Due Diligence and the Regulation of Transnational Economic Activity: Regulation (EU) No 511/2014 Compared to Other EU Due Diligence Schemes

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Abstract The Due Diligence obligation is a central component of the ABS Regulation No. 511/2014, which transposes the Nagoya Protocol into European Union law. This chapter explores the concept of 'due diligence' and the particular ways in which it got implemented by the Regulation. Built on the idea of a 'self-standing duty', the regulation absorbed the regulatory spirit of neighboring regulations of autonomous EU law. It is against this background, that Reg. 511/2014 has to be interpreted. We argue that the transposition into binding EU law transforms the standard of care into an objective one, leaning towards the standard established by due diligence in international business law ('what ought to be done needs to be done'). Concurrently, the subjective dimension is strict ('what the user ought to know') and correlates with the informational infrastructure stipulated by the respective due diligence regime. As far as the allocation of responsibilities between private and public actors is concerned, we identify Reg. 511/2014 as a rather peculiar due diligence regime compared to other EU Regulations.

Keywords Due diligence · Self-regulation · Risk management · Intermediaries · Compliance

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1 Introduction

The European Union's (EU) implementation of the Nagoya Protocol rests on the concept of 'Due Diligence' (DD). The central article 4.1 Regulation (EU) No. 511/2014[1] (ABS-Regulation) stipulates:

> Users shall exercise **due diligence** to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilize have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.

In contrast to early thoughts, which envisioned a reciprocal linkage of provider and user state regulation by allowing a direct enforcement of provider State rules by user state countries,[2] the EU Regulation stipulates a duty of care regarding lawful access as an EU *sui generis* obligation. This is not evident, since modern law encounters various forms of 'import' of foreign and 'export' of domestic law.[3] Yet, any enforcement of 'foreign' law in the realm of administrative law was felt as an encroachment on the territoriality principle, restricting user states' sovereignty. Therefore, the European legislator of Reg. 511/2014 opted for a scheme, which we call 'regulatory hinge joint'. The term describes a regulatory program, which allows for a *translation* of provider state regulation into a self-standing rule under user state law, thus mitigating potential territoriality concerns. Beyond that, member States remain free to implement their own access regulations.[4]

At the time when the draft of Reg. 511/2014 was being deliberated in the European Parliament, the concept of DD was broadly discussed in UN-fora,[5] the

[1] Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (2014) *Official Journal L150, p. 59.*

[2] Barber et al. (2003). This is standard practice in private international law, see Kegel and Schurig (2004), pp. 135ff. For the CBD, it was conceptualized under the principle of 'common but differentiated duties' as acknowledged in International Environmental Law, and implemented in the UNFCCC, see Godt (2003).

[3] Analyzed from the angle of both, public and private law. Public lawyers stress the "perforated sovereignty", e.g. Meyer (2018), pp. 66, 98 (analyzing standards and enforcement in transnational meat markets); Private lawyers focus on market regulation, e.g. Joerges (2013), p. 409 (proposing a concept of a "three dimensional conflict of laws").

[4] Some have and some have not. As of August 2020, only five countries have installed member state access regulations: France, Spain, Bulgaria Malta and Croatia, for further details see Winter in this volume.

[5] After John Ruggie as Special Representative had delivered his "Framework"-Report to the Secretary General in 2008, the UN Human Rights Council adopted the UN Guiding Principles on Business and Human Rights, UN Doc. A/HRC/17/31 (21 March 2011), on the relationship of DD-considerations and UN-principles on businesses and HR, see ILA Study Group on DD (2016), p. 28.

Organization for Economic Cooperation and Development (OECD)[6] and in academia.[7] At the same time, the EU Timber Reg. 995/2010,[8] which explicitly embraces a DD-system, was on its way to practical implementation.[9] Before that, DD had already become a well-established concept in business administration, routinely used in mergers and acquisitions,[10] and evolved into a tool to combine accounting rules and social responsibility (Directive 2014/95/EU[11]). The concept expanded, putting 'risk management' for all kinds of policy goals center stage. Today, various regulations subscribe to DD as architectural design (below, Sect. 3.3); covering a wide range of subjects. Reg. 2015/757,[12] for example, regulates carbon emissions from large vessels. The General Data Protection Regulation (Reg. 2016/679)[13] addresses the processing of personal data. And Reg. 2017/821 is about minerals and metals originating from conflict areas.[14]

The following analysis is interested in the precise content of the DD obligations contained in article 4.1 and article 4.5 Reg. 511/2014: What exactly do they require? The fulfillment of said DD obligations is to be declared when research funding is granted and when a product has reached the marketing stage ('monitoring'), and will be enforced through administrative supervision ('checks'). Considering that DD as a regulatory instrument is quite new, it is most likely that it will be the Court of Justice of the European Union (CJEU) that will determine the standard of care under article 4 Reg. 511/2014. Therefore, we ask: To what extent does article 4 Reg. 511/2014 borrow from earlier conceptualizations of DD in public international law and

[6] OECD Guidelines for Multilateral Enterprises, adapted on 25 May 2011 by OECD members as well as Argentina, Brazil, Egypt, Latvia, Lithuania, Morocco, Peru and Romania, http://oecd.org/daf/inv/mne/48004323.pdf (last visited 14.3.2019).

[7] At that time, the International Law Association (ILA) had already installed a 'Study Group on Due Diligence in International Law' (ILA Study Group on DD). The study group issued two reports, the first on 7 March 2014, the second in July 2016.

[8] Reg. (EU) No 995/2010 (2010) *Official Journal* L295, p. 23 (applicable since 03.03. 2013); complemented by Commission Implementing Reg. (EU) No. 607/2012 (2012) *Official Journal* L177, p. 16 and Commission Delegated Reg. (EU) No 363/2012 (2012) *Official Journal* L115, p. 12.

[9] Reg. 995/2010 is also referred to by the European Commission in its Guidance Document (2016) *Official Journal* C313/1 [hereinafter: EU Commission (2016)] at p. 11.

[10] Ibid.

[11] Dir. 2014/95/EU (2014) *Official Journal* L 330, p. 1 lays down the rules on disclosure of non-financial and diversity information by large companies, amending the general accounting Dir. 2013/34/EU (2013) *Official Journal* L182, p. 19. It requires companies to publish reports on their policies on environmental protection, social responsibility, treatment of employees, human rights, anti-corruption and diversity.

[12] Reg. (EU) 2015/757 of the EP and the Council on the monitoring, reporting and verification of carbon dioxide emissions from maritime transport (2015) *Official Journal* L123, p. 55, also abbreviated 'MRV-Regulation'.

[13] Reg. (EU) 2016/679 (2016) *Official Journal* L119, p. 1.

[14] Reg. (EU) 2017/821(2017) *Official Journal* L130, p. 1; complemented by Delegated Reg. 2019/429 (2019) *Official Journal* L75, p. 59.

international business law (Sect. 2)? Does the implementation in directly enforceable EU law give rise to an *autonomous* EU concept of DD, distinct from its predecessors? In order to identify the structures of such a unique European concept, we compare five European regulations which arguably rest on a DD scheme (Sect. 3). Subsequently, we scrutinize the DD scheme of Reg. 511/2014 in more detail (Sect. 4). At the end, we draw conclusions from the preceding inquiries (Sect. 5).

2 Conceptual Background of Due Diligence

The preconditions of what could be meant by 'Due Diligence' (DD), in fact, derive from two conceptual parents, namely DD in public international law (Sect. 2.1) and DD in international business law (Sect. 2.2). This legacy begs the question as to how to interpret DD regulations stipulated under EU law (Sect. 2.3).

2.1 Public International Law

In public international law, DD is conceived as a concept to mediate interstate relations when there is significant change. It has been traced back to Grotius.[15] In this context, it defines the yardstick against which to assess, whether a responsible state has complied with "certain obligations and standards".[16] Hence, also in international law DD refers to conduct.[17] It grew out of the debate on state responsibility.[18] The context is harm prevention and the addressee is the state deemed to be accountable for actual or future harm. The yardstick refers to traditional categories of human responsibility for harm, fault and reasonable care.[19] The reason is that in

[15] Kulesza (2016), p. 3. According to Freeman, as noted in his 1955 lecture at the Hague Academy of International Law, due diligence requires "nothing more nor less than the reasonable measures of prevention which a well-administered government could be expected to exercise under similar circumstances" (cited after ILA Study Group on DD, 2014, p. 3).

[16] Koivurova (2010).

[17] French, cited by ILA Study Group on DD (2016), p. 1.

[18] The ILC engaged in codifying the Law of state responsibility since the 1950, first focusing on wrongful acts, since the 1970s opening a second track on injurious consequences of acts not prohibited by international law. In 1996 draft Articles and Commentary dealing with prevention, co-operation, and strict liability for damages were proposed. In 2001, the ILC (International Law Commission) submitted Draft Articles on Prevention of Transboundary Harm from Hazardous Activities (the 'Prevention Articles'), *Int'l Law Comm'n, Rep. to the General Assembly on the Work of Its Fifty-third Session, U.N. Doc. A/CN.4/SER.A/2001/Add.1 (Part 2),* and in 2006 Principles on the Allocation of Loss in case of Transboundary Harm Arising Out of Hazardous Activities ('Loss Allocation Principles'), *Int'l Law Comm'n Rep. to the G.A, U.N. Doc. A/CN.4/SER.A/2006/Add.1*; ILA Study Group on DD (2016), p. 24; in depth: Kulesza (2016), p. 115ff.

[19] ILA Study Group on DD (2016), p. 2.

international law causal (non-fault) responsibility was not embraced as a legal concept for accountability.[20] While few 'certain obligations and standards' exist, the key point of reference is the 'do-no-harm-principle', which is acknowledged as a principle of customary international environmental law.[21] The required standard of care is to be determined based on the circumstances of the individual case.[22] Because of this flexibility, the level of care varies. While it is questionable to what extent subjective conditions like the economic stage of development, effective control (over a territory) and technological expertise are to be taken into account,[23] the specific duties of a given country depend on a balance test, which takes due regard of the level of effort required (reasonableness[24]) and the degree of harm (as a correlation between probability and grandeur of damage).[25] Scholars have described the DD principle as an instrument for transforming the duty 'not to do harm' into an obligation to install procedures which prevent significant transboundary damage.[26] This line of reasoning is explicit in cases involving environmental impact assessments.[27]

Since the beginning of the twenty-first century, international law has been moving towards binding multinational companies into the fabric of global governance and accountability. By and large, the Ruggie Report (2008[28] and 2011[29]) was seen as a turning point in this regard.[30] Earlier, the International Law Commission's (ILC) Principles of Loss Allocation of 2006 had already referred to the responsibility of private actors, resulting in a shared responsibility of industry (prevent harm, bear the costs, provide third party cost coverage by insurance or pooling) *and* states (to regulate).[31] Yet, with international legal subjectivity of multinational companies

[20] Ibid.

[21] Takano (2018), p. 2.

[22] ILA Study Group on DD (2014), p. 2; ILA Study Group on DD (2016), p. 15.

[23] ILA Study Group on DD (2016), p. 11 (on control) and pp. 14–16 (on economic differentiation in various contexts).

[24] "The golden thread", ILA Study Group on DD (2016), p. 8.

[25] ILA Study Group on DD (2016), pp. 12, 21, 23.

[26] Dupuy and Viñuales (2015), p. 60. McIntyre (2011), pp. 136, 143 clarifies that the International Court of Justice in the *Pulp Mills* case (Argentina v. Uruguay, 20.4.2010) as the respective landmark decision conceptualized procedural rules as preventive, but substantial rules as separate obligations, yet complementary. The Seabed Disputes Chamber of the International Tribunal for the Law of the Sea in its Advisory Opinion "Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area" (case no. 17, 1.2.2011), para. 120 concurs and suggests that the DD obligation is a conceptual bridge between harm prevention and precaution, cautioning: Brunnée (2016), p. 7.

[27] Bremer (2017).

[28] Known as "Framework for Business and Human Rights" (2008), published in *UN Doc. A/HRC/8/5*, p. 1.

[29] Known as "Guiding Principles on Business and Human Rights", above n. 5.

[30] Lambooy (2010), p. 429.

[31] ILA Study Group on DD (2016), p. 26. An even earlier precedent is the IMO-created fund for oil spills.

remaining an open question, responsibilities have evolved on various levels, eventually crystallizing in statutory requirements and private liability rules in state law.

Thus, in international law, DD has become a bifurcated concept. Primarily interstate, it defines the duty of states to anticipate harm and install a legal regime for prevention, sic. regulation. Secondly and independent of state obligations, DD refers to the (general) duty of industry to respect human rights.[32] The duty as such is not conditioned by size and not restricted to the confines of one undertaking. The central idea is that DD relates to the supply chain. It therefore became a corner stone principle of Corporate Social Responsibility. With regard to the scope of accountability, Principle 19 (b) (ii) of the UN Guiding Principles on Business and Human Rights (2011) installs "leverage" as a central term, defined as the "ability to effect change in the wrongful practices of an entity that causes harm".[33] The OECD-Guidelines explicitly refer to a business responsibility to "seek ways to prevent or mitigate adverse human rights impacts [. . .] even if they do not contribute to those impacts".[34] Thus, under international law, DD obligations with regard to third parties' actions appear to be similar for states and businesses.[35] With regard to the specific content, the duty is flexibly conditioned by subjective factors such as resources, time and size, and objectively by the nature and context of the operations, as well as the likelihood and severity of the risk.[36] Yet, the principle of DD does not define the substance/the result/the outcome—neither for states, nor for multinationals. It is a process-oriented, open-ended standard. Kulesza stresses that the principle of DD is not binding law.[37] It is a normative instrument to determine the appropriateness of state regulation (respectively its absence) *ex post*, thus 'good governance'.

[32] ILA Study Group on DD (2016), p. 29 recognizes that the terminology 'due diligence' was deliberately referenced to both, human rights law and business management practice, indicating this as "cleverly". Yet, the report cautions as to the misleading potential. With regard to the intention of finding a language familiar for both, human rights and the business community, see also Martin-Ortega (2014), p. 50.

[33] Wood (2012), p. 63 at 65 argues that leverage applies also to businesses which have not contributed to a harm and coin this type of accountability "leverage-based negative responsibility".

[34] Sec IV OECD Guidelines on Multinational Enterprises (2011 version), p. 31, para 3; p. 33, para 43.

[35] ILA Study Group on DD (2016), p. 32.

[36] ILA Study Group on DD (2016), pp. 34–35—(at p. 34 reminding that Guiding Principle 17 explains that business enterprises conducting appropriate human rights due diligence "should not assume that, by itself, this will automatically and fully absolve them from liability for causing or contributing to human rights abuses").

[37] Kulesza (2016), pp. 115ff.

2.2 International Business Law

In International business law, DD has been a long-standing practice, going back to US regulation of financial markets after the Great Depression of the 1930s.[38] It was a means to reduce liability. Over time, it expanded to include any investigation relating to the acquisition of companies or assets in the commercial context, risk analysis in finance, and pre-contractual inquiries in general.[39] DD became an ubiquitous and globally applied (not limited to the US) business management tool that can be equated with the defense requirement in article 38 United Nations Convention on Contracts for the International Sale of Goods (CISG) "to give timely notice".[40] Today, the standard example of DD in various industries is the process by which a potential acquirer evaluates a target company or its assets for acquisition.[41] More recently, it was integrated into corporate sentencing laws.[42] The original business theory behind DD holds that performing this type of investigation contributes significantly to informed decision making by: (a) enhancing the amount and quality of information available to decision makers and (b) ensuring that this information is systematically used to deliberate in a reflexive manner on the decision at hand and all its costs, benefits, and risks.[43] The legal rationale is driven by the 'caveat emptor principle' (buyer beware), and thus by the risk of the purchaser to lose the right to claim contractual remedies if the defect was evident to him/her at the time the contract was performed. In other words, the seller will only be strictly liable for so-called hidden defects. Again, the question of how much effort is reasonable depends on the circumstances.[44] The notion that the seller will only be liable for hidden defects stands in opposition to both, the fault-based causation principle, which underlies DD in public international law, and the contractual liability under

[38] § 11 US Securities Act of 1933, see Bainbridge and Anabtawi (2017), p. 255. Acknowledging these US roots: DiMatteo (2009), p. 292; the same is reported in the 'human rights' literature, see: Martin-Ortega (2014) at p. 51, referring to Spedding (2005).

[39] For structuring the process of the various types of DD in the acquisition process see Bainbridge and Anabtawi (2017), pp. 255–263.

[40] Art. 38 sec. 1 CISG reads: "The buyer must examine the goods, or cause them to be examined, within as short a period as is practicable in the circumstances." It might be worth mentioning that equivalent norms do exist in national law, e.g. in Germany and Austria. However, in these two countries this rule is limited to contracts between two professional traders. On the related CISG-case law, see Schwentzer (2019), para. 6.

[41] Hoskisson et al. (2004), p. 251.

[42] In these concepts, due diligence serves as a defense against liability (examples: sec. 90.1 UK Financial Services and Markets Act 2000, sec. 7.2 UK Bribery Act 2010, sec.11 (b) (3) (A) US Securities Act 1933) or to reduce a sentence (example: § 8 B2.1. US Sentencing Commission's Federal Sentencing Guidelines Manual (2018), available at https://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2018/CHAPTER_8.pdf, last visited 15.3.2019).

[43] Chapman (2006).

[44] Literature conceptualizes four stages of 'effort standards' on a continuum ranging from least to greatest efforts: "commercially reasonable efforts", reasonable efforts", "all reasonable efforts"/ "reasonable best efforts" to "best efforts", Bainbridge and Anabtawi (2017), p. 273.

general national laws.[45] Additionally—in contrast to most national systems of contractual liability—CISG liability is always limited in scope to 'direct' damages: Pure economic damages are not covered.[46]

To summarize, DD in the corporate world is qualified by the following characteristics: As a matter of principle, the exercise is undertaken in the firm's own interest and—in most cases—voluntarily.[47] The procedure is understood as multidisciplinary, not driven by law. It is structured as a risk assessment exercise and as a 'two party undertaking'. Both parties first agree on the scope, the timeline and the milestones. This approach highlights the nature of DD as industry self-regulation. The selling party is expected to submit documents, which the purchasing party then examines. A professional and strict 'out to know' standard applies; the addressee of this standard is the buyer, not the party which sets the risk in the first place. Still, it should be born in mind that in international business law, DD duties may also rest with the economic actor that 'sets the risk' in the first place (supportive/residual duties). A seller, for example, needs to make sure that all pertinent information is disclosed to the potential buyer in the documents he or she submits.[48]

2.3 EU Corporate Social Responsibility (CSR) Regulation

It is questionable whether the European legislator took one of the above predecessors as a clear model when drafting article 4 Reg. 511/2014. While legislative material suggests that the European Parliament was inspired by the debate in public international law,[49] the European Commission seems to have been influenced more by the debate in international business law.[50] The EU Commission explains DD in its Communication of 2016[51] as follows:

– Due diligence refers to the judgment and decisions that can reasonably be expected from a person or entity in a given situation. It is about gathering and using information in a systematic way. As such it is not intended to guarantee a certain outcome or aiming at perfection, but it calls for thoroughness and best possible efforts.

[45] Just as example, §§ 437, 280, 281 283, 311a German Civil Code (BGB).

[46] In a previous legal analysis (Godt and Burchardi 2018, p. 60), we inferred that a DD liability in Art. 4.5 Reg. 511/2014, which would encompass the liability for registered collections for the stop of downstream utilization, is not in line with the origins of due diligence liability.

[47] An element stressed by McCorquodale (2009), p. 392.

[48] Bell (2001), pp. 125f.

[49] In a resolution of the EU Parliament made in 2010 in context of CSR in international trade agreements, the model of public international law is clearly articulated, cp Resolution P7_TA(2010) 0446, p. 11 Sec. 26 lit. e.

[50] In document (COM SWD 2012 0292, p. 31), the Commission explicitly refers to an ICC document, which takes reference to existing DD processes inside firms.

[51] EU Commission (2016), p. 10.

- Due diligence goes beyond the mere adoption of rules and measures; it also entails paying attention to their application and enforcement. Inexperience and lack of time have been held by the courts not to be adequate defenses.
- Due diligence should be adapted to the circumstances — e.g. greater care should be applied in riskier activities, and new knowledge or technologies may require adaptation of previous practices.

This language resonates more with DD in business administration than with DD in public international law. Article 4 Reg. 511/2014 stipulates the following duties: "to ascertain", "to keep, seek, and transfer", "to obtain" and "to establish" (sic. "produce compliance") "or discontinue". These duties only make sense against the background of a standard situation in which a firm did not originally access the resource but purchased it further down the chain. However, in contrast to what the business community might have wished for (and the Commission Notice insinuates[52]), article 4 Reg. 511/2014 does not primarily stipulate a purchaser's defense (being fulfilled in the party's own interest), an 'estoppel'. Instead, it stipulates a legal duty—not vis-à-vis the provider state directly, but vis-à-vis the state of utilization.[53] Yet, what does this imply? When analyzing the adjudication of the International Court of Justice (ICJ) with regard to the 'no-harm-obligation', Brunnée found that at the level of substantive law, the court distinguishes between a "duty to take diligent steps to *prevent* harm"—which it then treats as a separate procedural obligation—and the "duty to take diligent steps not to *cause* harm", which the judges consider to be a duty that cannot be violated simply by a failure to act diligently.[54] She cautions that this conceptualization contradicts the take of international environmental law scholars on the concept. The majority considers violations of procedural obligations to be in breach of the duty to prevent harm, regardless of whether harm occurred or not. If one mirrors this juxtaposition with the first part of article 4.5 Reg. 511/2014 (duty *to produce* compliance with provider states laws) and the last part ("or discontinue utilization"), one might speculate whether the CJEU will follow the ICJ's interpretation and interpret the "*or*" of the last part of the sentence as equally procedural in nature.[55] This interpretation will be discussed in more depth below under Sect. 4.1.

Moreover, at the time when the ABS-regulation was negotiated, other EU DD Regulations on the management of supply chains were already being deliberated. They focus more on DD as a business management tool than on either of the

[52] EU Commission (2016), p. 10: "If a user — no matter at which step in the value chain — takes reasonable measures in seeking, keeping, transferring and analyzing information, the user will be compliant with the due diligence obligation under the EU ABS Regulation. This way the user should also avoid liability vis-à-vis subsequent users, although this aspect is not regulated by the EU ABS Regulation." To be clear: The Commission speaks about the contractual liability towards the purchaser, not the statutory obligation under Art. 4.5 Reg. 511/2014.

[53] A proposed 'triangular duty to comply' (a diagonal duty to the provider state, enforced vertically by the user state) was rejected in the legislative process. Instead, Art. 4 Reg. 511/2014 installs a vertical (user state) 'duty to *produce* (diagonal) compliance' vis-à-vis the provider state.

[54] Brunnée (2016), p. 7.

[55] In contrast to respecting the residual substance (sic. 'compliance with provider state laws').

described precedents in public international law and international business law. Their focus is on 'risk management'. It is therefore necessary to inquire which rationale these 'parallel' Regulations pursue and whether they implement elements that characterize them as an autonomous EU concept of DD. We focus on the following questions: How is the risk management process structured? In what way do intermediaries (such as registered collections or brokers) contribute to self-governance? How is the flow of information organized in the various EU DD schemes?

The observation that context matters more than precedents would be in line with modern legal system theory, which holds that 'legal transplants' will not simply be adopted.[56] Inversely, it is the legal environment, which will transform the original instrument so that a peculiar novelty will emerge.[57] While literature has emphasized that the decisive transforming contextual forces are legal cultures, power structures, and actors with specific interests,[58] we submit that for DD, the decisive factor is the legal environment, here EU law (below, Sect. 3). Therefore, our observations would better match with what Gunter Teubner more modestly called (again with different connotations) "legal irritant".[59]

3 EU Schemes of Regulatory Due Diligence (DD)

Before comparing five selected EU DD regimes (Sect. 3.3), we must first introduce the relevant elements and actors of EU DD (Sect. 3.1) as well as the EU regulatory environment into which the concept of due diligence was transplanted (Sect. 3.2).

3.1 Elements and Actors of EU Due Diligence

The terms 'due diligence' and 'risk management' are often equated with one another. As a matter of EU regulation however, DD is the overarching concept whereas risk management is one of its central components (see Fig. 1). Consequentially, a risk management exercise can be found in all EU DD schemes. The standard configuration consists of three interrelated steps:

[56] Legrand (1997) thereby rejects the notion of Watson (1974) to whom the tern 'legal transplants' is attributed.

[57] Watson (2000) responded to Legrand's critique that both approaches to legal transplants are not very far removed from each other. More recent: Grozev (2012); Short (2016).

[58] Winter and Kalichava (2019), p. 41; Siems (2014), pp. 139–145 identified five categories, which influence the implementation of the transplant in the novel environment; on legal transplants in the modern context of private international law: Siems (2018), pp. 236–238, and pp. 256–260.

[59] Teubner (1998), p. 11; similar: Chen-Wishart (2013), p. 1.

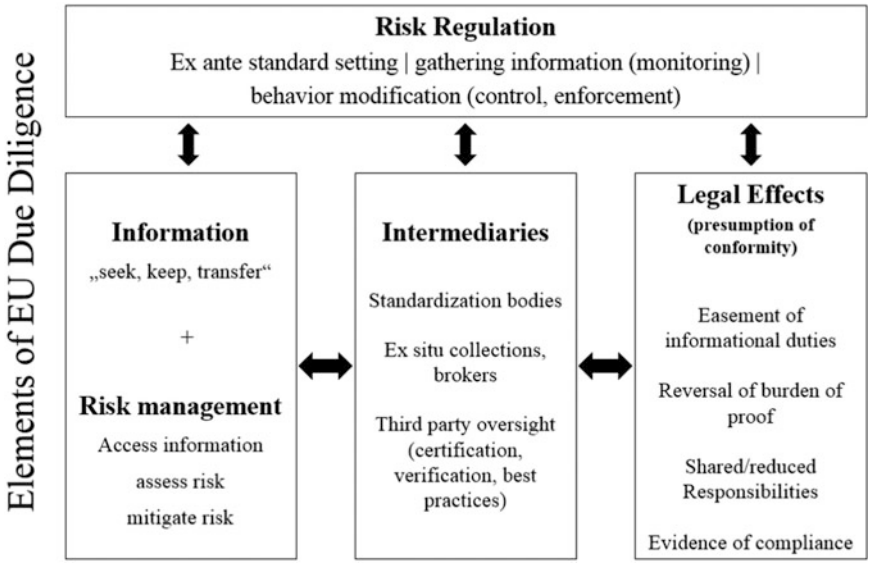

Fig. 1 Elements of EU due diligence. **Source:** Own illustration

(1) Access relevant information and document it,
(2) analyze the information, perform a risk assessment, and
(3) if necessary, use the available options of risk mitigation.

Yet, the structure and detailedness of this exercise varies considerably across regimes (below, Sect. 3.3). Most likely being the result of trade-offs in the EU lawmaking process, this divergence has a direct impact on the extent of user compliance measures (below, Sect. 4.4). In the system of EU DD, risk management is complemented by risk regulation. Risk regulation can also be understood as a three-pronged approach:[60]

(1) Ex ante standard setting
(2) Gathering of information (monitoring)
(3) Behavior modification (controls, enforcement)

As a business management tool, risk management is usually performed by private entities. Risk regulation on the other hand, is usually attributed to the state. However, as operational programs, risk management and risk regulation are open to both. The regulator, for example, may take a risk management approach when carrying out checks on target compliance via national competent authorities.[61] And regulatory targets (e.g. importers, manufacturers) may engage in risk regulation as 'classical' business self-regulation.

[60] Hood et al. (2001), p. 21.
[61] See e.g. Art. 9 Sec. 3 lit. a Reg. 511/2014.

Information fuels both risk management and risk regulation.[62] All EU DD regimes oblige the addressees of regulation to install internal systems and processes that help to seek, keep and transfer information. The regulatory goal of DD is essentially understood to be information management ("it is about gathering and using information in a systematic way").[63] In risk management, information is transferred between (economic) actors along a (supply-) chain pursuant to the requirements of internal information policies. At times, this may include disclosure vis-à-vis the public for the sake of accountability. When information is transferred to national regulators instead, it serves as valuable feedback about the effectiveness of regulation (=regulatory information). Information regarding transnational supply chains and economic conduct abroad is of particular importance, since it is not immediately accessible for either the regulator or consumers.[64]

With regard to transnational economic activity, the capacities of a state to regulate—i.e. formulating, implementing and enforcing rules—are typically cut-short by territorial borders.[65] The regulator may therefore decide to enlist the help of knowledgeable third parties—intermediaries—[66] in order to overcome some of those limitations.[67] Because of its dynamic, informational and situational nature, the concept of DD is well suited to accommodate specialized intermediaries. EU DD is no exception here—the regimes we analyzed all include intermediaries in one form or another. The reasons for doing so can be found in the operational capacity, expertise, independence, and legitimacy that some intermediaries possess.[68] Intermediaries, too, are accessible to both the regulator and the targets of regulation. As service providers, they may help firms to comply with their DD requirements, typically by providing third-party certification or verification. They may also assist the regulator in achieving its regulatory goals, for example by monitoring target behavior. When intermediaries are "orchestrated"[69] to work "directly or indirectly in

[62] Gellert (2015), p. 9.

[63] *Inter alia*, see Art. 5.2 Implementing Reg. 607/2012: "In applying their due diligence system operators shall be able to demonstrate how the information gathered was checked against the risk criteria provided for in Art. 6.1.b. of Reg. 995/2010, how a decision on risk mitigation measures was taken and how the operator determined the degree of risk."

[64] According to Haufler, mechanisms revolving around "information politics" have come to dominate transnational business regulation, Haufler (2018), p. 116.

[65] The disparities between global production and national regulation demarcate a "critical governance gap", which many scholars regard as the main driver behind the promulgation of corporate social responsibility and industry self-regulation, see Haufler (2018).

[66] *Inter-* means "between, among"; therefore, an intermediary denotes "someone who moves back and forth between two sides – a 'go-between'," https://www.merriam-webster.com/dictionary/intermediary (last visited: 15.04.2019).

[67] Abbott et al. (2017), p. 18. This way, EU public actors "increase their capacity to regulate global value chains", Partiti (2019), pp. 95, 105.

[68] Abbott et al. (2017), p. 20.

[69] Orchestration describes a form of public action that "mobilizes the voluntary participation of intermediaries in the regulatory process in order to address a target in the pursuit of public goals", Partiti (2019), p. 95f.

conjunction with a regulator to affect the behavior of a target", they become "regulatory intermediaries".[70] In its most dynamic form, this relationship can be expressed in the formula $\underbrace{R \leftrightarrow I \leftrightarrow T}$.[71] The arrows and the bracket denote the multidirectional flow of regulatory information[72] in what can be described as the 'best case scenario'.[73] By contrast, classical principal-agent relationships, where "regulation is prescriptive and compliance is based primarily on deterrence and sanctions" are marked by unidirectional flows of regulatory information.[74] While the EU DD schemes we analyzed by and large follow the dynamic RIT-model described above, not all the intermediaries contained therein are 'proper' regulatory intermediaries. This may indicate structural shortcomings in certain regimes (below, Sect. 3.4 f.).

Finally, yet importantly, it must be borne in mind that all three actors—regulators, intermediaries and targets—pursue their own agenda and that divergence of goals may render some intermediaries a less perfect choice than others in certain regulatory settings.[75] Intermediary 'capture' by either the regulator or the target[76] may occur as well. This would likely reduce the effectiveness of any DD scheme. Independence and impartiality of the intermediary are therefore basic requirements for proper decision-making in intermediary bodies.[77] Doubts along these lines may be counterbalanced by accreditation[78] or other forms of formal recognition.

3.2 EU Regulatory Environment

The fact that EU DD is broader than the ubiquitous risk management exercise can be attributed to the fact that DD as a concept fell on fruitful ground when it was transplanted into EU law. In 1985, the EU had already started to promote industry co-regulation in the area of technical harmonization in order to speed up the removal of technical barriers to trade and complete the EU Single Market before 1992.[79] A new European standardization policy was introduced, based on adherence to voluntary industry standards and conformity assessment by accredited certification bodies,

[70] Abbott et al. (2017), p. 19.

[71] R = regulator, I = intermediary, T = target (of regulation). Seminal: The RIT-Model by Abbott et al. (2017).

[72] Abbott et al. (2017), p. 26f.

[73] Below, Sects. 3.4, 4.4.

[74] Abbott et al. (2017), p. 17. With its procedural and open nature, due diligence is more or less the opposite.

[75] Abbott et al. (2017), p. 19f.

[76] Abbott et al. (2017), p. 28ff.

[77] Ensthaler et al. (2016), p II.

[78] Abbott et al. (2017), p. 23; Ensthaler et al. (2016), p. XVII.

[79] Lachaud (2018), p. 253.

the results of which would be mutually recognized by the EU Member States. Standard setting, i.e. norm building, was delegated to private European standardization bodies.[80] With its increased trust in business to regulate itself without compromising public health and security, the so-called "New Approach"[81] marked a paradigm shift in EU product safety law.[82] The trust afforded to industry was epitomized by the granting of presumptions of conformity. If a company used harmonized industry norms and standards or provided third party certification, then there would be a (rebuttable) presumption of conformity in favor of the company that its products comply with the basic regulatory requirements and could thus be placed on the market without any additional state approval being required.[83] Annex II of the Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, listing the "Means of proof of conformity and effects" under B. V. and VIII., read:

> Member States shall accept that the products [. . .] are considered to be in conformity [. . .] when their conformity is demonstrated by [. . .] certificates and marks of conformity issued by a third party; results of tests carried out by a third party; [. . .].

Verified compliance with the standards would not exonerate the manufacturer from its liability for defective products vis-à-vis consumers.[84] Nevertheless, the knowledge that the efforts to produce compliance were sufficient, would increase. The New Approach also defined a new role for the state. It was supposed to become a "regulatory gorilla in the closet"[85] that would largely refrain from regulation and only intervene in case a hazard relating to an identified product had surfaced. When the New Approach was revised and expanded via the "New Legislative Framework" in 2008,[86] its basic regulatory features were kept. However, the legal effects of the presumption of conformity were watered down.[87] Article 19.1 para 3 Regulation

[80] Ibid.

[81] Council Res. on a new approach to technical harmonization and standards (1985) *Official Journal* C136, p. 1.

[82] Schucht (2017), p. 46.

[83] Schucht (2017), pp. 47, 49.

[84] Council Dir. 85/374/EEC (1985) *Official Journal* (1985), L210, pp. 29–33. The European Product Liability Directive 85/374/EEC is based on causal (no-fault) liability.

[85] Verbruggen (2013). This is sometimes also referred to as the "shadow of hierarchy", Héritier and Eckert (2008).

[86] The 'New Legislative Framework' is formed by Reg. (EC) 764/2008, Reg. (EC) 765/2008 and Decision 768/2008, see Reg. (EC) No 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC *Official Journal* L218, pp. 21–29; Reg. (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (2008) *Official Journal* L218, pp. 30–47; Decision No 768/2008/EC on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (2008), L218, pp. 82–128.

[87] Schucht (2017), p. 49.

765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products stipulates:

> Where economic operators present test reports or certificates attesting conformity issued by an accredited conformity assessment body, market surveillance authorities shall take due account of such reports or certificates.

Taking due account of something (= being an indicator of proof) is not the same as accepting it as proof.[88] As Schucht reminds us, the implementation of the privileging presumption of conformity in specific harmonization legislation and in non-compliance proceedings has never really lived up to its intended role as evidence of compliance.[89] The Commission's 2002 Action Plan[90] and the 2003 Inter-Institutional Agreement on better law making[91] (both preceding the New Legislative Framework) undergird an understanding of co-regulation that is still very much top-down; something that is complementary rather than an alternative to legislation.[92] The result is "conditioned self-regulation", situated on a continuum between 'pure' self-regulation on the one hand and command and control legislation on the other.[93] That has consequences for both regulators and the regulatory targets, which are supposed to be in a position to regulate themselves effectively:

- National competent authorities may not have transparent criteria for the execution of their powers of intervention in case of an assumed breach of compliance.[94] The question becomes: *When to intervene?*
- A reliable, content-based means of providing compliance is not readily available for business.[95] Here: *When are efforts to produce compliance exhausted?*

Since manufacturers *and* market surveillance authorities could not maintain their roles as originally envisaged, both need to take risk-based approaches in their day-to-day activities as a consequence. Authorities are required to cooperate with economic operators when engaging in corrective action in order to prevent or reduce risks.[96] The idea is to afford economic operators the possibility of mitigating the risk (s) themselves.[97]

In the following section we will examine five selected EU Regulations, and re-encounter the identified elements, issues and limitations. It will become evident how the experiences made with the 'New Approach', in particular with regard to the

[88] Portalier (2017), p. 9; Schucht (2017), p. 49.

[89] Schucht (2017), p. 49f. See also Senden (2005), p. 11.

[90] EU Commission (2002).

[91] Inter-Institutional Agreement on better law-making (2003) *Official Journal* C321, p. 1.

[92] Best (2003), p. 3. Senden (2005), p. 12.

[93] Senden (2005), p. 12; Lachaud (2018), p. 254.

[94] Schucht (2017), p. 49f.

[95] Ibid.

[96] Art. 19.2 second sentence Reg. 765/2008—"well hidden" and sometimes overlooked, Schucht (2015), p. 656.

[97] Schucht (2015), p. 658f.

orchestration of private intermediary actors,[98] influenced the configuration of EU DD schemes decades later.

3.3 EU Due Diligence Schemes in Comparison

Despite the fact that the following five DD Regulations tackle very different subjects, some general observations can be made: The ABS Reg. 511/2014, the Timber Reg. 995/2010 and Reg. 2017/821 on conflict minerals and metals set out obligations regarding supply chains in commodities.[99] All three have in common that the term 'due diligence' literally appears in them. In contrast, Reg. 2015/757 on the monitoring of CO_2 emissions from maritime transport and the General Data Protection Reg. 2016/679 neither regulate supply chains in commodities, nor are they specifically labelled as DD regimes. Yet, the elements and actors of EU DD outlined above are all present, thus allowing for a direct comparison along a continuum of self-regulation. When juxtaposed, it becomes apparent that there are many features, which set the ABS Reg. 511/2014 apart from its relatives. Most importantly, three of the above Regulations seek to 'export' regulation, while Reg. 511/2014 and its direct conceptual precursor, the EU Timber Reg. 995/2010, aspire to 'import' regulation.[100]

3.3.1 Reg. (EU) 995/2010 Laying Down the Obligations of Operators Who Place Timber and Timber Products on the Market

Reg. 511/2014 and Reg. 995/2010 both contain a general obligation to 'exercise due diligence'. However, Reg. 995/2010 also contains a general prohibition of placing of illegally harvested timber on the internal market.[101] This prohibition was incorporated at the urging of the European Parliament,[102] which also tried to include a general prohibition of using illegally acquired genetic resources in Reg. 511/2014—but ultimately failed.[103] Thus, Reg. 995/2010 contains both procedural (DD) *and*

[98] Partiti (2019), p. 103f.

[99] Note: As the Guidance Document on the scope of application and core obligations of Regulation (EU) No 511/2014 makes clear, genetic resources fall outside the scope of the regulation when they are traded and exchanged as commodities and no research and development is taking place, EU Commission (2016), p. 7. With that caveat in mind, we decided to keep the term for purposes of comparability.

[100] For an overview on the global reach of EU law, see Scott (2014), who prefers to speak of 'action forcing contingent unilateralism' instead of 'exportation' (of regulation). See also Fishman and Obizdinski (2014) on the wider trade law implications of Reg. 995/2010.

[101] Art. 4.1 Reg. 995/2010; European Commission (2016).

[102] Levashova (2011), p. 294.

[103] European Parliament (2012), pp. 28, 54.

substantive (prohibition) obligations.[104] Meeting the DD requirements does not automatically shield a timber importer from subsequent findings of illegality by a national competent authority.[105] Instead, it is suggested that records, which show that a timber importer was duly diligent, may have a moderating influence on the calculation of penalties or fines.[106]

What stands out in Reg. 995/2010 is the dual system of privileged and unprivileged timber imports.[107] For imports that fall under either the CITES-regime (Convention on International Trade in Endangered Species of Wild Flora and Fauna)[108] or the FLEGT-scheme (Forest Law Enforcement, Governance and Trade Action Plan)[109]—and are thus registered during border controls—a presumption of conformity applies ("shall be considered to have been legally harvested for the purposes of this Regulation"). This so-called "green lane" exempts importers entirely from their DD obligations.[110] All other imports will trigger the general DD requirement of article 4.2 Reg. 995/2010 which mandates the use of a DD system. Its compulsory elements are outlined in a concise and clearly structured manner in article 6 Reg. 995/2010, further concretized by Implementing Reg. 607/2012. Alternatively, timber importers may use a DD system established by an accredited private monitoring organization (MO).[111] In that case, the obligation to maintain and regularly evaluate the DD system will fall to the MO, which will also need to verify its correct use by the importer and report any failure to do so to the competent national authorities.[112] Thus, MOs are directly involved with the national competent authorities, who control them.[113] Yet, hierarchical accountability[114] of MOs is based on formal recognition by the EU Commission, not national accreditation. On a final

[104] For a discussion of procedure vs. substance in Reg. 511/2014, see below under Sect. 4.1.

[105] Unwin (2011), p. 4f.

[106] Ibid.

[107] This is not dissimilar to the system of registered and non-registered collections under Reg. 511/2014. Users obtaining genetic resources from unregistered collections will not benefit from Art. 4.7 Reg. 511/2014.

[108] Reg. (EC) No 338/97 transposing the Convention on International Trade in Endangered Species of Wild Flora and Fauna [CITES] (1997) *Official Journal* L61, p. 1.

[109] Reg. (EC) No 2173/2005 (2005) *Official Journal* L347, p. 1. 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 products 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. EU FLEGT Facility, Import Procedures for FLEGT-licensed products, available under http://www.flegtlicence.org/eu-import-procedures-for-flegt-licences (last accessed 28.9.2019).

[110] Importers who first place such timber on the market can assume that the respective wood is marketable without constraints (EU Commission, 2016, 10A, 11).

[111] Art. 4.3 Reg. 995/2010.

[112] Art. 8.1 lit. b and c Reg. 995/2010.

[113] 'Supervisory accountability', Moser and Leipold (2019), p. 7. Cp Art. 8.4 Reg. 995/2010, Art. 6 Reg. 607/2012.

[114] Ibid.

note, it must be borne in mind that while MOs engage in operational burden-sharing in support of their clients,[115] timber importers retain full legal responsibility for using the DD system properly.[116]

3.3.2 Monitoring, Reporting and Verification (MRV) of CO_2 Emissions from Large Vessels—Reg. (EU) 2015/757 (as Amended by Delegated Regulation 2016/2071)

Since January 2018, large merchant vessels calling ports in the European Economic Area (EEA) must carry on board valid documents of compliance with the requirements of Reg. 2015/757. Compliance, here, is directed towards information about the total amount of CO_2 exhausts from a given ship ("disclosure")[117] and not towards total emissions caps.[118] The MRV Regulation 2015/757 obliges ship owners (usually companies) to accurately monitor their ships' CO_2 emissions and fuel consumption based on a previously drawn up monitoring plan and submit a verified emissions report to the EU Commission before the end of each reporting period. Verification itself is performed by accredited third-party verifiers. Their first task is to review ship owners' monitoring plans for, *inter alia*, completeness and accuracy.[119] When the verifier concludes that the monitoring plan is in conformity with the respective requirements of Reg. 2015/757, it will use the monitoring plan as a basis when assessing a ships annual emissions report.[120] Eventually, the verifier will issue a verification report, stating that the emissions have been determined in accordance with the Regulation and the monitoring plan. Finally, the verifier will issue timely limited documents of compliance based on the verification report and submit them to the EU Commission and the respective flag states (which are not necessarily EU Member States).[121] During inspections and in cases where emission report data is not available from Commission publications, the competent authorities of EU Member States will view these documents as (rebuttable) evidence of compliance. This is the presumption of conformity contained in article 19.1 Reg. 2015/757.

In Reg. 2015/757, the focus of the risk assessment (performed by the intermediary) is on identifying potential risks related to the monitoring process, such as misstatements and non-conformities with the monitoring plan and the respective requirements of the Regulation.[122] Here, the verifier may conduct on-site visits,

[115] Ibid., 'market accountability'.
[116] Unwin (2011), p. 12f.
[117] Fedi (2017), p. 383.
[118] Deane et al. (2017), p. 2.
[119] Art. 6 Reg. 2015/757.
[120] Art. 13.2 Reg. 2015/757.
[121] Art. 17 Reg. 2015/757.
[122] Arts 5 and 11 Commission Delegated Reg. (EU) 2016/2072 (2016) *Official Journal* L320, p. 5.

enquire with relevant staff, inspect documents and engage in active observation in order to verify the proper implementation of the (self-) monitoring and reporting system. Intervention by the regulator is limited to penalizing the failure to comply with monitoring and reporting obligations set up by the Regulation. The broad regulatory authority and margin of discretion afforded to the verifier[123] mandate high levels of expertise, professional independence and impartiality. Consequently, article 16 Reg. 2015/757 stipulates that verifiers shall be accredited for their activities by a national accreditation body pursuant to Reg. 765/2008.[124]

3.3.3 Reg. (EU) 2016/679 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data

The General Data Protection Regulation 2016/679 (GDPR) aims at protecting natural persons with regard to the processing of personal data and lays down rules relating to the free movement of such data as well. The obligatory risk management exercise can be found in article 24.1 GDPR. It mandates the controller (as the entity that collects data from the data subject) to *"[. . .] implement appropriate technical and organizational measures to ensure and to be able to demonstrate that processing is performed in accordance with this Regulation [. . .]"*. This is where regulatory intermediation comes in: Data protection certification mechanisms may be used for demonstrating compliance with the Regulation. Pursuant to article 42.2 GDPR, certification may also be used to demonstrate the existence of appropriate safeguards provided by processors of personal data located in third countries (outside the EU and EEA areas). However, this presumption of conformity is narrower than its wording might suggest. If one looks at the specific provisions dealing with the responsibilities of controllers and processors,[125] it becomes apparent that certification mechanisms, as referred to in article 42 GDPR, may merely be used "as an element" by which to demonstrate compliance. They do not serve as evidence of compliance[126] and can be a "snapshot" of compliance at most.[127] There is not even a reversal of the burden of proof in the GDPR.[128] The privilege afforded by article 42 GDPR is rather geared towards the calculation of administrative fines for infringements, where certifications can have a mitigating effect pursuant to article 83.2 lit. j GDPR.

[123] Fedi (2017), p. 405f.

[124] Commission Delegated Reg. (EU) 2016/2072 further details the accreditation of verifiers, which are subject to, *inter alia*, annual surveillance and extraordinary assessments by the national accreditation bodies.

[125] E.g. Arts 24.3 and 28.5 GDPR.

[126] Lachaud (2016), pp. 814, 820ff.

[127] Eckhardt (2017), para 45.

[128] Art. 82.3 GDPR.

GDPR data protection certifications can be issued, renewed and withdrawn either by (private) certification bodies or by the competent supervisory authorities themselves.[129] In the GDPR, national supervisory authorities remain very much at the helm of most regulatory functions, such as monitoring, enforcement, industry guidance and investigations of non-compliance.[130] Moreover, they approve the certification criteria developed by certification bodies and may order a certification body to withdraw a certification or not to issue one, in case the requirements for certification are no longer met. Certification bodies are also obliged to inform supervisory authorities about the reasons for granting or withdrawing certifications.[131] Finally, supervisory authorities are responsible for the accreditation of certification bodies.[132] As far as the distribution of responsibility among regulatory actors is concerned, it should be noted that certification does not shield the data processor from liability or reverse liability by shifting it to the certifier. Burden sharing is not an issue either: As a consequence of the "empty" presumption of conformity described above, the duties as stipulated remain with each participant (regulator-intermediary-target).[133]

3.3.4 Reg. (EU) 2017/821 Laying Down Supply Chain Due Diligence Obligations for Union Importers of Tin, Tantalum, Tungsten, Their Ores, and Gold (3TG) Originating from Conflict-Affected and High-Risk Areas[134]

Reg. 2017/821 seeks to curtail opportunities for armed groups to trade in 3TG minerals and metals by holding EU importers of those commodities publicly accountable via the mandatory disclosure of information on their supply chain. It therefore establishes a system of supply chain DD. When compared with the EU DD schemes analyzed above, it becomes apparent that Reg. 2017/821 takes the broadest conceptual approach yet: Beyond risk management-, information management- and intermediary audit obligations, it incorporates "structural obligations",[135] which assign responsibility for the supply chain DD policy directly to the senior management of Union importers.

In order to determine whether their supply chain DD practices are in conformity with the requirements of Reg. 2017/821, Union importers have two options. Either

[129] Art. 42 GDPR.

[130] See Art. 58 GDPR for a list of investigative and corrective powers of the supervisory authorities.

[131] See Art. 43.5 GDPR.

[132] Pursuant to Art. 43.1 GDPR, accreditation may also be carried out in conjunction with national accreditation bodies named in accordance with Reg. 765/2008.

[133] This is even provided for in the Regulation itself, see Art. 42.4 GDPR.

[134] For the international background of Reg. 2017/821, see Martin-Ortega (2014), pp. 62ff; also Partiti and van der Velde (2017).

[135] Heße and Klimke (2017), p. 449.

they carry out audits of their own supply chain DD practices via an independent third party, or they demonstrate that they sourced their minerals and metals exclusively from smelters and refiners that have been "white-listed" by the EU Commission.[136] In the latter case, a privileging presumption applies, exempting Union importers from the obligation to carry out third-party audits.[137] In Reg. 2017/821, there is only an indirect flow of regulatory information from the intermediary to the regulator, when importers submit their mandatory third-party audit reports to the national competent authorities. The latter are the ones carrying out (*ex-post)* checks of Union importers by, *inter alia*, conducting on-site inspections and by examining the documents and records that demonstrate compliance with the supply chain DD obligations.[138] Third parties operate almost exclusively as service providers for Union importers. Hitting a low point of intermediary accountability, Reg. 2017/821 does not require accreditation or formal recognition of third-party auditors by a national accreditation body, a competent national authority, or the EU Commission. That certainly raises questions of credibility and intermediary capture.[139] It is interesting to note that like Reg. 511/2014, Reg. 2017/821 does not contain a general import prohibition. The obligations contained in Reg. 2017/821 are purely procedural in nature. What stands out is the frequent referral to the standards laid down in the OECD DD Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas (2013),[140] especially with regard to the risk management obligations of Union importers. One example is article 5.3 Reg. 2017/821, obliging Union importers to design their risk mitigation strategies by relying on the measures suggested in Annex III of the OECD DD Guidance. The OECD DD Guidance, however, is a (non-binding) soft law instrument. Relying on that instead of listing the risk management duties of importers fully within the Regulation itself, has been criticized as hardly harmonious and possibly even violating the principle of determinacy.[141]

3.4 Interim Conclusion

When one compares the level of detail that Reg. 511/2014 and its immediate relatives—Reg. 995/2010 and Reg. 2017/821—afford to the risk management

[136] Art. 9 Reg. 2017/821.

[137] Art. 6.2 last sentence Reg. 2017/821. This is reminiscent of the 'green lane' under Reg. 995/2010 (see above).

[138] Arts 3.2 and 11 Reg. 2017/821.

[139] Business representatives (just like NGOs) were involved at every stage of the EU negotiation process that led to Reg. 2017/821, see Partsch (2018). The regulatory markup of Reg. 2017/821 suggests that they were successful in achieving regulatory concessions.

[140] OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas (Second Edition, OECD, 2013).

[141] Teicke and Rust (2018), p. 43.

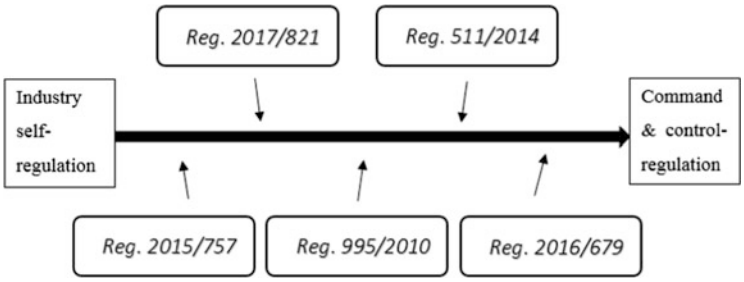

Fig. 2 The (self-) regulatory continuum of EU due diligence. **Source:** Own source

exercise, the EU Timber Reg. 995/2010 stands out in terms of clarity and comprehensiveness. Its risk management obligations are highly (pre-) structured and outlined further in Implementing Reg. 607/2012. The elements of risk management in article 6.1 Reg. 995/2010 are labelled accordingly[142] The procedural (DD) and substantive (import prohibition) obligations are separated and recognizable as such.[143] And finally, the addressees are clearly identifiable ('importers').That clarity was not duplicated in article 4 Reg. 511/2014 on user obligations: Risk mitigation is referred to only indirectly in article 9.1 Reg. 511/2014 (recognized best practices), Article 4.5 Reg. 511/2014 demands risk assessment procedures without using that term, obtaining genetic resources from registered collections pursuant to article 4.7 Reg. 511/2014 is not labelled as a risk mitigation procedure, and identifying 'users' of genetic resources will not be as straightforward as identifying those who import timber and put in on the market. In Reg. 2017/821 the risk management process is, again, more structured, and the criteria for risk mitigation are "surprisingly far reaching."[144]

When we now add Reg. 2015/757 and Reg. 2016/679 to the picture, we can go one step further and conceptualize a (self-) regulatory continuum of EU DD. The extreme points of this continuum are the command-and-control model of regulation on the one hand, and industry self-regulation without any state involvement on the other. Thus, we can qualify the Regulations analyzed as follows (Fig. 2):

Compared to DD in the corporate world, it becomes evident that none of the EU Regulations delegates full self-regulatory discretion to industry. In the MRV-Reg. 2015/757, the intermediary takes over a good amount of regulatory functions, with the regulator more or less staying in the "regulatory closet".[145] Yet still, the Regulation meant a switch from voluntary self-monitoring to a compulsory control

[142] Procedures providing access to information, risk assessment procedures and risk mitigation procedures in Art. 6.1 lit. a-c Reg. 995/2010.

[143] For a discussion of substantive elements in Reg. 511/2014 see below, Sect. 4.1.

[144] Teicke and Rust (2018), p. 41. Those criteria are largely contained in soft law, which is also problematic, see the discussion above in the preceding paragraph.

[145] Verbruggen (2013).

system.[146] Likewise, none of the Regulations is purely based on command and control mechanisms. Even in the GDPR, certification is an "arrangement mixing public and private involvement".[147] Still, the GDPR affords the least 'trust' to self-regulation.[148] Regulatory cooperation (and therefore wiggle-room for industry) is replaced by oversight, which is why Lachaud suggests calling certification under the GDPR "monitored self-regulation" instead of co-regulation.[149] Remaining self-regulatory features such as monitoring and enforcement via certification[150] are designed as substitutable and can be provided by either the certification bodies or the supervisory authorities.

If we look at the respective presumptions of conformity, we see that the benefits afforded by them—and thus the level of legal certainty—decrease, the further we move towards the command and control end of the spectrum (above, Sect. 3.3.3). Towards the other end, article 19.1 Reg. 2015/757 obliges Member States to regard the documents of compliance issued by verifiers as "evidence of such compliance," thus bearing close resemblance to how presumptions of conformity were originally envisioned under the New Approach (above, Sect. 3.2). The presumptions of conformity contained in Reg. 2017/821 and Reg. 995/2010 are exempting the regulatory target from the need to carry out third-party audits or DD altogether. Both are significant alleviations of burden. However, they are the result of something that can be attributed to the regulator (who registered 'green lane' wood or 'white-listed' certain smelters). They are not a consequence of industry co- and self-regulation, such as adherence to harmonized norms or third-party certification (above, Sect. 3.2). The Regulations dealing with supply chains in extractive[151] industries (timber, genetic resources, conflict minerals) are nestled somewhere in between the two extremes, with the ABS-Reg. 511/2014 leaning more towards the command-and-control end of the spectrum. Here, the presumption of conformity *is* a result of intermediation—but it is limited in scope, only alleviating the user from having to access the relevant information him-/herself, not more. Likewise limited is the functional scope of the intermediary itself. The absence of any enforcement, monitoring or reporting duties on the part of registered collections is a deviation from how the concept of DD is arranged in the other Regulations. Registered collections do not function as risk-absorbers for users (e.g. by monitoring behavior

[146] Fedi (2017), p. 410.

[147] Lachaud (2018), p. 252.

[148] This may also be due to the 'delicate' subject matter—personal data—and the accountability principle that Reg. 2016/679 is built on, see Art. 5 Reg. 2016/679. As of October 2019, there are still not approved private GDPR certification mechanisms, let alone accreditation bodies.

[149] Lachaud (2018), p. 251. Where oversight is not possible, e.g., when personal data is transferred to third countries, certification must be backed up by binding and enforceable commitments (e.g. contractual or otherwise) of the controller or processor in the third country.

[150] Spindler (2016), p. 409.

[151] We use this term with the proviso, naturally, that environmental impacts are different in the case of genetic resources (collecting/sampling) when compared to timber (logging) and minerals (mining).

for compliance or by helping to interpret rules). There is also no formal regulatory feedback (e.g. via reporting duties) from registered collections to the regulator. Depending on their position and tasks, regulatory intermediaries may provide authorities with feedback on rule deployment and by pointing out boundaries to effective enforcement and/or monitoring.[152] This feedback appears particularly important for dynamic rule development[153] within transnational regimes marked by enforcement gaps. The only other regime where there is no regulatory feedback from the intermediary to the regulator is Reg. 2017/821. We therefore do not consider registered collections and third-party auditors to be regulatory intermediaries in the classical sense. They are 'functional'[154] intermediaries whose job is the procedural safeguarding of information for the downstream supply chain, without having any supervisory authority.[155]

The aforementioned limitations translate into a strong role for national competent authorities in Reg. 511/2014. Users might expect something else when reading the term 'due diligence'.[156] At the same time, the risk for industry to fail with their own duties seems markedly higher than in the other Regulations. The more risk, the higher the duties.[157] It is worth discussing in this regard, if other actors can be considered as regulatory intermediaries.[158] The Guidance Document speaks of "specialized companies or organizations" with a "similar function" to registered collections.[159] It goes on to note that intermediaries such as registered collections and brokers "are best placed to inform the user about the legal status of the material they hold".[160] Currently, associations of users and other interested parties (such as e.g. commercial bio-prospectors or brokers[161]) can apply for the recognition of 'best practices' under article 8 Reg. 511/2014.[162] Yet, monitoring and enforcement duties

[152] Abbott et al. (2017), p. 24.

[153] Abbott et al. (2017), p. 23.

[154] "Driven by functional considerations", see Abbott et al. (2017), p. 19.

[155] Below, Sect. 4.2.

[156] Especially if one follows the 'logic' that new forms of co- and self-regulation (especially in the international sphere) are indicative of a power shift to the private sector at the expense of public authority, Partsch (2018), p. 482; Green (2013). Also, Reg. 511/2014 does not use words like 'audit', "certification" and 'verification' which relate to third-party quality control (as a common feature of industry self- and co-regulation).

[157] Bell (2001), p. 124.

[158] Brès et al. (2019) developed a typology along the axis 'formalized vs. unformalized' and 'unofficial vs. official'.

[159] EU Commission (2016), p. 5.

[160] Ibid.

[161] Commercial bio-prospectors/brokers had already engaged in developing codes of conduct in the past. For examples see Godt et al. (2020), § 3 VIII, 1–3.

[162] Until today, applications under Art. 8 Reg. 511/2014 were only successful for associations of collections, thus mostly complementing Art. 5 Reg. 511/2014. The first 'best practices' acknowledged on 10.5.2019 is the CETAF Code of Conduct, see https://cetaf.org/sites/default/files/documents/leaflet-a4_codeofconduct_hd.pdf (last accessed 06.03.2020), for background Neumann

on part of associations establishing best practices are too limited (article 8.1 Reg. 511/2014 mentions only "oversight"[163]), and there is no regulatory feedback.[164] Second, if brokers or associations of users were to be assigned regulatory functions beyond article 8 Reg. 511/2014, notions of accountability (and upstream "trust") would have to be addressed by e.g. accreditation or formal recognition.[165]

4 Lessons to Be Learnt for Articles 4.1 and 4.5 Reg. 511/2014

Against the background of both preceding sections, we can draw conclusions as to how article 4 Reg. 511/2014 is to be interpreted. First, it must be understood as a compromise. The fuzzy concept of DD has spoken to various audiences. Environmental lawyers found the prospect of enhanced responsibility appealing, the business community was attracted by the prospect of more self-regulation and practices familiar to them. This ambiguity served to organize the necessary majorities. Therefore, the concrete content of the DD standard under article 4 Reg. 511/2014 neither derives from the model forerunners, nor from any particular legal family (civil law or common law), nor is it simply a management tool. But some legacies of the predecessors will remain. Second, Reg. 511/2014 must be understood as autonomous Union law. When DD was incorporated into Reg. 511/2014, the requirement to be duly diligent was stripped off its (inter-) governmental context and became a *behavioral* standard for firms—directly applicable, aiming at enforcement.[166] With the choice of the specific measure of a Regulation under article 288 sec. 2 TFEU, DD shifted from soft law to hard law.[167] Article 4 Reg. 511/2014 stipulates an *ex ante* standard of care (as in international business law), not a liability rule where the standard of care is evaluated *ex post* (as in international public law). DD was embedded in a set of parallel Regulations, which differ from each other due to sectorial specificities. However, together they define a new type of Regulation, aiming at risk regulation in transnational (supply-) chains.

(2018). Two other applications from the cosmetics industry have remained (until today, Oct. 2020) unsuccessful.

[163] Unfortunately, this is not really elaborated on. Annex IV to Commission Implementing Reg. (EU) 2015/1866 merely stipulates that associations and interested parties provide a description of how the overseeing will be carried out when applying for the recognition of best practices.

[164] There is passive regulatory feedback (per Commission request) from associations establishing best practices in cases of non-compliance by users implementing those practices, see Art. 12 Commission Implementing Reg. (EU) 2015/1866.

[165] In case of user associations, that would mean an overlap of the intermediary and the target, Abbott et al. (2017), p. 26.

[166] Lambooy (2010).

[167] Martin-Ortega (2014), p. 52.

Considering this new mixture, the following section will identify what exactly the legislator stipulated.

4.1 Procedural or Substantive?

The duty under article 4.1. Reg. 511/2014 "to ascertain that [. . .resources] have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements" is explained as "to keep, seek, transfer" in article 4.3 Reg. 511/2014 and coupled with "to obtain", "to establish" (sic. "produce compliance"), "or discontinue" under article 4.5 Reg. 511/2014. The question is, if there is a reason for the CJEU to interpret the "or" as a legislative means to put the obligations before and after the "or" on the same doctrinal footing. That would mean interpreting the duty "to discontinue" as procedural. The consequence of this reading is that the discretion of when "to discontinue" would rest with the user. The duty to do so would exist, but it could essentially not be enforced. This argumentation would be in line with the procedural DD-reading of the preceding models in international public law and in international business law. It could also be inferred from the rejection of a transnational implementation of article 15 NP, which would have substantially linked user measures to provider measures.[168] Such a reading would imply two further consequences. First, the search for remedying an incompliant situation could be infinite; the agency would have no authority to order a shutdown of operations. Secondly, if conceptualized as procedural, one could infer from article 4.7 Reg. 511/2014 that recipients of genetic resources from a [registered] collection [. . .] are preempted from liability. The argument would be that article 4.7 stipulates a real privilege for the user and shields him/her from a shutdown under article 4.5 Reg. 511/2014.[169]

This reading has to be opposed for the following reasons: With due diligence becoming part of an enforceable Regulation, it was stripped off its intergovernmental *and* purely business self-regulatory contexts. As binding and directly enforceable EU law, article 4 Reg. 511/2014 directly defines the standard of firms' conduct. While the legislator of Reg. 511/2014 rejected to install a substantial obligation to 'comply with foreign law' (more precisely, to link an [actual] domestic legal consequence to a [past] violation of foreign law), it did install an (actual) "duty to ascertain that the *resource* utilized *was* accessed in compliance with provider states laws". This rule *mediates* the substantive 'obligation to obey the foreign law' by a duty to check the legal status *of the object*. The technique resembles the concept of

[168] The consequences of the EU-rejected model for possible scenarios of transnational enforcement are discussed by Godt et al. (2020), § 2 II 5 b-f.

[169] Art. 5.7 Reg. 511/2014 reads: "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".

liability in private law, which prescribes a (non-enforceable) substantive obligation for everyone 'not to do harm' (lat. '*neminem laedere*'). Yet, the legal consequences of a violation of this substantive norm—such as injunctions and damage claims—carry conditions, which go beyond the causal link of result and behavior (lat. '*caveat emptor*').[170] With due respect to national differences and therefore generalizing: Injunctions require that the *result* can be (normatively) qualified as 'unlawful'—conceptualized as an objective standard.[171] In most jurisdictions, additional damage claims require 'fault'; meaning that the preceding *behavior* can be qualified as 'sub-standard'—conceptualized as a subjective standard.[172]

In the common law context, the tort of negligence consists of two parts: The objective part asks for the 'standard of care', the subjective part asks, if the specific individual in the case at hand could act as required (again more or less standardized). The standard examples here are children or freshmen surgeons.

As a *legal transplant,* DD changes its context when implanted into *statutory law*. The juxtaposition between substance and procedure cannot be the same when compared to the jurisprudence in public international law. Before the (substantive) appraisal that a resource was accessed in violation of foreign law can trigger a legal action, additional conditions must be met. In this context, DD defines the standard of care which triggers the legal action (injunction; shutdown of operations). The substantive standard 'compliance with foreign law' remains the normative objective, the general obligation. The Commission clearly stated that it understands the "duty to discontinue" as an "obligation of result".[173]

Thus, the legal action is conditioned. In contrast to the current status in public international law (above), the European legislator substantively *qualified* the 'standard of care' (article 4.5 Reg. 511/2014) by the word "or discontinue". This language links procedure with substance. It requires, first, "efforts to remedy",[174] but does not

[170] This is exactly how national legislators transposed the norm into national laws, e.g. for Germany, see § 2 of the German Law transposing Reg. 511/2014. It reads: (1) The competent authority adopts the necessary orders to remedy breaches of the legal acts designated in section 1 paragraph (1). (2) Should a user fail to comply with an order in accordance with paragraph (1), the competent authority may in individual cases seize the unlawfully-utilized genetic resource or prohibit specific utilization activities. This shall be particularly considered if the user is unable to submit the information required in accordance with Article 4 paragraph 3 of Regulation (EU) No. 511/2014.

[171] A situation which is "simply" unlawful does not give rise to individual obligations. Modern rule of law implies that preceding related conduct is in some way "blameworthy" in order to trigger legal consequences.

[172] This is what in German doctrine is conceptualized as "outer care". This does not equate with "guiltiness" which is "inner care" in the German doctrinal tradition. In the fault based German tort tradition, it is the inner care which provides for the basis of a single general clause of § 823 German Civil Code (BGB) which imbeds both, intent and negligence. For a profound critique, see Brüggemeier (2004), pp. 76ff.

[173] EU Commission (2016), p. 11.

[174] Art. 4.5 Reg. 511/2014 stipulates "When the information in their possession is insufficient or uncertainties about the legality of access and utilization persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilization".

stop there.[175] Efforts might not last indefinitely. This qualification has two consequences: First, a normative reading—and one that deliberately avoids to simply equate compliance with substance—of the wording "or discontinue" requires an action plan with qualitative milestones and quantitative timelines.[176] It does leave space for discretion.[177] Second, single procedural steps cannot escape the normative substantive requirement ("or discontinue").[178] Therefore, the acquisition of material from a registered collection cannot escape the injunction commanded by article 4.5 Reg. 511/2014, as will be explained in the next section.

4.2 A Shift of Responsibilities?

The comparison with the other regulations clarifies that Reg. 511/2014 does not integrate a "regulatory intermediary" which might increase legal certainty for users. Classical elements of industrial self-regulation are scaled down. Registered collections (article 5 Reg. 511/2014) secure information, but there is no information flow to the regulator, no coordination or any other third-party quality control. In the broader context, registered collections and recognized best practices (article 8 Reg. 511/2014) appear rather peculiar. It is therefore, that we conceptualize them as purely informational ('functional') intermediaries (above, Sect. 3.4). And while the function of registered collections is to secure the important information about the 'country of origin' for the downstream supply chain, 'recognized best practices' are a tool to help users to comply with their DD obligations. However, article 4.5 Reg. 511/2014 has no connection to the "legality of access and utilization"; article 4.7 Reg. 511/2014 only says: "shall be considered to have exercised due diligence as regards the seeking of information". These stipulations are even missing with regard to 'recognized best practices'. Thus, Reg. 511/2014 does not provide for a legal assumption of lawful acquisition.[179] Indemnity is not granted. It narrowly relates to seeking information, and therefore can only help to provide evidence that the standard of care was met (with regard to 'seeking information'). This legal concept

[175] From the perspective of the competent authority, this triggers a conditioned program of actions. A first step will see the CA order the user to submit ABS documentation.

[176] From the perspective of the Competent Authority that means, if papers are not produced upon request, the CA will order the discontinuation of utilization until the papers are produced.

[177] In principle, utilization without ABS-documents has to be stopped. However, a respective order might be unproportionate. Recent experience has shown, that political turmoil or other political reasons result in 'no-answers' of competent authorities in provider states. In those cases, the CA of the user state may provide for a temporary allowance.

[178] Third, if it turns out that the approval of use is either impossible, or the user is unwilling to engage in action, the CA is entitled to prohibit utilization (including the publication of results) *ad infinitum*. The German law provides for the genetic resource(s) to be confiscated and destroyed.

[179] Godt and Burchardi (2018), p. 64f.

of article 5 Reg. 511/2014 does not prevent state held collections from doing more.[180]

In line with the preceding DD regulation on tropical timber, one might have expected that the ABS-regulation would install something akin to a monitoring organization, which develops standards as a means of self-regulation, evidenced by certification.[181] Yet, this element of industrial self-regulation was not taken on board in Reg. 511/2014.[182] As substitutes, 'registered' collections were envisioned. Yet, they fulfill a different function, and do not define the professional standard for users. The only regulatory effect is that the acquisition of resources from registered collections reverses the burden of proof regarding the question whether all pertinent information pursuant to article 4.3 Reg. 511/2014 was accessed. Thus, they have an upstream function for users,[183] but they do not belong to that group.

4.3 The Objective Standard of Care: Or "What Ought to Be Done?"

The standard of care as developed in tort law consists of two facets, an objective and a subjective one. The objective facet defines the standard of care of 'what ought to be done'. The subjective facet is composed of two different questions and will be dealt with in the subsequent two sections (4.4 and 4.5). Under the forerunner models of DD, the standard of care derives from an equation of likelihood (risk) with the extent of the harm. What, however, is the expected harm when the user of a resource is not able to establish compliance and the situation remains 'ABS-incompliant'?

In principle, and in contrast to the predecessors of EU DD, a lack of ABS-compliance neither results in a direct environmental damage, nor is a domestic

[180] The first registered collection (May 2018) is the German Collection of Microorganisms and Cell Cultures DSMZ. This collection pursues a specific service agency-approach for German research. It provides a legal check for access compliance, when requested by connected institutions; for background: Hartmann-Scholz (2018). In February 2020, the French Collection for Plant-associated Bacteria (CIRM-CFBP) became the second registered collection; in April 2020, the French 'Pierre Fabre Research Institute Library of dry ground plant parts' became the third registered collection, https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Register-of-Collections.pdf (last accessed 22.09.2020).

[181] Originally, the EP had proposed certification of the economic operators by the monitoring organizations. However, certification is not considered as ultimately necessary for due diligence. Yet, independent third-party auditing is mentioned as an element in the OECD DD Guidance and the UN-Expert Group Guidelines, as acknowledged by Martin-Ortega (2014), p. 73.

[182] It seems that the efficacy of certification was doubted in international fora (for the emerging conflict mineral regime, see Martin-Ortega (2014), p. 71; for diamonds see Ekmen (2011). In the realm of genetic resources, it has been argued that the affected industries are too dispersed as to come to grips with certification.

[183] Something, which was reiterated explicitly for conflict minerals in Recital 12 of Regulation 2017/821.

rule (contractual promise; financial regulation) or an international human right violated.[184] Only foreign administrative law is not complied with. This is a significant deviation from earlier models, and most probably the central source of misunderstanding and the lack of acceptance. As a matter of principle, the very reason for territoriality is the breaking down of sovereign governmental power into spatial pieces. It is for democratic reasons that we do not owe respect to foreign law. This is exactly the reason why the European legislator rejected the direct binding force of foreign law and stipulated a self-standing DD obligation. Yet, modern law is familiar with both, accepting the violation of foreign domestic law (tax evasion is the simplest example), and the importation of foreign law. The central questions here are: What is being imported, why and under which conditions? Importation of norms is standard in private international law. In public law, it is accepted when negotiated under an international treaty.[185] Here, the only basis is the sovereignty of the provider state, its accession to the Nagoya Protocol and the implemented ABS-Regulation. In combination with the underpinnings of DD in business administration, it is sometimes purported that the DD duties are to be determined fully by the user.

We submit that the listed duties must be read autonomously with the legislative intent of the EU lawmaker in mind (see already above, Sect. 2.2). The legislator had rejected to bind the user directly to 'compliance with provider state law' (which would ultimately result in instant discontinuation). The listed duties "to ascertain, to keep/seek/transfer, to obtain, to discontinue" describe an exercise of (legislative) translation (comparable to the discipline of private international law). The listed duties fall into two distinct categories:

The first set of procedural duties (to ascertain, to keep/seek/transfer, to obtain as stipulated in article 4.3 Reg. 511/2014) submit the user to undertake "efforts to obtain" regarding 'compliance with foreign law'. These efforts might differ among sectors, but they are of an objective nature. The chapeau-term 'due diligence' does not mean that the user has the authority to determine the duties. Article 4 Reg. 511/2014 duties are not primarily in the interest of the user.[186] Due to the fact that industry did not engage in norm building, the element of 'objective determination' of what 'ought to be done' remained somewhat under-conceptualized in the EU Regulation (above, Sect. 3.2). This gap will only subsequently be filled by the

[184] Unless we qualify the matter in terms of the dissemination of the benefits from science with regard to the human right to science, which is provided for in Art. 27 Universal Declaration of Human Rights (1948) G.A. Res. 217A (III) *UN Doc. A/810*, p. 71 and Art. 15 International Covenant on Economic, Social and Cultural Rights (1966) G.A. Res. 2200A (XXI) *United Nations Treaty Series 993*, p. 3; see also Morgera (2018/19), p. 55.

[185] Cf. the United Nations Framework Convention on Climate Change 'UNFCCC' (1992) G.A. Res. 48/189 *United Nations Treaty Series 1771*, p. 107, the principle of origin under the Treaty on the Functioning of the European Union 'TFEU' (2012) *Official Journal* C326, p. 47, EU Reg. 995/2010.

[186] It is in the interest of the user to be given support by the user state; this is the guiding implementation principle of the Dutch competent agencies, see van Winkoop (2018).

Guidance Paper(s) exercise,[187] to be orchestrated by the implementing agencies. The consequence for the interpretation of these duties is that they are to be determined according to the respective industrial sector (only in this regard "subjectively"). Therefore, the efforts under article 4 Reg. 511/2014 are double-conditioned: At the beginning, the user is only submitted to the duties under Reg. 511/2014, provided that the provider state is a party of the Nagoya Protocol and has enacted respective ABS-regulation. Only then, the Regulation is applicable. Yet still, in order to know if the Regulation applies in the first place, the user has to inquire the origin of the resource, as acknowledged in the Commission's Notice.[188]

The nature of these duties is determined by the respective supply chains of a given sector. Being the 'downstream' user in one country, one has to ascertain that the resource was legally acquired. That means that a user has to inquire if preceding 'upstream' owners/users complied with the respective statutory laws of an 'upstream' provider country (therefore going beyond the mere 'adoption of rules and measures'). This is the peculiar feature of article 4 Reg. 511/2014: What 'ought to be done' (objectively) is essentially determined by provider state legislation,[189] ergo foreign law (which is only enforceable in that given country). Yet, it is the user state law, which determines the objective standard of care ('thoroughness and best possible efforts') with regard to the resource used. If doubts remain, it is up to the purchaser to refuse the resource or to contact the provider in order to 'produce compliance'. In constitutional terms, the proprietary freedom of the user is burdened with a duty to inquire possible legal restrictions originating in a foreign country. If compliance cannot be established, the use must be discontinued. The central question is, when are 'efforts to produce compliance' exhausted? As long as 'efforts are not yet exhausted', the user has a valuable defense against a shutdown order. It shifts the burden of argumentation regarding the exhaustion of efforts to the competent agency. The evaluation of exhausted means of efforts is the precondition for an order to discontinue.

In comparison, the duty to discontinue under article 4.5 Reg. 511/2014 is of a different nature than those duties stipulated under article 4.3 Reg. 511/2014. Besides being a substantive duty (above, Sect. 4.1), the duty to discontinue is to be determined by the user state—neither by the provider state nor by the user. Said duty mirrors—at a different regulatory level—the international duty of the EU and its

[187] After the horizontal Guidance Paper (EU Commission 2016) eight vertical Guidance Papers (3rd version April 2017) were drafted for the following sectors: animal breeding, biotechnology, cosmetics, foods and feeds, plant breeding, pharmaceuticals, the biocontrol and bio-stimulants sector, and for ex-situ collections. After deciding not to adopt them as official guidance papers, competent authorities will move forward with singular examples and (published) explanations.

[188] EU Commission (2016), p. 12.

[189] Notwithstanding the fact that respecting foreign law is limited by restrictions, such as the temporal scope (cut-off date 12.10.2012), the material scope ('commodities', strongly disputed 'derivatives', 'digital sequence information'), the interpretation of the term 'utilization' (discussed is the exemption of activities defined as 'pre-' or 'post-utilization' which would fall under 'utilization' defined by provider state laws).

Member States as parties to the Nagoya Protocol. The competent authorities will execute said international duty by issuing an order to discontinue. The decision is at the discretion of the user state. A consequence of this is that said state could also decide to tolerate the incompliance with foreign law, e.g. if a permit cannot be achieved in wartimes or when the provider state rejects co-operation. Then, it is for the user state to decide if it accepts that efforts have been exhausted without the possibility to achieve compliance.

The point in time when to discontinue will crystallize from various sources, while the administration enjoys wide discretion to determine said point in time. It primarily depends on whether the procedural part has come to an end. The respective behavioral standard differs from sector to sector and is distinct as far as professions are concerned (researchers, collections (registered/non-registered), industry). The practical thing to do will be to come up with an implementation plan that is structured according to timescales and includes milestones and a cut-off day.

4.4 The Subjective Standard of Care or "What Ought to Be Known?"

The subjective standard is part of the DD forerunner models. In public international law, it comes in as a category of fault, linked to the duty to prevent harm. In international business law, the subjective standard is part of the purchaser's defense. In both models, 'knowledge' and 'ought to know' are equated. It is closely connected to 'what ought to be done', since more knowledge might have prompted more activity. In both preceding DD models, the question of 'what ought to be known' is determined *ex post.* In contrast, article 4 Reg. 511/2014 installs an *ex ante* duty. This is a significant requirement. The rule of law mandates that the law has to inform the addressee in advance about what he/she needs to know in order to comply. The classical public law requirements of foreseeability and determinacy are *ab initio* in tension with DD. What did the legislator mean?

As seen in Sect. 3, the user has to install a reasonable risk management system. This system determines what the user knows and can know. This correlation of knowledge and information management is linked to the correlation of the normative duty and informational infrastructure: the more risk, the higher the duties; the stronger the informational architecture, the lower the risk of industry to fail with their own duties. Since Reg. 511/2014 installed a rather weak informational architecture, industry itself will need to engage in establishing a suitable management system. 'What should have been known' will then depend on 'what should have been done' in terms of the management system. The importance of the correlation becomes evident when the user only becomes aware of the incompliant use of a resource after he/she had filed a DD declaration and the competent agency raised concerns. In such a case, the relevant point in time when the DD efforts should have started will not be the moment in which the user acquired positive knowledge, but

the moment in which the user *could have known* that the use is non-compliant. This is an important element of the business legacy of the concept of DD (above, Sects. 2.2, 2.3). In addition, the standard of care depends on the respective business *usance*, not on the actual knowledge. While the DD defense might be brought forward, it is up to the agency to determine if reasonable efforts were exhausted in the given time period. As identified, this evaluation is not at the discretion of the user under Reg. 511/2014. Thus, the point in time when the user 'ought to have known' will affect the decision for the shutdown of operations. This may be a surprising result for some corporate compliance officers. Consequently, we may see disputes as to when efforts are objectively exhausted—companies might argue that further steps can still be undertaken and that time would not yet have elapsed.[190] It is up to the agency to identify if all *reasonable* measures were taken and the efforts therefore exhausted.

4.5 The Professional Standard: A Firm's Capacities

How much do subjective capacities matter, which traditionally have an impact on fault in private law? The Commission Notice[191] explicitly refers to the strict business standard: "Inexperience and lack of time are traditionally not seen as valuable defenses as to due diligence". Both are typical defenses rejected by civil law courts.[192] In administrative law, subjective categories principally play no role. They are categories of criminal law which affect the length and nature of a sentence. In negligence literature, the capacity estoppel is by and large rejected. The only exceptions are children and, in some jurisdictions, mental sickness. Thus, in the given context of Reg. 511/2014, the estoppel of individual capacities can clearly be rejected. However, it seems that the Commission, here, refers to the procedural duties. With regard to the substantive duty (to discontinue), it makes sense to take the attributes of the user and the surrounding situation into account, such as the size of a business, its role as a global player in a certain field, prior dealings of the firm with the domestic Competent Authority in the provider state, or respective negotiations between provider and user state governments.

[190] This is exactly the opposite rationale, when compared to the due diligence concept in international business law. Here, it is the buyer who argues that all efforts have been exhausted.

[191] EU Commission (2016), p. 10.

[192] See Landgericht Stuttgart, Germany 31 August 1989, IPRax 1990, 317; District Court Roermond (*Fallini Stefano v. Foodik*), Netherlands 19 December 1991, available under http://cisgw3.law.pace.edu/cases/911219n1.html; Supreme Court (*Trekking shoes case*) Austria 27 August 1999, available under: http://cisgw3.law.pace.edu/cases/990827a3.html.

5 Conclusion

Only in broader terms can DD be understood as a "single concept" of transnational governance. The two conceptual parents provided the EU legislator with a toolbox to choose from. In the context of EU DD, a notion of hybrid public-private risk regulation materialized. Differences emerge due to sectorial adaptations, which gave rise to a distinct category of "orchestration" (sic. the mix of public-private engagement[193]). It is against this framework that specific articles of the Regulations have to be interpreted.

In comparison with the other Regulations, the DD concept of Reg. 511/2014 turns out to be much more "public". Despite the absence of a clear prohibition—such as the import prohibition in the Timber Reg. 995/2010—and despite the non-existence of mandatory reporting duties, the procedural duties in Reg. 511/2014 are not 'open ended', and they are not at the discretion of the user. Since organized industry did not take part in norm production, there is very little articulation of the private side (sic. industrial self-organization) in this Regulation. That raises the relative power of the state.[194] It is this analytic framework, which guides the interpretation of the contested rule of article 4.5 Reg. 511/2014. The 'duty to discontinue' is of a substantive quality—however, it is an integrated part of a 'program of duties'. The effect is that it proceduralizes a straightforward prohibition and provides leeway for agency discretion. If non-compliance is detected, a firm may take efforts to bring its use into compliance. In other words, DD in this Regulation gives room to 'produce compliance'. If compliance cannot be produced, a closing order has to follow. This is the Regulation's unique technique to install the ABS-regime in a transnational fashion, in fact 'importing' provider state regulation. The user is submitted to 'his/her' home country administration. Once it is determined, that a provider state is not communicating any more (or not willing or able to examine the case), the user is freed from the hassle to deal with a foreign government enforcing the 'sovereign property rights' in its resources. It is up to the user state to assert the situation. This is of a double advantage for industry. Technically, the elements of corporate DD are melted down to a defense against the order to discontinue. Due to the underdeveloped informational infrastructure in Reg. 511/2014, the agencies discretion requires forensic sensitivity regarding the gathering of information necessary to evaluate the user's compliance. This implies the possibility of random checking. The heavy burden for the competent national authority is counter-balanced by article 9.3 Reg. 511/2014, which says that agencies should take a risk-based approach when checking on users.

[193] Partiti (2019).

[194] In this regard see also Bartley (2014), p. 102ff., who discusses how the transnational timber regime (including Reg. 995/2010) "re-centers" the state and reduces the relative space for private authority (by prioritizing the legality of timber over sustainability); very similar Partiti (2019), p. 103: "Orchestration, however, is a two-way street. It also affects the roots of public authorities' understanding and operationalization of concepts such as [. . .] due diligence".

The analysis displays Reg. 511/2014 as a fine example for Pierre Legrand's skepticism towards legal transplants, and supports Teubner's reflection of 'legal irritants'. While two different models inspired the law-making process, we see the EU regulatory environment having a strong impact on the newly implemented legal institution. Despite the fact that DD came around as a novel, innovative legal institution, preceding and following Regulations shape a regulatory concept of EU due diligence. The strict form of an EU Regulation has an impact on the content, but more importantly, the compromises enshrined in legal language make due diligence under Reg. 511/2014 a unique, EU-autonomous legal instrument.

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Global Transformations in the Use of Biodiversity for Research and Development

Post Nagoya Protocol Implementation Amid Unresolved and Arising Issues

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