," Zeitschrift für geistiges
Eigentum / Intellectual Property Journal 3 (2011) 477; Rejecting: Joachim Taupitz,
"Menschenwürde von Embryonen – europäisch-patentrechtlich betrachtet," GEUR 124
(2012) 4; Andreas Plonner, "Aber Brüstle: EU access to the ECHR and the future of
European patent law?" Queen Mary JIP 3 (2012): 100; prior to the ECHR judgment, supporting
the plaintiffs position: Joseph Strauss, "Zur Patentierung humaner embryonaler
Stammzellen in Europa. Verwende die Stammzellenforschung menschliche Embryonen
50 Opinion of the European Parliament’s Committee on Agriculture and Rural Development
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 8 Sec. 2.

about uses in user states is transparent and accessible.56 Providers will depend
on accidental discovery of use and commercialization. No means for struc-
tured 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 pri-
marily 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 lit-
tle 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 pro-
vider 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
pres-
ervation 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, devel-
opped, and make their way up to market commercialization, coupled with gen-

eral rules which allow providers to seek judicial redress.57 This idea departs
from a different regulatory concept. Neither is it reduced to documentation
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 multi-level 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 by submitting 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.68

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.69

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

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

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69 This scheme rules qualifications protected by a business secret to remain undetected.

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other competences 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 (Söötigennotbebac.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 rests 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.

(i) The "piggy-back" implementation reduces costs for users, since they need to communicate with only one agency. The declaration can be delivered at the occasion of the 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.
(pharmaceuticals, food ingredients and additives, chemicals and cosmetics). Complemented by funding organizations and ex situ collections, 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 it 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 pesticides67 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 be 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 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 jure 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 generic 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

64 On collections see Godt, Šuljić and Wolff, NP-Umsatz (Study 7), 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, Šuljić and Wolff, NP-Umsatz (Study 7), 3.
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 be helpful. If the restriction is too narrow, the information might trigger re-negotiations with the provider state. Individual violations can be exercised with fines; Godt, Šuljić and Wolff, NP-Umsatz (Study 7), Annex 27.
70 Godt, Šuljić and Wolff, NP-Umsatz (Study 7), 48.
71 EU Regulation on ABS Article 9 Sec. 3b.
72 Godt, Šuljić and Wolff, NP-Umsatz (Study 7), (documented for several areas of laws).
73 Since the agency would 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.
75 This is in need of reform (see supra notes 37 and 38 for respective critiques of the EP-Agricultural Committee and NGOs).
76 Therefore, I support the EU Regulation on ABS in that it originated from a pure central implementation scheme.
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

1 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

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1 O. Lague, Europe’s medicinal and aromatic plants: their use, trade and conservation (Cambridge (UK); TRAFFIC International, 1998); Thomas Geburek, and Jure Turek, eds., Conservation

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PART I

Access and Benefit-Sharing Regimes in Europe

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Foreword

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

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

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

The publication of this book coincides with the entry into force of a new EU regulation that fully implements the mandatory elements of the Nagoya Protocol in the Union. The EU and its 28 Member States are now well prepared to implement the Protocol, once it enters into force ninety days after the deposit of the fifteenth 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 raising 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