

## D6.2: Report on adapting methods for legal analysis of emerging technologies

[WP6 – Generalizing project methods, and exploitation measures]

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## Abstract

The report outlines a revised general approach for legal analysis of emerging technologies. It elaborates and adapts the original approach developed in the SIENNA methodological Handbook which was applied to SIENNA legal studies in human genomics, artificial intelligence and robotics and human enhancement technologies. The proposed approach consists of four general steps: (1) specification of scope of legal analysis; (2) identification of legal issues; (3) analysis of international, regional (including EU) and national legal norms relevant for the identified issues and (4) identification of gaps and challenges in the existing legal frameworks with regard to the identified issues. The annex of the report includes two brief legal case-studies on three-dimensional printing and augmented reality technologies, illustrating how the major points of the revised approach could be applied to emerging technologies.

### Document history

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### Information in this report that may influence other SIENNA tasks

Linked task	Points of relevance
T6.6: Formulate a sustainability plan	The approach will be included in the sustainability plan (D6.5)



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## Executive summary

This report aims to outline a general methodology for legal analysis of emerging technologies, elaborating and adapting the original approach, developed in the SIENNA methodological Handbook.

**Chapter 1** describes the objectives of the report and its background, as well as its scope and limitations.

**Chapter 2** presents the evaluation of the original SIENNA Handbook approach for legal analysis, which was conducted after the approach was applied to legal studies on human genomics, artificial intelligence and robotics and human enhancement technologies. The main outcome of the evaluation is that the Handbook approach turned out to be flexible enough to be tailored to the three highly divergent fields of emerging technologies that were studied in SIENNA, but at the same time it left many substantive methodological choices to be made in the process. Therefore this report attempts to provide somewhat more specific guidance on how to address some methodological challenges, that would simultaneously remain sufficiently flexible to be applied to different future and emerging technologies.

The main part of the report, **chapter 3**, proposes a revised approach consisting of four general steps: (1) specification of scope of legal analysis; (2) identification of legal issues; (3) analysis of international, regional (including EU) and national legal norms relevant for the identified issues and (4) identification of gaps and challenges in the existing legal frameworks with regard to the identified issues. The four steps are discussed consecutively in the sections of the chapter 3.

The section on the **first step** addresses the scope of legal analysis, suggesting to break down the examined wide technological area into three levels: general technology level, artefacts and procedures level and applications level, drawing from Philip Brey's Anticipatory Technology Ethics approach. It also emphasises the need to adopt a contextualised perspective on the analysed technology, paying attention to the complex character of the whole sociotechnical landscape, as well advises not to focus only on what is utterly new about it, but to notice also what is 'just' exacerbated or reinforced.

The section on the **second step** stresses that issue identification phase needs to be done with caution, not to reproduce the unfair societal power inequalities by overlooking risks pertinent to disadvantaged groups. It also highlights the necessity to consciously adopt a frame that could structure the potentially vast area of legal issues. Acknowledging that there are many possible frames of reference, it argues for the adoption of a human rights perspective and outlines four general benefits of applying it in the area of emerging technologies. It also emphasises that applying human rights lenses is not equal to analysing only matters of international human rights law or constitutional law and it explains how specific 'lower-level' legal issues like liability, safety, personal data, property etc. can be linked to human rights. Noting that there are many ways of conducting legal analysis inspired by human rights, it draws from the human rights-based approach paradigm and its principles of comprehensiveness (equal consideration of different types of rights), non-discrimination and equality and participation. The section also describes two basic means of identifying issues envisaged by this approach: literature review and stakeholder engagement. It pays particular attention to expert interviews (with a broad understanding of 'expertise' in this type of data collection, which includes also knowledge acquired through analysing or addressing problems in practice).



The next section discusses the **third step**, pertaining analysis of legal norms relevant to the identified issues. It highlights that even when emerging technologies bring previously unknown capabilities and there is no explicit legal guidance related to them, this does not entail that they would operate in a legal void in a strict sense. Further, it also emphasises that the material for analysis should not be restricted to international human rights law or constitutional law, but shall include also all relevant ‘lower-level’ legal sources linked to the identified issues seen through the human rights lenses. It briefly discusses the doctrinal method of analysis, including different possible levels of doctrinal analysis, from rather ‘thin’, largely semantic description to a more ‘thick’ one, to a greater extent based also on purposive, systematic and contextual methods of interpretation. The section moreover refers to analysing some regulatory-design characteristics of examined norms, including their underlying normative outlooks. In addition, it addresses the benefits and the challenges of a comparative analysis of different national orders.

The last section describes the last, **fourth step** – assessment of the adequacy of the examined legal frameworks. It re-emphasises that a lack of dedicated legislation does not necessarily mean that there is a legal gap. The section describes two parallel risks to be avoided in adequacy assessment: jumping too quickly to conclusions that the current legal framework is outdated and too rigidly sticking with the current law. To avoid such risks, it advocates a systematic case-by-case approach. It argues that a key element in such case-by-case evaluation would be assessing whether the examined norms remain ‘fit for purpose’ – with possible purposes ranging from specific goals of ‘local’ significance within a legal system up to fundamental purposes of a whole legal order, like human rights (with the latter type of fitness being crucial). Next, it briefly describes two general (non-exhaustive) ways in which law may fail to accomplish its aims, referring to broad categories of under-inclusiveness and over-inclusiveness of law. The two categories encompass both problems of conceptual mistargeting and more practical over- or under-enforcement, as well both situations where there is a need for new specific norms or where whole (set of) norms became obsolete, and situations where scope of current norms “only” needs to be narrowed or widened.

Following the **concluding chapter**, which summarizes the key point of the main body of the report, the **Annex** contains two brief case-studies pertaining to two other examples of emerging technologies: three-dimensional printing and augmented reality technologies. It also identifies other examples of future and emerging technologies.



## List of acronyms/abbreviations

Abbreviation	Explanation
<b>AI</b>	Artificial intelligence
<b>AR</b>	Augmented Reality
<b>CoE</b>	Council of Europe
<b>D</b>	Deliverable
<b>EU</b>	European Union
<b>HET</b>	Human enhancement technologies
<b>HRBA</b>	Human-rights based approach
<b>RRI</b>	Responsible research and innovation

**Table 1:** List of acronyms/abbreviations

## Glossary of terms

Term	Explanation
<b>Hard law</b>	Authoritative rules backed by coercive force exercised at the national level by a legitimately constituted (democratic) nation-state and constituted in the supranational context by binding commitments voluntarily entered into between sovereign states (typified by public international law). <sup>1</sup>
<b>Law</b>	Encompasses both hard law and soft law.
<b>Regulation</b>	The intentional use of authority to affect behaviour of a different party according to set standards. Law is one of the institutions for purposively attempting to shape behaviour and social outcomes, but there may be other means, including the market, social norms, and technology itself. Regulation can also mean a species of hard law, e.g., a type of EU legal act with a direct effect defined by Article 288 of the Treaty on the Functioning of the European Union <sup>2</sup> or, in some instances, a legal act adopted at the national level.
<b>Self-regulation</b>	Normative instruments, i.e., codes of conduct, ethical codes, adopted by private non-governmental entities. <sup>3</sup>

<sup>1</sup> Brownsword, Roger, Eloise Scotford, and Karen Yeung, “Law, Regulation and Technology: The Field, Frame, and Focal Questions”, in Roger Brownsword, Eloise Scotford, and Karen Yeung (eds.), *The Oxford Handbook of Law, Regulation and Technology*, Oxford University Press, Oxford, 2017, pp. 3-40.

<sup>2</sup> According to this provision, “To exercise the Union's competences, the institutions shall adopt regulations, directives, decisions, recommendations and opinions. A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States. A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. A decision shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them. Recommendations and opinions shall have no binding force.”

<sup>3</sup> Goncales, Maria Eduarda, Maria Ines Gameiro, “Hard Law, Soft Law and Self-regulation: Seeking Better Governance for Science and Technology in the EU”, Working paper, 2011.



<b>Term</b>	<b>Explanation</b>
<b>Soft law</b>	Normative, non-binding instruments emanating from law-making bodies including resolutions, recommendations, guidelines, communications, notices etc. (public, top-down instruments). The lack of binding force is the main feature distinguishing soft from hard law. <sup>4</sup>

**Table 2:** Glossary of terms

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<sup>4</sup> Ibid.



# 1. Introduction

## 1.1 Background and objectives

The aim of this report is to outline a general methodology for legal analysis of emerging technologies. It elaborates and adapts the original approach, developed in the SIENNA consortium's methodological handbook (the SIENNA Handbook).<sup>5</sup>

The report builds upon three main sources. First, it takes as a starting point the approach for legal study presented in the SIENNA Handbook. Second, it draws from the results of legal analyses conducted in the SIENNA project. In 2018-2019, we have carried three legal studies that applied the SIENNA Handbook approach to human genomics, artificial intelligence (AI) and robotics and human enhancement technologies (HET).<sup>6</sup> We have looked back at these analyses to assess to what extent the original approach worked in practice when applied to the three different technological domains, whether it could be used also in other fields and how could it be improved. Third, we have conducted a supplementary literature review of the existing methodological reflections in the area of law, technology and regulation. There have been several attempts in this area to provide some methodological guidance that could be valid in different technological domains – and this report aims to draw from these discussions and to contribute to them, based on SIENNA results.<sup>7</sup>

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<sup>5</sup> Rodrigues, Rowena, Stearns Broadhead, Philip Brey, Zuzanna Warso, Tim Hanson, Lisa Tambornino, Dirk Lanzerath, *SIENNA D1.1: The Consortium's Methodological Handbook*, 2018.

<sup>6</sup> Slokenberga, Santa, Konrad Siemaszko, Zuzanna Warso, and Heidi C Howard, *SIENNA D2.2 Analysis of the Legal and Human Rights Requirements for Genomics in and Outside the EU*, 2019; Rodrigues, Rowena, Konrad Siemaszko, and Zuzanna Warso, *SIENNA D4.2: Analysis of the Legal and Human Rights Requirements for AI and Robotics in and Outside the EU*, 2019; Warso, Zuzanna, and Sarah Gaskell, *SIENNA D3.2: Analysis of the Legal and Human Rights Requirements for Human Enhancement Technologies in and Outside the EU*, 2019.

<sup>7</sup> Among others, see Cockfield, Arthur and Jason Pridmore, "Synthetic Theory of Law and Technology", *Minnesota Journal of Law, Science, and Technology*, Vol. 8, Issue 2, 2007, pp. 475-513; Moses, Lyria Bennett, "Recurring dilemmas: The law's race to keep up with technological change", *University of Illinois Journal of Law, Technology & Policy*, Vol. 1, Issue 7, 2007, pp. 239; Koops, Bert-Jaap, "Ten Dimensions of Technology Regulation-Finding Your Bearings in the Research Space of an Emerging Discipline" in Morag Goodwin, Bert-Jaap Koops, and Ronald Leenes (eds.), *Dimensions of technology regulation*, Wolf: Nijmegen, 2010, pp. 311-326; Brownsword, Roger, and Morag Goodwin, *Law and the Technologies of the Twenty-first Century: Text and Materials*, Cambridge University Press, 2012; Koops, Bert-Jaap, "A taxonomy for descriptive research in law and technology", in Palmerini, Erica, and Elettra Stradella (eds), *Law and technology. The challenge of regulating technological development*, Pisa University Press, 2013, pp. 37-57; Moses, Lyria Bennett, "How to think about law, regulation and technology: Problems with 'technology' as a regulatory target", *Law, Innovation and Technology*, Vol. 5, Issue 1, 2013, pp. 1-20; Brownsword, Roger, Eloise Scotford, and Karen Yeung, "Law, Regulation and Technology: The Field, Frame, and Focal Questions", in Roger Brownsword, Eloise Scotford, and Karen Yeung (eds.), *The Oxford Handbook of Law, Regulation and Technology*, Oxford University Press, Oxford, 2017, pp. 3-40; Mandel, Gregory N., "Legal Evolution in Response to Technological Change", in Roger Brownsword, Eloise Scotford, and Karen Yeung, (eds.), *The Oxford Handbook of Law, Regulation and Technology*, Oxford University Press, 2017, pp. 225 -246; Leenes, Ronald, Erica Palmerini, Bert-Jaap Koops, Andrea Bertolini, Pericle Salvini, Federico Lucivero, "Regulatory challenges of robotics: some guidelines for addressing legal and ethical issues", *Law, Innovation and Technology*, Vol. 9, Issue 1, 2017, pp. 1-44; Brownsword, Roger, "Law Disrupted, Law Re-Imagined, Law Re-Invented",





## 1.2 Structure of the report, its scope and limitations

Chapter 2 of the report very briefly outlines the general structure of the original SIENNA Handbook approach for legal analysis and presents key conclusions from the evaluation of the original methodology. Chapter 3 contains a proposal for a revised, general approach. It outlines and discusses four general steps of legal analysis of emerging technologies: (1) specification of scope; (2) identification of legal issues; (3) analysis of international, regional (including EU) and national legal norms relevant for the identified issues and (4) identification of gaps and challenges in the existing legal frameworks with regard to the identified issues. Finally, following conclusions of the main body of the report, two very brief case-studies are presented in the Annex, applying the major steps of the revised approach to examples of other types of future and emerging technologies: three-dimensional printing (3D printing) and augmented reality (AR) technologies.

In the field of technology, law and regulation many authors have convincingly argued for a broad understanding of regulation, which is non-extensive with the law (in a conventional, state-centric sense),<sup>8</sup> but rather denotes any forms of “sustained and focused attempt to alter the behaviour of others to standards or goals with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information gathering and behaviour-modification”.<sup>9</sup> In this understanding, regulation may encompass not only governance documents such as standards or self-regulation instruments but also social norms, markets and technology itself (the latter has been framed as ‘techno-regulation’<sup>10</sup> or ‘code’, ‘architecture’ or ‘design’<sup>11</sup>).<sup>12</sup> While broadening the scope of studying technologies to different forms of regulating human behaviour has certainly brought many seminal insights in the field, in this report, which outlines an approach for *legal* analysis, we will focus mostly on one of the modes of regulation: law. The law itself, however, will be understood broadly, as encompassing both hard law, soft law and case-law.

With the main goal of this report being to propose a revised approach for legal analysis, the two brief case-studies in the Annex are only meant to serve as very short, indicative illustrations of how the general outline of this approach could be applied to other examples of emerging technologies. With this limited scope of the task and limited resources available for the case studies, there are by no

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*Technology and Regulation*, 2019, pp. 10-30; Leenes, Ronald, "Of horses and other animals of cyberspace", *Technology and Regulation*, 2019, pp. 1-9; Leenes, Ronald, "Regulating New Technologies in Times of Change" in Leonie Reins (ed.), *Regulating New Technologies in Uncertain Times*, Springer, The Hague, 2019, pp. 3-17; Guihot, Michael, "Coherence in technology law", *Law, Innovation and Technology*, vol. 11, Issue 2, 2019, pp. 311-342; Liu, Hin-Yan, Matthijs Maas, John Danaher, Luisa Scarcella, Michaela Lexer & Leonard Van Rompaey, "Artificial intelligence and legal disruption: a new model for analysis", *Law, Innovation and Technology*, Vol. 12, Issue 2, 2020, pp. 205-258; Crootof, Rebecca, Ard, BJ, "Structuring Techlaw", *Harvard Journal of Law & Technology*, Forthcoming, 2021, <http://dx.doi.org/10.2139/ssrn.3664124>, pp. 1-82.

<sup>8</sup> Brownsword, Roger, Eloise Scotford, and Karen Yeung, op. cit., 2017, p. 6.

<sup>9</sup> Black Julia, "What Is Regulatory Innovation?", in Julia Black, Martin Lodge and Mark Hatcher (eds.), *Regulatory Innovation*, Cheltenham: Edward Elgar, 2005, p. 11.

<sup>10</sup> Brownsword, Roger, "Code, control, and choice: why East is East and West is West", *Legal Studies*, vol. 25, Issue 1, 2005, pp. 1-21

<sup>11</sup> Lessig, Lawrence, "The Law of the Horse: What Cyberlaw Might Teach", *Harvard Law Review*, vol. 113, no. 2, 1999, pp. 501-546

<sup>12</sup> Leenes, Ronald, op. cit., 2019a, p. 4.



means to be understood as exhaustive legal analyses of the two technologies. Moreover, as the proposed approach is dedicated for a legal analysis of a length comparable to the SIENNA legal studies (with some options for adjustments), the much shorter case-studies follow major aspects of the approach, but not necessarily every element of it.

## 2. Evaluation of the original SIENNA approach for legal analysis

Put very briefly, the original SIENNA Handbook approach for legal analysis consisted of the following general steps. First one was mapping the subject of the research by identifying main legal issues. It was followed by studying relevant international, regional and EU law and a comparative analysis of certain aspects of selected EU and non-EU countries' legislation pertinent to the examined areas. It was moreover accompanied by a cross-level comparison and identification of key challenges and gaps. The basic normative presupposition of the whole approach was that the development and use of new technologies ought to remain consistent with human rights.<sup>13</sup>

The main goals of the evaluation of the original SIENNA Handbook approach were to see how it worked in practice in the three technological domains studied in SIENNA and what can we learn from this experience. The assessment was conducted by the main authors of the legal analysis reports, based on the common guiding questions shared by the task coordinator. The questions regarded among others: the exact steps of the analyses (and whether they differed from the approach outlined in the SIENNA Handbook), key advantages and disadvantages and limitations of the applied approach, as well as suggested potential modifications.

Crucially, the parallel assessment of the legal analyses of the three technological areas allowed to reflect on how the original SIENNA approach worked with regard to the three emerging technologies that have very significant differences. Among others, while AI and robotics may be seen as part of a larger area of computer sciences and engineering, genomics can be described as belonging to health and life sciences domain. Moreover, while the latter two can be perceived as technological fields defined by their intrinsic characteristics, human enhancement domain is rather defined by a particular purpose: it can involve *any* kind of technology used for enhancement. Furthermore, the three areas are at very different stages of advancement, both in terms of their technical development, as well as their regulatory environments. Genomics is a well-established field with continued important developments and with mature, dedicated legal frameworks on both national and international level. AI (and, partly, robotics) is a quickly expanding area which has been in a particular focus of regulators and policymakers in the last years. Human enhancement, in turn, has not yet caught a comparable level of regulatory attention and many (though not all) of its aspects are at early stages of advancement. Hence, the legal analyses of these three areas conducted in SIENNA have already provided a good

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<sup>13</sup> For more details, see: Rodrigues, Rowena, Stearns Broadhead, Philip Brey, Zuzanna Warso, Tim Hanson, Lisa Tambornino, Dirk Lanzerath. op. cit. 2018, pp. 35-45.



testbed for a general application of the SIENNA Handbook approach for different emerging technologies.

The evaluation provided two general conclusions. First, the major steps outlined in the original SIENNA Handbook approach were followed in the examination of all three very diverging technological areas and these steps helped to compile valuable data about the complex topics. However, more concrete operationalisation of the steps was left to be done during each of the analyses. In other words, the original approach proved, in general, to work well with very different technological areas, but important methodological choices were left to be made in the implementation process. For instance, the original methodology did not specify how to approach the very broad domains, in the sense of advising at what level of abstraction should the areas be studied. As whole fields? Or should they be rather broken down to more specific aspects, and if yes – then how? Similarly, while the original approach indicated that in the first step key legal issues related to the technological areas shall be identified based on the literature review, it did not provide any specific guidance how to select from a plethora of issues that can be potentially found in the relevant literature (what can be considered to be a *key legal issue*? What are the criteria? And is any topic discussed in legal debates around the technological area a *legal issue*?). Moreover, while the original approach outlined in the SIENNA Handbook referred to the identification of gaps and assessment of existing legal frameworks adequacy to deal with the challenges posed by developments in the examined technological areas, it offered little advice on how to assess the adequacy.

There are multiple possible answers to these and similar methodological questions and the choices were left to be made in practice of legal analysis. This openness allowed to tailor the Handbook approach to the needs of three divergent technological fields that were studied in the project. In this sense it was functional to a certain extent, but on the other hand, it created a risk of overlooking some methodological choices. The key question is therefore whether a more concrete, systematic methodological guidance could be provided, with more explicit considerations of different choices made through the process – which would be still applicable to different types of emerging technologies. This is what the next chapter of the report will aim for: provide a revised, more systematic step-by-step approach, which still could be used for different emerging technologies.

## 3. A revised approach for legal analysis of emerging technologies

### 3.1 Introduction

The key objectives of legal analysis in the proposed approach include identification of legal issues associated with the examined technology, analysis of the law pertinent to the identified issues and identification of potential gaps and challenges in the existing legal frameworks with regard to the issues (that is, assessing the adequacy of the existing law to deal with the issues). These objectives in general follow the overall aims of the SIENNA legal research, as defined in the SIENNA Description of Action document and elaborated in the SIENNA Handbook. It is worth to note, however, that these aims are very similar to what Micheal Guihot has argued to constitute general “unifying principles of



technology law” – a field characterised, he has claimed, by research which “grapples with the adequacy of regulation to deal with a threat or risk posed by a particular technology.”<sup>14</sup>

Following the above objectives, the proposed approach for legal analysis of emerging technologies consists of four general steps:

- (1) specification of scope of legal analysis;
- (2) identification of legal issues;
- (3) analysis of international, regional (including EU) and national legal norms relevant for the identified issues;
- (4) identification of gaps and challenges in the existing legal frameworks with regard to the identified issues.

In the following sections, we describe each of the four steps.

### 3.2 Specification of scope of legal analysis

In the first, preliminary step, the scope of legal analysis needs to be specified. When the subject of study is defined in general terms – such as “AI”, “robotics”, “genomics”, “human enhancement technologies”,<sup>15</sup> “neurotechnologies”, “biotechnologies”, “nanotechnologies” etc. – what is crucial is the decision about how to approach such broad fields. Should one attempt to see the technological area in question as a whole – or rather look at legal aspects of its specific manifestations? What level of abstraction should be adopted?<sup>16</sup>

There are two parallel risks that need to be avoided here.<sup>17</sup> The first risk would be using only very broad, general categories. This might be unhelpful because of being too abstract, as technology field usually consists of different products or applications, which involve divergent sets of legal issues. The second risk would be looking only on concrete instances of the technology in question. Here a danger would be missing a bigger picture, being distracted by potentially non-relevant features of these specific cases and seeing them in isolation. One might then overlook common underlying challenges and focus only on symptomatic, surface issues, failing to see their deeper sources.<sup>18</sup>

While there are several ways to mitigate these risks, one possibility would be to use different levels of analysis of a technological field, adopting the Anticipatory Technology Ethics approach, developed by

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<sup>14</sup> Guihot, Michael, op. cit., 2019. p. 26. Michael Guihot’s approach refers also to an additional part: a regulatory response to identified gaps and challenges. The approach proposed in this report, following the scope of this task, focuses on descriptive legal analysis, though such analysis would lay ground for possible prescriptive elements (recommendations).

<sup>15</sup> AI, robotics, genomics and human enhancement technologies were the technology fields studied in the SIENNA project.

<sup>16</sup> Level of abstraction is one of the features of technology dimensions described in Koops, Bert-Jaap, op. cit., 2010.

<sup>17</sup> Leenes, Ronald, op. cit., 2019b.

<sup>18</sup> Liu, Hin-Yan, Matthijs Maas, John Danaher, Luisa Scarcella, Michaela Lexer, Leonard Van Rompaey, op. cit., 2020, pp. 3-12.



Philip Brey, and applying it to a legal analysis.<sup>19</sup> Such adopted approach would involve asking questions about *legal* aspects of (1) the *technology level*, the most general level, which would focus on legal issues that are likely to arise in all or nearly all applications of the technology; the *artefact* or *product level*, relating to legal issues of technological artefacts (physical entities) and procedures (for achieving practical aims) that are being developed on the basis of the technology; and (3) the *application level*, which would look at legal issues connected to certain ways of using an artefact or procedure, in specific context and by particular users.<sup>20</sup> This perspective would enable to consider both legal aspects that are common among different uses and sectors (at the technology level), avoiding what has been criticised as a piecemeal approach.<sup>21</sup> At the same time, it would allow to break down a potentially huge technological area into smaller, organised parts and to look at legal issues specific for certain artefacts or applications (at the other two levels), which despite their significance could be omitted if one tried to examine only what is general. Last but not least, this perspective sets a framework in which legal issues could be later identified and studied (in the second and third step, according to the approach proposed in this report) in an organised manner, which may help to properly map legal frameworks relevant for the identified issues (for example, workplace application would divert attention to labour law, etc.) and, at a later stage of legal intervention,<sup>22</sup> this could contribute to adequately choosing means of addressing the identified problems (among others choosing between a general and sectoral regulations).

Arguably, at each of the three levels, it would be vital not to take the object of analysis in isolation, that is abstracting the examined technology from the reality in which it functions (or in which it is likely to function in the future if it is still at an early stage of development). Instead, a more contextualised approach would be needed, entailing two closely related aspects. First would be taking notice of the complex character of technologies as involving relations between, among others, different physical objects, know-how and personnel<sup>23</sup> (including “multiple layers of contractors, distributors, and downstream logistical partners around the world”<sup>24</sup>). The second aspect would be paying attention to ways in which the technology in question interacts with the world already in place, “how people use technology in their lives and in their social relations with others (...) including relations of power and

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<sup>19</sup> Brey, Philip, “Anticipatory Ethics for Emerging Technologies”, *Nanoethics*, Vol. 6, Issue 1, 2012, pp. 1–13. This approach was also used in SIENNA ethical analysis of AI and robotics and, partly, of human enhancement technologies, see: Jansen, Philip, Philip Brey, et al., *SIENNA D4.4: Ethical Analysis of AI and Robotics Technologies*, 2020; Jensen, Sean R, *SIENNA D3.4: Ethical Analysis of Human Enhancement Technologies*, 2020; see also Rodrigues, Rowena, Stearns Broadhead, Philip Brey, Zuzanna Warso, Tim Hanson, Lisa Tambornino, Dirk Lanzerath. op. cit. 2018, pp. 20-21.

<sup>20</sup> Brey, Philip, op. cit., 2012; Rodrigues, Rowena, Stearns Broadhead, Philip Brey, Zuzanna Warso, Tim Hanson, Lisa Tambornino, Dirk Lanzerath. op. cit. 2018.

<sup>21</sup> Liu, Hin-Yan, Matthijs Maas, John Danaher, Luisa Scarcella, Michaela Lexer, Leonard Van Rompaey, op. cit., 2020, pp. 3-12.

<sup>22</sup> The stage of addressing the legal challenges (‘fixing’ the spotted problems) is outside the scope of this report.

<sup>23</sup> Jones, Meg Leta, “Does Technology Drive Law: The Dilemma of Technological Exceptionalism in Cyberlaw”, *University of Illinois Journal of Law, Technology & Policy*, 2018, pp. 249-284, [pp. 257-258]; Balabanian, Norman, “On the Presumed Neutrality of Technology”, *IEEE Technology and Society*, Vol. 25, Issue 4, 2006, pp. 15-25.

<sup>24</sup> Crawford, Kate, and Vladan Joler, *Anatomy of an AI System*, <https://anatomyof.ai/>, 2018.



control”.<sup>25</sup> In other words, it would be useful to frame the object of analysis more in terms of what Lyria Bennett Moses called a ‘sociotechnical landscape’.<sup>26</sup>

Moreover, with the aim of identifying legal challenges and potential gaps in existing legal frameworks, focusing only on ‘pure’ novelty (only on what is genuinely new, unprecedented about a technology) might not be helpful. Such an approach could lead to overlooking important impacts that refer to elements that are perhaps not utterly new but are made newly *salient* by a technology – vital elements of social life that existed before, but are now emphasised, reinforced and exacerbated.<sup>27</sup>

Applying this kind of contextualised approach,<sup>28</sup> which does not limit itself only to utterly new issues, for example, to AI and robotics, could allow to notice such heterogeneous legal aspects as labour and environmental concerns related both to the extraction of natural resources used in some of their products components<sup>29</sup> and connected to processing large amounts of data in training of algorithms.<sup>30</sup> Furthermore, it would also enable to take into consideration impacts of the dominant market position of the key players in the IT sector,<sup>31</sup> their business models<sup>32</sup> or their corporate governance structures.<sup>33</sup>

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<sup>25</sup> Balkin, Jack M., "The path of robotics law", *California Law Review Circuit*, Vol. 6., 2015., pp 45-60, [pp. 45,47]. Jack M. Balkin made this argument responding to Calo, Ryan R, "Robotics and the Lessons of Cyberlaw." *California Law Review*, 2015, pp. 513-563. Ryan R. Calo had analysed new technologies (internet and robotics) through lenses of their “essential qualities”, that is sets of specific characteristics that distinguish a given technology from its predecessor and constituent technologies. For a discussion on this debate and for possibilities to draw lessons from it for a broader reflection about “legal disruption caused by new technologies”, see Hin-Yan Liu, Matthijs Maas, John Danaher, Luisa Scarcella, Michaela Lexer Leonard Van Rompaey, op. cit., 2020, pp. 14-18.

<sup>26</sup> Moses, Lyria Bennett, op. cit., 2013.

<sup>27</sup> Balkin, Jack M, op. cit., 2015, pp. 46-47; Balkin, Jack M., “Digital Speech and Democratic Culture: A Theory of Freedom of Expression for the Information Society”, *New York University Law Review*, Vol. 79, Issue 1, 2004, pp. 1-55 [p. 2].

<sup>28</sup> For an emphasis on the importance of the context in the *ethical* analysis of AI, see Anaïs Ressayguier, *Ethics as Attention to Context: Recommendations for AI Ethics. Annex 6 to SIENNA D5.4: Multi-Stakeholder Strategy and Tools for Ethical AI and Robotics*, 2021.

<sup>29</sup> Such as cobalt, a key component of rechargeable batteries used in electronic – see Amnesty International, "This Is What We Die For: Human Rights Abuses in the Democratic Republic of the Congo Power the Global Trade in Cobalt", London, Amnesty International, 2016, pp.1-62. See also Crawford, Kate, and Vladan Joler, op. cit., 2018, for an impressive example of seeing AI through contextualised lenses, recognising its relations to “human labor, data and planetary resources” (on an example of Amazon Echo).

<sup>30</sup> Ibid; Dhar, Payal, "The Carbon Impact of Artificial Intelligence", *Nature Machine Intelligence*, 2020, pp. 423-425; Tubaro, Paola, Antonio Casilli, and Marion Coville, “The Trainer, the Verifier, the Imitator: Three Ways in which Human Platform Workers Support Artificial Intelligence”, *Big Data & Society*, Vol.7, Issue 1, 2020, pp. 1–12.

<sup>31</sup> Nemitz, Paul, “Constitutional democracy and technology in the age of artificial intelligence”, *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences*, Vol. 376, Issue 2133, 2018, pp. 1-14.

<sup>32</sup> Amnesty International, “Surveillance giants: How the business model of Google and Facebook threatens human rights”, London, Amnesty International, 2019, in general, see Zuboff Shoshana, *The Age of Surveillance Capitalism: The Fight for a Human Future at the New Frontier of Power*, Profile Books, London, 2019.

<sup>33</sup> As Michael Veale has observed commenting on the High-Level Expert Group on Artificial Intelligence (HLEG) policy recommendations: “If movements like Tech Won’t Build It and Google Walkout have taught anything, it’s that there is some, perhaps limited, hope in the moral of individual workers. (...) What is needed is a challenge to corporate governance. Yet any such reforms which might shake-up corporate decision-making or board



It could be argued that these aspects are not distinctive for AI and robotics (in the sense that these features are also shared by some other technologies) or that they are not essential for them (because these technologies could perhaps work without these elements, in different circumstances, and still be classified as AI and robotics). However, abstracting from this type of aspects involves a risk of missing important legal challenges that do in fact occur in real world and consequently, it could lead to a flawed assessment of the current legal frameworks and misguided legal interventions. In other words, focusing only on “shiny new” features may distract from background elements that are ‘more of the same’, “only” exacerbated or simply put in new circumstances – but are still normatively important.<sup>34</sup>

### 3.3 Identification of legal issues

The next step is the identification of legal issues related to the contextualised description of the three levels of the studied technology. Following the general objectives of the approach proposed in this report (which include identifying possible risks and gaps), legal issues will be understood here as potential challenges for legally protected values and interests.<sup>35</sup> With this practical orientation, it is important from the start to recognise the significance of the issue identification step. The initial framing and selection of issues related to the examined technology shapes the whole subsequent analysis. For this reason, it needs to be done in caution, being aware that apparently neutral or objective selection and framing involves a danger of making implicit biased assumptions about those who may be affected by the technology – and consequently influence whose risks effectively will be taken into account. It may be helpful to draw here from one of the essential features of feminist legal methods, that is: paying attention to implicit biases in legal analysis (or law, legal doctrine etc.) that leave out or disadvantage women or other groups. Katharine T. Bartlett referred to this method as “asking the «woman question»”, and provided the following guiding questions that could be of use also in the context of the discussed step : “What assumptions are made by (...) analysis (...) about those whom it affects? Whose point of view do these assumptions reflect? Whose interests are invisible or peripheral? How might excluded viewpoints be identified and taken into account?”.<sup>36</sup>

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representation are conspicuously completely absent from HLEG recommendations”, Veale, Michael, “A Critical Take on the Policy Recommendations of the EU High-Level Expert Group on Artificial Intelligence”, *European Journal of Risk Regulation*, 2020, pp. 1–10, [p. 5].

<sup>34</sup> Crotoft, Rebecca and Ard, BJ, op. cit., 2020, p. 7 and p. 57.

<sup>35</sup> Such understanding of legal issues in the context of new technologies draws from: Cockfield, Arthur and Pridmore, Jason, op. cit., 2007, pp. 504-505. In the approach presented by the A. Cockfield and J. Pridmore, identification of traditional interests and values protected by law is a first part of the first step of the analysis, followed by “assessing whether the interest is being unduly disrupted by technology change” and the second step, which “scrutinizes the broader context of technology change and its potentially unanticipated adverse outcomes for the traditional interest as well as for other protected interests the law seeks to protect” and then “seeks to find legal solutions to protect the traditional interest that are less deferential to precedent and traditional doctrine”, *ibid.*

<sup>36</sup> Bartlett, Katharine T., “Feminist Legal Methods”, *Harvard Law Review*, Vol.103, Issue 4, 1990, pp. 829-888, [p.848]. See also: Levit, Nancy, Robert RM Verchick, and Martha Minow, *Feminist legal theory: A primer*, New York University Press, New York, 2016, pp. 41-44. These kinds of questions are highly relevant at each step of legal analysis of emerging technologies, but perhaps in particular during the stage of selecting and framing the legal issues.



Emerging technologies may raise a great number of legal issues – a situation that particularly calls for some frame that could structure the vast domain. There are many possible (and partly overlapping) lenses that could be used.<sup>37</sup> This could be, for example, specific areas of law (e.g. criminal law, intellectual property law, torts), theories (such surveillance studies or feminism) or ethical meta-regimes (such as three stances in Roger Brownsword’s bioethical triangle: utilitarian, dignitarian and human rights perspectives<sup>38</sup>). However, we would argue that human rights may offer particularly well-suited frames of reference for identifying legal issues in diverse types of emerging technologies, across many technological domains.<sup>39</sup>

### **Why a human rights perspective?**

The relevance of human rights perspective in the area of emerging technologies has been particularly visible in the last 25 years both in terms of expanding academic literature and in the growing number of international laws and policies on particular technologies,<sup>40</sup> but also noticeable in general approaches to science and technology governance, such as responsible research and innovation (RRI).<sup>41</sup> Adopting this perspective would mean looking at legal issues through the lenses of human rights, that is: trying to identify what human rights may be affected by the analysed technology. There are at least four arguments for using this frame.

First, in communities that are politically and legally committed to respecting human rights – as is Europe, through the European Union (EU), the Council of Europe (CoE) and through respective

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<sup>37</sup> Guihot, Micheal, op. cit., 2019.

<sup>38</sup> Brownsword, Roger, “Ethical Pluralism and the Regulation of Modern Biotechnology”, In: Francioni, Francesco (ed.), *Biotechnologies and International Human Rights*, Oxford, Hart Publishing, 2007, pp. 45-70; see also Brownsword, Roger, and Morag Goodwin, op. cit., 2012, p. 185, for corresponding three “main normative frameworks at play in technology regulation”, that is “utilitarianism (goal oriented), deontology (duty based) and liberalism (rights based)”.

<sup>39</sup> Referring to the earlier categorisation of possible lenses, human rights may be understood both as one of ethical meta-regimes and an area of law.

<sup>40</sup> Among many others, these instruments include Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003), and the Universal Declaration on Bioethics and Human Rights (2005) within the UN system and Convention on Human Rights and Biomedicine (Oviedo Convention, 1997) – just for the biotechnology field. This trend is also clearly visible more recently in the AI area – a recent Berkman Klein study of 36 “principles’ documents aimed at providing normative guidance regarding AI-based systems” (p.3) indicated that “64% of our documents contained a reference to human rights, and five documents took international human rights as a framework for their overall effort” – Fjeld, Jessica, Nele Achten, Hannah Hilligoss, Adam Nagy, and Madhulika Srikumar, *Principled artificial intelligence: Mapping consensus in ethical and rights-based approaches to principles for AI*, Berkman Klein Center Research Publication, Cambridge, 2020, p. 6. For a general overview of the increasing role of human rights in the area of technology regulation, see also e.g. Murphy, Thérèse, “Repetition, Revolution, and Resonance: An Introduction to New Technologies and Human Rights” in Thérèse Murphy (ed.), *New Technologies and Human Rights*, Oxford, Oxford University Press, 2009; Brownsword, Roger, and Morag Goodwin, op. cit., 2012, pp. 225–245.

<sup>41</sup> For an overview, see e.g. Koops, Bert-Jaap, “The Concepts, Approaches, and Applications of Responsible Innovation” in Koops, B. J., Oosterlaken, I., Romijn, H., Swierstra, T., & Van den Hoven, J. (Eds.), *Responsible Innovation, Volume 2*, Springer, Cham, 2015, pp. 1-15; Ruggiu, Daniele, “Anchoring European governance: Two versions of responsible research and innovation and EU fundamental rights as ‘Normative anchor points’”, *NanoEthics* vol. 9, Issue 3. 2015, pp. 217-235.





constitutional regimes of their member states,<sup>42</sup> human rights constitute foundational principles, with which the whole legal order must comply. They serve as a common touchstone (or an ‘anchor point’<sup>43</sup>), shared in pluralistic societies. Moreover, they are understood as being universal.

Second, as a holistic framework, human rights allow to consider a wide variety of challenges under a common thread.<sup>44</sup> They offer protection both against state and non-state actors (although traditionally state-centric, human rights framework lays responsibility to respect human rights also for business enterprises<sup>45</sup> and in general, they can affect private actors through the so-called horizontal effect). They encompass different sets of rights: civil and political, social, economic and cultural rights, including consumer rights<sup>46</sup> and environmental rights.<sup>47</sup> As such, they can accommodate under a coherent framework both “hard” impacts of new technologies, such as health, safety and environmental risks, as well as “broader” concerns, such as privacy or equality.<sup>48</sup> This creates an opportunity for a fair hearing of different types of concerns, a one that would not marginalise considerations that are not conceptualised as technical safety risks (while including the latter as well).<sup>49</sup>

Third, human rights perspective offers at the same time a framework of well-developed legal standards that put flesh on the bones of abstract norms and a language that is open to reinterpretations over time – a dimension that is crucial in the context of emerging technologies. Their dynamic interpretation has been done both by institutional actors (courts and other responsible bodies<sup>50</sup>) and, importantly,

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<sup>42</sup> Rodrigues, Rowena, Stearns Broadhead, Philip Brey, Zuzanna Warso, Tim Hanson, Lisa Tambornino, Dirk Lanzerath, op. cit., 2018, p. 37.

<sup>43</sup> Leenes, Ronald, Erica Palmerini, Bert-Jaap Koops, Andrea Bertolini, Pericle Salvini, Federico Lucivero, op. cit., 2017; Ruggiu, Daniele, op. cit., 2015.

<sup>44</sup> Palmerini, Erica, “The interplay between law and technology, or the RoboLaw project in context”, in Erica Palmerini and Elettra Stradella (eds.), *Law and Technology. The Challenge of Regulating Technological Development*, Pisa University Press, Pisa, 2013, p. 7-24 [p. 23].

<sup>45</sup> UN Human Rights Council, Human rights and transnational corporations and other business enterprise, resolution A/HRC/RES/26/22, 15 July 2014; Donahoe, Eileen and Eileen Megan and MacDuffee Metzger, “Artificial Intelligence and Human Rights”, *Journal of Democracy*, Vol. 30, 2019, pp. 115 - 126.

<sup>46</sup> E.g. Article 38 of the Charter of Fundamental Rights of the European Union, *OJ C 326*, 26.10.2012.

<sup>47</sup> E.g. Article 37 of the Charter of Fundamental Rights of the European Union, see also general: Knox, John H., and Ramin Pejan, eds. *The human right to a healthy environment*, Cambridge University Press, 2018.

<sup>48</sup> On “hard” v. “soft” or “broader” impacts, see van Lente, Harro, Tsjalling Swierstra and Pierre-Benoît Joly, “Responsible innovation as a critique of technology assessment”, *Journal of Responsible Innovation*, Vol. 4, Issue 2, 2017, pp. 254-261, (arguing “that TA [technology assessment], even in its participatory and anticipatory forms, was almost exclusively directed to ‘hard’ impacts, whereas RI [responsible innovation] and RRI [responsible research and innovation] are broader in the sense that they also give room to ‘soft’ impacts”); see, however, van Est, Rinie, “Responsible Innovation as a source of inspiration for Technology Assessment, and vice versa: the common challenge of responsibility, representation, issue identification, and orientation”, *Journal of Responsible Innovation*, Vol. 4, Issue 2, 2017, pp. 268-277 (questioning the validity of the distinction between “hard” and “soft” impacts, and noticing that in fact Technology Assessment has been including broader ethical and societal risks into consideration, after it has experienced “an argumentative turn with the aim of deepening the political and normative debate about innovation”).

<sup>49</sup> Brownsword, Roger, and Morag Goodwin, op. cit., 2012, p. 113; Lee, Maria, “Beyond Safety? Broadening Scope of Risk Regulation”, *Current Legal Problems*, Vol. 62, 2009, pp. 242-285.

<sup>50</sup> Letsas, George, “Strasbourg’s interpretive ethic: lessons for the international lawyer”, *European Journal of International Law*, Vol. 21, Issue 3, 2010, pp. 509-541.



by other actors, including civil society organisations.<sup>51</sup> A significant part of civil society has been referring to human rights to articulate their claims. This naturally includes organisations that place human rights explicitly at the core of their activities, but also – among others – trade unions, consumer associations, environmental organisations, patient organisations etc., many of which are also active in the area of emerging technologies.<sup>52</sup> Therefore using the human rights perspective allows to coherently map the legal issues of the examined technology with reference to well-developed and broadly recognised legal concepts and at the same time permits to incorporate varied concerns raised by different civil society actors.

Fourth, human rights provide lenses that enable to consider unequal impacts of emerging technologies on different groups in society and to expose how emerging technologies interact with the existing power imbalances. This is because principles of equality and non-discrimination lie at the very heart of human rights law<sup>53</sup> and protection of an individual from abuses of power, public or private, is one of the key functions of human rights.<sup>54</sup>

### Applying the human rights perspective

It is vital to emphasise that applying the above human rights perspective to the identification of legal issues is not meant to reduce the analysis to international human rights law or constitutional law in the sense of ignoring ordinary legislation (civil law, criminal law, public law...) or such matters as civil liability, safety or property. Human rights are meant here to provide *a lens* for issue identification, which affects how the problems are perceived – but a lens is not equal to what is seen through it.

The basic idea behind this frame is that due to international human rights law (and in case of many states, additionally thanks to respective constitutions), human rights radiate through the whole legal order and specific legal problems can be linked to human rights, that is be understood as falling under the scope of a particular right (or a number of rights).<sup>55</sup> In this context, it needs to be reminded that determining that an interest at stake falls within the scope of a human right is not equal to establishing that interference with this interest constitutes a violation of the right in question. A crucial feature of

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<sup>51</sup> For criticism of two misconceptions of human rights: one claiming that human rights are “abstract ideals, which easily can be reduced to rhetorical appeals” and second, according to which they are rigid norms that “have a closed and compelling meaning”, see: Arnaldi, Simone, Guido Gorgoni, and Elena Pariotti, “Responsible Research and Innovation between “new governance” and fundamental rights”, in Robert Gianni, John Pearson, and Bernard Reber (eds.), *Responsible research and innovation: From concepts to practices*, Routledge, 2018, pp. 153-71, [p. 163].

<sup>52</sup> Kohler-Koch, Beate, and Christine Quitkat, *De-mystification of participatory democracy: EU-governance and civil society*, OUP Oxford, 2013, p. 11.

<sup>53</sup> Fariior, Stephanie, “Introduction”, in Fariior, Stephanie, (ed). *Equality and Non-Discrimination under International Law: Volume II*, Routledge, 2017, p. XI.

<sup>54</sup> Freeman, Michael, *Human Rights: An Interdisciplinary Approach*, Polity Press, Cambridge, 2011, p. 201.

<sup>55</sup> On ‘radiation’ of human rights through whole legal order, see for example: Kumm, Mattias, “Who is afraid of the total constitution? Constitutional rights as principles and the constitutionalization of private law”, *German Law Journal*, Vol., Issue 4, 2006, pp. 341-369 (for the original German context of this term), and Kadelbach, Stefan, Thilo Rensmann, Eva Rieter, “Introduction” in Stefan Kadelbach, Thilo Rensmann, Eva Rieter (eds.), *Judging International Human Rights. Courts of General Jurisdiction as Human Rights Courts*, Springer International Publishing, Cham, 2019, p. 3 (for its application in a broader, international context).



most human rights is that they do not have an absolute character (with few exceptions, such as the prohibition of torture and other forms of ill-treatment) and therefore they may be restricted under specified conditions when it is justified by the protection of other human rights or a number of other important values, such public safety.<sup>56</sup> At this step of issue identification, the questions of violations (and all the balancing exercises related to it) do not have to be answered,<sup>57</sup> it matters here mostly whether a certain right (or rights) may be applicable to a problem at hand.

Within this structure distinguishing a scope and a violation of a human right, it is possible to adopt a wider or a narrower interpretation of the scope.<sup>58</sup> While the choice of the wider option does not necessarily entail a higher level of human rights protection in the end (as it depends on how broad limitations would be accepted), it is arguably preferable, among others as it requires more transparent explanation why and how a certain right needs to be limited, rather than introducing the limitation in a disguise of interpreting a right (defining its scope).<sup>59</sup> In the approach proposed in this report, we also recommend adoption of this wider interpretation, following Robert Alexy's broad understanding of the scope, according to which "everything which has at least one characteristic, which—viewed in isolation—would suffice to bring the matter within the scope of the relevant right, does so regardless of what other characteristics it has. [...] Within the semantic leeway of the concepts defining the scope, wide interpretations are to be adopted".<sup>60</sup>

It is worth to note that even with this broad reading of the scope, determining the meaning of human rights with the aim of linking a particular legal problem with specific rights is not always straightforward and often would require knowledge of interpretation adopted in human rights bodies case-law and soft-law. What further complicates this picture is that so far we have been using the general term of 'human rights', while in reality, human rights law is a highly complex field, with global, regional and national dimensions, where each of the levels consists of different actors and norms. For example, on the global level of the United Nations system, there are general human rights conventions and conventions dealing with particular groups (e.g., children, women, migrant workers) or themes (e.g. torture, racial discrimination), similarly on the regional level, where in addition there are different regional systems. While many common points can be found across all these legal orders, there are also significant differences both in textual formulations and interpretations of particular rights.<sup>61</sup> Crucially, these systems do not operate in isolation – they draw mutual inspirations, but, perhaps even more importantly, in case of legal orders with overlapping territorial jurisdictions, they also enter into more direct relations. Taking into account this "multi-layered nature of human rights law"<sup>62</sup> on the one hand,

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<sup>56</sup> Gerards, Janneke, Hanneke Senden, "The structure of fundamental rights and the European Court of Human Rights", *International Journal of Constitutional Law*, Vol. 7, Issue 4, 2009, pp. 619–653, [p. 622-623].

<sup>57</sup> This question may, however, come back at the stage of identifying gaps.

<sup>58</sup> Gerards, Janneke, Hanneke Senden, op. cit., 2009, pp. 625-629.

<sup>59</sup> Van der Schyff, Gerhard, "Interpreting the protection guaranteed by two-stage rights in the European Convention on human rights: The case for wide interpretation" in Eva Brems, and Janneke Gerards, (eds), *Shaping Rights in the ECHR*, Cambridge University Press, 2013, pp. 65-84 [p. 73]

<sup>60</sup> Alexy, Robert, *A theory of constitutional rights*, Oxford University Press, 2010, p. 210.

<sup>61</sup> Brems, Eva, Desmet, Ellen, "Human rights integration: theorizing the multi-layered nature of human rights law", *European journal of Human Rights*, vol. 3, 2014, pp. 289–292.

<sup>62</sup> Ibid.



but on the other a need to reduce this great complexity, this approach recommends taking into consideration articulations of human rights from different levels, but not necessarily from all parallel regional systems or national constitutions. In Europe, this would mean focusing on United Nations, Council of Europe and the European Union.

To conclude the discussion of the second step so far, applying human rights perspective frames what kind of issues would be considered in the analysis. It determines that this would not be just any kind of legal problems that potentially could be raised in the context of the technology in question, but the ones that affect human rights in the above sense. This, however, of course does not entail that only issues articulated explicitly in human rights language shall be considered, as this would unduly narrow the analysis. Legal challenges formulated in other terms also should be taken into account, though in their case there is a need to spot their human rights aspects – for instance, notice how safety challenges may be falling within the scope of the right to health,<sup>63</sup> how liability issues may be linked to the right to an effective remedy<sup>64</sup> or intellectual property questions can be viewed from the perspectives of a right to property and a right to enjoy the benefits of scientific progress and its application.<sup>65</sup> This linking exercise does not mean that, for example, specific matters related to adequate product safety regime should be reduced to the right to health understood as some vague, abstract principle. Such understanding would misconceive the nature of complex obligations imposed on states by human rights law, which include in this instance e.g. obligation to take necessary measures (including regulatory measures) to protect consumers from practices detrimental to their health from manufactures.<sup>66</sup>

### **Lessons from the human rights-based approach**

However, choosing human rights as frames of reference is only a first step here, as there are many ways of conducting legal analysis based on or inspired by human rights<sup>67</sup> and not all of them would be equally supportive to the listed above benefits of applying these lenses to emerging technologies. One of the perspectives that could be especially helpful is the human-rights based approach, understood

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<sup>63</sup> UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4, par. 51.

<sup>64</sup> See for instance The Council of the Europe Commissioner for *Human Rights, Unboxing artificial intelligence: 10 steps to protect human rights*, 24.05.2019. <https://rm.coe.int/unboxing-artificial-intelligence-10-steps-to-protect-human-rights-reco/1680946e64>

<sup>65</sup> UN Committee on Economic, Social and Cultural Rights (CESCR), *General comment no. 21, Right of everyone to take part in cultural life (art. 15, para. 1a of the Covenant on Economic, Social and Cultural Rights)*, 21 December 2009, E/C.12/GC/21.

<sup>66</sup> UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4, par. 51.

<sup>67</sup>For an overview of the diversity of approaches in human rights law research, see in particular Gonzalez-Salzberg, Damian, Loveday Hodson, (eds), *Research Methods for International Human Rights Law: Beyond the Traditional Paradigm*, Routledge, 2020; as well as: Andreassen, Bård A., Hans-Otto Sano, and Siobhán McInerney-Lankford, (eds), *Research methods in human rights: A handbook*, Edward Elgar Publishing, 2017 and Coomans, Fons and Grunfeld, F. and Kamminga, Menno T., “Methods of Human Rights Research: A Primer” *Human Rights Quarterly*, Vol. 32, 2010, pp. 179-186.



here not just as any approach that refers to human rights as its basis,<sup>68</sup> but rather as a particular paradigm that has first emerged within the development sector (later to be used also in many other contexts, including in the area of new technologies<sup>69</sup>) and that has gained a particular prominence within the United Nations system.<sup>70</sup> While there is no one universally accepted definition of the human rights-based approach (HRBA),<sup>71</sup> it is usually distilled to a set of standard common principles, among which there are<sup>72</sup>: (i) comprehensiveness (a holistic approach to human rights, in light of the principles of on the indivisibility, interdependence and interrelatedness of all human rights<sup>73</sup>); (ii) non-discrimination and equality (what entails a particular focus on the situation of vulnerable groups) and (iii) participation (broad and meaningful participation in the decision-making process).

In the context of identification of legal issues of emerging technologies, these principles could be translated into the following practical recommendations. Firstly, with regard to the comprehensiveness principle, when examining human rights affected by the analysed technology, it is important to consider different types of rights (that it is, adopt a holistic approach to human rights). This might require actively seeking some types of issues related to rights that tend to be underrepresented in general human rights debates (these are most often social and economic rights,<sup>74</sup> though this might depend upon a particular technological domain). It might be also helpful in this point to take into account various stages of the analysed technology life cycle, as there might be different types of human rights affected at different stages<sup>75</sup> (here again, the contextualised approach is crucial).

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<sup>68</sup> The term „human rights-based approach” has been used in such a very broad sense for example in Smuha, Nathalie, “Beyond a Human Rights-Based Approach to AI Governance: Promise, Pitfalls, Plea”, *Philosophy & Technology*, 2020., pp. 1-14.

<sup>69</sup> Niklas, Jędrzej, “Human rights-based approach to AI and algorithms: concerning welfare technologies” in Woodrow Barfield, (ed). *The Cambridge Handbook of the Law of Algorithms*. Cambridge University Press, 2020, pp. 517-542; Land, Molly K., Jay D. Aronson, “The Promise and Peril of Human Rights Technology,” in Molly K. Land and Jay D. Aronson, (eds.) *New Technologies for Human Rights Law and Practice*, Cambridge University Press, 2018, pp. 1-10.

<sup>70</sup> Niklas, Jędrzej, op. cit., 2020; for a synthetic overview of the HRBA history, see: Miller, Hannah, Robin Redhead, “Beyond ‘rights-based approaches’? Employing a process and outcomes framework”, *The International Journal of Human Rights*, Vol. 23, Issue 5, 2019, pp. 699-718.

<sup>71</sup> For that reason the word is also often used in plural, as “human rights-based approaches” (Vandenhoe, Wouter, Paul Gready, “Failures and Successes of Human Rights-Based Approaches to Development: Towards a Change Perspective”, *Nordic Journal of Human Rights*, Vol. 32. Issue 4, 2014, pp. 291-311). For the reasons of simplicity, in this report it will be used in singular, assuming that this can justified by the ‘family resemblance’ of different streams within this paradigm (based on a standard set of principles).

<sup>72</sup> Gready, Paul, “Rights-based approaches to development: what is the value-added?”, *Development in Practice*, Vol. 18, Issue 6, 2008, pp. 735-747; Niklas, Jędrzej, op. cit., 2020.

<sup>73</sup> The basic ideas behind these principles are that there is no hierarchy between rights, that despite differences they share some common characteristic and enjoyment of one rights requires the enjoyment of others – Whelan, Daniel, J., *Indivisible Human Rights: A History*, Philadelphia, University of Pennsylvania Press, 2010, pp. 3-8

<sup>74</sup> On the traditional neglect of social and economic rights (and more optimistic developments in more recent times), see e.g. Young, Katherine, “Introduction”, in Katherine Young (Ed.), *The Future of Economic and Social Right*, Cambridge: Cambridge University Press, 2019, pp. 1-34.

<sup>75</sup> See, for instance, Jasanoff, Sheila, J. Benjamin Hurlbut, and Krishanu Saha, “CRISPR democracy: Gene editing and the need for inclusive deliberation”, *Issues in Science and Technology*, Vol. 32, Issue 1, 2015, pp. 25-32. (describing how early discussion about genetic engineering focused on the risks at the research phase, that is on



Secondly, pertinent to the non-discrimination and equality principle, it is vital to specifically take into account legal issues relevant for vulnerable groups<sup>76</sup>, people exposed to structural discrimination<sup>77</sup> and weaker parties in law (such as employees, consumers, patients).<sup>78</sup> While there are significant differences between these three categories (among others, while the first two relate rather to personal and general characteristics, the last one refers more to relational categories connected to certain activities), what they have in common is that they designate people in some way systemically disadvantaged compared to other groups. Hence, paying particular attention to these groups in issue-identification is aimed at ensuring that human rights frame delivers its promise of universality and equal enjoyment of rights (recognising that “equal treatment of persons in unequal situations will invariably operate to perpetuate rather than to eradicate injustices”<sup>79</sup>). As for the third principle, participation, it would be incorporated in the context of tools used for the identification of issues, which will be discussed in the next section.

### Issue identification methods

This approach envisages two general ways for identifying legal issues: through a literature review and through the stakeholders engagement. The literature review should involve legal academic literature and legal policy studies, but also, if available, relevant studies or reports from civil society organisations. The rationale for the inclusion of the latter categories is similar as for the use of

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the dangers related to the accidental release of harmful organisms from a lab environment, neglecting the questions of impacts of deliberate releases for commercial use and developments at industrial scale). On the other hand, discussions around AI tend to focus on impacts of the deployment phase, while the ‘production’ phase (e.g. working conditions of microworkers involved in developing AI) tend to be overlooked – Tubaro, Paola, Antonio A. Casilli, and Marion Coville. op. cit., 2020., see also, for a broader account of labour behind the digital services: Gray, Mary L., Siddharth Suri, *Ghost work: How to stop Silicon Valley from building a new global underclass*, Eamon Dolan Books, 2019.

<sup>76</sup> There are many conceptualisations of vulnerability, but put in simple, yet very suitable terms, vulnerable groups are these groups that are “in reality more likely to encounter discrimination or other human rights violations than others” (Reichert, Elisabeth, *Understanding Human Rights*, London, Sage Publications, 2006, p. 71.), compare also Andorno’s definition: “heightened susceptibility of certain individuals or groups to being harmed or wronged by others or by the state” Andorno, Roberto, “Is vulnerability the foundation of human rights?”, in: Masferrer, Aniceto, and Emilio García-Sánchez (eds), *Human dignity of the vulnerable in the age of rights: interdisciplinary perspectives*. Springer, 2016., pp. 257-272. For an example of using the frame of ‘vulnerability’ in the context legal analysis of emerging technologies, see: Rodrigues, Rowena, “Legal and human rights issues of AI: Gaps, challenges and vulnerabilities”, *Journal of Responsible Technology*, vol. 4, 2020.

<sup>77</sup> “Structural discrimination refers to rules, norms, routines, patterns of attitudes and behaviour in institutions and other societal structures that, consciously or unconsciously, present obstacles to groups or individuals in accessing the same rights and opportunities as others and that contribute to less favourable outcomes for them than for the majority of the population” – European Commission against Racism and Intolerance (ECRI), *General Policy Recommendations No. 2: Equality Bodies to Combat Racism and Intolerance at National Level*, adopted on 7 December 2017, par. 20.

<sup>78</sup> On weaker parties in the context of new technologies, see in particular: Koops, Bert-Jaap, “Law, technology, and shifting power relations”, *Berkeley Technology Law Journal*, vol. 25, 2010; in broader contexts, see for instance: Ciacchi, Colombi Aurelia, “Judicial Governance in Private Law through the Application of Fundamental Rights”, *Austrian Law Journal*, vol.1, issue 1, 2014, pp 120-134.

<sup>79</sup> Gallagher, Anne, “Ending the Marginalization: Strategies for Incorporating Women into the United Nations Human Rights System”, *Human Rights Quarterly*, 1997, vol. 19, issue 2, p. 290.



stakeholder engagement at this stage, which can be broken down to the following three general reasons.

First, these sources may suggest new issues, that have been omitted by academia and policymakers (i.e. the list of issues to be considered may be longer than it seemed). Furthermore, issues that have been already recognised by academics and policymakers may be framed in a significantly different manner by other actors (the issues on the list may be seen from a different perspective).<sup>80</sup> In addition, these other actors may have different opinions about the issue's relative importance (which challenges are crucial, which are minor), what may be helpful in deciding about how to narrow down the scope of the legal analysis (if the list of the analysed issued needs to be shortened, which issues should be kept?).

There are numerous tools for stakeholder engagement. Inclusion of participatory elements in the Technology Assessment has already quite a long history<sup>81</sup> and empirical methods in legal research in general also have developed extensively.<sup>82</sup> A systematic analysis of different empirical tools and methods is beyond the scope of this report and eventually in practice, the choice will be affected also by the available resources. However, individual expert interviews may be particularly worth noting here, as a method which may yield relatively much information for issue-identification while being comparatively low-cost and demanding less methodological expertise (compared both to larger quantitative surveys, as well other qualitative instruments like focus groups).

Expert interviews are a type of individual interviews, conducted with persons who have privileged access to information about particular matters.<sup>83</sup> Their special knowledge about a particular problem may be an outcome of a formal training or education, but not necessarily – it can be also acquired through “activity which is aimed at the problem and, therefore, with a view to analyzing and/or helping to solve the problem in any way”<sup>84</sup>; hence apart from trained professionals, this category may also

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<sup>80</sup> E. Tendayi Achiume, United Nations Special Rapporteur on contemporary forms of racisms, has noticed that “unlike the dominant, usually legalistic formulations of discrimination and intolerance that can dominant [sic] the official human rights corpus, when movement actors and those intimate with racial oppression articulate their experiences of structural subordination as well as the interventions they believe are necessary to address them, they speak in terms of the need to change power relations, and to pay close attention to economic, political and financial structures with global dimensions”, Achiume, E. Tendayi, “Putting Racial Equality onto the Global Human Rights Agenda”, *Sur International Journal on Human Rights*, vol. 28, 2018, pp. 141-150; see also Gangadharan, Seeta Peña, Jędrzej Niklas, “Decentering technology in discourse on discrimination”, *Information, Communication & Society*, vol. 22, issue 7, 2019, pp. 882-899, for a study on very divergent ways different civil society organisations conceptualise problems around algorithmic discrimination.

<sup>81</sup> Van Est, Rinie, Frans Brom, “Technology assessment: Analytic and democratic practice” in Dan Callahan, Peter Singer (eds.), *Encyclopedia of applied ethics*, Academic Press, 2011, pp. 306-320.

<sup>82</sup> See, generally Cane, Peter, and Herbert M. Kritzer (eds.), *The Oxford Handbook of Empirical Legal Research*. Oxford University Press, 2010; Leeuw, Frans L., Hans Schmeets, *Empirical legal research: A guidance book for lawyers, legislators and regulators*, Edward Elgar Publishing, 2016.

<sup>83</sup> Meuser, Michael, Ulrike Nagel, “Experts and Changes in Knowledge Production” in Alexander Bogner, Beate Littig and Wolfgang Menz (eds), *Interviewing Experts*, Palgrave Macmillan, 2009; Korkea-aho, Hanna Emiliqa, Leino-Sandberg, Päivi, “Interviewing lawyers: a critical self-reflection on expert interviews as a method of EU legal research”, *European Journal of Legal Studies*, Vol. 12, Issue 1, 2019, pp. 17-47, [p. 31-32.]

<sup>84</sup> Meuser, Michael, Ulrike Nagel, op. cit., 2009, p. 24.



include, for example, members of civil society groups.<sup>85</sup> As other types of qualitative methods, expert interviews cannot provide strictly generalizable findings (for instance, it would not give information about the most often indicated legal issues pertinent to the analysed technology in a society), but they contribute to "understanding of key patterns or themes"<sup>86</sup>, what is crucial at this step of issue-identification. Expert interviews may be conducted with an 'exploratory' aim (providing a clearer initial orientation in the field or a particular part of it), with a more specific goal of accessing systematic information on a concrete matter, as well as to learn how an interviewee conceptualises elements in the field, their relations, importance, hierarchies, boundaries etc.<sup>87</sup> Thus, they may help both with identifying new legal issues and getting a deeper and broader understanding of the recognised legal issues.

A further benefit of expert interviews (expert being, it is important to remind here, also people who gained their privileged knowledge through engaged activities aimed at analysing and/or addressing a problem<sup>88</sup>) is that this method may to a lesser extent suffer from what Maria C. Powell and Mathilde Collin called "participatory paradoxes".<sup>89</sup> This term was associated by them with some forms of stakeholder engagement procedures in the area of science and technology governance which involve "recruitment of unorganized and nonopinionated citizens (usually volunteers) with little background on the scientific issue at hand", even though "these are the citizens the least likely to have the energy, capacity, or collective power to engage with scientists and/or make their voices heard on the political level over the short or long term."<sup>90</sup> The method of expert interviews, in turn, provided that sampling of interviewees includes representatives of various types of relevant civil society groups, may potentially allow to engage "uninvited' participation"<sup>91</sup> – which may arguably produce results that could be more helpful for identifying legal issues. By this term, Peter Wehling referred to a form of societal engagement with sciences and technologies by such actors as patient, consumer or environmental groups, who continuously engage with a science or technology without waiting for an invitation, consciously organising themselves and trying to be as well-informed as possible about the technological or scientific issues that they consider relevant for them (not acting as "blank minds") and that do not "bracket" their particular interests, need and values, but on the contrary, explicitly promote them.

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<sup>85</sup> Ibid.

<sup>86</sup> Webley, Lisa, "Qualitative approaches to empirical legal research" in Peter Cane, and Herbert M. Kritzer (eds.) *The Oxford Handbook of empirical legal research*, Oxford University Press, 2010.

<sup>87</sup> These goals are adapted from the distinction of three types of expert interviews: 'explanatory', 'systematizing' and 'the 'theory-generating' from: Alexander Bogner, Wolfgang Menz, "The Theory-Generating Expert Interview: Epistemological Interest, Forms of Knowledge, Interaction", in Alexander Bogner, Beate Littig and Wolfgang Menz (eds), *Interviewing Experts*, Palgrave Macmillan, 2009, pp. 46-58.

<sup>88</sup> Meuser, Michael, Ulrike Nagel, op. cit., 2009, p. 24.

<sup>89</sup> Powell, Maria C., Mathilde Colin. "Participatory paradoxes: Facilitating citizen engagement in science and technology from the Top-Down?", *Bulletin of Science, Technology & Society*, vol. 29, issue 4, 2009, pp. 325-342 [p. 327].

<sup>90</sup> Ibid.

<sup>91</sup> Wehling, Peter, "From invited to uninvited participation (and back?): rethinking civil society engagement in technology assessment and development", *Poiesis & Praxis*, vol. 9, issue 1-2, 2012, pp. 43-60.





## Conclusions

The result of the analysis after the first two steps would be a list of selected legal issues related to the technology perceived in a contextualised manner. The legal issues would be seen through the human rights perspective and they would be organised along the three levels (of the technology in general, product and applications level). Applying the human perspective at this stage does yet mean reaching conclusions on the compatibility of the analysed technology (or its products or applications) with human rights. This kind of assessment is left in this approach for the fourth step (identification of gaps and challenges), while the first two steps are meant to produce more of a map of affected (but not necessarily violated) human rights.

### 3.4 Analysis of international, regional (including EU) and national legal norms relevant for the identified issues

Once we have a list of legal issues, the next step would be to analyse the current legal norms relevant to the identified challenges raised by the technology in question. Even when new technologies bring previously unknown artefacts and create unprecedented capabilities and there is no explicit legal guidance on these matters, this does not mean that they emerge in a legal void in a strict sense. Most likely, there would be some more general legal norms that could be applied: if brought to a market, there would be some *ex ante* product safety requirements; some *ex post* liability regime would be triggered if a harm occurs; if personal data are processed, data protection regime would come into play; if offered to consumers, consumer law would apply; if applied in the area of health care, health law could be of relevance, etc. etc.<sup>92</sup> Large areas of law are more or less technology-neutral, what allows to fit newcomers into the existing legal categories. This does not mean that such categorisation is always easy and noncontroversial (on the contrary, quite likely it could be highly debatable within a legal community), moreover, even seemingly feasible application of existing norms might produce normatively undesirable outcomes – what might lead to a conclusion that some regulatory intervention might be required. However, before reaching this conclusion, it is necessary first to understand what the current legal frameworks say about the problems in question.<sup>93</sup> The last point leads to two further remarks about the relation of this stage of the proposed approach to the previous one.

First, the goal of this step would not be to map all legal norms that could be applied to the technology in question (this would be most likely impossible to do, and informative value of such an endeavour would also be questionable). The analysis should be guided by the legal issues identified and selected in the previous step, that is: it should determine what does the current law say about these issues. Second, while the issues have been described using the human rights lenses, the material for the analysis is not restricted to human rights law in the sense of international or constitutional law explicitly guaranteeing human rights – it would need to include also ‘lower-level’ legal sources

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<sup>92</sup> Brownsword, Roger, and Morag Goodwin, op. cit., 2012, p. 371.

<sup>93</sup> Leenes, Ronald, op. cit., 2019a, p. 6, see also: Crootof, Rebecca, Ard, BJ, op. cit., 2020 and Eichensehr, Kristen E., "Cyberwar & International Law Step Zero", *Texas International Law Journal*, vol. 50, issue 2, 2015, pp. 357-378.



(legislative acts or even non-legislative acts adopted by executive, where relevant), linked to the issue in question. If the analysis is aimed at broad description of the law pertinent to the selected issues, it needs also to take into consideration the multi-layered character of the current legal orders and analyse both national and international law (including regional law and supranational law, such as Council of Europe legal instruments and European Union Law in Europe), as well as various types of legal sources: hard law, soft law and case-law.

At this stage, the doctrinal method would come most clearly into play, with its aims of describing the existing law “in a way that is as neutral and consistent as possible in order to inform the audience how the law actually reads”,<sup>94</sup> systematising fragmented rules into a coherent system (a shared framework of concepts and categories) and making them intelligible to a reader.<sup>95</sup> Basically, it can be described as a “two-part process involving both locating the sources of the law and then interpreting and analysing the text”.<sup>96</sup> In practice, the degree of complexity of doctrinal legal research may significantly vary.<sup>97</sup> While this is true for both parts of the process, it is particularly the second part, interpretation and analysis, that may involve different levels of depth, from ‘thin’, straightforward and largely semantic description, to more ‘thick’ description, applying to a greater extent purposive, systematic, and contextual methods of interpretation. By purposive interpretation, it would attempt to understand legal categories and norms in light of what they aim to achieve<sup>98</sup> and what is the rationale behind them<sup>99</sup>, for example, what interests they seek to protect.<sup>100</sup> Through systematic interpretation, the analysis would draw attention to the place of examined legal norms within legal system and their relations with other norms,<sup>101</sup> including their relations to fundamental legal concepts, i.e. basic foundations upon which a given legal (sub)field is built.<sup>102</sup> In addition, with contextual methods of interpretation, analysis would not be reduced only to ‘black-letter’ law, but would also look at ‘law-in-action’. While today it seems to be broadly accepted that “true understanding of the law necessarily involves insight into its working”,<sup>103</sup> a discussion continues whether this could be incorporated into doctrinal work or rather remains outside of it, for instance as a ‘law-in-context’ approach.<sup>104</sup> To some extent, the inclusion of case-law as a material for analysis provides some information on how

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<sup>94</sup> Smits, Jan M., “What is Legal Doctrine? On the Aims and Methods of legal-dogmatic research”, in Rob van Gestel, Hans-W. Micklitz and Edward L. Rubin (eds.), *Rethinking Legal Scholarship: A Transatlantic Dialogue*, Cambridge University Press, New York, 2017, pp. 207-228 [p. 210].

<sup>95</sup> Ibid.

<sup>96</sup> Hutchinson, Terry, "Doctrinal Research" in Dawn Watkins, Mandy Burton,(eds.), *Research methods in law*, Routledge, 2017, p. 18.

<sup>97</sup> Ibid., p.17

<sup>98</sup> See also Koops, Bert-Jaap, op. cit. 2013, p. 49.

<sup>99</sup> Mandel, Gregory N., op. cit., 2017.

<sup>100</sup> Cockfield, Arthur and Pridmore, Jason, op. cit., 2007.

<sup>101</sup> Feteris, Eveline T., Feteris, Olivier, *Fundamentals of legal argumentation. Vol. 1*, Springer, Dodrecht, 2017, p.9.

<sup>102</sup> Koops, Bert-Jaap, op. cit. 2013,p. 53.

<sup>103</sup> Smits, Jan M., op. cit., 2017, p. 224.

<sup>104</sup> Ibid.



legislation works in practice, but very likely it may not represent the whole social reality.<sup>105</sup> Ideally (and likely going beyond the doctrinal method), law-in-action would be discovered through the use of empirical legal methods, but in an often case of more limited resources, information on practice may be partly supplemented through secondary data, for instance, publications on research findings by academia, civil society organisations or international organisations.

Beside norms' purposes, their place within a legal system and their context, other aspects that could be particularly useful in an analysis of emerging technologies relate to regulatory-design characteristic of the examined norms.<sup>106</sup> These include, among other, normative outlook that (usually implicitly) underlies a regulation,<sup>107</sup> such as the three ethical paradigms described by Roger Brownsword: utilitarian, dignitarian and human rights.<sup>108</sup> In some cases, legislative acts may straightforwardly embed a particular ethical stance, often though they would use terms only signalling an ethical stake, but framed in a way that is neutral between different ethical regimes (such as 'public order' or 'human dignity').<sup>109</sup> Sometimes one legal instrument may also refer to more than one paradigm.<sup>110</sup> In these implicit, uncertain or mixed cases, interpretations in case-law may be particularly helpful in identifying the (currently dominant) normative outlook underlying the regulation in question.

In addition to looking at a single legal system at the national level, a comparative analysis between different national legal orders could bring valuable insights. Emerging technologies are rarely restricted within an area of a single national jurisdiction and their interactions with varied legal orders may differ. Among others, some states may decide to specifically address the challenges associated with a given technology with some form of a bespoke legislative response – and a comparative analysis would allow to see a broader spectrum of regulatory options of this kind (their diversity) and also, possibly, some shared patterns in parallel developments. The difficulty of such comparisons is that even seemingly similar novel solutions may in fact work very differently in varied national contexts, among others because their interplay with other elements of the legal system (or of the legal culture) may produce divergent legal outcomes.<sup>111</sup> The situation is usually further complicated, when, as it often is the case, there are no bespoke legislative responses to the examined emerging technology. As indicated above in relation to a single legal order, what needs to be analysed in such cases is usually a complex patchwork of existing norms relevant for the issues selected for examination, what requires a fair share of knowledge of the studied legal orders – probably exceeding what has been described as a 'tourist'

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<sup>105</sup> For example, absence or limited case-law on a given matter does not necessarily always have to mean that a legal problem does not exist in reality – it may as well mean that victims of illegal practices do not report it - Van Hoecke, Mark, "Methodology of comparative legal research", *Law and method*, vol. 12, 2015, pp. 1-35 [p. 7].

<sup>106</sup> Rodrigues, Rowena, Stearns Broadhead, Philip Brey, Zuzanna Warso, Tim Hanson, Lisa Tambornino, Dirk Lanzerath, op. cit. 2018, p. 40.

<sup>107</sup> Koops, Bert-Jaap, op. cit. 2010, p. 319.

<sup>108</sup> Brownsword, Roger, op. cit., 2007.

<sup>109</sup> Ibid., p. 66.

<sup>110</sup> Ibid., p. 60.

<sup>111</sup> See e.g. Van Hoecke, Mark, "Legal culture and legal transplants", in Richard Nobles, David Schiff, *Law, Society and Community: Socio-Legal Essays in Honour of Roger Cotterrell*, Routledge, 2016, pp. 273-291.



level comparative analysis.<sup>112</sup> What additionally aggravates these challenges is that sometimes diverging norms and doctrines ‘in books’ may ‘in action’ lead to similar legal results (and the other way around – similar ‘law in books’ and diverging ‘law in action’).<sup>113</sup> For these reasons, in this part of the analysis the functional method could be particularly helpful, with its focus on actual societal problems (e.g. a harm inflicted in an accident with a technology X) and legal ways they are solved in different jurisdictions.<sup>114</sup>

From a pragmatic point of view, it is important to keep in mind that law that is relevant for emerging technologies – even when limited to a number of selected legal issues – often constitutes a complex patchwork of different legal regimes with myriad ambiguities. To a certain extent, this is not a phenomenon limited only to this area, but rather a general feature of law’s complexity, subtleness and its often reliance on detailed, nuanced qualitative distinctions.<sup>115</sup> Christopher McCrudden has noticed that “If legal academic work shows anything, it shows that an applicable legal norm on anything but the most banal question is likely to be complex, nuanced and contested”.<sup>116</sup> In the area of emerging technologies, these general features are often aggravated, among others because there has been less time to build a (relative) consensus within legal community on new artefacts or forms of conduct. Therefore in practice, the scope of this step of analysis may also require further adjustment to the available resources – and there is a number of possible ways to do it. Among others, one might select only a limited number of legal issues that would be identified in the previous step for further analysis (and/or make them more specific, if necessary). Possible criteria to be taken into account in this second selection could include the following: prominence in policy and legal discussions (choosing the most debated issues or on the contrary, the issues that tend to be overlooked); greater potential to affect human rights (taking into account the severity of impacts and the likelihood of their occurrence); impacts on vulnerable groups and, crucially, the time when the challenges are expected to occur (arguably, impacts that may be already affecting human rights or might do so in the near future should be prioritised over more speculative, distant future potential threats<sup>117</sup>). The disadvantage of this kind

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<sup>112</sup> On ‘tourist’ level comparative analysis, see: Van Hoecke, Mark, op. cit., 2015, p. 8: “comparatists often act like tourists who visit a foreign city and notice that things are different, be it to some extent similar too, compared to their home-town. After their visit they will be able to describe what they have seen to their family and friends at home, but they will lack a more general framework used, for instance, by specialists in architecture or art historians to describe the same sights in a (very) different way”.

<sup>113</sup> Ibid., pp. 10-11.

<sup>114</sup> Ibid., p. 28.

<sup>115</sup> Smits, Jan M., op. cit., 2017, p.215; Singer, Joseph William, “Normative Methods for Lawyers”, *University of California Los Angeles Law Review*, vol. 56, 2009, p. 9.

<sup>116</sup> Christopher McCrudden has made this remark in the context of interdisciplinary research projects, where he observed a tendency to “view law too often as a datum, as fact, unproblematic, and one-dimensional. Where lawyers are involved in an empirical project, the tendency, in my experience, is to ask lawyers to identify “the law,” stripped of complexity, and preferably in the form of a rule or obligation that is specific to a limited social setting.”, McCrudden Christopher, “Legal Research and the Social Sciences”, *Law Quarterly Review*, vol. 122, 2006, pp. 632–650, [p. 648].

<sup>117</sup> On the last point, see insightful: Birhane, Abeba, Jelle van Dijk, "Robot Rights? Let's Talk about Human Welfare Instead", *Proceedings of the AAAI/ACM Conference on AI, Ethics, and Society*, 2020, pp.1-7 (arguing that the “robot rights” debate signals “that, grounded in their materialist techno-optimism, scientists and technologists are so preoccupied with the possible future of an imaginary machine, that they forget the very real, negative



of limitation is that it would leave more issues out of sight (except for their identification in the previous step). On the positive note, staying with a more in-depth analysis could produce much more solid ground for assessment of the adequacy of legal frameworks in the next step. An opposite strategy would be keeping a larger number of issues, but choosing only to *map* the relevant law, without a deeper analysis of the identified sources. This would of course significantly limit the potential to draw conclusions about the adequacy of the examined legal frameworks, but on the other hand it would provide a broader ‘guide’ where to look for relevant legal norms, and as such potentially serve as one of “building blocks” for future, more in-depth analysis.<sup>118</sup>

### 3.5 Identification of gaps and challenges in the existing legal frameworks with regard to the identified issues

After reaching a proper understanding on what does the current law say about the identified legal issues raised by the examined technology, the analysis could tackle the question of the adequacy of the existing legal frameworks.

Although it should be clear at this point, it is nevertheless worth to reiterate that lack of legislation dedicated specifically for the examined technology, or the fact that the law does not mention it explicitly, do not necessarily mean that there is a legal gap. Oliver Wendell Holmes famously mocked an unnamed Vermont justice of peace who had to rule on a case brought by one farmer against another for breaking a churn – apparently the judge said that he thoroughly analysed the law and found nothing about churns, and for this reason gave judgement for the defendant.<sup>119</sup> The fact that we are dealing with a new artefact or procedure that creates new capabilities and relevant law predates its invention does not *in itself* necessarily change this observation. In fact, it has been noticed in a similar context that “jurists always work with means that are older than the facts, a feature that is nicely expressed by the principle of non-retroactivity of the law”.<sup>120</sup> However, in some cases this ‘working with older means’ can be problematic and there have been many examples where a sociotechnical change<sup>121</sup>

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impact their intermediary creatures - the actual AI systems we have today - have on actual human beings” and that “the real and urgent issues that are emerging with the mass deployment of seemingly invisible AI systems need to be discussed now because they currently impact large groups of people.” – p. 2, p. 4)

<sup>118</sup> Van Hoecke, Mark, “Legal Doctrine: Which Method(s) for What Kind of Discipline?”, in Mark Van Hoecke (ed.), *Methodologies of Legal Research: Which Kind of Method for What Kind of Discipline?*, Oxford: Hart Publishing, 2011, vi., (noticing that “the more simple versions of that research being the necessary building blocks for the more sophisticated ones”).

<sup>119</sup> Holmes, Oliver Wendell, “The path of the law”, *Harvard Law Review*, vol. 110, issue 5, 1997, pp. 991-1009 [pp. 1005-1006] (originally published in 1897); reminded in the context of new technologies in: Moses, Lyria Benett, op. cit. 2007.

<sup>120</sup> Rommetveit, Kjetil, Niels van Dijk, Kristrún Gunnarsdóttir, Kate O’Riordan, Serge Gutwirth, Roger Strand and Brian Wynne, “Working responsibly across boundaries? Some practical and theoretical lessons” in René Von Schomberg, Jonathan Hankins, (eds). *International handbook on responsible innovation: A global resource*, Edward Elgar Publishing, 2019, pp. 83-100, [p.94].

<sup>121</sup> Cf. Moses, Lyria Bennett, op. cit., 2013.



required some form of legal intervention (judicial or legislative).<sup>122</sup> The goal of this step of a legal analysis would be to consider to what extent and why this could be the case for the examined technology.

It would be important to avoid at this point two risks (again). First would be jumping too quickly to conclusions that the current law is outdated and that new technology requires an urgent and bespoke regulatory intervention – a tendency that Ronald Leenes called a “flawed law syndrome”.<sup>123</sup> The second risk to be avoided would be to rigidly deny any need for legal changes when faced with normative challenges raised by emerging technologies, claiming that eventually any problems will be solved by the existing means – as Frank H. Easterbrook put in the last sentence of his famous paper: “let the world of cyberspace evolve as it will, and enjoy the benefits.”<sup>124</sup> One could argue that the history of ‘cyberspace’ has shown that overly ‘letting the world of cyberspace evolve as it will’ (or rather, leaving it to be regulated to the given extent to the market, social norms and design choices of tech companies<sup>125</sup>) might not bring the best of possible benefits – or at least not for all.<sup>126</sup> What is needed instead is a systematic case-by-case approach.

Taking into account the „fundamentally *purposive* orientation of the regulatory enterprise”,<sup>127</sup> a key aspect of assessing the adequacy of a legal framework would be evaluating whether it remains ‘fit for purpose’,<sup>128</sup> in the sense that the application of existing norms would allow to achieve the law purposes. The relevant purposes may be specific for a particular norm, for a set of norms, for a legal subfield or of a general nature, having a fundamental character for the whole legal order – like human rights. In a hierarchical legal system, a legal framework may turn out to be defective even when it continues to succeed in effectively achieving a specific purpose which is ‘local’ within a legal system, while failing at realising constitutive goals of a legal order (in particular, failing to adequately respect, protect or fulfil human rights). While this approach may appear as following a regulatory-instrumentalist mind-set (with its focus on whether the law is instrumentally effective in attaining regulatory purposes<sup>129</sup>), it can also be described in coherentist<sup>130</sup> terms: as fundamental purposes of a legal order form an inherent part of law,<sup>131</sup> assessing the effectiveness of achieving them can also be seen as evaluating its internal coherence.

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<sup>122</sup>For both historic and contemporary examples, see: Brownsword, Roger, "Law Disrupted, Law Re-Imagined, Law Re-Invented", *Technology and Regulation*, 2019, pp. 10-30.

<sup>123</sup> Leenes, Ronald, op. cit., 2019a, p. 4.

<sup>124</sup> Easterbrook, Frank H, "Cyberspace and the Law of the Horse", *University of Chicago Legal Forum*, 1996, pp. 207-216 [p. 216]

<sup>125</sup> On social norms, markets and design (code) as modes of regulation, see seminal Lessig, Lawrence, "The Law of the Horse: What Cyberlaw Might Teach", *Harvard Law Review*, vol. 113, no. 2, 1999, pp. 501-546.

<sup>126</sup> Cf. Zuboff, Shoshana, *The age of surveillance capitalism: The fight for a human future at the new frontier of power*, Profile books, 2019.

<sup>127</sup> Brownsword, Roger, Eloise Scotford, and Karen Yeung, op. cit., 2017, p. 8.

<sup>128</sup> Ibid.

<sup>129</sup> Brownsword, Roger, op. cit., 2019, p. 14.

<sup>130</sup> Ibid.

<sup>131</sup> Cf. Dworkin, Ronald, *Law's Empire*, Harvard University Press, 1986.



There are different possible ways to conceptually break down varied manners in which the law may fail to accomplish its aims in the context of emerging technologies.<sup>132</sup> One option would be to use two broad (albeit non-exhaustive) categories of under-inclusiveness and over-inclusiveness of law.<sup>133</sup> Law would be under-inclusive if it fails to cover range of activities necessary to fulfil its purposes.<sup>134</sup> This may happen both when the scope of a particular legal instrument is too narrow, but also when new specific rules are needed as a mere expansion of the existing legislation would not be sufficient. Moreover, the under-inclusiveness may also take a form of under-enforcement, which can occur e.g. when a sociotechnical change increases the costs of detection and enforcement – while the law-in-books may seem adequate, in practice its intended effectiveness is significantly diminished.<sup>135</sup> The over-inclusiveness, in turn, would occur when the law would unnecessarily restrict valuable activity (when, for instance, a sociotechnical change would eliminate harm that used to justify such restrictions).<sup>136</sup> This category covers both a situation when a whole legal norm (or set of norms) becomes obsolete<sup>137</sup> and when the problem is “only” with a scope of a norm, that would remain valid if narrowed. And similarly, it can also be manifested in a form of over-enforcement, when intensified enforcement (resulting from e.g. lowered costs of detection and enforcement) produces effects that exceed norm’s legitimate purpose.<sup>138</sup>

## 4. Conclusions

The aim of this report was to outline a refined, general methodology for legal analysis of emerging technologies, elaborating and adapting the original approach, developed in the SIENNA methodological Handbook. The Handbook approach turned out in practice flexible enough to be tailored to the three highly divergent fields of emerging technologies that were studied in the project and helped to compile valuable data in the SIENNA legal studies. At the same time, it left many substantive methodological choices to be made in the process. In this report, we attempted to provide somewhat more specific guidance on how to address some methodological challenges, that would simultaneously remain sufficiently flexible to be applied to different future and emerging technologies.

The report proposed an approach for legal analysis consisting of four general steps: (1) specification of scope of legal analysis; (2) identification of legal issues; (3) analysis of international, regional (including EU) and national legal norms relevant for the identified issues and (4) identification of gaps and challenges in the existing legal frameworks with regard to the identified issues. Subsequently, all four steps were discussed in more details.

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<sup>132</sup> See e.g. Brownsword, Roger, Eloise Scotford, and Karen Yeung, *op. cit.*, 2017, p. 11.

<sup>133</sup> This division (and the whole paragraphs) extensively draws from Moses, Lyria Benett, *op. cit.*, 2007 and Crootof, Rebecca and Ard, BJ, *op. cit.*, 2020, though it arranges the categories in a partly different way from the authors of both articles.

<sup>134</sup> Crootof, Rebecca and Ard, BJ, *op. cit.*, 2020, p. 26.

<sup>135</sup> *Ibid.*, p. 28.

<sup>136</sup> *Ibid.*, p. 26, p.30.

<sup>137</sup> Moses, Lyria Benett, *op. cit.*, 2007.

<sup>138</sup> *Ibid.*, Crootof, Rebecca and Ard, BJ, *op. cit.*, 2020.



The section on the first preliminary step addressed the scope of legal analysis, suggesting to break down the examined wide technological area into three levels: general technology level, artefacts and procedures level and applications level, drawing from Philip Brey's Anticipatory Technology Ethics approach. It also emphasised the need to adopt a contextualised perspective on the analysed technology (at all three levels), paying attention to complex character of the whole sociotechnical landscape, as well advised not to focus only on what is utterly new about it, but to notice also what is 'only' exacerbated or reinforced.

In the section on the second step, we stressed that issue identification phase needs to be done with caution, not to reproduce unfair societal power inequalities by overlooking risk pertinent to disadvantages groups. We have also highlighted the necessity to consciously adopt a frame that could structure the potentially vast area of legal issues. Acknowledging that there are many possible frames of reference, we argued that human rights may offer a particularly fitting perspective in legal analysis of emerging technologies. Noticing its prominence in the area of technology regulation in the last 25 years, we outlined four general grounds for choosing human rights perspective: (1) human rights' function as foundational principles of legal orders; (2) their holistic character that allows to consider under a common thread a wide variety of diverging challenges that may be associated with emerging technologies, both 'hard' and 'soft' impacts; (3) their dual character, entailing both well-developed, specific *legal* standards and a normative language that is open to reinterpretations over time and that is used by a large and diverse pool of civil society groups active in the area of emerging technologies; and (4) the fact they inherently enable to consider inequalities and power imbalances related to emerging technologies. At the same time, we emphasised that applying human rights lenses is not equal to analysing only matters of international human rights law or constitutional law – lenses are not what is seen through them. Specific legal issues like liability, safety, personal data, property etc. can be linked to human rights, i.e. be interpreted as falling under the scope of a particular right or rights. We then briefly discussed question of applicability of a human right to specific issues and how this does not mean reducing these issues to human rights understood as 'some vague principles'.

Noting that there are in fact many ways of conducting legal analysis inspired by human rights, we turned to the human rights-based approach paradigm to draw some practical recommendations from its principles of comprehensiveness (equal consideration of different types of rights), non-discrimination and equality and participation. We then described two basic means of identifying issues envisaged by this approach: literature review and stakeholder engagement, and explained why there is a need to look beyond the academic and policy literature, reaching out to sources from broadly understood civil society, both in terms of primary and secondary data (i.e. both fieldwork and desk research). We paid particular attention to expert interviews as a method that may produce relatively much relevant information while being comparatively less resource-intensive (emphasising the broad understanding of 'expertise' for this type of data collection, which shall include also knowledge acquired through addressing problems in practice).

In the section related to the third step, pertaining analysis of legal norms relevant for the identified issues, we highlighted that even when emerging technologies bring previously unknown capabilities and there is no explicit legal guidance related to them, this does not entail that they would operate in a legal void in a strict sense, as most likely there would be some general, partly technology-neutral law





that would be applicable to them. Further, we also emphasised again that the material for analysis is not restricted to international human rights law or constitutional law, but includes also all relevant ‘lower-level’ legal sources (like legislative acts) linked to the identified issues. We also briefly discussed the doctrinal method that comes as the most applicable at this point and took notice of different possible levels of doctrinal analysis in this step, from rather ‘thin’, largely semantic description to a more ‘thick’ one, based to a larger extent also on purposive, systematic and contextual methods of interpretation (the latter brought additionally into view the law-in-context approach). We referred further to analysing regulatory-design characteristics of examined norms, including their underlying normative outlooks. In addition, benefits and challenges of a comparative analysis of different national orders were briefly addressed. Noting upfront an often pragmatic necessity to adjust the scope of analysis to the available resources also at this step, we outlined two possible (non-exhaustive) ways of doing it, with their respective drawback and benefits.

The next section discussed the last, fourth step, relating to the assessment of adequacy of the examined legal frameworks. We re-emphasised that lack of dedicated legislation does not necessarily mean that there is a legal gap – but in some cases application of the existing norms may indeed be normatively problematic and this step would be precisely aimed at identification of this type of instances. We referred to the parallel two risks to be simultaneously avoided in such enterprise – jumping too quickly to conclusions that the current legal framework is outdated (e.g. as older than the technology in question) and too rigidly sticking with the current law (assuming it will always eventually work just fine) – and advocated a systematic case-by-case approach. We argued that a key element in such case-by-case evaluation would be assessing whether the examined norms remain ‘fit for purpose’ – with possible purposes ranging from specific goals which are ‘local’ within a legal system up to fundamental purposes of a whole legal order, like human rights (and with the latter type of fitness being crucial). Next, we briefly described two general (non-exhaustive) ways in which law may fail to accomplish its aims referring to categories of under-inclusiveness and over-inclusiveness of law. The two categories encompass both problems of conceptual mistargeting and more practical over- or under-enforcement, as well both situations where there is need for new specific norms or to eliminate whole (set of) norms, and situations where a scope of current norms “only” needs to be narrowed or widened.

The above four steps-approach elaborates the original SIENNA methodology, but still remains partly in a form of a general outline – and each of the steps could be further developed with more details. Based on the lessons learned in SIENNA legal studies, it does, though, provide some guidance in a number of methodological cross-roads that may be in practice encountered in legal analyses of different kinds of emerging technologies and highlights others additional points that require an enhanced attention along the way.



# Annex

## 1. Introduction

This section contains two brief case-studies, which apply major aspects of the revised approach to examples of other types of future and emerging technologies: three-dimensional printing (3D printing) and augmented reality (AR) technologies. The case-studies do not aim to provide an exhaustive legal analysis of the two technologies, but rather to sketch out some indicative examples how some elements of the general outline of the approach presented in the main report could be used.

There is no universally agreed definition of future and emerging technologies and using this label to describe particular technologies is often contested. However, Daniele Rotolo, Diana Hicks and Ben R. Martin identified the following five features that are frequently attributed in literature to emerging technologies: (i) radical novelty, (ii) relatively fast growth, (iii) coherence, (iv) prominent impact, and (v) uncertainty and ambiguity.<sup>139</sup> Consequently, they proposed the following definition: emerging technology is a *“radically novel and relatively fast growing technology characterised by a certain degree of coherence persisting over time and with the potential to exert a considerable impact on the socio-economic domain(s) which is observed in terms of the composition of actors, institutions and patterns of interactions among those, along with the associated knowledge production processes. Its most prominent impact, however, lies in the future and so in the emergence phase is still somewhat uncertain and ambiguous.”*<sup>140</sup> They emphasised that ‘emergence’ is a process, not a static property and the listed attributes do not have to reach some absolute level for a technology to be labelled as ‘emerging’.<sup>141</sup>

This report adopts their definition and treats ‘future technologies’ as an early stage type of emerging technologies (where levels of novelty and uncertainty and ambiguity are higher, while—usually—levels of actual impacts and coherence lower<sup>142</sup>). Examples of future and emerging technologies include, in addition to the technologies that have been studied in SIENNA (human genomics, AI and robotics, human enhancement technologies), among many others, the following: quantum computing, augmented and virtual reality, internet of things, biometrics, climate engineering, 3D printing, cloud computing, regenerative medicine or neuromorphic computing.<sup>143</sup>

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<sup>139</sup> Rotolo, Daniele, Diana Hicks, and Ben R. Martin, "What is an emerging technology?", *Research policy*, vol. 44, issue 10, 2015, pp. 1-44.

<sup>140</sup> *Ibid.*, p. 13

<sup>141</sup> *Ibid.*, p. 14.

<sup>142</sup> *Ibid.*, pp. 14-15.

<sup>143</sup> See e.g. Garcia, Eva, Manuel Noya, Agata Gurzawska, *Windows to the future around top trends in Emerging Technologies. Roadmapping exercise - top 20 trends in technology aiming at shaping the world in the coming decades, structured into 'Dreams' and potential 'Nightmares'*, 2020, [https://www.prefet.net/wp-content/uploads/2021/01/prefet\\_future-technology-trends-roadmapping-exercise.pdf](https://www.prefet.net/wp-content/uploads/2021/01/prefet_future-technology-trends-roadmapping-exercise.pdf); Spaulding, Jeremy, Spencer Stuckey, *Grey Zones: Emerging Technology Development and Impact in Emerging and Developing Markets*, Wilson Center, Washington, 2020; European Commission, *Horizon 2020 - Work Programme 2018-2020*



## 2. Case study 1: Augmented Reality (AR)

The following case study will apply the major aspects of the revised approach to augmented reality (AR), a group of technologies that allow digital content to be layered over the real world.<sup>144</sup> First, it will identify some legal issues pertaining to this technology, breaking down the technological area into three levels: general technology level, artefacts and procedures level and applications level. Second, an attempt will be made to map the main legal norms relevant for the selected issues. Third, the occurrence of potential gaps in the analysed existing legal frameworks (or rather the scarcity of the very regulations) will be indicated.

### 2.1. Selected legal issues related to augmented reality (AR)

In this section, a non-exhaustive overview of selected legal issues pertinent to AR has been presented. The overview has been based on desk research of available sources such as recent legal academic literature and civil society studies. When choosing the topics, effort has been made to adopt broad understanding of human rights, consider different sets of them and, where possible, concentrate in particular on vulnerable groups. As a result, four main legal problems have been identified and described, namely: privacy and data protection issues; property issues; freedom of expression issues and trademark and consumer protection issues.

#### Privacy and data protection issues

The most apparent group of legal issues related to AR, as indicated in the available sources, pertains to the widely understood right to privacy. According to Roesner et al, certain concerns can be raised both with regard to AR's capacity for constant, real-time recording of everything that its user hears and sees (the input), as well as to the information overlaid on the user's perception of the world (the output).<sup>145</sup> When it comes to the former, the authors point out the more and more inconspicuous form factors of modern AR devices, whose presence – contrary to traditional recording equipment (e.g. shoulder camcorders) – does not serve as a clue that recording may be taking place (in particular in spaces where a certain level of privacy is expected).<sup>146</sup>

Such expansion of (mostly non-consensual) surveillance by definition poses threat to the general right to privacy, but also has its specific social dimension. As Franks argues, there is every reason to believe that the most destructive effects of increasingly sophisticated technologies of surveillance will be felt by the marginalised groups the most, in particular women and racial minorities.<sup>147</sup> The author is

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*Future and Emerging Technologies*, 2018, [https://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-fet\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-fet_en.pdf).

<sup>144</sup> Lemley, Mark A. and Eugene Volokh, Law, "Virtual Reality, and Augmented Reality", *University of Pennsylvania Law Review*, Vol. 166, Issue 5, 2018, p. 1054.

<sup>145</sup> Roesner, Franziska, Tamara Denning, Bryce Clayton Newell, Tadayoshi Kohno, Ryan Calo, "Augmented Reality: Hard Problems of Law and Policy", *Proceedings (adjunct) of 2014 ACM International Joint Conference on Pervasive and Ubiquitous Computing (UbiComp 2014)*, September 2014, pp. 1283-1287.

<sup>146</sup> *Ibid*, p. 1286.

<sup>147</sup> Franks, Mary Anne, "The Desert of the Unreal: Inequality in Virtual and Augmented Reality", *UC Davis Law Review*, Vol. 51, 2017, pp. 499-538.



especially concerned about the impact that surreptitiousness of recording capabilities of AR sunglasses (e.g. Google Glass or Snap Inc. Spectacles) can have on women and girls in the context of intimate surveillance abuses, such as stalking or filming private or sexual behaviour without consent. Franks indicates also potential risks of harnessing AR surveillance technologies to enhance state monitoring of communities of colour.<sup>148</sup>

Apart from AR devices' ability to monitor third persons seamlessly without their knowing that they are being monitored, Kotsios indicates another two features of AR systems that could impact the right to privacy: instant uploading of the gathered data on the web and biometrics.<sup>149</sup> When it comes to uploading of footage, whenever an AR user decides to upload a picture or video of a third person, an unlimited amount of people with Internet connection could gain access to such data as the image of this person, time and location of their actions or people he or she interacted with. Due to the vast amount of people to whom this data could become available, the effect of interference with the third person's privacy multiplies. Furthermore, with regard to the use of biometrics and face recognition in AR systems, an issue of concern arises as to the ability to identify in real time the third persons that AR user is looking at (or taking photographs of them that could be processed later). Although currently available devices (the most prominent being Google Glass) do not allow face recognition, Kotsios fears that the introduction of wearable AR devices which are 'rooted' (i.e. given privileged control of the device, thus overcoming the limitations put by the producers of the operating systems and devices) remains only a matter of time.<sup>150</sup>

Certain risks are also indicated specifically with relation to the potential use of biometrics in AR by state bodies. Heller invokes the examples of Chinese police who apply facial recognition to crowds in order to identify suspects, as well as the development of AR interfaces for targeting enemies in the battlefield, and fears that there is a great potential of hacking such systems.<sup>151</sup> This, as Heller argues, could result in misidentification of friendly targets or allies, and thus put human life, health or personal liberty at risk.

Human rights issues can also arise in relation with output generated by AR devices when, for instance, AR users are provided with truthful information that they should not obtain or, at least, legally use when making decisions. Roesner et al invoke an example in which an AR system uses facial recognition to pull up job candidate's race, sex, religion, national origin, age, disability, genetic information, parental status, gender status or sexual orientation, and the employer, even unconsciously, incorporates one or more of these factors into the decision on not hiring the candidate.<sup>152</sup> As a result, by rendering more personal data available, AR can contribute to conscious or unconscious discrimination in employment and many other areas of life.

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<sup>148</sup> Ibid, p. 524.

<sup>149</sup> Kotsios, Andreas, "Privacy in an augmented reality", *International Journal of Law and Information Technology*, Vol. 23, Issue 2, Summer 2015, pp. 157-185.

<sup>150</sup> Ibid, p. 171.

<sup>151</sup> Heller, Brittan, "Reimagining Reality: Human Rights and Immersive Technology", *Carr Center Discussion Paper Series*, Issue 008, 2020.

<sup>152</sup> Roesner, p. 1287.



Privacy and data protection issues related to AR can be structured according to Brey’s three-level Anticipatory Technology Ethics approach. The table below illustrates an attempt to apply this approach to selected issues described with relation to privacy.

Technology level	Artefact level	Application level	
Collection of personal data, including biometric data	AR eyewear and its ability to input and output information	<ul style="list-style-type: none"> <li>• Job recruitment process</li> <li>• Face recognition of suspects</li> <li>• Targeting enemies in the battlefield</li> </ul>	<i>Privacy and data protection</i>

**Table 3. Examples of legal issues related to AR on technology, artefact and application level – privacy and data protection**

### Property issues

Regulation of AR technologies cannot only be limited to privacy issues. Katell et al observe that “the embeddedness in physical space adds another dimension to the regulatory challenges because it implies that AR’s disruptive potential cannot be addressed merely through the lens of informational privacy as an issue of data protection”.<sup>153</sup> Therefore, certain other bodies of law governing physical spaces should be harnessed, among others property law.

Ownership issues occur in particular when it comes to location-based AR games (the most prominent example being Pokémon Go), in which artefacts created as part of augmented reality are superimposed on possessions in the physical world.<sup>154</sup> In 2016, Pokémon Go became a phenomenon worldwide, attracting millions of players who, in pursuit of virtual characters, trespassed or even destroyed private or public property, whose owners have never been asked for permission to place such artefacts on it. This led to a series of conflicts between game users and physical space owners,

<sup>153</sup> Katell, Michael, Francien Dechesne, Bert-Jaap Koops and Paulus Meessen, “Seeing the whole picture: visualising socio-spatial power through augmented reality”, *Law, Innovation and Technology*, Vol. 11, Issue 2, 2019, pp. 279-310.

<sup>154</sup> van Est, Rinie and Joost Gerritsen, with the assistance of Linda Kool, “Human rights in the robot age. Challenges arising from the use of robotics, artificial intelligence, and virtual and augmented reality”, Expert report written for the Committee on Culture, Science, Education and Media of the Parliamentary Assembly of the Council of Europe (PACE), Rathenau Instituut, The Hague, 2017.



and demonstrated AR's potential to introduce competing normative understandings and legal claims about physical space.<sup>155</sup>

Although lawsuits filed by property owners against the game's developer were based on harm caused to real property by increasing the number of trespassers in their residential areas, and plaintiffs invoked a specific 'right not to be mapped', Judge and Brown argue that neither the existing laws on intellectual property nor those for real property are designed to address these types of harms.<sup>156</sup> They suggest, instead, that municipalities introduce, for instance, zoning rules and regulations in order to manage the use of augmented reality, and therefore create both areas free from AR, as well as zones designated specifically for it.<sup>157</sup>

### **Freedom of expression issues**

Questions can also be raised as to the scope of protection afforded by the freedom of expression with regard to activities undertaken in augmented reality.

Blitz considers this issue in the context of using AR technologies to play games that involve shooting at targets, the most troubling scenario being the one where targets are not some fictional characters but actual people, or games where players eliminate each other by pressing a button on an AR app on their smartphone.<sup>158</sup> The author contemplates whether the use of the AR technology to engage in simulated shooting in a real-life setting could count as a form of expression – controversial, but protected by the law.

Other challenges that AR can pose with relation to the freedom of expression (and with visible implications for rights of other persons), according to Pisanu et al, can be a result of the technological ability to virtually place objects on top of real objects, in particular illegal, offensive or harmful content.<sup>159</sup> Therefore, a risk can occur when e.g. a far-right group earns the possibility of labelling migrants' houses or a group of bullies starts placing offensive slogans in their victim's virtual garden. The authors argue that there is a pressing need for regulating this issue, mapping out the risks and building safeguards for the rights of third persons.<sup>160</sup>

### **Trademark and consumer protection issues**

The increasing adoption of augmented reality technologies for commercial use implies that issues related to trademark cannot be disregarded in this context. There are already AR applications available for download which display images of content that either is or contains a trademark. With AR eyewear growing in popularity, it is predicted that soon the practice of "digital billboard replacement" will be

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<sup>155</sup> Katell et al., p. 290.

<sup>156</sup> Judge, Elizabeth F. and Tenille E. Brown, "Real Property, and Zoning", *Laws*, Vol. 7, Issue 23, 2018.

<sup>157</sup> *Ibid.*

<sup>158</sup> Blitz, Marc Jonathan, "Augmented and virtual reality, freedom of expression, and the personalization of public space" in Woodrow Barfield and Marc Jonathan Blitz (eds.), *Research Handbook on the Law of Virtual and Augmented Reality*, Edward Elgar Publishing Limited, Cheltenham, 2018, p. 317.

<sup>159</sup> Pisanu, Gaspar, Daniel Leufer and Isedua Oribhabor, Augmented reality & augmented risks: why AR is a digital rights issue, Access Now, 16 October 2020.

<sup>160</sup> *Ibid.*



adopted, meaning that one business will be able to pay for replacing its competitor’s product signs (existing in real world) with its own virtually superimposed logo.<sup>161</sup>

Such instance of harnessing AR to associate digital content owned by one party with physical content owned by another obviously can result, according to Wassom et al, in consumer confusion, as well as may infringe trademark rights.<sup>162</sup>

Technology level	Artefact level	Application level	
The embeddedness of AR in physical space	AR eyewear/other devices capable of seeing virtual objects/characters superimposed onto the real ones	<ul style="list-style-type: none"> <li>Games involving interaction with virtual characters and objects in real space (e.g. Pokémon GO)</li> </ul>	<i>Property issues</i>
		<ul style="list-style-type: none"> <li>Games involving e.g. “shooting” at actual bystanders</li> <li>Placing offensive slogans or objects on third persons’ premises</li> </ul>	<i>Freedom of expression issues</i>
	AR eyewear/other devices capable of displaying images that are (or contain) trademarks	<ul style="list-style-type: none"> <li>Digital billboard replacement</li> </ul>	<i>Trademark and consumer protection rights issues</i>

**Table 4. Examples of legal issues related to AR on technology, artefact and application level – property, freedom of expression, trademark and consumer protection**

<sup>161</sup> Wassom, Brian D., Amber M. Underhill and Andrew L. Rossow, “Trademark law and the right of publicity in augmented reality” in Woodrow Barfield and Marc Jonathan Blitz (eds.), *Research Handbook on the Law of Virtual and Augmented Reality*, Edward Elgar Publishing Limited, Chettenham, 2018, p. 201.

<sup>162</sup> Ibid, p. 202.



## 2.2. Main legal norms relevant for the selected issues

The following table presents a general mapping of the most important international and European Union legal sources applicable to issues identified in section 1. Since no dedicated legal norms, specific for the augmented reality, could have been indicated so far, the mapping includes only norms of general application relevant for the technology in question.

Legal issue	Applicable provisions of international and EU law
Privacy and data protection issues	<ul style="list-style-type: none"> <li>• Universal Declaration of Human Rights (UDHR): prohibition of arbitrary interference with one’s privacy, family, home or correspondence, as well as attacks upon one’s honour and reputation (Article 12)</li> <li>• International Covenant on Civil and Political Rights (ICCPR): as above (Article 17)</li> <li>• European Convention on Human Rights (ECHR): the right to respect for his private and family life, his home and his correspondence (Article 8)</li> <li>• Charter of Fundamental Rights of the European Union (CFR): the right to respect for his or her private and family life, home and communications (Article 7); the right to the protection of personal data (Article 8); non-discrimination (Article 21)</li> <li>• General Data Protection Regulation (GDPR)<sup>163</sup>: processing shall be lawful only if and to the extent that the data subject has given consent to the processing of his or her personal data for one or more specific purposes (Article 6)</li> <li>• Directive on equal treatment in employment and occupation:<sup>164</sup> prohibition of direct or indirect discrimination (Article 2)</li> </ul>
Property issues	<ul style="list-style-type: none"> <li>• UDHR: the right to property (Article 17)</li> </ul>

<sup>163</sup> European Parliament and of the Council, Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (consolidated), 27.04.2016.

<sup>164</sup> European Council, Directive 2000/78/EC of 27 November 2000 establishing a general framework for equal treatment in employment and occupation, 27.11.2000.





	<ul style="list-style-type: none"> <li>• ECHR: the right to the peaceful enjoyment of one’s possessions (Article 1 of Protocol No. 1)</li> <li>• CFR: the right to own, use, dispose of and bequeath his or her lawfully acquired possessions (Article 17)</li> </ul>
Freedom of expression issues	<ul style="list-style-type: none"> <li>• UDHR: freedom of opinion and expression (Article 19)</li> <li>• ICCPR: freedom of expression (Article 19)</li> <li>• ECHR: the right to freedom of expression (freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers) (Article 10)</li> <li>• CFR: as above (Article 11)</li> </ul>
Trademark and consumer protection issues	<ul style="list-style-type: none"> <li>• EUTMR Regulation<sup>165</sup></li> <li>• CFR: Union policies shall ensure a high level of consumer protection (Article 38)</li> <li>• Directive on consumer rights<sup>166</sup></li> </ul>

Table 5. AR legal issues and examples of relevant international and EU law

### 2.3 Identification of potential gaps in the analysed existing legal frameworks

Following the desk research into the legal framework related to augmented reality, a conclusion should be drawn as to the lack of specific legal norms pertaining to this field of emerging technologies. Furthermore, the examples where existing legal categories have been applied to resolve cases involving AR are too scarce to evaluate if such use of general norms leads to satisfactory results (from the point of view of human rights). To make the matter worse, it is virtually impossible to find relevant references to specific gaps in the existing legislation in academic legal literature outlets. For these reasons, a decision has been made to abstain from completing this section of the case study, in order to avoid misleading conclusions on the adequacy of the existing framework that would not have sufficient grounds.

<sup>165</sup> European Parliament and the Council, Regulation (EU) 2017/1001 of 14 June 2017 on the European Union trade mark, 14.06.2017.

<sup>166</sup> European Parliament and the Council, Directive 2011/83/EU of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (consolidated), 25.11.2011.



### 3. Case study 2: 3D printing

This section will apply the major aspects of the revised approach to 3D printing. Firstly, it will identify a number of legal issues pertaining to this technology, breaking down the technological area into three levels: (1) general technology level, (2) artefacts and procedures level, and (3) applications level. Subsequently, it will present an overview of the current legal landscape on the matter, before making an assessment of its limitations.

In this sense, it will follow the proposed four-step approach to the legal analysis of emerging technologies, consisting in the specification of scope of such analysis, the identification of legal issues<sup>167</sup>, the analysis of relevant legal norms, and the identification of gaps and challenges in the existing legal framework.

#### 3.1 Selected legal issues related to 3D printing

Additive manufacturing, also known as 3D printing, refers to the construction of a three-dimensional object from a three-dimensional digital file or blueprint, through layer-manufacturing techniques.

Like any emerging socially disruptive technology, 3D printing presents far-reaching legal and ethical implications<sup>168</sup>. In particular, numerous legal questions regarding its accordance with and protection of fundamental human rights need to be addressed.

To begin with, at a general technology level,<sup>169</sup> the main overarching issues common to all 3D printing techniques and subfields (e.g. manufacturing and prototyping, medicine, industry) concern safety and security<sup>170</sup>—in that additive manufacturing allows for the printing of money, weapons, as well as prohibited or restricted items—, liability<sup>171</sup>—in that it is unclear whether the manufacturer, the supplier, the owner of the printer, or the individual who either printed or used a 3D printed item should be held liable—, as well as intellectual property.<sup>172</sup>

Additionally, at a more practical level, further legal issues arise in connection to specific artefacts and procedures designed and developed for practical application.<sup>173</sup> In particular, several legal issues arise in the medical sphere as far as the 3D printing of organs is concerned, i.e. informed consent<sup>174</sup>—in that it is unclear whether it should also encompass the matter of manipulation and further use of printed

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<sup>167</sup> For reasons of clarity, the first two steps have been presented jointly.

<sup>168</sup> It is also worth mentioning that a new process called 4D printing is being developed, which builds on the basics of 3D printing, and gives artefacts the ability to adapt after printing under specific environmental conditions, by either changing shape or function as a result of external stimuli (e.g. water, temperature). On the matter, see Ramalho, A., and E. Lauro, "What will happen when 4D printing hits design town? Copyright and Design law perspectives. Copyright and Design Law Perspectives", forthcoming in B. Pasa (ed.), *Il Design, L'innovazione Tecnologica e Digitale*, ESI Press, Rome, 2020.

<sup>169</sup> Philip A.E. Brey, "Anticipatory Ethics for Emerging Technologies", *Nanoethics*, Vol. 6, 2012, pp. 1-13.

<sup>170</sup> European Union, Charter of Fundamental Rights of the European Union, 2012/C 326/02, Brussels, 26.10.2012. <https://www.refworld.org/docid/3ae6b3b70.html>, Article 6 (Right to liberty and security).

<sup>171</sup> *Ibid*, Articles 38 (Consumer protection) and 47 (Right to an effective remedy and to a fair trial).

<sup>172</sup> *Ibid*, Article 17.2 (Right to property).

<sup>173</sup> Philip A.E. Brey, *op. cit.*, 2012.

<sup>174</sup> European Union, *op. cit.*, 2012, Article 3.2 (Right to the integrity of the person).



items, e.g. for research purposes—, confidentiality and data processing<sup>175</sup>—in that medical secrecy would seem hard to enforce, given that bioprinted items would contain extremely confidential information about patients’ characteristics—, as well as the already mentioned liability, safety and security,<sup>176</sup> and intellectual property<sup>177</sup> issues.

Lastly, one further set of legal issues arises in connection to 3D printing’s application level,<sup>178</sup> if one were to consider this technology-in-use in a medical context for the commercialisation and ultimate transplantation of 3D bioprinted organs, such problems may include all the above-mentioned issues, as well as the matters of equality<sup>179</sup> and discrimination<sup>180</sup>— in that personalised medicine would increase the disparities between the rich and the poor in terms of equal access to such benefits.

Charter of Fundamental Rights of the European Union	First level	Second level	Third level
Article 3 (Right to the integrity of the person)		x	x
Article 6 (Right to liberty and security)	x	x	x
Article 8 (Protection of personal data)		x	x
Article 17 (Right to property)	x	x	x
Articles 20-26 (Equality)			x
Article 21 (Non-discrimination)			x
Article 38 (Consumer protection)	x	x	x
Article 47 (Right to an effective remedy and to a fair trial)	x	x	x

Table 6. Examples of affected fundamental rights on technology, artefact and application level of 3D printing

<sup>175</sup> Ibid, Article 8 (Protection of personal data).

<sup>176</sup> In fact, as stated by Gilbert *et al.*, “[u]nlike most structures implanted in the body (stents, pacemakers, cochlear implants, artificial hips or knees), bioprinted engineered tissue initiates an ongoing interaction with the recipient’s body, and variations may not be controllable. This has consequences for accurate risk-benefit analyses and for generalising the results of clinical trials”, See Gilbert, F., C. D. O’Connell, T. Mladenovska, and S. Dodds, "Print me an organ? Ethical and regulatory issues emerging from 3D bioprinting in medicine", *Science and engineering ethics*, vol. 24, issue 1, 2018, pp. 73-91, p. 80.

<sup>177</sup> In particular, according to Tran, one of the central issues of bioprinting from an intellectual property standpoint relates to whether bioprinting is patentable at all. The author argues in the sense that bioprinting products and bioprinting processes should be considered separately; additionally, Tran highlights that patents on the latter have already been filed and approved, while patents on the former still raise a number of legal questions, which so far remain unsolved. See J.L. Tran, "Patenting bioprinting", *Harvard Journal of Law & Technology Digest*, Vol. 29, 2015 Symposium, 2015.

<sup>178</sup> Philip A.E. Brey, *op. cit.*, 2012.

<sup>179</sup> European Union, *op. cit.*, 2012, Articles 20-26 (Equality).

<sup>180</sup> Ibid, Article 21 (Non-discrimination).



For reasons of brevity, the following overview will only consider the issues of intellectual property and its ramification from the perspective of 3D bioprinting.

### 3.1.1 Intellectual property

In particular, matters of intellectual property arise in relation to the legal status of 3D models used for 3D printing. While numerous issues may arise on the matter involving copyright, trademarks, and patents, the core legal concerns seem to be threefold.

Firstly, intellectual property issues emerge when the 3D model used for additive manufacturing is based on items protected by intellectual property. In this sense, 3D models would likely also be protected by copyright as a *digital copy* of the original item, and their (legal) distribution would be limited substantially. Nevertheless, additional problems would emerge from the illegal circulation of 3D models based on copyrighted items.<sup>181</sup> Indeed, this could open the way to a market of cloned copyrighted items, which could be easily downloaded and printed by anyone with access to the digital copy and a 3D printer.<sup>182</sup> At the same time, having too stringent regulations in place to prevent the spread of illegal copies of copyrighted items, e.g. encrypting such items to prevent non-authorized personnel from accessing them, might cause additional issues. For instance, this could prevent people from knowing the content of the item they are downloading, and may result in individuals unknowingly breaching copyright through the download and reproduction of illegal items, without being aware of their content and status. Of course, a copyright-based 3D model would also have an impact on the end product itself, in that this would be a three-dimensional copy of the initial copyright-protected item.

Secondly, when a 3D model used for 3D printing is not based on (a third-party's) intellectual property, but constitutes creative work, copyright issues emerge in relation to the circulation of such model, given that the corresponding rights belong to its author. As a means of example, works of art are considered to be at high risk of counterfeiting, but it is unlikely that traditional intellectual property laws could limit the adoption of 3D printing by end consumers at large, thus significantly reducing the risk of distributing creative 3D models. In this sense, a *democratisation* of 3D printing would lead to copyright infringements being extremely difficult to identify, as authors would not have effective tools at their disposal to monitor when their designs are printed.

Thirdly and lastly, 3D models may also not be based on intellectual property, while also not constituting creative work: this is the case of 3D computer-aided design (CAD) models. One wonders whether such models, unreadable by human beings and resulting from the automatic translation of either an on-screen drawing or a laser-scanning, may also be connected to the notion of "computer programs" as addressed by the 2009 Software Copyright Directive,<sup>183</sup> while stating that "the development of computer programs requires the investment of considerable human, technical and financial

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<sup>181</sup> In this regard, depending on whether the item in question was identified as a 3D replica as opposed to a 3D computer-aided design (CAD), the consequences may change from a legal standpoint.

<sup>182</sup> In this sense, see Vijayavenkataraman, S., W. F. Lu and J. Y. H. Fuh, "3D bioprinting-an ethical, legal and social aspects (ELSA) framework", *Bioprinting*, 1, 2016, pp. 11-21, p. 16.

<sup>183</sup> European Parliament and the Council, Directive 2009/24/EC of the European Parliament and of the Council of 23.4.2009 on the legal protection of computer programs (Codified version), OJ L 111, 5.5.2009. <http://data.europa.eu/eli/dir/2009/24/oj>



resources".<sup>184</sup> Additionally, European case law on the matter<sup>185</sup> highlighted the relevance of an author's intellectual property being derivable from the work itself, as well as the extent to which this should be demonstrated. Nonetheless, this has not helped to definitively solve this question of whether CAD models can be protected by copyright, which remains open.<sup>186</sup>

The main underlying issues on the technology level being laid down, one further problem emerges in connection to the procedure level, which is connected with 3D bioprinting, and the 3D printing of organs in particular. That is, if intellectual property issues concerning the 3D model also transfer to the printed item—which appears reasonable so far—, questions of ownership of printed organs would arise as well. In particular, as a means of example, but not limited to, would the individual owning intellectual property on the 3D model of the organ have the right to have a say in who may receive such an organ? This would raise issues connected with the anonymity of organ donations according to EU law.<sup>187</sup> Additionally, would it be possible for donors of cells to claim ownership of the 3D bioprinted organs that have been created using their cells? Would the 3D printed organ be owned by the individual for which it was created? What if the organ turns out to be defective, who should be held liable?<sup>188</sup>

### 3.2 Current regulatory landscape. European regional regulations and potential gaps

From a regulatory standpoint, European regional soft law and regulations are in place to regulate 3D printing product for medical application<sup>189</sup> as well as intellectual property issues related to additive manufacturing.<sup>190</sup>

At the same time, comprehensive intellectual property regulations in the medical area do not seem to be currently in place at a European level. In this regard, some preliminary steps have been made concerning the possible application of Patent law in relation to the protection of elements of the 3D

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<sup>184</sup> Ibid.; Ma, V. C. K., "3D Printing and the Law: The legal implications of our third industrial revolution", *Intersect: The Stanford Journal of Science, Technology, and Society*, 11(1), 2017, p. 4.

<sup>185</sup> Court of Justice of the European Union, C-5/08, *Infopaq International A/S v. Danske Dagblades Forening*, 16 July 2009.

<sup>186</sup> On the matter, see Margoni, T., "Not for Designers: On the Inadequacies of EU Design Law and How to Fix It", *Journal of Intellectual Property, Information Technology and E-Commerce Law*, Vol. 4, Issue 3, 2013, pp. 225-248, as well as Mendis, D. "The Clone Wars' - Episode 1: The Rise of 3D Printing and its Implications for Intellectual Property Law - Learning Lessons from the Past?", *European Intellectual Property Review*, Vol. 35, Issue 5, 2013, pp. 155-169.

<sup>187</sup> European Commission, *Human Organ Transplantation in Europe: An Overview*, Luxembourg, 2003. [https://ec.europa.eu/health/ph\\_threats/human\\_substance/documents/organ\\_survey.pdf](https://ec.europa.eu/health/ph_threats/human_substance/documents/organ_survey.pdf)

<sup>188</sup> Such issues are specific to bioprinting. See Vijayavenkataraman, op. cit., 2016.

<sup>189</sup> European Parliament and the Council, Regulation 2017/745 on Medical Devices, 5.4.2017. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745>. See in particular Articles 10 and 109.

<sup>190</sup> In particular, on the areas of concern that should be addressed in regard to additive manufacturing's intellectual property issues, see European Parliament, *Resolution of 3 July 2018 on three-dimensional printing, a challenge in the fields of intellectual property rights and civil liability*, Strasbourg, 3.7.2018. [https://www.europarl.europa.eu/doceo/document/TA-8-2018-0274\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-8-2018-0274_EN.html).



printing process through patents.<sup>191</sup> In particular, the matter of patentability of bioprinting technologies may be partially addressed by the European Patent Convention (EPC).<sup>192</sup>

Needless to say, a very limited analysis in this overview does not allow to draw clear conclusions on the adequacy of the current regulatory landscape. Still, for the purpose of this case study, one can argue that European law being predominantly characterised by general legal frameworks aimed at the creation of overarching guidelines—as opposed to case-specific regulations—allows for the addressing of legal issues related to 3D printing and bioprinting within the current regulatory landscape. At the same time, it appears that both additive manufacturing’s intellectual property issues and medical 3D printing issues are currently being regulated in a moderately comprehensive way, while gaps still remain at the intersection of the two issues, leaving intellectual property issues related to medical 3D printing unregulated.<sup>193</sup> In this sense, it is vital that European regulations stay current through regular monitoring of the relevant research and related adjustments and updates in this regard.<sup>194</sup>

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<sup>191</sup> European Commission, *The Intellectual Property Implications of the Development of Industrial 3D Printing*, Brussels, 2020, <https://op.europa.eu/en/publication-detail/-/publication/e193a586-7f8c-11ea-aea8-01aa75ed71a1>

<sup>192</sup> The European Patent Convention. <https://www.epo.org/law-practice/legal-texts/epc.html>

Note that the EPC—although initially discussed in the Council of Europe—is not linked directly to the Council of Europe system, nor to EU law, but to a specialised regional organisation.

<sup>193</sup> Lales, Georgios, Elissavet Anestiadou, Vasiliki Bisbinas, Jasjit S. Suri, and Georgios Tsoulfas, *3D Printing: Applications in Medicine and Surgery*, Elsevier, Amsterdam, 2020, p. 65-66.

<sup>194</sup> European Commission. [https://ec.europa.eu/growth/content/pharmaceuticals-eu-refines-intellectual-property-rules\\_en](https://ec.europa.eu/growth/content/pharmaceuticals-eu-refines-intellectual-property-rules_en)