



# Due Diligence and ABS Compliance under EUR 511/2014

A LSE INMARE Recommendation

Lead Author: Siva Thambisetty\*

POLICY BRIEFING 33

25 JANUARY 2019

THIS WORK WAS FUNDED BY A HORIZON 2020 GRANT AS PART OF THE **INMARE** PROJECT.

SEASCAPE BELGIUM ACTED AS SYMPOSIUM PARTNERS

Due diligence has a stable if malleable, presence in international law often starting as soft law guidance that over time hardens into legal rules and principles. While it is possible to refer to elements of due diligence broadly, the exact scope of the concept depends on the regulatory or international law context in which it is used – such as environmental law, human rights related to responsible business conduct, the elimination of violence against women, or rules around the supply of conflict minerals.

The EU has chosen due diligence as the vehicle to support and balance the effective implementation of benefit-sharing commitments set out in EUR 511/2014.<sup>1</sup> While one of the stated aims of the EUR is related to ‘improving conditions for legal certainty in connection with the utilisation of GR and ATK’<sup>2</sup> the evolving nature of access and benefit-sharing (ABS) related behavior necessitates principles that can guide individuals and institutions when faced with unprecedented circumstances.

There are three critical and interconnected reasons that drive the need for this Recommendation. First due diligence lends itself well to constructive ambiguity that can be harnessed to build consensus around best practices. Secondly due diligence as a positive obligation is separate from the underlying responsibility to follow ABS rules in provider countries. Thirdly, if due diligence is not tethered to the foundational responsibility to respect ABS rules, it may encourage ‘tick-box’ compliance that will frustrate the purpose of the Nagoya Protocol and the international consensus achieved under the Convention of Biological Diversity.

This document is presented as a first guide to developing principles of due diligence that are specific to the access and benefit-sharing context in international law and as a guide to scientists, universities, technology managers and businesses navigating the line between legally required and ethically aspirational behavior. It is hoped that the community will return to this document to update and consolidate practices over time.

The Recommendation is the product of a *Symposium on the Use and Circulation of Genetic Resources*, conducted on the 11 and 12th of September at the London School of Economics. All participants are co-producers of this document. The Principles were informed by the results of a survey on 98 EU users of genetic resources and associated traditional knowledge. The project is led by Dr Siva Thambisetty Associate Professor of Law, LSE and was developed as part of the INMARE project funded by EU Horizon2020.

\* I am grateful to Dr Prabha Nair, Post-doctoral research officer and Dr Oonagh McMeel, Senior Project Officer, Seascope Belgium for research and organizational assistance. Co-producers of this document are as follows: Prabha Somanathan, Oonagh McMeel, Margo Bagley, Alain Pottage, Ken Shadlen, Pablo Ibanez-Colomo, Bruce S. Manheim, Devanand Crease, Henning Grosse Ruse-Khan, Linda Kahl, Manuel Ruiz Mueller, Marcel Jaspers, Marco Sarmento Rebelo (ICNF Portugal), Michelle Rourke, Narendran Thiruthy, Paul Oldham, Pedro Batista, Pierre du Plessis, Robert Blasiak, Kunihiko Kobayashi, Frederic Perron-Welch, Marco D’Alessandro, (Swiss Federal Institute of Intellectual Property), Jan-Bart Calewaert, Mathew Ryan, Dominic Berry, Filip Colson, Anne-Emmanuelle Kervella, Todd Kuiken, Viola Prifit, Laura Bradford (Senior Legal Advisor, University of Cambridge).

1 EUR 511/2014 on **Compliance Measures for Users From the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union**

2 Recital 9.

# Due Diligence and ABS Compliance under EUR 511/2014

## An LSE INMARE Recommendation

London School of Economics and Political Science

**T**he Nagoya Protocol<sup>3</sup> (NP) regulates the circulation and use of genetic resources and associated traditional knowledge, in order to implement the third objective of the Convention on Biological Diversity (CBD) relating to ‘the fair and equitable sharing of the benefits arising out of the utilization of genetic resources’.<sup>4</sup> The Protocol requires that benefits arising from the utilization of Genetic Resources (GK) and Associated Traditional Knowledge (ATK) are shared fairly and equitably, thereby contributing to the conservation and sustainable use of biodiversity. Among other aims, the Preamble recognizes the potential role of access and benefit-sharing (ABS) to contribute to achieving Millennium Development Goals, now referred to as the UN Sustainable Development Goals.<sup>5</sup>

The Nagoya Protocol is addressed to State Parties, and does not apply directly to users and providers of genetic resources. In order for it to be applicable to individuals or non-State entities it must first be implemented at the national level. EU Regulation 511/2014 implements the Nagoya Protocol in the European Union by obligating Member States to legislate at the national level.

The effective implementation of the Nagoya Protocol through EUR 511/2014 relies on users of genetic resources, including scientists, pursuing a due diligence standard of conduct. A course of conduct that is diligent and reasonable under the Regulation must also align with the moral and legal responsibility to support the

effective implementation of the Nagoya Protocol. To this end, due diligence is a springboard rather than a cap, on justice and ethically minded behavior.

The provisions of the EUR 511/2014 as enforced in national legislations in Member States will be interpreted and negotiated by those to whom it is addressed, as compliance practices related to the access and use of genetic resources evolve. This Recommendation is addressed to scientists and other users, and to the ecosystem of institutions that support the work they do. The compliance ecosystem in Europe, which includes scientific institutions, research councils, universities, research networks, research publications, businesses and corporate entities, must support users in their pursuit of due diligence in a manner that is in keeping with the spirit and intent of the Nagoya Protocol.

This Recommendation is one of the first interdisciplinary attempts internationally to give content to the meaning of due diligence in an ABS context.<sup>6</sup> It builds on the due diligence requirements set out in the Regulation and the official Guidance document on EUR 511/2014<sup>7</sup>, but does not replace legal advice on access requirements in the EUR or national ABS regulations in specific provider countries. This is a living document, which we hope will be updated by the community of users newly tasked with obligations intended to realize the Nagoya Protocol.

3 The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity is a supplementary agreement to the Convention on Biological Diversity. Available here <https://www.cbd.int/abs/about/default.shtml>

4 ‘the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies’ (Art 1) available here <https://www.cbd.int/convention/articles/default.shtml?a=cbd-01>

5 See Goal 15, in particular target 15.6 ‘Promote fair and equitable sharing of the benefits arising from the utilization of genetic resources and promote appropriate access to such resources, as internationally agreed. Available here <https://www.un.org/development/desa/disabilities/envision2030-goal15.html>

6 Due diligence in international human rights law typically develops through soft law measures that harden into legal requirements. Due diligence lends itself to the context in which it unfolds, and therefore elaboration of this standard of conduct in the context of ABS rules is necessary. This is particularly true as anything other than the most egregious ‘harm’ in an ABS context can be diffuse or difficult to articulate. Although due diligence cannot be a defense to any liability under provider country laws, it can be used as an aid to discern the extent of the foundational responsibility on the part of individuals and institutions governed by implementing measures under EUR 511/2014 to further the objectives of the Nagoya Protocol internationally.

7 Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union.

C/2016/5337 [Hereafter Guidance Document]. Available here [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C\\_.2016.313.01.0001.01.ENG](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG)

## 1. General and Essential Characteristics of Due Diligence<sup>8</sup>

- 1.1 In EUR 511/2014 due diligence is an obligation of conduct applicable to individual users as well as entities of all sizes.<sup>9</sup>
- 1.2 For multinational commercial entities general due diligence includes internationally recognized standards of responsible business conduct (RBC) as specified by OECD guidelines.
- 1.3 Due diligence must be appropriate to an individual or entity's circumstances, including the limitations of individuals working within business or corporate relationships.
- 1.4 Due diligence processes are ongoing and responsive. They include feedback loops so that individuals and entities can progressively learn. They seek to prevent adverse implications and involve multiple processes and objectives.
- 1.5 It is recommended that each person or entity as user address their own responsibility with respect to adverse impacts of their action or non-action to the best of their ability.
- 1.6 Due diligence is a guide, and should not be treated as a cap, on actions that facilitate effective implementation of the EUR 511/2014 and objectives of the Nagoya Protocol.

## 2. Due Diligence in an ABS context

- 2.1 Due diligence is a standard of conduct that is tethered to the foundational responsibility to mitigate adverse ABS related implications in light of the objectives of the Nagoya Protocol.
- 2.2 Due diligence in an ABS context is both a standard of conduct and an obligation of result. If it becomes clear that prior informed consent (PIC)

or its equivalent and mutually agreed terms (MAT) should have (but have not) been obtained and the user cannot obtain the same, utilization must be discontinued.<sup>10</sup>

- 2.3 The obligation of result in the EUR 511/2014 does not extend to ensuring contractual performance of mutually agreed benefit-sharing. Contractual performance would nonetheless benefit from due diligence standards of conduct because the foundational responsibility to facilitate the effective implementation of the Nagoya Protocol remains.
- 2.4 Due diligence is not a defense against liability under provider country laws.<sup>11</sup> Adequate efforts must be made to investigate and comply with local ABS laws at all times.

## 3. Meaningful Stakeholder Engagement

- 3.1 Where due diligence is related to provider country interaction, stakeholder engagement including with local communities who hold traditional knowledge, is best characterized by two-way communication and good faith on part of the participants on both sides.

## 4. Impact studies and modeling of adverse implications

- 4.1 Initiatives to develop impact studies and models of adverse implications of conduct that falls short of diligent will help clarify the purpose and scope of due diligence. Adverse implications include frustrating the objectives of the Nagoya Protocol.
- 4.2 These impact studies will complement the development of best practices and tether such practices to the avoidance of adverse implications and to furthering the objectives of the Nagoya Protocol and EUR 511/2014.<sup>12</sup>

---

8 These essential characteristics and principles are of a general nature and adapted from the OECD Due Diligence for Responsible Business Conduct (30 May 2018), the EUR 2017/821 laying down supply chain due diligence obligations for Union importers of tin, tantalum and tungsten, their ores, and gold originating from conflict-affected and high-risk areas (not yet in force), the EU Timber Regulation 995/2010 to the ABS context in light of the evolution of due diligence as a standard of conduct in international law, as well as from the text of and Guidance notes to EUR 511/2014.

9 Natural and legal person, See Guidance Document [2.4]

10 Guidance Document [3.1]. In international law due diligence is normally not a standard of result, only of conduct. EUR 511/2014 appears to introduce a limited standard of result extending to PIC (or equivalent) and MAT only. In EUR 511/2014 this is not however a standard of result that extends to ensuring that fair and equitably sharing of benefits takes place, the assumption is that legally enforceable contractual obligations represented by PIC and MAT suffice to ensure this. Notably, PIC and MAT are only needed if a specific country has regulations in place that require PIC and Mat. A country can decide not to require PIC and MAT. See Art 6.1 of the Nagoya Protocol.

11 EUR 511/2014 applies to 'utilization by users in the EU', and Art 4 that sets out the obligations of users only uses the term 'ascertain' with respect to due diligence by users based in the EU. In Article 4, there is no explicit reference to 'access' and whether due diligence must also be applied when it comes to following provider country laws. However this can be gathered from the wording of recital 24 and 9 ('It is also essential to prevent the utilisation in the Union of genetic resources or traditional knowledge associated with genetic resources, which were not accessed in accordance with the national access and benefit-sharing legislation or regulatory requirements of a Party to the Nagoya Protocol, and to support the effective implementation of benefit-sharing commitments set out in mutually agreed terms between providers and users'); and that users also have to 'ascertain' in Art 4 that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.

12 While due diligence obligations of business organization under human rights guidance is not legally enforceable, there are many tools developed by NGOs to assess 'impact' and 'adverse implications' of actions taken on human rights. Similar efforts must be made by scientific bodies to explain and extrapolate the proximate and projected implications of not achieving the objectives of the Nagoya Protocol.



## 5. Best practices and sector specific guidance

- 5.1 A best practice must adhere to the principles of due diligence both as a standard of conduct and an obligation of result, when appropriate.<sup>13</sup>
- 5.2 Best practices and sector specific guidance must align with the objectives of the EUR 511/2014 including the effective implementation of the Nagoya Protocol.

## 6. The formation, performance and transfer of contractual obligations

- 6.1 Actions taken to negotiate, agree and perform contracts between users and providers must align with the responsibilities of all users to support the effective implementation of benefit-sharing as set out in mutually agreed terms under the Nagoya Protocol. The standard of conduct must be reasonable, affordable and facilitate legal certainty.<sup>14</sup>
- 6.2 Even where it is not possible to externally verify performance of contracts, change of intent and transfer to third parties must be conducted diligently. Such actions must aim to avoid or mitigate adverse or potentially adverse, implications for provider countries.<sup>15</sup>
- 6.3 If delaying benefit-sharing until a point at which there are benefits to be shared, due diligence must take account of the fact that provider countries often have little or no leverage on triggers for contractual performance.
- 6.4 Benefit-sharing can be as ambitious and aspirational as possible once all legal and procedural standards of conduct are met.

- 6.5 Benefits upfront in favor of delayed and speculative but potentially larger benefits must be agreed in as transparent a manner as possible.<sup>16</sup>

- 6.6 Benefit-sharing does not depend on the commercialization of the results of the utilization of genetic resource, and scientists and researchers must strive to share benefits in accordance with mutually agreed terms.<sup>17</sup>

## 7. Scrutiny of Third Party Conduct

- 7.1 Due diligence is the standard of care with which third party actions and intent must be investigated and scrutinized.
- 7.2 Due diligence requires users to use suitable leverage with collaborators and third parties to abide by the terms of access and benefit-sharing agreements.<sup>18</sup>
- 7.3 Commercial impetus and the demands for confidentiality of commercial information can inhibit transparency in benefit-sharing which might otherwise ensue as a result of diligent conduct. Greater transparency, use of available leverage and open negotiations in the pursuit of due diligence can aid rather than contradict, responsible corporate behavior in an ABS context.

## 8. Disclosure, Transparency and public confidence

- 8.1 Due diligence includes transparency of information with due regard to confidentiality of business arrangements and competitive concerns.<sup>19</sup>
- 8.2 Public reporting where possible will increase peer group confidence.
- 8.3 Due diligence reporting and transparency is enhanced by acknowledgement of the

---

13 See n 10 above.

14 Agreements here refer to private law contracts that establish conditions of access, use of resources and sharing of benefits including in the pursuit of commercial and non-commercial research.

15 It can be challenging to enforce any international contract. ABS contracts present additional difficulties. In a context in which harm sought to be avoided is difficult to conceptualize and external verification of performance triggers is nearly impossible, it is important to realize that that ABS contractual performance is in reality, mostly voluntary.

16 Young and Tvedt point out that given the difficulty of ensuring larger, more speculative benefits further down the line the temptation to settle for immediate and tangible benefits instead, is high for two reasons. First a secure small payment is often considered to be comparable in value to a speculative large payment. Second, a payment now is generally thought of as more valuable than a payment later. Young and Tvedt *Drafting Successful Benefit Sharing Contracts* (Brill 2017) p 141. Additionally there is nothing in the EUR that specifies when benefit-sharing obligations must be fulfilled, or how or when the provider's benefit-share should be calculated.

17 EUR 511/2014 does not provide a scheme for benefit-sharing beyond due diligence in compliance with local provider country laws.

18 As in the human rights context, this might require asking difficult questions of collaborators and colleagues. Such scrutiny however is essential to ensure that contractual intent at the beginning of the access process is not frustrated.

19 See Art 7 on scope of disclosure obligations in EUR 2017/821.

source or origin<sup>20</sup> of genetic resources used in publication or patent applications, even if they are representationally, structurally or functionally transformed in the research and utilization process.

- 8.4** There are diverse immediate sources of traditional knowledge including those documented in scientific publications. If the user knows the indigenous community who holds the Associated Traditional Knowledge, disclosure in publications or patent applications should be traced to the community rather than just the scientific publication reporting on the traditional knowledge.
- 8.5** Transparency in use of all relevant traditional knowledge can aid efforts to map and demarcate traditional knowledge that is merely relevant from cases where traditional knowledge associated with genetic resources is tangibly used.
- 8.6** Any track and trace methods used as part of diligent conduct should aim to acknowledge legal track and trace as well as scientific and technical efforts to do so.
- 8.4** Transparency must ideally account for discontinuous scientific use that might require technical and scientific information to be kept beyond the legally required 20-year period.

## **9. Chain of custody of genetic resources and associated traditional knowledge:**

- 9.1** In case of genetic resources accessed through intermediaries, it is prudent to obtain information regarding the chain of custody namely the succession of commercial and non-commercial operators who have used the genetic resource.<sup>21</sup>
- 9.2** At all times, practices and measures including scientific and technical actions in the chain of custody over genetic resources must be reasonably tested against due diligence and foundational responsibilities to follow provider country laws as well as obligations under EUR 511/2014.

## **10. Technical and scientific constraints**

- 10.1** There may be extraordinary cases, such as public health concerns of international dimension where due diligence in the obligatory sense may make adhering to scientific protocols difficult.<sup>22</sup> In such cases, and in the absence of sector specific guidance, it is advisable to assess whether technical and scientific protocols suffice as part of the appropriate, proportional and objective standard of due diligence.

## **11. Derivatives and Digital Sequence Information**

- 11.1** Users should aim to apply the principles in this Recommendation to digital sequence information and derivatives to the best of their ability, and to apply a standard of conduct that does not frustrate the effective implementation of the Nagoya Protocol.

## **12. Networks and organizations in compliance ecosystem**

- 12.1** Funding organizations and formal research networks must develop effective messaging and develop incentives for the internalization of due diligence norms.
- 12.2** Ratings or standards of ABS compliance may be used creatively to ensure diligent conduct, for example by research councils and grant making bodies.<sup>23</sup>

---

20 When origin and source are used together, the former may refer to in situ origins, whereas 'source' may refer to immediate source such as a collection. However in some legal systems 'source' may cover both - the country of origin, if applicable and known to the user/applicant, and if not, any other applicable and known source. For a detailed explanation of this concept of 'source' see the Submission by Switzerland in Response to Document WIPO/GRTKF/IC/30/9 'The Declaration of the Source of Genetic Resources and Traditional Knowledge in the Swiss Patent Act and Related Swiss Regulations on Genetic Resources' Available here [http://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_31/wipo\\_grtkf\\_ic\\_31\\_8.pdf](http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_31/wipo_grtkf_ic_31_8.pdf) The LSE survey also found that the majority of users are in favor of such disclosure in patents and publications for both genetic resources and associated traditional knowledge.

21 See Guidance on EUR 511/2014 on indirect acquisition of Genetic Resources by intermediaries [2.1.3].

22 As reflected in clause 8 or Art 4, EUR 511/2014.

23 One of the ways in which to do this might be to assume due diligence in compliance for all users, which will be retracted in case of non-compliance. The consequent loss aversion could become a powerful incentive to comply.



## SIVA THAMBISETTY

Dr Siva Thambisetty is an Associate Professor of Law at the LSE. Her research interests include comparative and international patent law, emerging technologies, and institutional and regulatory aspects of intellectual property. She convenes advanced modules on patent Law, technology and innovation on the LLM and Executive LLM, and teaches copyright and patent law on the LLB program.

Dr Thambisetty has been consulted by a number of bodies including the Nuffield Bioethics Council, UK Intellectual Property Office and the UK Government's Commission for Intellectual Property Rights. Some of her publications appear in the *Journal of Law and the Biosciences*, *Oxford Journal of Legal Studies*, *Jurimetrics*, *European Intellectual Property Review*, *Intellectual Property Quarterly*, *Nature Biotechnology* and the *Journal of World Intellectual Property Law*.

She is on the Faculty Advisory Board of the South Asia Centre at the LSE and currently holds a Horizon 2020 grant under the INMARE project to analyse the Implementation of the Nagoya Protocol in Europe.

LONDON | JANUARY 2019



THE LONDON SCHOOL  
OF ECONOMICS AND  
POLITICAL SCIENCE ■

Department of Law  
The London School of Economics and Political Science  
Houghton Street  
London  
WC2A 2AE

[lse.ac.uk/law](https://lse.ac.uk/law)

