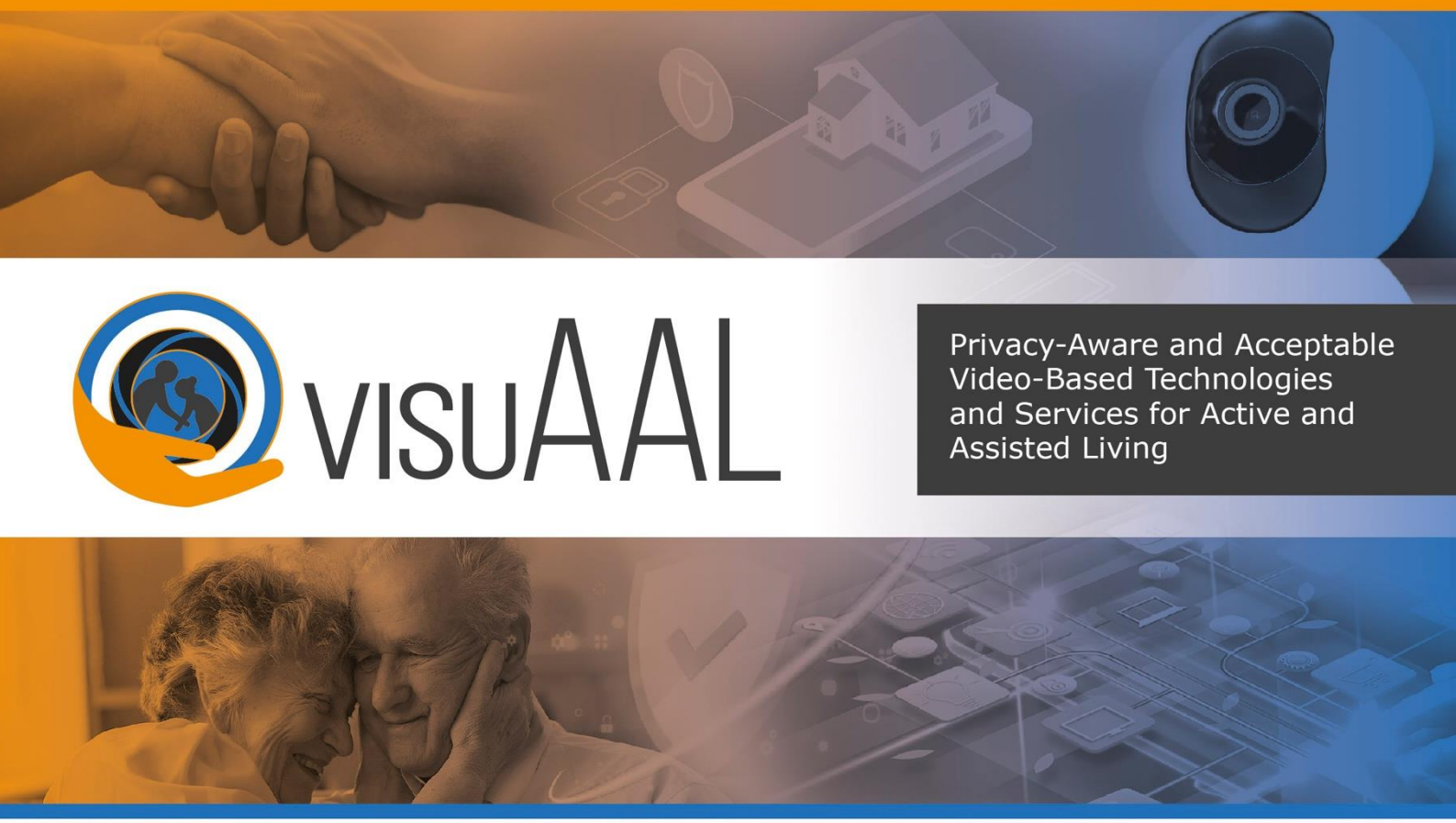

visuAAL

Privacy-Aware and Acceptable Video-Based Technologies and Services for Active and Assisted Living

D1.6. Active Assisted Living – legal tectonic plates

White paper on the legal framework for video-based assisted technologies

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1. Introduction and methodologies

Undoubtedly, emerging information and communications technologies (ICT) may have major impacts on our fundamental rights. This is especially true for monitoring technologies used for Active and Assisted Living purposes (hereinafter 'AAL' technologies). Research has revealed their potential in augmenting various health-related functions, such as fall detection, sleep monitoring, breathing monitoring, epilepsy monitoring, facial expression monitoring, vital signs monitoring and activity monitoring.[1] Consequently, the impacts AAL technologies may have on fundamental rights can be profound.

A major complexity around AAL technologies relates to the applicable legal framework, which can be extremely unclear and complex. In this regard, Colonna reviewed the legal and regulatory challenges facing the use of lifelogging technologies for the frail and sick. Her work provides an analytical legal framework that is wide in scope and touches upon various legal domains, including data protection rules, cyber security laws, medical device regulations, general product safety regulations, consumer protection rules, criminal laws, intellectual property concerns, contract laws and health-care laws.[2] Colonna observed that the current legal framework of lifelogging is a patchwork and is highly fragmented, and that coherent legal regulation is needed to ensure privacy protection and product safety.[3]

More recently, the GoodBrother White Paper identifies seven legal aspects that are central to the use of video and audio based AAL tools, including: (1) data protection and design requirements of data protection law; (2) cyber security; (3) medical device regulation and health laws; (4) general product safety regulation; (5) consumer protection; (6) intellectual property; and (7) AI Regulation.[4]

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[1] Supriya Sathyanarayana and others, 'Vision-Based Patient Monitoring: A Comprehensive Review of Algorithms and Technologies' (2018) 9 Journal of Ambient Intelligence and Humanized Computing 225.

[2] Liane Colonna, 'Legal and Regulatory Challenges to Utilizing Lifelogging Technologies for the Frail and Sick' (2019) 27 International Journal of Law and Information Technology 50.

[3] ibid.

[4] GoodBrother Working Group 1, 'State of the Art on Ethical, Legal, and Social Issues Linked to Audio- and Video-Based AAL Solutions' (2021) <https://goodbrother.eu/wp-content/uploads/2021/12/GoodBrother-State-of-the-art-on-ethical-legal-and-social-issues-linked-to-audio-and-video-based-AAL-solutions.pdf> accessed 16 February 2022.

Building on the frameworks established in state-of-the-art research, this whitepaper aims to explore and present the current legal framework of AAL technologies in a systematic manner. It does so by mapping out legal issues in multiple relevant legal domains, including: (1) general product safety regulations (2) medical device regulation; (3) data protection; (4) cybersecurity; (5) competition law; (6) consumer protection; (7) contract law; (8) criminal law. As compared with the GoodBrother White Paper, this White Paper includes more legal domains, such as competition law, contract law, and criminal law. This is because both AAL technologies and the legal frameworks surrounding them are constantly evolving, and because our exposure to AAL technologies within the visuAAL project enabled us to discover more links between AAL and these new legal domains. Gaps, uncertainties, and contradictions in these legal domains will be highlighted and discussed in the context of AAL technologies in the following sections. Research regarding the interactions between AAL technologies and EU data protection norms have resulted in a publication.[5]

[5] See Zhicheng He, 'Privacy-Enhancing Technologies for Active and Assisted Living: What Does the GDPR Say?', *Proceedings of the 15th International Conference on PErvasive Technologies Related to Assistive Environments* (Association for Computing Machinery 2022) <https://doi.org/10.1145/3529190.3534719> accessed 1 August 2022.

Maksymilian Kuźmicz

2. General product safety regulations

One of the very first questions concerning AAL is whether we can classify it as a product (good), or as a service.[6] This classification is vital as different legal norms apply to products than to services. Legislation is more developed and detailed in the case of products than services, due to historical reasons. In the EU, the Product Liability Directive (PLD),[7] which lays down fundamental rules governing liability for defective products in the EU, is applicable only to products, not to services. There are no clear criteria which allow for a sharp border to be drawn between products and services. Usually, the most frequently used ones are: tangibility (products are tangible, services are not), possibility to be stored (products can be stored, services cannot), and the determining factor for quality (production in case of products, interaction in case of services).[8] PLD defines product as "all movables even if incorporated into another movable or into an immovable" (art. 2). In the General Product Safety Directive (GPSD)[9], product means "any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned" (art. 2(a)). That definition aims to limit the scope of the PLD to the products sold to consumers but does not provide criteria to define products as such. A more detailed definition

[6] Problem noticed also by the European Parliament: European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence, 2020/2014(INL), n. 8.

[7] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ *L 210,* 07/08/1985, p. 0029 - 0033.

[8] Parry G., Newnes L., Huang X., "Goods, Products and Services" [in:] *Service Design and Delivery. Service Science: Research and Innovations in the Service Economy*, (eds.) Macintyre M., Parry G., Angelis J., 2011, https://doi.org/10.1007/978-1-4419-8321-3_2

Gadrey J., "The Characterization of Goods and Services" 2005 *The Review of Income and Wealth* 46, https://doi.org/10.1111/j.1475-4991.2000.tb00848.x.

[9] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 011, 15/01/2002, p. 0004 - 0017.

may be found in the VAT Directive[10], where goods are understood as “tangible property” (art. 14(1)), and in the proposed Common European Sales Law[11], that defines goods as “tangible movable items” (art. 2(h)). The proposed Regulation on General Product Safety[12] significantly amends the definition laid down in GPSD by stating that “product means any item, interconnected or not to other items, supplied or made available, whether for consideration or not, in the course of a commercial activity including in the context of providing a service – which is intended for consumers or can, under reasonably foreseeable conditions, be used by consumers even if not intended for them” (art. 3(1)).

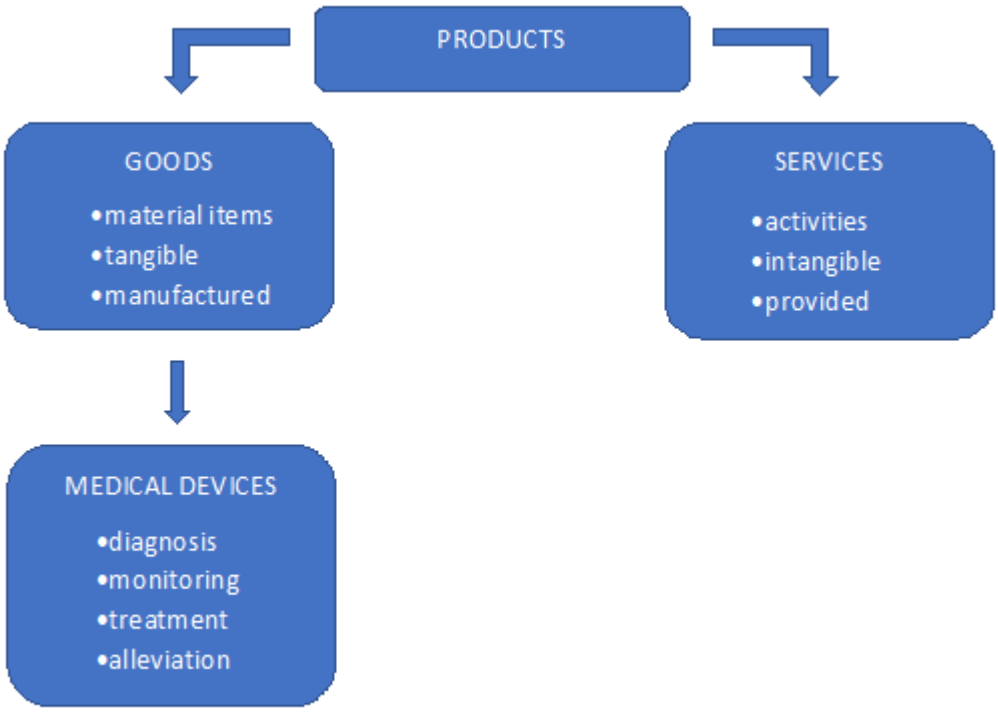

Figure 1. Division of products into goods and services

[10] Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax, OJ L 347, 11/12/2006, p. 1.

[11] Proposal for a Regulation of the European Parliament and of the Council on a Common European Sales Law, COM/2011/0635 final - 2011/0284 (COD).

[12] Proposal for a Regulation of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council, COM/2021/346 final.

There was a lack of clarity surrounding the extent to which software applications may fall into the scope of a product safety laws. In the context of the EU law, the Commission stated that “software that is not a medical device may fall under the ambit of the General Product Safety Directive. However, it is equally possible that the software in question falls outside the regulatory framework altogether to the extent that the product is not manufactured”.[13] Moreover, in the case C-502/13 Commission v. Luxembourg,[14] the Court classified e-books as “electronically supplied services”. However, in the case C-410/19 TSI v CA,[15] CJEU ruled that “the concept of ‘sale of goods’ must be interpreted as meaning that it can cover the supply, in return for payment of a fee, of computer software to a customer by electronic means where that supply is accompanied by the grant of a perpetual licence to use that software”. After the judgement, it seems that the main factor which determines if a software is a good or service is the type of licence. If the licence is perpetual, the software shall be considered as a good, while if temporary, it could be considered as a software. Further case law may bring more clarity in that matter.

After deciphering whether an AAL system constitutes a product or a service, it is next important to determine whether it is a medical good and/or service. Medical products and services are governed by stricter regimes, imposing higher norms and stricter liability. If we agree that AAL systems do not support people just because of their age but because of limited ability caused by ageing, then such systems may be covered by Medical Device Regulation.[16] Art. 2(1) of the Regulation defines a medical device as an “any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: […] - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability”. However, given the lack of case law, it is not clear whether the presented interpretation will be accepted. These issues are discussed more in details in the following chapter.

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[13] European Commission, Commission Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps (EU Framework Working Document), COM (2014) 219 final.

[14] Case C-502/13, Commission v Luxembourg, ECLI:EU:C:2015:143.

[15] Case C-410/19, TSI v CA, ECLI:EU:C:2021:742.

[16] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1–175.

Even if AAL systems would not be classified as medical devices, they still fall into the scope of numerous legal norms regulating general product safety. This means that individuals may be able to bring a claim for injury caused by the defect of a product. PLD states that “a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account” (art. 6(1)). Those defects may be of various nature and be connected with the manufacturing, design, presenting and marketing of the product (art. 6 and 7 PLD). Moreover, most national laws of the EU Member States establish liability resulting from negligence (fault-based liability), or a strict liability regime (non-fault liability).[17] However, as these doctrines are fact-intensive, information about the logic of the AAL system and information about its functioning at the moment of a harmful event would be necessary for a successful claim.[18]

[17] Andoulsi I., Wilson P., “Understanding Liability in eHealth: Towards Greater Clarity at European Union Level” [in:] *eHealth: Legal, Ethical and Governance Challenges*, (eds.) George C., Whitehouse D., Duquemoy P., 2012.

[18] Terry N.P., “Mobile Health and Wearable Technologies: Systemic Liability” 2015 *American Association for the Advancement of Science Workshop*, https://www.aaas.org/sites/default/files/Terry%20Mobile%20Health%20and%20Wearable%20Technologies%20Systemic%20Liability.pdf.

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3. Medical device regulation

According to Merriam-Webster Dictionary, safety means 'the condition of being safe from undergoing or causing hurt, injury, or loss'.[19] There is no doubt that users of AAL are entitled to comprehensive safety. In fact, people use AAL solutions in pursuit of a healthier and more independent life at their homes, i.e., more safety under their private dwellings. Therefore, the safety of products and systems is an extremely important consideration.

Countries have different product safety regulations for different products. For example, in the field of AAL solutions, relevant EU product safety regulations include, among others, General Product Safety Directive, Medical Devices Regulation, Radio Equipment Directive, and Machinery Directive. Which law applies to which product depends on the feature of that product (for example the 'intended use').[20] However, whether and to what extent the required safety of products is protected under the legal frameworks remain uncertain. This results from the diversity of AAL solutions and the complexity of the legal frameworks of product safety.

Given the importance of medical safety, many countries have enacted specific medical device regulations, such as the EU and China. Medical device regulations define what is medical device and set out specific safety requirements for them. Generally, safety requirements for medical device are stricter than those towards consumer products. Therefore, whether a product is a medical device or not decides what norms apply to it and thus the safety standards to be met.

A major question is whether AAL technologies constitute medical devices.[21] Traditionally, the term medical device is more often used in treatments in medical settings, such as hospitals. But with the advances in telemedicine, self-management tools, an emerging trend of healthcare is the shift from the hospital to home-based care and the extension of care beyond the formal healthcare systems.[22]

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[19] Merriam-Webster, 'Definition of SAFETY' (*Merriam-Webster*) <https://www.merriam-webster.com/dictionary/safety> accessed 17 February 2022.
[20] Colonna (n 2).
[21] Sara Gerke, Timo Minssen and Glenn Cohen, 'Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare', *Artificial Intelligence in Healthcare* (Elsevier 2020) <https://linkinghub.elsevier.com/retrieve/pii/B9780128184387000125> accessed 5 May 2021.
[22] Bengt Andersson and others, Healthcare and Care through Distance-Spanning Solutions – 24 Practical Examples from the Nordic Region (Nordic Welfare Centre 2020).

Interviewees from a UK Government-commissioned report responded that it is getting more difficult to distinguish between a wellbeing device and a medical device.[23] Digital technologies applied in the AAL context is just an example that demonstrates this trend. However, this trend may create a regulatory "grey zone" and raise legal issues such as whether such technologies (e.g., digital self-management tools) fall into the scope of medical devices.

Even if a health monitoring tool is not a medical device, it may still be regulated by more general product safety regulations, such as the EU General Product Safety Directive. But this may not always be the case. It was noted that whether the General Product Safety directive applies to eHealth applications that are not medical devices is not clear because the directive applies to 'manufactured products' but not software.[24] In this connection, whether an AAL solution is provided as a product or a service may also bring legal uncertainties under general product safety regulations.[25] This is because these types of regulations normally regulate 'products' that have a physical shape, but it is not always clear whether and how do product safety regulations apply to services. The interaction between AAL technologies and the general product safety regulations is discussed in more detail in Section 2 above.

The status of standalone software under the legal frameworks of product safety regulations may be complex. The first question in this regard is whether an AAL solution that is based purely on standalone software can be classified as medical device. The UK National Health Service (NHS) has noted this complexity for developers. NHS reported that half of all developers did not intend to seek EU CE marking, which means that they did not intend their products to be categorised as medical devices. This resulted from the ambiguity and misunderstanding of whether algorithms constitute medical devices.[26]

US and EU legislations base their determination on the intended use of the software. This means that under US and EU laws, healthcare software or algorithms can be

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[23] Jack Malan and others, 'Framing the Nature and Scale of Cyber Security Vulnerabilities within the Current Consumer Internet of Things (IoT) Landscape' 102.

[24] Nadezhda Purtova, Eleni Kosta and Bert-Jaap Koops, 'Laws and Regulations for Digital Health' in Samuel A Fricker, Christoph Thümmler and Anastasius Gavras (eds), *Requirements Engineering for Digital Health* (Springer International Publishing 2015) <https://doi.org/10.1007/978-3-319-09798-5_3> accessed 15 June 2021.

[25] Colonna (n 2).

[26] NHSX, 'Artificial Intelligence: How to Get It Right Putting Policy into Practice for Safe Data-Driven Innovation in Health and Care' (2019) <https://www.nhsx.nhs.uk/ai-lab/explore-all-resources/understand-ai/artificial-intelligence-how-get-it-right/>.

regulated as medical devices, subjecting them to the regulatory requirements under medical regulations.[27] But a problem with basing such determination on the "intended use" is that the regulatory responsibilities may be easily circumvented on the ground that the "actual use" of such products differs from their "intended use".[28]

The status of the end users of AAL solutions may also bring complexity in the determination of what laws apply and who takes what responsibility. While many AAL solutions were used or expected to be used by users in their private home outside of medical settings, these solutions may well be prescribed or recommended by professional healthcare providers, such as doctors or nurses. Depending on the exact context, users may be considered patients or consumers, which will have an impact on what rights they are entitled in the case of a damage.

[27] World Health Organization, *Ethics and Governance of Artificial Intelligence for Health: WHO Guidance* (World Health Organization 2021) <https://www.who.int/publications/i/item/9789240029200>.

[28] Timo Minssen, Marc Mimler and Vivian Mak, 'When Does Stand-Alone Software Qualify as a Medical Device in the European Union?—The Cjeu's Decision in Snitem and What It Implies for the Next Generation of Medical Devices' (2020) 28 Medical Law Review 615.

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4. Cybersecurity

The security of AAL technologies is dual faceted. It concerns not only product safety, but also cybersecurity. While the emphasis used to be more placed on the physical safety of a product, the importance of cybersecurity has becoming more recognised given the rapid advancement of emerging information technologies in practice and beyond.

Government agencies are paying attention to cybersecurity concerns of digital health technologies and solutions. For example, a UK government-commissioned report found that consumer wearable health-tracking devices collect a large amount of health data. These devices can communicate with each other through wireless protocols such as Wi-Fi and Zigbee, which are both not properly encrypted.[29] Another report issued by the European Union Agency for Network and Information Security (ENISA) found that IoT products used in smart home environment contexts may cause severe security concerns, but the industry lacks the incentive to enhance security.[30] One of ENISA's recommendations is that EU policymakers should adopt clearer liability rules.[31]

These cybersecurity concerns need rapid regulatory responses. Legal scholars also recognised that cybersecurity is an important legal issue in relation to the use of emerging information technologies (such as AI) in healthcare.[32] Countries are waking up and acting. In the EU, relevant cybersecurity instruments introduced in the last decade include, among others, the GDPR (especially Article 32), the Network and Information System Security Directive (NIS Directive) and the Cybersecurity Act. The NIS Directive is expected to be updated by the Directive on measures for a high common level of cybersecurity across the Union (NIS 2 Directive), which will effectively oblige more organisation to take cybersecurity measures. The draft NIS 2 Directive has been endorsed by the Council and the European Parliament and is

[29] Malan and others (n 9).
[30] European Union Agency For Network And Information Security, 'Security and Resilience of Smart Home Environments' (European Union Agency For Network And Information Security 2015) Report/Study <https://www.enisa.europa.eu/publications/security-resilience-good-practices> accessed 9 May 2021.
[31] ibid.
[32] Gerke, Minssen and Cohen (n 7).

pending final approve by the co-legislators.[33] Cases like WannaCry (the attack on the UK NHS system) has motivated the creation of the new EU Cybersecurity Act, which sets out the European cybersecurity certification framework.[34] In China, various laws, regulations and standards in relation to cybersecurity were adopted in the last few years, including the 2016 Cybersecurity Act, the 2021 Regulations on the protection of critical information infrastructure and so on.

[33] See more updates on NIS 2: https://www.europarl.europa.eu/thinktank/en/document/EPRS_BRI(2021)689333.
[34] ibid.

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5. Competition law

Legal questions concerning AAL systems arise also in the field of competition law (antitrust law in common law tradition). It is very much aligned with the fact that the effectiveness of such systems is possible thanks to the big scale of the business. One can say that they are data-run and every new client can support significant development of offered product/service by providing new data for the AI. It encourages companies to expand, marge and cooperate.

The first question in the context of the competition is whether the particular company has got a dominant position in the market. In the case *Hoffmann-La Roche* ECJ defined such a position: "[the dominant position] relates to a position of economic strength enjoyed by an undertaking, which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers".[35] Company fulfilling such conditions is a subject to a specific limitation as their actions may be seen as an abuse of a dominant position, which is prohibited by the art 102 TFEU. Because of the specific market of the AAL presumably, multiple companies will have a dominant position in particular markets.

European law also prohibits cartels, understood as any form of cooperation between undertakings which has as its "object or effect the prevention, restriction or distortion of competition within the internal market" (art. 101(1) TFEU). What is important no formal agreement is needed but just "the meeting of minds".[36] Cooperation of the AAL producers is possible if it "contributes to improving the production or distribution of goods or to promoting technical or economic progress while allowing consumers a fair share of the resulting benefit" (art. 101(3) TFEU) and do not annihilate the competition.

[35] Case C-85/76, *Hoffmann-La Roche,* ECLI:EU:C:1979:36.

[36] Case C-T-8/89, DSM NV v Commission of the European Communities, ECLI:EU:T:1991:76

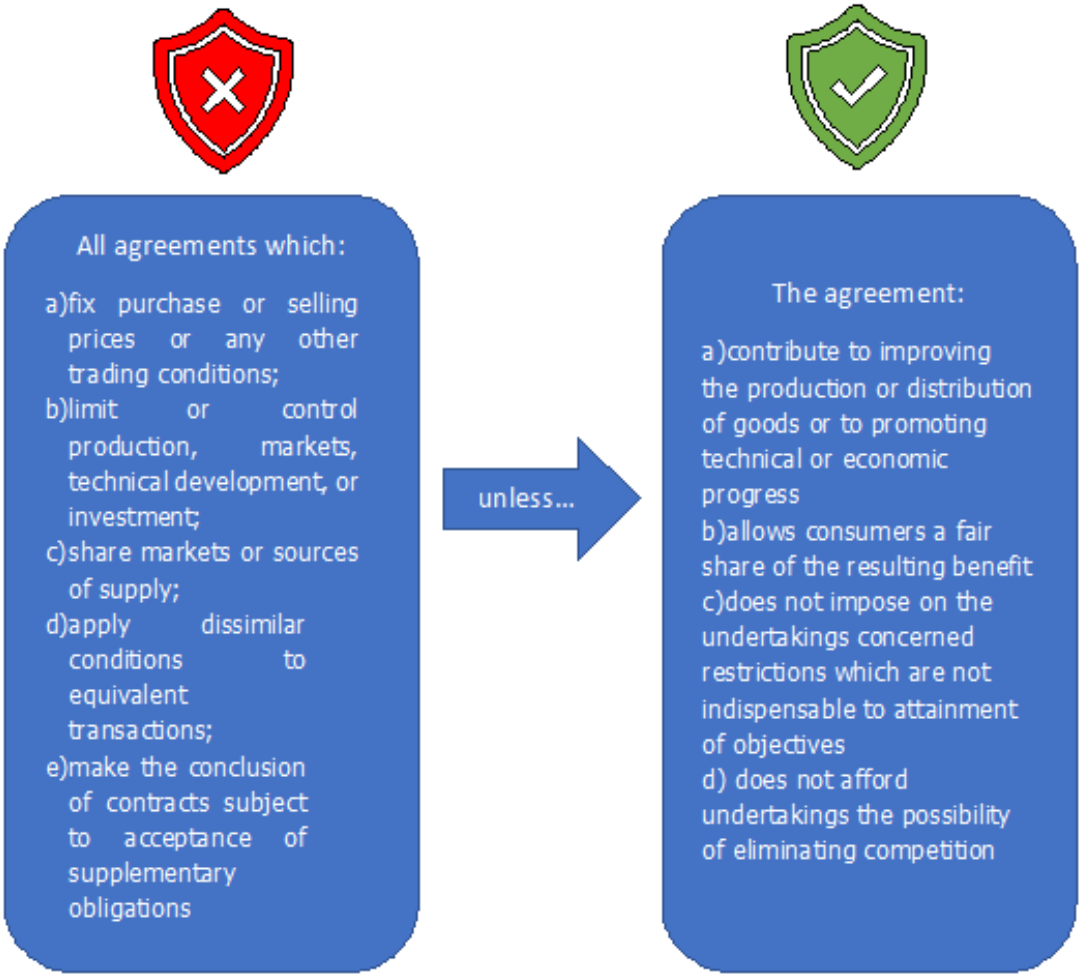

Figure 2. Forbidden and allowed agreements

Possible mergers of AAL companies are not prohibited in the EU but may be subject to the special procedure. The main goal of the EU policy is to prevent concentration which may lead to artificial dominant position or monopolies, and distortion of competition. Whether a merger shall be notified to national authorities or to the European Commission depends on a set of criteria, including global turnover, the number of Member States where the merging companies operate, and their turnover in each country. Issues concerning mergers are regulated in the EU by the Merger Regulation of 2004,[37] updating which the Commission works since 2014.

[37] Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation), OJ L 24, 29.1.2004, p. 1–22.

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6. Consumer protection law

A vital legal issue connected with AAL systems is consumer protection law. In general, it aims to protect individuals who purchase goods and services for their personal use, outside of their profession, from unfair or deceptive business practices. In the EU, it is considered to be a fundamental right, protected by art. 38 of the Charter of Fundamental Rights of the European Union. That article itself does not establish any essential rules but only states that “Union policies shall ensure a high level of consumer protection”. More detailed solutions can be found within multiple legal acts. Out of that mosaic of consumer protection rules, there are four of the biggest relevance for AAL technologies:

1) Consumer Rights Directive,[38]
2) E-Commerce Directive,[39]
3) Unfair Commercial Practises Directive,[40]
4) Directive on certain aspects of the sale of consumer goods and associated guarantees.[41]

[38] Directive 2011/83/EU of the European Parliament and of the Council 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, OJ L 304, 22.11.2011, p. 64–88.

[39] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce'), OJ L 178, 17.7.2000, p. 1–16.

[40] Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (‘Unfair Commercial Practices Directive’), OJ L 149, 11.6.2005, p. 22–39.

[41] Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC, OJ L 136, 22.5.2019, p. 28–50.

Figure 3. Key consumer protection acts

One of the most vital tools of consumer protection is an informational obligation.[42] Information obligation is regulated by various rules of different legal acts, including aforementioned consumer protection directives, but also by the GDPR, and proposed AI Act. In general, a producer or service provider is obliged to give an information about the main characteristics of the goods or services, the work of the product, safety measures that consumer need to comply with, and warnings.[43] The very core of the informational obligation is the right of the consumer to know what they buy.[44] It is not clear till which extend it means that consumer has got a right to understand the mechanics behind the product or the service, and as a consequence till which extend AAL providers are obliged to disclose how their system work.

The arising question is about the special conditions for the transition period in case of changing of the AAL provider. As the system is vital for the well-being of the user and supports their life, it is desirable to guarantee the consumer smooth transition and the

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[42] Grundmann S., Kerber W., Weatherill S., "Party Autonomy and the Role of Information in the Internal Market – an Overview", [in:] *Party Autonomy and the Role of Information in the Internal Market*, (eds) Grundmann S., Kerber W., Weatherill S., 2012.

[43] Kuźmicz M., "Information obligation as a balancing tool in the context of Active and Assisted Living" [in:] ICCHP-AAATE 2022 Open Access Compendium "Assistive Technology, Accessibility and (e)Inclusion", eds. Petz A., Hoogerwerf E-J., Mavrou K., 2022, ICCHP-AAATE 2022 Open Access Compendium "Assistive Technology, Accessibility and (e)Inclusion".

[44] Beales H., Craswell R., Salop S., "The efficient regulation of consumer information" 1981 *Journal of Law and Economics.*

access to the fully functioning AAL system during the transition period. It could be achieved by regulated rules of transition. Law can also demand producers to use devices which can be used with various software and different operators.

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7. Contract law

Buying and selling AAL technology is regulated by the general contract law. There is no harmonised EU contract law, and contracts are governed by national law. However, some aspects of contract law are regulated by the consumer protection law.[45] EU law regulates also a conflict of law rules, i.e., which national law should govern a particular contract, and which court shall have jurisdiction. Brussels Ia Regulation[46] contain rules on which court shall have jurisdiction over a dispute in civil and commercial matters. Providing AAL systems to individuals will be governed by this regulation, but contracts with care facilities or other professional agents fall outside of the scope of the regulation. Law applicable to particular contract is decided based on Rome I Regulation,[47] which in principle gives parties freedom of choice.

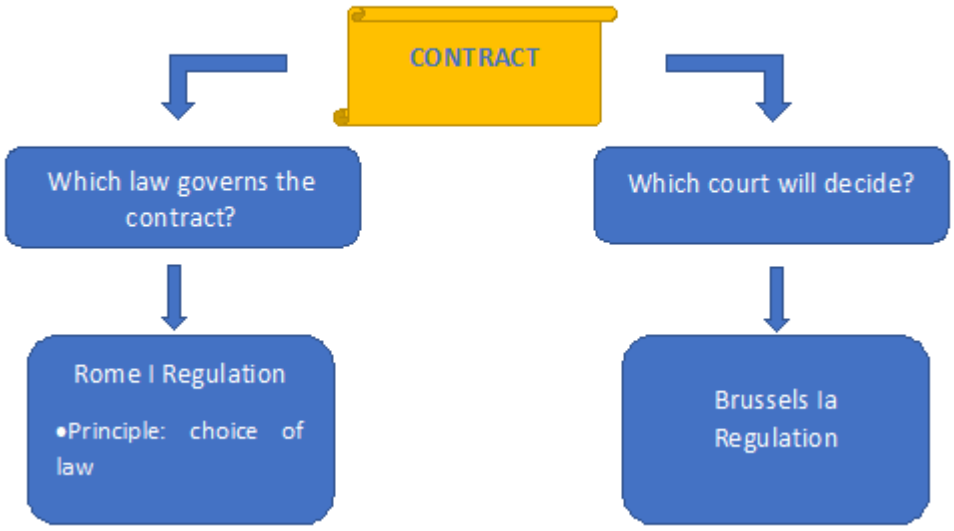

Figure 4. European Private International Law sources

[45] Schurr F. A., "The Relevance of the European Consumer Protection Law for the Development of the European Contract Law" (2007) *Victoria University of Wellington Law Review* 38.

[46] Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, OJ L 351, 20.12.2012, p. 1–32.

[47] Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I), OJ L 177, 4.7.2008, p. 6–16.

The issue of which information should be disclosed is crucial. On the one hand, the buyer has a right to know what the subject of the contract is, which broadly means to understand sufficiently how the system works. It can be argued that the way system works, and what data processes, are essential parts of the characteristic of a contract's object. At the same time, the seller cannot disclose too much without significant financial harm – the value of his product or service is often based on know-how. As the contract law differs among the Member States of the EU, the answer will depend on the market on which the product/service is offered.

In the context of AAL, contracts between professionals may often utilise software licences. Licensing may be understood as a contract between the copyright owner (software developer), and the licensee, which governs the distribution and use of software, including rights to modify the software.[48] Such contracts usually have limited warranties, and precise the users' rights on reverse engineering, exhausting, and reproductions.[49] AAL technologies may require contracts involved in a complex and interconnected environment, that could be challenging for at least two reasons. Firstly, "licensees are expected to have all licensing documents applicable to their infrastructure, at their disposal".[50] Secondly, "each software vendor may opt for their own particular licensing restrictions giving rise to a complex web of legal obligations".[51]

The very personal and sensitive character of the support provided by the AAL systems calls for the special rules for the termination of the agreement. On the one hand, the user should not be left without necessary support without a reasonable notice period. On the other hand, the user shall have the right to demand the immediate termination of providing service, as it is connected with processing the user's data. However, current legal rules do not provide such a possibility. Immediate termination of a contract is usually possible only in the case of breaching of contract.

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[48] O'Regan G., "Legal Aspects of Computing in World of Computing" [in:] O'Regan G., *World of Computing*, 2018.

[49] Mahajan A, "Intellectual Property, Contracts, and Reverse Engineering after PROCD: A Proposed Compromise For Computer Software" 1999 *Fordham Law Review* 67.

[50] Colonna L., "Legal and regulatory challenges to utilizing lifelogging technologies for the frail and sick" 2019 *International Journal of Law and Information Technology* 27, https://doi.org/10.1093/ijlit/eay018.

[51] Ibidem.

The possibility of immediate termination may be included in the contract itself but is not required by law.

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8. Criminal law

AAL technologies implicate criminal law in multiple ways. While some issues, like a criminal liability for recklessness or rules of obtaining data for the purpose of criminal investigation, are already regulated, for the others it is not clear how the law shall deal with them, i.e., the obligation to interfere with the user behaviour if it was recognised as illegal.

Firstly, there is a question of criminal liability for bodily harm or even the death of the user through gross negligence. In general, gross negligence means that an individual has exhibited a wanton and reckless disregard for life or safety.[52] Moreover, in most states, criminal codes also contain crimes of unintentional causing severe harm, and manslaughter, which can be caused also by the operation of the AAL system.

A second issue concerns whether AAL devices should assist in preventing or reporting crimes. Here, a critical issue is whether the AAL tool used is capable of correctly recognizing criminal behaviour. To put it differently, the device must be able to distinguish between unusual, albeit legal behaviour from illegal behaviour. When it comes to the reporting duty, there is a question of how it should be fulfilled: by sending a visual material to the provider of the system and then, after assessment, to the investigatory authorities, or directly to them. Finally, in the case of a non-feasance (i.e. failure to perform an act that is required by law), there is a question of the criminal liability: whether it was negligence or deliberate action, and if we can assign the liability to a particular person (designer, programmer, servicer etc.) which in many jurisdictions is the only way of persecuting for crimes (no criminal liability of legal persons).[53] However, also in that states where the criminal liability of legal persons is provided, distinguishing a responsible individual is still a necessary step to establishing criminal liability of the legal person. In the USA, Canada and the UK, legal persons are criminally liable regardless of the conviction of their representatives whose actions resulted in crime. Multiple EU countries introduce changes towards that solution, although in 5 Member States (Bulgaria, Germany, Greece, Latvia, and Sweden) legal persons are free from criminal liability.

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[52] Horder J., “Gross Negligence and Criminal Culpability” 1997 *University of Toronto Law Journal* 47.

[53] Vermeulen G., De Bondt W., Ryckman Ch., *Liability of legal persons for offences in the EU*, 2012.

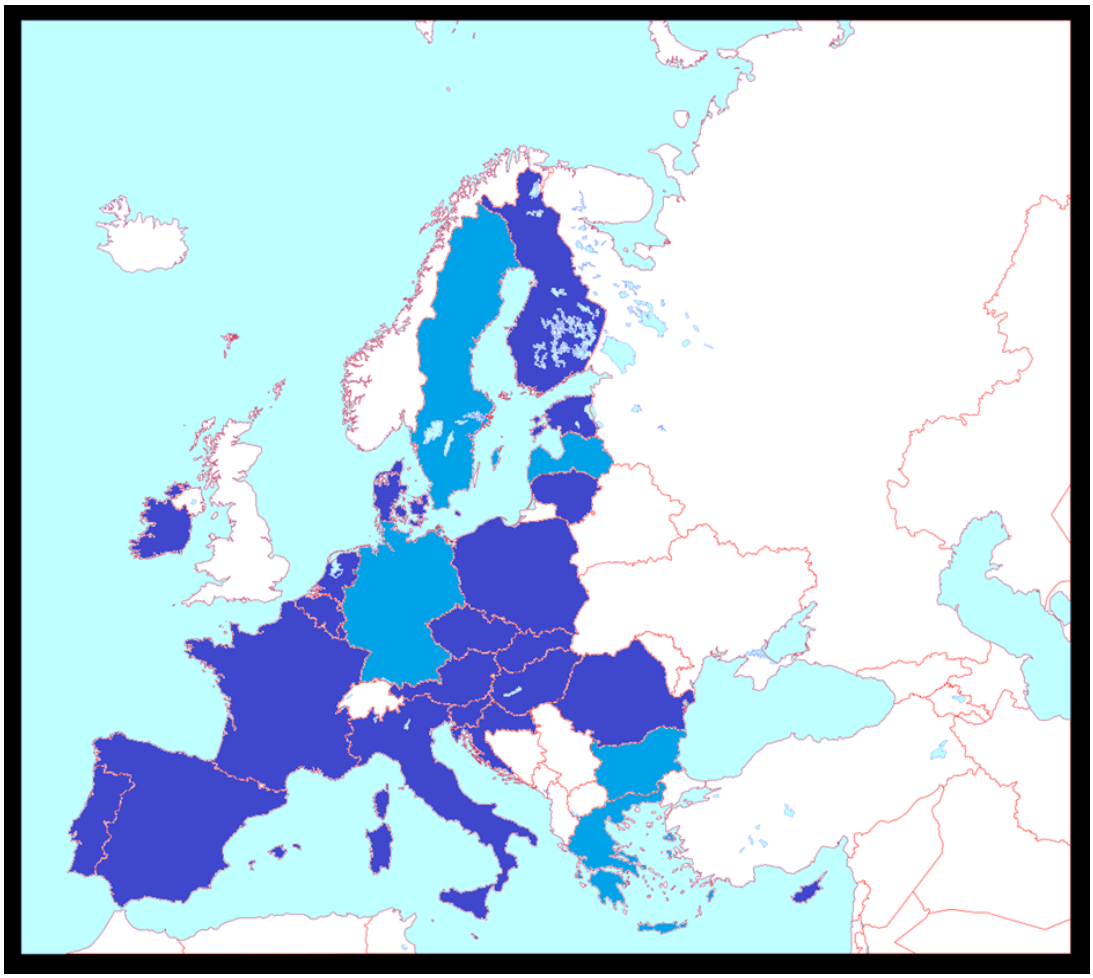

Figure 5. EU countries with criminal liability of legal persons (dark blue), and without (light blue)

It may happen that a person using an AAL system commits a crime. If they were supported by the lifelogging technology, did the provider participate in the criminal offence and to what extent? As a co-perpetrator or as an accessory? This problem is strictly related to the previous one because criminal liability cannot be established without participation in the action. The question of criminal liability for actions committed while using an AAL system is particularly complex when it comes to the attempt of suicide or euthanasia. While not allowed in many countries and punishable, they may be seen as a vital aspect of the right to self-determination,[54]

[54] Heirwegh T., Euthanasia, one's final human right?, 2016.

Zdenkowski G, Human rights and euthanasia, 1997.

Australian Human Rights Commission, *Euthanasia, human rights and the law*, 2016.

Shala I., Gusha K., "The Debate Over Euthanasia and Human Rights" 2016 *European Scientific Journal* 12.

and as consequence providers of AAL systems should not be obliged to stop their users.

There are some crimes that can be committed by the AAL technologies without the active participation of the user or provider, and with the correct functioning system. Recording naked people or people during an intimate action without their consent constitutes a criminal offence in most jurisdictions. In the case of the user, the consent can be presumed from the contract or included in it. Such a solution cannot be applied when it comes to third parties. A question that arises is whether implicit consent is provided when a third party enters the space covered by lifelogging or if the explicit statement given to the user will be sufficient. However, both seem to not protect potential victims from being recorded and they have rather low value as evidence.

Another issue concerns the storage of data and sharing it with public authorities for the purpose of criminal proceedings or the prevention of crimes. AAL devices offer intelligence agencies an abundance of ways to listen and watch a target or to profile an individual or a group of individuals. While the potential strengthening of security is potentially high, the capability of these devices to intrude into the private lives of individuals is perhaps even higher. Critical factors concerning the lawfulness of surveillance include which kinds of data are collected, how long the data is stored and how the data is handled and shared by the authorities. From the perspective of the AAL system's provider, there is also the important question concerning whether information about the functioning of the system, including the algorithm, shall be disclosed, too.

In the EU, AAL providing companies classified as telecommunication providers may be obliged to retain data and then turn these data over to law enforcement agencies.[55] The Convention on Cybercrimes[56] requires that countries have legal

[55] Joined Cases C-203/15 and C-698/15, *Tele2 Sverige AB v Post-och telestyrelsen* and *Secretary of State for the Home Department v Watson and others* , EU:C:2016:970, and C-623/17 *Privacy International,* EU:C:2020:790: CJEU banned a general obligation on providers of electronic telecommunications services to retain data and then specified when data retention is compatible with EU law. In particular, "the instruction for the preventive retention of data of all users of electronic communications systems must be limited in time to what is strictly necessary". (Case C-511/18, *La Quadrature du Net and Others,* EU:C:2020:791). It does not, however, "preclude systematic recording" of traffic data (C-597/19, *M.I.C.M.,* EU:C:2021:492).

[56] Convention on Cybercrime, Budapest 2001.

provisions “to order or similarly obtain the expeditious preservation of specified computer data, including traffic data” (art 16), “to search or similarly access: a) a computer system or part of it and computer data stored therein; and b) a computer-data storage medium in which computer data may be stored” (art 19), and “to: a) collect or record through the application of technical means on the territory of that Party, and b) compel a service provider, within its existing technical capability: i) to collect or record through the application of technical means on the territory of that Party; or ii) to co-operate and assist the competent authorities in the collection or recording of, traffic data, in real-time, associated with specified communications in its territory transmitted by means of a computer system” (art 20).

AAL systems may facilitate the government’s access to its citizens (albeit through their data), and subject citizens to additional scrutiny and approbation. As a result, individual autonomy may be compromised. People aware of being subjected to constant observation, monitoring and judgment may be more pressured to consider the outside world in their internal decision making, which will make their actions not truly voluntary.[57] It provokes another question: can the fact of acting with the functioning AAL device be relevant from a legal point of view and limit the liability of the person?

[57] Nissenbaum H., Privacy in Context: Technology, Policy and the Integrity of Social Life, 2010.

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