8 Strict Liability for "Registered Collections"? Assessing Regulation (EU) No 511/2014

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8.1 Content and Scope

This legal expertise, which was commissioned by the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) in September 2017,[10] investigates the question if liability for *ex situ* collections is exacerbated by registration under Article 5 Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (EU ABS Regulation).[11] This question arose in the course of the international debate as some national jurisdictions privileged basic research by shifting the duty to declare utilization to registered collections.[12]

The analysis covers three distinct questions:

- Do Article 4.7 and Article 4.5 of the EU ABS Regulation impose a ´strict liability´ on registered collections (*infra 2*)?
- What exactly is the standard of care required by registered collections (*infra 3*)?
- Can collections limit their liability via contractual clauses (*infra 4*)?

The analysis concludes with a birds-eye-view on the issue at hand (*infra 5).*

Three limitations restricted the scope of the study at the outset:

- We assumed that German law is the applicable law for claims of contractual and tortious liability: Since the EU ABS Regulation itself does not regulate liability, the rules applicable to the liability regime fall within the purview of national law. The aim was to focus the analysis exclusively on the effects of the norm triangle of Article 4.5, Article 4.7 and Article 5 of the EU ABS Regulation. However, as it is possible to choose the applicable law or contracts and (in a limited manner) for torts (delicts), this assumption is not necessarily realistic and clearly limits the extent to which the analysis can be generalized.
- The second limitation pertains to the fact that we concentrated on the relationship between the registered collection and the user who receives genetic resources from that collection. We excluded the relationship between the collection and the provider country

[10] Full-length expertise available in German language under https://www.bfn.de/fileadmin/ABS/documents/ABS_Dokumente_ab_September_2015/20180618_Haftung_Registrierter_Sammlungen_gemaess_VO_EU_Nr.511_2014_.pdf.

[11] Off. J. of 20.5.2014 L 150/59.

[12] C. Chiarolla, Commentary on the ABS Provisions of the Draft Biodiversity Law of France, in: B. Cool-seat/F. Batur/A. Broggiato/J. Pitseys/T. Dedeurwaerdere (eds), Implementing the Nagoya Protocol, Brill/Nijhoff: Leiden/Boston, 2015, 77-114 (p. 89).

as well as the relationship between the recipient and the competent national authority (CNA).

- The third limitation is the assumption that registered collections submit to the regulations of the Nagoya Protocol (Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) required). Therefore, the question of when collections "utilize" – and **therefore** require PIC and MAT – is also excluded in the present analysis.

8.2 Interpretation of Article 4.7 of the EU ABS Regulation

The interpretation of Article 4.7 of the EU ABS Regulation is central to this analysis. In principle, the norm can be interpreted in three different ways: It can broaden the liability of collections (strict liability), it can shield them from liability, or it has no effect at all since it regulates something else.

Article 4.7 of the EU ABS Regulation stipulates:

"Users obtaining a genetic resource from a collection included in the register of collections within the Union referred to in Article 5.1, shall be considered to have exercised *due diligence* as regards the seeking of information listed in paragraph 3 of this Article."

The BfN tender for this expertise was motivated by the widespread belief that Article 4.7 of the EU ABS Regulation increases the liability of registered collections. The underlying notion was that of a seesaw, i.e. the privileged treatment of one party comes at the expense of the other party. Article 4.7 EU ABS Regulation, so the argument goes, contains a privilege on behalf of the receiver of material from registered collections. Yet, the user of that material may still have to stop use under the last sentence of Article 4.5 of the EU ABS Regulation. Therefore, Article 4.7 of the EU ABS Regulation could be interpreted as a mechanism that shifts responsibility from the user to the registered collection.

From a tort lawyer´s perspective, the inferred transformation of the general process-oriented rule of "*due diligence*" under Article 4.1 of the EU ABS Regulation into a strict guarantee under Article 4.7 of the EU ABS Regulation is not at all intuitive. In principle, anyone is responsible to adhere to his or her **own** standard of care.

Therefore, we undertook **four inquiries *de lege artis*** in our expertise: a literal interpretation, an inquiry into the legislative history, a systematic analysis of Regulation (EU) No 511/2014 as a whole (2.1), and last but not least, an inquiry into the telos of "Regulatory *Due Diligence*" (2.2.).

8.2.1 Literal Interpretation, Legislative History and Systematic Analysis

The **literal interpretation** inquired into whether Article 4.7 of the EU ABS Regulation implies a legal fiction in favour of the receiver. The German language text version suggests this interpretation. The consequence would be a conclusive assumption that the user is diligent; the duty is shifted to the registered collection and the liability of collections is transformed into a causal (strict) liability. However, other language versions of the text suggest that it is a pro-

cedural regulation, implying (at least for German dogmatic culture) that the assumed fact is rebuttable.[13] In German language versions of subsequent documents submitted by the European Commission (EC), the provision is indeed explained as a **rebuttable presumption**. Therefore, we find that the German version of the EU ABS Regulation is misleading in this regard. In accordance with the majority of the language versions, we interpret Article 4.7 as being procedural. It aims at the presumption of a fact, namely that PIC and MAT were sought as documented (not the law) – this fact is rebuttable. We conclude that Article 4.7 does not aim to substantively change the liability of registered collections from fault based to causal strict liability. The receiver retains the duty to exercise *due diligence*. The privilege enshrined in Article 4.7 of the EU ABS Regulation is the reversal of the burden of proof.

With regard to the **legislative history**, we found that Article 4.7 of the EU ABS Regulation did not change throughout the parliamentary process. Only the last sentence of Article 4.5 of the EU ABS Regulation was introduced at a later stage. The addressee of this norm, however, is the user, not specifically a registered collection. Based on the inquiry into the legislative history, a conceptual shift in the liability regime from negligence to strict liability cannot be inferred.

The **systematic analysis** examined the triangular relationship between the last sentence of Article 4.5, Article 4.7 and Article 5 of the EU ABS Regulation. In a binary world of two liability concepts (negligence and strict liability), three interpretations are possible. One possibility is to argue that the **final result** in Article 4.5, i.e. to "discontinue utilization", transforms the fault-based standard of the general norm of Article 4.1 into a causal, strict liability, as indicated above. This then implies that collections would be held liable for any shutdowns, e.g. of production. The second possibility is to construe Article 4.7 as a shield against potential shutdowns – as users are considered to have exercised *due diligence* – with the effect that no damages could occur. As a result, registered collections would also be protected, very much like an umbrella. This concept would imply that the fault-based concept of Article 4.1. is not altered by Article 4.5. The third alternative is to argue that all three norms stipulate different things.

With regard to the systematic interpretation, we conclude that Article 4.5 of the EU ABS Regulation stipulates a liability that is of a **hybrid nature**. The law combines the duty standard with a conclusive result. It neither leaves the fault concept in Article 4.1 completely untouched, nor does it install a straightforward strict liability. *Tertium datur.* There are two modern models for such a combination: The liability of internet providers and *Due Diligence* Liability in the Convention on Contracts for the International Sale of Goods (CISG), the latter may be even more important for the given context.

The **liability of internet providers** ties the infringement by a responsible person to the provider company, which can stop the infringement. It submits the non-infringing internet provider to a duty standard with a final result: It might have the duty to delete the content from its server. In this case, a **dynamic duty** with escalating steps is applied, since the provider has to inform the infringer, check the content. In the end, if the infringing activity does not stop, it is up to the provider to delete the content. In a similar vein, the last sentence of Article 4.5 of

[13] Acknowledging that other jurisdictions, e.g. France, recognize also the possibility of rebuttable legal fictions.

the EU ABS Regulation denotes a result-based endpoint and complements the basic norm in Article 4.1 of the EU ABS Regulation. Ordinarily, the user "exercises *due diligence* to ascertain that […]". Article 4.5 of the EU ABS Regulation now adds a provision in the event that **subsequent uncertainties** materialize – since normally the user, being diligent, would have asked the other party (i.e. the provider) for clarification. Subsequent uncertainties typically arise at the end of a transfer chain where persons/companies are affected which are not identical to those who/which fell short of their duties and contributed to the persistence of uncertainties. Consequently, Article 4.7 of the EU ABS Regulation has no operational meaning for Article 4.5 of the EU ABS Regulation beyond reversing the burden of proof. Within the system of Article 4 of the EU ABS Regulation, just like Article 4.5, Article 4.7 serves to complement Article 4.1 of the EU ABS Regulation.

The central location of the *due diligence* concept in Article 4.1 of the EU ABS Regulation suggests that the **CISG**-rules, especially as applied in the context of international corporate mergers and acquisitions,[14] are supposed to shape the Regulation's concept of liability. The CISG stipulates a so called "**defect liability**". In essence, it denotes that the seller is only strictly liable for so-called **hidden defects**. The rationale is that open defects can be detected by the buyer. This is where *due diligence* comes in – International sales law is the origin of the due diligence requirements. However, under the CISG, *due diligence* is not the basis for liability (as in the EU ABS Regulation) but a defence instead: The buyer can only hold the seller liable for open defects, i.e. where the seller is notified of them. In addition, we found that *due diligence* liability under the CISG is always limited in scope – pure economic damages are not covered. Transposed to the given context, this means that the idea that the *due diligence* liability in Article 4.5 of the EU ABS Regulation would, as a matter of fact, encompass the liability for having to stop utilization is not in line with the origins of *due diligence* liability.

Thus, there are two strong systematic arguments against a clear-cut liability as the prevailing concept here. First, strict liability - for being an exception to the rule - requires explicit legislation and is usually coupled with mandatory insurance. However, Article 4.5 of the EU ABS Regulation is silent on collections. It only regulates "the user". Second, *due diligence* liability under the CISG is limited in scope to direct damages and does not cover economic losses. Therefore, we conclude that Article 4.5 cannot systematically be interpreted as a provision that transforms a collection's liability into a strict liability with respect to the mandated discontinuation of utilization.

8.2.2 **The Telos of Due Diligence Liability**

Finally, we looked for the telos of *due diligence* liability and inquired into related regulations for guidance on how to interpret the norm triangle. We compared the EU ABS Regulation with four selected product regimes, which contain privileging presumptions and include some

[14] See also COM Guidance (2016/C 313/01), p. 11.

form of regulatory intermediary:[15] tropical timber (Regulation (EU) No 995/2010[16]), personal data (Regulation (EU) 2016/679[17]), carbon emissions from large vessels (Regulation (EU) 2015/757[18]), and medical products (Directive 93/42 EEC[19]). We included medical products because of recent case law on the liability of intermediaries. The main questions were:

- What is the liability concept in the respective regulations?
- How are privileging presumptions (akin to the one in Article 4.7 of the EU ABS Regulation) construed?
- How are intermediaries conceived? Do privileges result in a burden-shift to intermediaries?

As a regulatory concept, *due diligence* implements a type of non-governmental self-regulation ultimately rooted in globalization: The essential function is transnational. It links the regulatory requirements of one country to enforcement in another country. Originally, the concept grew out of compliance with technical standards. Today, it has become a mechanism to import or export regulation, binding together regulatory regimes, which are otherwise territorially limited: With respect to data protection and carbon emissions from ships, we **export** EU regulation. With timber and genetic resources, we **import** regulation (without directly enforcing extraterritorial laws). The underlying model of *due diligence* is business administration, not law. Its core is dynamic information and not static law, squeezed into the binary code of legal and illegal. Typically, *due diligence* regimes install two mechanisms, namely an intermediary between the company and government authorities, and a presumption of compliance that verifies and/or documents the adherence to certain standards.

Tropical Timber – Regulation (EU) No 995/2010

Regulation (EU) No 995/2010 laying down the obligations of operators who place timber and timber products on the market (EU Timber Regulation) is a direct conceptual precursor to the EU ABS Regulation, with which it shares several attributes, the most notable of which is a dual system of privileged and unprivileged timber imports. For those imports that fall under either the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)-regime (Regulation (EC) No 338/97)[20] or the Forest Law Enforcement, Governance

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[15] C. Godt, „Due Diligence“ Modernes Umweltmanagement oder Regulierungsverweigerung? E.-W. Luthe/U. Meyerholt/R. Wolf (eds), Der Rechtsstaat zwischen Ökonomie und Ökologie, Mohr Siebeck: Tübingen, 2014, 115-132 (p. 126).

[16] Off. J. L of 12.11.2010, 295/23; complemented by Implementing Regulation 607/2012 (Off. J. ABl.EU of 7.7.2012, L 177/16) and Delegated Regulation 363/2012 (Off J. of 27.04.2012, L 115/12).

[17] Off. J. of 4.5.2016, L 119/1.

[18] Off. J. of 19.5.2015, L 123/55.

[19] Off. J. of 12.7.1993, L 169/1. The Directive has been repealed by the Medical-Devices-Regulation (EU) 2017/745, Off. J. of 5.5.2017, L 117/1.

[20] Off. J. of 3.3.1997, L 61, transposing the Convention on International Trade in Endangered Species of Wild Flora and Fauna, 1973 [CITES].

and Trade (FLEGT)-scheme (Regulation (EC) No 2173/2005),[21] and are thus registered during border controls, a privileging presumption applies ("shall be considered to have been legally harvested for the purposes of this regulation"), which exempts importers from their *due diligence* obligations. Importers who first place such timber on the market can assume that the respective wood is marketable and therefore they are acting in good faith. For wood that is not covered by either a FLEGT-license or a CITES permit (so-called "green lane"), a general *due diligence* standard applies: Operators placing timber on the internal market for the first time shall exercise *due diligence* to minimize the risk of placing illegally harvested timber on the internal market.

However, timber importers can alleviate some of their *due diligence* duties by using a *due diligence* system established by an accredited monitoring organization, Article 4.3 EU Timber Regulation. Like registered collections, **monitoring organizations** are controlled by the competent national authorities and act as service providers for users. In the case of the EU Timber Regulation, they verify the proper use of their *due diligence* systems by timber importers. They have to have the appropriate expertise and the capacity to exercise their functions. The operational tasks of actually using the *due diligence* system (seeking information, assessing and mitigating potential risks) and the legal risk (liability[22]) remain fully with the importer[23] – there is no shift of duties. In contrast to the EU ABS Regulation, the EU Timber Regulation contains a general prohibition of placing illegally harvested timber on the market, Article 4.1 EU Timber Regulation. There is no such prohibition regarding genetic resources. This may be why the EU-parliament insisted on inserting the rather potent mechanism of the last sentence of Article 4.5 of the EU ABS Regulation. For users obtaining genetic resources from a registered collection, acquisition in good faith is derogated from by means of the last sentence of Article 4.5 of the EU ABS Regulation.

Data Protection – Regulation (EU) 2016/679

The General Data Protection Regulation (EU) 2016/679 contains a somewhat hidden presumption of conformity in the first sentence of Article 42.2, which provides that data protection certification may be used for the purpose of demonstrating the existence of appropriate safeguards provided by processors of personal data located in third countries (outside the EU). Certifications are issued and renewed by certification bodies, which need to demonstrate a level of expertise regarding data protection in order to be accredited by the supervisory authorities. Certification, as such, does not exclude the liability of the data processor nor does it reverse liability by shifting it to the certifier. The duties, as stipulated by the Data Protection Regulation, remain with each participant (user-intermediary-public authority), which is

[21] Off. J. of 30.12.2005, L 347. Licensing scheme within the FLEGT-Regulation. The respective licenses can only be issued by countries that have a Voluntary Partnership Agreement (FLEGT-VPA) with the EU in place, confirming that the timber productions at hand were logged in full compliance with the laws of the exporting country. FLEGT is the acronym for the EU's Forest Law Enforcement, Governance and Trade Action Plan, which was established in 2003.

[22] A. Fishman/K. Obizdinski, European Union Timber Regulation: Is It Legal? RECIEL 23 (2) 2014, p. 263.

[23] Client Earth, October 2011, p. 12, 13 (last accessed 30.05.2018).

even provided for in the Regulation itself: "A certification does not reduce the responsibility of the controller or the processor for compliance with this Regulation and is without prejudice to the tasks and powers of the competent supervisory authorities", Article 42.4 EU Data Protection Regulation. It should be noted that the presumption of conformity, here, is an empty one:[24] There is no privileging presumption that the data processor is actually in compliance with the requirements of the Data Protection Regulation. The certification merely documents the security level regarding data protection laws for the individual whose personal data is being processed, much like the Technischer Überwachungsverein (Technical Inspection Association, TÜV) approval for medical products documents conformity with technical standards (see *infra*). Furthermore, as something inherently peculiar to the EU Data Protection Regulation, there is no reversal of the burden of proof: The processor has to actively prove that it is not in any way responsible for the event giving rise to the data protection violation, Article 82.3 Data Protection Regulation. A certification, here, may be used as an element by which to demonstrate compliance, but it can be a snapshot at most,[25] showing only conformity with the requirements of the Regulation for one particular moment in time – otherwise, any later infringements would not be contestable.

Because of its special nature with respect to accountability principle,[26] the EU Data Protection Regulation is only of limited usability as far as a direct comparison of privileging presumptions is concerned. The term *due diligence* itself may not appear in the Regulation, there is however a call for something which can only be described as a *due diligence* system in Article 24.1 Data Protection Regulation. A **clear separation of duties** and responsibilities of each actor (data processor – intermediary certification body – supervisory authorities), which excludes any shift of liability, is nowhere more apparent than in this Regulation. Furthermore, in accordance with the other instruments we examined, the EU Data Protection Regulation clearly shows that the **procedural safeguarding of information** (to prove compliance) is a core function of privileging presumptions.

Carbon Emissions from Large Vessels – Regulation (EU) 2015/757

Since January 2018, large vessels, have to carry "documents of compliance" **issued by an accredited verifier** when entering European ports. Compliance is directed towards information about the total amount of carbon-exhausts from a given ship, not towards compliance with emission caps. The duties rest with the ship owners (usually companies). They have to submit monitoring plans to the verifiers, which detail the methods chosen by companies to monitor and report the CO2-exhausts from their ships. According to Article 7 Regulation (EU) 2015/757, companies have to review (and potentially adjust) their monitoring plans on an annual basis. The verifiers then review the monitoring plans for, inter alia, completeness and accuracy (Article 6 Regulation (EU) 2015/757) and check, whether reviews successfully culminated in modification of the monitoring report. Eventually, the verifier will issue timely lim-

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[24] E. Lachaud, Why the certification process in the General Data Protection Regulation cannot be successful, Comp. L. & Sec. Rev. 32 (2016), 814 (820, 823).

[25] J. Eckhardt, in: H. A. Wolff/S. Brink (Hrsg.), Beck Online-Kommentar Datenschutzrecht, Beck: München (21. Ed. 2017) DS-GVO, Article 42.45.

[26] See also Article 5 Regulation (EU) 2016/679.

ited documents of conformity. The competent authorities will view these documents as (rebuttable) evidence of compliance – this is the privileging presumption contained in Article 19.1 Regulation (EU) 2015/757. The primary goal of these documents is not to guarantee material validity, but instead to allow for the transparency/traceability of controls.

Medical Products – Directive 93/42 EEC

In contrast to pharmaceuticals, medical products are **not** submitted to a prior **public** authorisation, which secures safety and for which a company is held strictly liable if it does not comply with the terms of the authorisation. Medical products are merely controlled by so called "notified bodies" – in Germany, this body is the TÜV. There is no strict liability in place, neither for the manufacturer, nor for the surveying verifier.

The verifier issues a "conformity statement" with technical standards, based on documentation provided by the manufacturer. The TÜV neither tests the product, nor does it check the company. It does not secure safety as such – only compliance with the respective technical standards. The statement allows marketability. For possible violations of the duty of care, the verifier is obliged to take out civil liability insurance.

In the "Silicon"-case decided by the Court of Justice of the European Union in February 2017, the Court ruled that the exact duties of verifiers are determined by the EU Directive autonomously in the first place. Only where the liability regime is not stipulated or not in full by European Union´s law itself, liability is governed by national law. While the Directive was silent about the disputed duty to perform unannounced inspections on-site, the Court interpreted this silence as evidence that – then – there must be no general duty to perform on-site inspections. However, if there is concrete evidence of danger, the verifier has to react and secure safety – otherwise it will be liable. This indicates a dynamic conception of the duties of the verifying bodies.

The lesson to be learnt for the given context is the following: Article 5 EU ABS Regulation, which determines the duties of collections, is silent on liability. Consequentially, for collections registered under Article 5, liability is to be based upon national law. A strict liability standard is an exception to the rule and requires positive regulation. More importantly, the provision does not mandate collection holders to take out insurance. This link between mandatory insurance and augmented forms of liability is a characteristic of all strict liability regimes recognized by the EU and its Member States.[27] That registered collections and their duties are construed in a different manner is further support for the argument against the EU ABS Regulation establishing a result-based strict liability for registered collections.

8.2.3 **Conclusion**

Our analysis reveals that Article 4.7 EU ABS Regulation stipulates a presumption of facts and is **procedural** in nature. It does not presume that "PIC and MAT are correct" (material validity), but it presumes that PIC and MAT were accessed. This reading is supported by

[27] Cf. the decisions of the Cour de Cassation (France) (Ch. Com.) from 8.3.2017 and 14.6.2017, commented by S. Mirabel and printed in Le Droit Maritime Français 2017, S. 596 ff. und S. 612 ff.

statements of the Commission,[28] which indicate that *due diligence* "is not intended to guarantee a certain outcome" but to ensure that "the necessary information related to genetic resources is available all throughout the value chain". The privilege of Article 4.7 EU ABS Regulation is limited to the fact that those who receive genetic resources from registered collections do not have to seek PIC and MAT themselves. It neither reverses the ABS-duty, thus shifting it to registered collections, nor does it create strict liability. These findings are supported by the telos inquiry. It reveals that the core of all *due diligence* systems is risk management as a dynamic concept. The duty of care shifts over time and depends on the circumstances. The function of the intermediary is to raise the level of information and transparency. An intermediary does not take over responsibilities outside the stipulated realm; the respective presumptions only reverse the burden of proof and change the level of required evidence. Overall, the concept of *due diligence* remains intact: Each player in the chain retains its duties. The regulation itself does not stipulate any shift, duplication, or extension of these duties.

8.3 What is the Standard of Care for a Registered Collection?

8.3.1 The Dual Structure of Article 5 of the EU ABS Regulation

What exactly are registered collections required to do under Article 5 of the EU ABS Regulation?

As a matter of principle, the standard of care for registered collections can be found in Article 5 EU ABS Regulation; the legal basis is national law. Interviews conducted with technical experts evidenced that they clearly distinguish between the five requirements in Article 5.3 of the EU ABS Regulation: Sub-sections (a) and (c) to (f) are deemed to be technical requirements demanding **technical** expert knowledge, whereas sub-section (b) is deemed to be something else.

Sub-sections (a) and (c) to (f) stipulate the application of standardized procedures in the course of the collection's workflow as well as the collection and documentation of externally and internally generated **scientific-technical data** for reasons of **traceability**. With regard to these technical requirements, it is common sense among scientists that the standard of care cannot be absolute. Scientific documentation is ubiquitously faulty. This is inherent to science. Although documentation should be correct for its own sake, single entries are often wrong for various reasons, which are elaborated upon in our study (e.g. spelling errors, mixing-up badges). As far as incoming material is concerned and ABS and MAT mistakes rest on objectively faulty scientific documentation, the standard of care, by law, cannot be strict but is – on grounds of reasonableness - limited to a professional, careful and mindful comparison of data, which might give rise to doubts.

This supports the finding made for Article 4.7 of the EU ABS Regulation above (*supra 2*): What matters, is the individual standard of care. The yardstick for the standard of care is the function of a collection: It is the intermediary function to secure the information right at the beginning of the utilization chain between providers and later users. As an intermediary, the

[28] COM Guidance (2016/C 313/01), p. 11.

instrument of “registered collections” is installed to raise the trust of both provider states and users. It is not installed to serve the interests of European users only. In contrast, since users have always trusted public collections, it seems that having “registered” collections as an instrument, should primarily increase the trust of providers.

In contrast, sub-section (b) requires “**supply only with documentation**”. The central question for the expertise to answer was whether this duty implies that collections have to examine the (legal) correctness of PIC and MAT. More concretely: Is there a duty to perform a legal inquiry into whether the provider country is a party to the CBD and the Nagoya Protocol, or if the signing authority is competent? What is the duty of care in a situation in which a scientist plausibly argues that he applied for PIC and MAT but received no answer? We argue that the requirement in sub-section (b) to “supply with documentation” is different from “legal examination”. The full text states: “supply only with documentation providing evidence that the resources were accessed in accordance with applicable ABS-legislation”. We interpret this norm as being **descriptive**, referring only to the process of documentation. It does not require the collection to “provide evidence on third party rights”, which is a standard formulation for legal service contracts. The documentation has the function of presenting evidence for the fact that PIC and MAT were sought. In legal philosophy, the requirement to “provide evidence that the resources were accessed in accordance with applicable ABS legislation” qualifies as a so-called “**normative fact**” (in German: “Normtatsache”).[29] These are hybrids between facts and norms but are to be treated as facts. Whereas Eike Schmidt´s analysis on how to deal with normative facts was geared towards delineating the tasks of legislation and the judiciary, we propose to transpose his ideas to delineate the tasks of an executive agency and a scientific collection. The collection´s task must be limited to reviewing the **plausibility** and **completeness** of facts. They do not have an enforcement duty. Therefore, they do not owe an in-depth legal analysis by law but merely an informed, educated review of the data and its completeness. We resort to the *due diligence´*s risk based approach: The more problematic and dubious the source region, the higher the standard of care would have to be. This is similar to what the Timber Regulation asks for in Article 6.1, sub-section (b) Regulation (EU) No 995/2010 by requiring the prevalence of illegal timber harvesting in the country of harvest be taken into account in the risk assessment. Apart from the above-mentioned arguments, however, any collection is free to provide an additional legal service on a contractual basis to check for “third party rights” on top of the regulatory required standard of care, e.g. like the German Collection of Microorganisms and Cell Cultures (DSMZ) does.

8.3.2 **Survey of Technical Mistakes and Challenging MAT-provisions**

Recognizing that collections are intermediaries, we made three observations at the outset that inform our survey on technical mistakes and challenging MAT-provisions:

- The benchmark for the duty of care regarding external mistakes is less strict than for internal mistakes: The collection has control over its own (internal) processes.

[29] E. Schmidt, Der Umgang mit Normtatsachen, in: C. Broda/E. Deutsch/ H.L. Schreiber/H. J. Vogel (eds), Festschrift R. Wassermann, Neuwied/Darmstadt: Luchterhand, 1985, 807.

- The situation with regard to incoming material (*infra 1-4*) is different to the one regarding outgoing material (*infra 5*).
- The law clearly distinguishes between **subjective and objective standards**: In CISG case law, subjective capacities are irrelevant (lack of staffing, money, time and experience does not shield against liability). The rationale is that the professional standard does not care about internal shortfalls. The "objective" standard denotes what the recipients can rightfully expect. This is determined by the collections' role in science, the material collected and by the goals of the collection itself (e.g. being a service-provider).

We identified five particularly challenging situations with regard to technical errors and specific MAT-provisions, such as use-restrictions:

1. In the category of **external mistakes regarding incoming material** (accession), the depositor might submit no PIC/MAT. He/she might argue that the country of origin has no legislation in place, research is free, or authorization was requested but not obtainable. We take the position that the standard of care for registered collections requires the collection to demand that the supplier of genetic resources submits a respective declaration. Article 5 does not require the collection to perform a legal review, as stated above. However, in a situation where the authorization is not obtainable for political reasons (the presumption is: timely limited), the material can be deposited in the collection for a reasonable time, but it cannot be transferred to third parties. At the same time, the scientific standard regarding the principle of reproducibility/verifiability of scientific results must not be undermined.
2. Regarding **external mistakes when transferring material** to third parties, the essential element of defect liability can be transposed to this context (even if the CISG would not directly apply). It seems reasonable to offset the duty to check for external mistakes with the respective *due diligence* of the professional recipient. The standard here is whether the recipient "ought to have known".
3. A more complicated situation arises where the supplier of genetic resources requests **secrecy**. According to Article 7.5 of the EU ABS Regulation, business secrets are to be respected. However, Nagoya-relevant information cannot be kept secret. Thus, the challenge here is to distinguish business secrets from Nagoya-relevant information: The country of origin is certainly Nagoya-central, and must be disclosed (unlike, for example, the exact geographical coordinates of the discovery). If a supplier demands this information to be kept confidential, the resource cannot be stored in the registered part of the collection. The omission of this information when transferring material will result in liability of the collection.
4. **Accessions with use restrictions**. When taking in a sample which is restricted by a contractual "no deposit"- clause, the collection evidently violates its duty to exercise *due diligence* as the acceptance of this material violates the contract. As a Nagoya-collection, they are expected to conduct a plausibility test, and this is not plausible. They violate the invested trust of the supplier (unless it is collusive). The situation is similar with regard to restrictions such as "no commercial use". If such material is supplied as a Budapest-deposit (patent filing), which mandates transfer to interested (commercial) third parties, collections would act in a grossly negligent way by accepting it. Not only would they violate a duty vis-à-vis the provider country, they would al-

so make a process-related mistake by accepting material into the collection of which they know that it will be used in a way that is not in compliance with the contract. The same is true for collections, which cannot assure that use restrictions will be processed properly. If that is the case, a registered collection should not accept material with such a restriction into its collection.

5. The accession situation is to be distinguished from the **transfer of "use restricted" material** to third parties ("outgoing material"). In principle, restrictions are common practice and therefore unproblematic. The collection is not responsible for the user. It is not an extended arm of the national enforcement agencies of the provider countries. A use restriction is not a straightforward prohibition but only a duty to re-negotiate. However, the situation is different with regard to "non-commercial use" clauses. While parties often feel safe when using this clause, the term is in fact highly misleading. Its content is determined by legal traditions – and differs respectively: In industrial countries, commercial use starts with placing a product on the market (intention of making profit). Research before that moment (regardless of who conducts it) can then be qualified as non-commercial use. In most developing countries, however, commercial use is marked by the transition from basic to applied research and thus depends on the respective actors. Whose definition prevails in case of a conflict?

Since it is a part of public law, PIC authorization is governed by the law of the provider country. The MAT, in contrast, is governed by the contractual statute (between the provider state and the user). That means it is **not** up to the collection to re-define the terms of the contract. Therefore, the DSMZ has rightfully changed its standard terms and conditions recently. We argue that the transfer of "non-commercial use" restricted material to commercial partners requires a **three-step-test**: (1) When a collection transfers material to non-experienced recipients, it is necessary that the collection clarifies the term. Otherwise, the recipient will be deceived. (2) When the collection transfers a "non-commercial use"-restricted sample to a multinational, we consider the transfer contract null and void for being collusive. Damages for contractual liability could therefore not be adjudicated. The EC rightfully interprets a clause stipulating "non-commercial use" as "no transfer to third commercial parties".[30] Again, it is the (external) expectation of a registered collection that determines the informational duties. (3) The limitations stated here do not apply, however, when the country of origin understands "non-commercial research" as industrialized countries (here: the place of residence of a registered collection) do, i.e. as extending until market placement.

8.4 Contractual Limitation of Liability

With regard to contractual limitations of liability, we found no peculiarities. Liability can be limited in kind, in time and in amount, as far as the usual limits are respected (these are stricter in Europe than in the US[31]). Liability can exclude slight/ordinary negligence but not

[30] EU Sectorial Guidance Document - Collections (Version V 3.0. of 22.12.2017), p. 20.

[31] L. A. Dimatteo, International Contracting: Law and Practice, Wolters Kluwers: Alphen, 3rd edn 2013, pp. 173-179.

gross negligence. One can reduce deadlines and the amount if these limits remain reasonable. The exclusion of “liability for the legal analysis of third party rights” would, under normal conditions, simply be declaratory and would not regulate anything. However, if the collection had contractually taken over the service of examining existing third-party rights, such an exclusion would be void. One cannot exclude liability for primary contractual duties.

8.5 Conclusion

We conclude that the key rationale of what registered collections ought to do in order to meet the standard of care is epitomized by the question “Do collections have the duty to monitor the change of intent of their recipients?” We argue that this is **not** the case: Article 5 of the EU ABS Regulation aims to install registered collections as intermediaries. Neither are they extensions of the enforcement agencies of provider countries nor extensions of the provider state itself. Consequently, it is not within the purview of collections to inform the provider states about potential changes of intent by the users. Equally, they do not become risk absorbers for recipients, as they do not issue guarantees in the vein of “free from third party rights”. Their function is to ”secure information in the chain“.

Discussion

In the discussion, the EC confirmed that registered collections are not a checkpoint but that their main function is to secure information and to lower risk that genetic resources have been obtained in contravention of ABS rules. One participant suggested that the need to provide documentation contributes to lowering risk and is an improvement on the past, when there was often little or no documentation accompanying genetic material in collections.

A number of reasons were identified as to why collections are not in a position to check if PIC and MAT are formally correct. It was noted there are issues of practicality and feasibility, e.g. there are no standards in the bilateral ABS system, there are language barriers etc., meaning that no collection would have the ability or resources to check all the documentation. A couple of participants highlighted the need for a balanced and practical approach, which takes into account what is possible for collections to do, such as checking whether there is access legislation or a national focal point (NFP) and whether the relevant documents have been provided. In order to check the documentation is legally correct, collections would have to go back to each provider country and ask for conformation, which is not regarded as the role of the collection when accepting material. It was pointed out that documents, e.g. signature, time stamps etc. can be falsified but the role of the collection is to conduct a “plausibility check” only and not an in-depth legal check of the documents.

It was reiterated that users still have to look at the documentation provided by registered collections, i.e. the user still has a due diligence obligation which cannot be taken away. One participant noted that only the individual researcher knows what he or she is doing with the material and can check whether this is in accordance with the conditions of PIC and MAT and that many researchers often do not disclose to the collection or perhaps even colleagues what they are doing, e.g. due to competition. One participant also commented that many commercial users do not necessarily do commercial research on genetic material received

from collections, i.e. they also do basic research such as referencing functions, comparing samples for taxonomic purposes etc.

Prof. Godt confirmed in the discussion that according to her legal analysis, the EU ABS Regulation does not place strict liability on collections. The decision by the EU court on medical products was referred to again and it was noted that this decision indicates that where liability of the intermediary is envisaged by an EU regulation, this must be coupled with compulsory insurance. As there is no need for registered collections to take out insurance, it was concluded that strict liability is not likely to be intended by the EU ABS Regulation.

13 Program

Program

Meeting of the European Competent National Authorities implementing the Nagoya Protocol and the corresponding EU Regulation

Isle of Vilm, Germany
April 23 - 26, 2018

After entry into force of the Nagoya Protocol and the corresponding Regulation (EU) No. 511/2014 the European member states are now obligated to take steps towards their operationalization. In several EU member states “Competent National Authorities” (CNA) are in the course of formation. To foster this process and to be mutually supportive among the member states there is a great demand to exchange information on ongoing technical and structural processes as well as early implementation experiences.

Following the successful meeting of European CNAs last year in Germany on the island of Vilm, the Nagoya CNA–Unit of the German

Federal Agency for Nature Conservation (BfN) will organize once more a platform for exchange in 2018.

The upcoming informal meeting will complement the half-day meetings of EU CNAs occasionally taking place before EU ABS Expert Group meetings in Brussels. It will provide an ideal opportunity to identify, present and discuss challenges as well as possible solutions on all relevant topics related to the implementation of Regulation (EU) No. 511/2014, in particular on first registration processes of collections, experiences in user controls and checkpoint communiqués as well as on any best-practice-procedures, tools or mechanisms for exercising due diligence.

The output of the meeting will be a report containing abstracts of contributions of the experts as well as workshop proceedings including the collected views on different subjects to support the future work of the EU CNAs.

Monday, 23.04.2018

Arrival of the participants at the island of Vilm

18.30 *Dinner*

20.30 **Welcome and brief introduction to the meeting**

- THOMAS GREIBER, FEDERAL AGENCY FOR NATURE CONSERVATION

21.00 *Informal get-together*

Tuesday, 24.04.2018

08.00 *Breakfast*

09.00 **Implementation of Regulation (EU) No. 511/2014: Status quo and current challenges**

- EU COMMISSION: MERY CIACCI

09.30 **Risk-based plans / selection of potential users / remote inspections / onsite inspections** *(ca. 15 min. presentations)*

- PRESENTATION OF FIRST EXPERIENCES AND VIEWS BY

- Denmark: Eva Juul Jensen, Gry Errboe, Danish Environmental Protection Agency
- Germany: Thomas Greiber, Sebastian Jank, Federal Agency for Nature Conservation
- Netherlands: Abel van Winkoop, Nethterlands Food and Consumer Product Safety Authority
- Poland: Magdalena Jankiewicz-Damska, Ministry of the Environment
- Sweden: Louise Bednarz, Swedish Environmental Protection Agency
- UK: Slides presented by Thomas Greiber on behalf

11.00 Coffee/tea

11.15 Risk-based plans etc. (continued)

- Discussion: all Member States

12.00 **Brief update: Any implementation progress in other Member States** *(max 5 min. slots)*

- Updates by other participants
  - Austria
  - Belgium
  - Czech Republic
  - Croatia
  - Finland
  - Hungary
  - Spain

12.30 Lunch

14:00 **Practical scenarios**

(Member States to hand in cases before the meeting)

- Case 1: Development of recombinant proteins
- Case 2: Tracing the transport of nitrogen through ecosystem with isotopes
- China
- Case 4: Lundbeck
- Others?

15.30 Coffee/tea & cake

16.0 **Round of "stupid" questions**

- Companion animals: Mari Rusanen, Natural Resources Institute Finland

- Member States to pose questions and raise implementation challenges (any question is a good question)
- Discussion

17.00 **End of day 1**

18.30 *Dinner*

20.00 *Informal gathering*

Wednesday, 25.04.2018

08.00 *Breakfast*

09.00 **Registration of collections under Article 5 of Regulation (EU) No. 511/2014 – first application**
- Dr. Amber Hartmann-Scholz, German Collection of Microorganisms and Cell Cultures (DSMZ)
- Questions & answers

10.30 **Potential liability of registered collections – legal implications of Article 4 (7) of Regulation (EU) No. 511/2014**
- Prof. Dr. Christine Godt, University of Oldenburg
- Questions & answers

11.15 *Coffee/tea*

11.30 **Discussion**
- Member States only

12.30 *Lunch*

14.00 **Best practices under Article 8 of Regulation (EU) No. 511/2014 – application for recognition by CETAF**
- Dirk Neumann, Bavarian Natural History Collections & Bavarian State Collection of Zoology (on behalf of CETAF)
- Questions & answers

15.30 *Coffee/tea*

15.45 **Awareness raising and capacity building – measures to inform / involve user sectors in Member States**

- GERMANY: RESULTS OF POTENTIAL USER SURVEY & PROJECT ON STAKEHOLDER CAPACITY-BUILDING, ELLEN FREDERICHS & UTE FEIT, FEDERAL AGENCY FOR NATURE CONSERVATION
- POLAND: BOŻENA HACZEK, MINISTRY OF THE ENVIRONMENT

17.00 **Way forward & end of meeting**

17.30 Reception at the invitation of the German Federal Agency for Nature Conservation (BfN)

21.00 Informal gathering and farewell

Thursday, 26.04.2018

07:30-09:00 Breakfast

07.25 First boat from the Isle of Vilm, arrival in Lauterbach at 7.35
08.25 Boat from the Isle of Vilm, arrival in Lauterbach 8.35

Train connection from Lauterbach/Mole at 8.00/9.00, arrival in Bergen auf Rügen at 8.20/ 9.20, direct train from Bergen auf Rügen at 9.27 to Berlin Central Station, arrival at 13.16

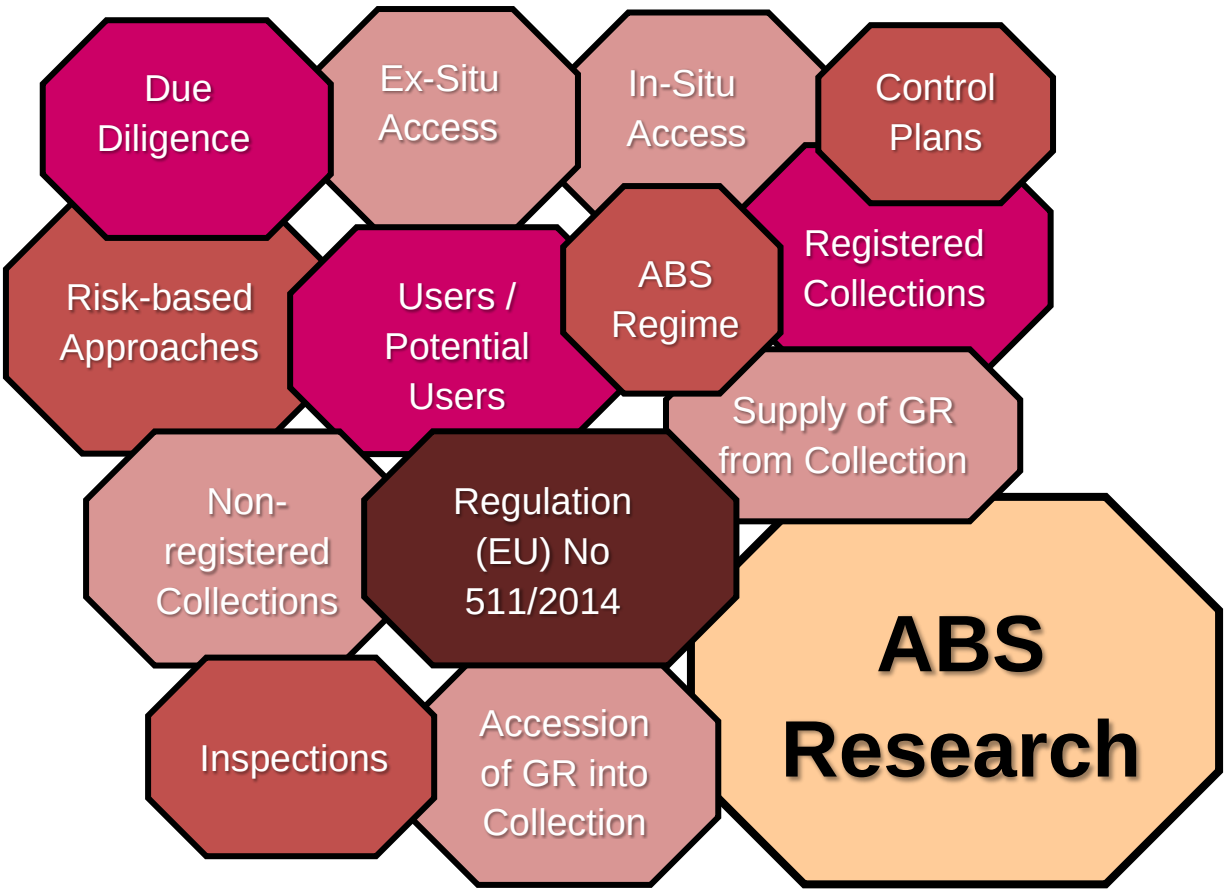
09.20 Boat from the Isle of Vilm, arrival in Lauterbach at 9.30
Train connection from Lauterbach/Mole at 10.00, arrival in Bergen auf Rügen at 10.20,
direct train from Bergen auf Rügen at 10.55 to Berlin Central Station, arrival at 15.16

The Isle of Vilm, 94 hectares in area, is a beautiful nature paradise, a Baltic Sea coast treasure. The island's natural beauty has long fascinated people. The first steps to protect its ancient forest from logging were taken back in 1812. In 1936, the Isle of Vilm was set aside as a nature reserve. Since 1990, it has been one of the core areas of the Southeast-Rügen Biosphere Reserve.

Ute Feit, Thomas Greiber and Elizabeth Karger (Eds.)

Second Meeting of the European Competent National Authorities Implementing the Nagoya Protocol and the Corresponding EU Regulation

Final Report



Federal Agency for Nature Conservation

BfN-Skripten 515

2018

Second Meeting of the European Competent National Authorities Implementing the Nagoya Protocol and the Corresponding EU Regulation

Final Report of an International Meeting hosted by the Nagoya CNA-Unit of the German Federal Agency for Nature Conservation on the Isle of Vilm, Germany, 23 - 26 April 2018

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Thomas Greiber
Elizabeth Karger

BfN
Federal Agency for Nature Conservation

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