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The EU AI Act's Alignment within the European Union's Regulatory Framework on Artificial Intelligence

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Summary: The European Union (EU) Artificial Intelligence (AI) Act is the first horizontal regulation on AI, aiming to regulate the development, placement on the market, and use of AI systems in the EU. The initial proposal was published by the European Commission (EC) in April 2021, and after an intensive three-year period of discussions, revisions, and negotiations, on December 9, 2023, a provisional agreement was reached on the final text. This marked the culmination of a series of ethical policy and legislative foundations that have created a broad and highly influential regulatory framework on AI in the EU. However, the consistency of the final draft within this established institutional environment on AI merits a close examination. This paper studies the AI Act text and its alignment within this framework. It will use the partial institutional analysis method to map the regulatory landscape, identify the most important sources within the said scope, and critically assess their consistency.

Keywords: artificial intelligence, European Union, EU AI act, trustworthy AI, regulatory frameworks, institutional analysis, consistency assessment

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1 Introduction

In April 2021, the EC published its long-awaited proposal for the AI Act.[1] This was followed by the release of the 'General Approach of the Council on the AI Act.[2] On December 9, 2023, the European Parliament and the European Council reached a provisional agreement on the final text, and it was released in 2024.[3] The AI Act establishes the world's first most comprehensive law on AI, aiming to provide AI stakeholders with harmonized rules, obligations and measures regarding the development, placement on the market, and use of AI systems.[4] Despite originating in the EU, this regulation has a global impact potential.[5] The AI Act sorts of AI systems into four risk categories: minimal, limited, high, and unacceptable.[6] It allows for the utilization of minimal risk AI applications and specifies transparency requirements those classified as limited. For applications in the high-risk category, the AI Act imposes strict obligations whereas it bans those classified as unacceptable.[7]

The AI Act, however, does not stand alone. It is integral to a broader regulatory framework and for this reason, discussing its alignment within is crucial to evaluate the capacity of the whole governance system to respond to the needs of the stakeholders in the current process of AI transformation.[8] When examining the academic work published on this subject, a search, spanning from 2021 to 2024 circumscribed to the keywords and expressions 'European Union', 'Artificial Intelligence Act', 'AI Ethics', 'Policy on AI', 'AI Legal Framework', and', 'Trustable AI' was conducted across the Scopus, Web of Science, and editorial specific databases (Taylor and Francis, Emeral, Springer and IEEE) within the social and computer sciences domains. It identified that seven academic publications

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1 EUROPEAN COMMISSION. Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union legislative acts. 2021a. COM (2021) 206 final.

2 COUNCIL OF THE EUROPEAN UNION. Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts – General approach. 2022. [Interinstitutional File: 2021/0106(COD)].

3 COUNCIL OF THE EUROPEAN UNION. Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts. 2024. [Interinstitutional File: 2021/0106(COD)].

4 MAZZINI, Gabriele, BAGNI, Filippo. Considerations on the regulation of AI systems in the financial sector by the AI Act. Frontiers in Artificial Intelligence, 2023, vol. 6, p.4.

5 ALMADA, Marco, RADU, Anca. The Brussels Side-Effect: How the AI Act Can Reduce the Global Reach of EU Policy. German Law Journal, 2024, pp. 1–18.

6 NOVELLI, Claudio, et al. AI Risk Assessment: A Scenario-Based, Proportional Methodology for the AI Act. Digital Society, 2024, vol. 3, no. 1, pp. 1–2.

7 NOVELLI, Claudio, et al. Taking AI risks seriously: A new assessment model for the AI Act. AI & SOCIETY, 2023, pp. 1–5.

8 See also KERIKMÄE, Tanel; MÜÜRSEP, Peeter; PIHL, Henri Mert; HAMUĽÁK, Ondrej; KOCHARYAN, Hovsep. Legal Person or Agenthood of Artificial Intelligence Technologies. Acta Baltica Historiae et Philosophiae Scientiarum, 2020, vol. 8, no. 2, pp. 73–92. ISSN 2228-2009. DOI 10.11590/abhps.2020.2.0.

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out of the thousands of combined results yielded, were relevant enough or focused on the scope of this paper in particular. Smuha et al.'s,[9] Laux et al.'s,[10] and Varošanec's[11] are notable, for having undertaken an early assessment of the AI Act's conformity within the ethical foundation. Specifically, Laux et al. articulate a critique regarding the European Union's oversimplified conceptualization of trust with this regulation. Concurrently, Floridi et al.[12] developed a procedure called capAI to scrutinize the AI Act's consistency within the EU ethical foundations on AI, which was extended by Alì & Yu,[13] Justo-Hanani,[14] and Raposo.[15] The first two also studied the consistency between the AI Act and the EU policy background, while Raposo's paper between the AI Act and the other laws. Nevertheless, they have relied on the first draft and concentrated a single type of regulatory source, be it the ethical principles, the policy or legislative initiatives. Not only the AI Act has undergone changes between the publication of the first and final drafts, but it is opportune and necessary to go through the final version and reexamine its alignment within the complete regulatory framework that could be considered foundational to the governance of AI in the EU and, most probably, in the world.

This paper uses a methodological approach relying on a partial institutional analysis to map the regulatory landscape focusing on ethical, policy and legal foundations at the EU level and identify the most important sources. As Joamets & Vasquez[16] explained, this method is a practical way to understand the value of various types of regulations as the structured manifestation of collective values and norms in given contexts. In this paper, the institutions under review are formalized ethics, public policy and law. Ethics provides the moral compass needed to navigate the complexities and challenges AI technology poses to society

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9 SMUHA, Nathalie A, et al. How the EU Can Achieve Legally Trustworthy AI: A Response to the European Commission's Proposal for an Artificial Intelligence Act. SSRN Scholarly Paper, 2021, pp. 1–64.

10 LAUX, Johann, WACHTER, Sanda, MITTELSTADT, Brent. Trustworthy artificial intelligence and the European Union AI act: On the conflation of trustworthiness and acceptability of risk. *Regulation & Governance*, 2024, vol. 18, no. 1, pp. 3–32.

11 VAROŠANEC, Ida. On the path to the future: Mapping the notion of transparency in the EU regulatory framework for AI. *International Review of Law, Computers & Technology*, 2022, vol. 36, no. 2, pp. 95–117.

12 FLORIDI, Luciano, et al. capAI – A Procedure for Conducting Conformity Assessment of AI Systems in Line with the EU Artificial Intelligence Act. *SSRN Scholarly Paper,* 2022, pp. 1–82.

13 ALI, Gabriele Spina, YU, Ronald. Artificial Intelligence between Transparency and Secrecy: From the EC Whitepaper to the AIA and Beyond. *European Journal of Law and Technology,* 2021, vol. 12, no. 3, pp. 1–25.

14 JUSTO-HANANI, Ronit. The politics of Artificial Intelligence regulation and governance reform in the European Union. Policy Sciences, 2022, vol. 55, no. 1, pp. 137–159. https://doi.org/10.1007/s11077-022-09452-8

15 RAPOSO, Vera Lúcia. Ex machina: Preliminary critical assessment of the European Draft Act on artificial intelligence. *International Journal of Law and Information Technology*, 2022, vol. 30, no. 1, pp. 88–109.

16 JOAMETS, Kristi, VASQUEZ, Maria Claudia Solarte. Regulatory Framework of the Research-Based Approach to Education in the EU. TalTech Journal of European Studies, 2020, vol. 10, no. 3, p. 111.

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(Robles Carrillo, 2020),[17] policy refers to the operational guidelines established at the supranational level (EU system) supporting AI's adherence to established standards and objectives,[18] and law defines the rules that are enforceable because they have been passed following the corresponding legislative procedure.[19] The sources selected will be organized systematically based on their semantical elements, coding the terms and subject matter of their provisions. These elements will represent the deep documental breakdown aimed at gathering data against which that the interpretative assessment will follow.

Moreover, as the principles of AI trustworthiness,[20] human-centricity,[21] and excellence [22] prominently surface not just in the normative discourse within the overarching framework but also in academic literature, they are key departure points in the exploration of aspects concerning the coherence and synergy of the final draft of the AI Act with regulations outlined in the AI Governance framework.

The next section is a short conceptual background. The third section presents the institutional analysis and details the selected sources among existing regulatory framework. The fourth conducts the consistency assessment providing insights into the AI Act's alignment. The last section concludes the findings, highlights the contributions of this paper.

2 Background

This section defines the key concepts explored in the literature that were used while establishing the foundation for the methodological approach and tools employed in the alignment assessment. The scope of this paper is also shaped by these conceptual foundations, which call for proper delineation of the meanings that inform this research. First, several annotations are needed concerning the partial institutional analysis, which is generally connected to the area of legal sociology studies.[23] In this work, even though intending to look for path dependencies in legal development as well as complementarities and

17 ROBLES CARRILLO, Margarita. Artificial intelligence: From ethics to law. *Telecommunications Policy*, 2020, vol. 44, no. 6, pp. 1–16.

18 JUSTO-HANANI (n. 13).

19 GREENSTEIN, Stanley. Preserving the rule of law in the era of artificial intelligence (AI). *Artificial Intelligence and Law*, 2022, vol. 30, no. 3, pp. 291–323.

20 HUPONT, Isabelle, et al. The landscape of facial processing applications in the context of the European AI Act and the development of trustworthy systems. *Scientific Reports*, 2022, vol. 12, no. 1, pp. 1–14.

21 SIGFRIDS, Anton, et al. Human-centricity in AI governance: A systemic approach. *Frontiers in Artificial Intelligence*, 2023, vol. 6, pp. 1–9.

22 NIKOLINAKOS, Nikos Th. A European Approach to Excellence and Trust: The 2020 White Paper on Artificial Intelligence. In NIKOLINAKOS, Nikos Th (ed), *EU Policy and Legal Framework for Artificial Intelligence, Robotics and Related Technologies—The AI Act*. Springer International Publishing, 2023, pp. 217–220.

23 SCHNEIBERG, Marc, Clemens, Elisabeth S. The Typical Tools for the Job: Research Strategies in Institutional Analysis*. *Sociological Theory*, 2006, vol. 24, no. 3, pp. 195–227.

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compatibilities between rules, in the interest of precision, the method is used narrowly. Therefore, it remains at the level of the study of formal and informal institutions on AI regulatory framework at the EU level. Formal institutions are not only the entities characterized by established, codified rules and structures, such as legal systems and government agencies and corporations, but also the normative expressions that they issue, such as policies, laws and administrative orders, that may be enforced by an authoritative body.[24] In contrast, informal institutions are based on unwritten rules, traditions, and social practices that govern individuals' behaviours and societal expectations,[25] or soft laws and standards that do not have the intensity and level of formalization of the binding ones. These all form a body of rules that comprise a regulatory environment which encapsulates regulatory frameworks across diverse subject matters and jurisdictions.

In here, distinguishing between ethics, policy and law in the regulatory framework of AI is important, but so it is to understand the alignment among principles, policies and legal acts.[26] Because it ensures coherence,[27] facilitates innovation while increasing safety and trust.[28] Such considerations are also seen to address societal changes and guides responsive legislative development.[29] Legal and policy alignment refers to the creation of synergy inside the regulatory frameworks that systematically assess and address the sociotechnical changes enabled by technologies like AI, focusing on when and why these changes necessitate new regulations.[30] Consequently, the EU 'regulatory framework' of AI refers to the structured set of ethical guidelines, policies and laws developed to govern the development, placement on the market, and use of these systems.[31] It

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24 JOAMETS (n. 13) pp. 119–122.

25 Ibid pp. 116–119.

26 See e.g. BROWN, Rafael; TRUBY, John; IBRAHIM, Imad Antoine. Mending Lacunas in the EU's GDPR and Proposed Artificial Intelligence Regulation. *European Studies – the Review of European law, Economics and Politics*. 2022, vol. 9, no. 1, pp. 61–90, DOI: 10.2478/eustu-2022-0003.

27 CUBIE, Dug, NATOLI, Tommaso. Coherence, Alignment and Integration: Understanding the Legal Relationship Between Sustainable Development, Climate Change Adaptation and Disaster Risk Reduction. In FLOOD, Stephen, et al. (eds). *Creating Resilient Futures: Integrating Disaster Risk Reduction, Sustainable Development Goals and Climate Change Adaptation Agendas*. Springer International Publishing, 2022, pp. 51–57.

28 PATANAKUL, Peerasit, PINTO, Jeffrey K. Examining the roles of government policy on innovation. *The Journal of High Technology Management Research*, 2014, vol. 25, no. 2, pp. 97–107.

29 (SOLARTE-VASQUEZ, Maria Claudia, HIETANEN-KUNWALD, Petra. Responsibility and Responsiveness in the Design of Digital and Automated Dispute Resolution Processes: Internationales Rechtsinformatik Symposium Iris 2020. *Verantwortungsbewusste Digitalisierung / Responsible Digitalization*, 2020, pp. 452–455.; LIU, Fanjue, et al. When citizens support AI policies: The moderating roles of AI efficacy on AI news, discussion, and literacy. *Journal of Information Technology & Politics*, 2023, vol. 0, no. 0, pp. 1–17.)

30 MAAS, Matthijs M. Aligning AI Regulation to Sociotechnical Change*, SSRN Scholarly Paper,* 2021, pp. 13–16.

31 O'SULLIVAN, Shane, et al. Legal, regulatory, and ethical frameworks for development of standards in artificial intelligence (AI) and autonomous robotic surgery. *The International Journal of Medical Robotics and Computer Assisted Surgery*, 2019, vol. 15, no. 1, pp. 1–12.

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could be argued that this framework has been forming since the adoption of the *General Data Protection Regulation of the EU* (GDPR) in 2016,[32] and it includes a wide range of sources such as *European Commission Staff Working Document: Liability for Emerging Digital Technologies*,[33] *Coordinated Plan on Artificial Intelligence 2021 Review*,[34] or the *Proposal for an AI Liability Directive*.[35]

At the same time, this framework reflects an emerging governance system of AI. By which is meant the overall approach including the various institutionalized tools, solutions, and levers that influence the development, placement on the market, and use of AI technologies, as suggested in Butcher & Beridze stated without excluding the various existing actions promoting ethics and trust in this technology.[36] Ethics in AI are the principles and practices that ensure AI technology is developed and used in ways that are fair, unbiased, non-discriminatory, and beneficial to society, with special attention to avoiding unintended consequences and protecting vulnerable population.[37] Choung et al. states that the determination of such standards demands a fine-tuned balance between using the benefits of AI and adhering to societal norms and values.[38] Ethical AI, in essence, gets human closer to trusting these technologies. In turn, trust in AI should be understood as a multidimensional and multilevel construct linked to human-like trust and functionality trust in AI systems. The former is about AI's benevolence and integrity, akin to the social and cultural values associated with the algorithms and the ethics underlying the design of AI technology. The latter, pertains to the reliability, competency, expertise, and robustness of AI. This conceptualization acknowledges the complexity of trust by distinguishing between trust in the technology's functional capabilities and trust in its coincidence with human values and ethical principles.[39] In addition, this understanding does not equal trust and trustworthiness as a feature or attribute of AI. Trustworthiness is a quality of being worthy of trust. It refers to the characteristics or behaviours of an individual or

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32 REGULATION (EU) 2016/679 of the European Parliament and of the Council 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 (General Data Protection Regulation), OJ L119, 4.5.2016, pp. 1–88.

33 EUROPEAN COMMISSION. Commission Staff Working Document: Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts. 2021b. SWD(2021) 84 final.

34 EUROPEAN COMMISSION. Coordinated Plan on Artificial Intelligence 2021 Review. 2021c. COM(2021) 205 final.

35 EUROPEAN COMMISSION. Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive). 2022. COM(2022) 496 final.

36 BUTCHER, James, BERIDZE, Irakli. What is the State of Artificial Intelligence Governance Globally? *The RUSI Journal,* 2019, vol. 164, no. 5–6, pp. 88–96.

37 HAGENDORFF, Thilo. The Ethics of AI Ethics: An Evaluation of Guidelines. *Minds and Machines*, 2020, vol. 30, no. 1, pp. 99–120.

38 HOUNG, Hyesun, DAVID, Prabu, ROSS, Arun. Trust and ethics in AI. *AI & SOCIETY*, 2023, vol. 38, no. 2, pp. 735–736.

39 Ibid

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entity that inspire trust. Trustworthiness is evaluated based on factors such as integrity, reliability, competence, and communication. It is more objective than trust and can be assessed through evidence of past actions, reputation, and other indicators that suggest a party is likely to be reliable in the future.[40]

In view of the relevance assigned to 'human-centricity' and 'excellence' in AI governance, these are code words becoming as crucial as 'trust' and 'ethics'. Sigfrids et al explained 'human-centricity' from two perspectives; design and policy application.[41] While the design perspective is enhancing human-technology interactions and human performance by prioritizing human needs, capabilities, and values of AI products, the policy applications perspective relates to the integration of ethical and human rights principles to guide AI development and deployment, intended to enhance human welfare and freedom while ensuring respect for fundamental rights.[42] This paper focuses on this last perspective. 'Excellence' in the context of AI governance is connected to the creation of an ecosystem with certain features. While the denotative meaning of excellence is "t*he quality of being outstanding and involves surpassing ordinary standards through, consistently delivering superior performance or results.*"[43], this study relies in the understanding of Nikolinakos,[44] on technical excellence in engineering and software development. His definition centres on crafting durable, efficient, and cost-effective systems, to which attention to details is given. It demands adherence to high coding and design standards, ensuring systems are scalable and maintain performance integrity. Other codes such as 'lawful' or 'robust' are explained in the assessment section.

3 Partial Institutional Analysis

The descriptive part of the analysis of informal (ethics) and formal (policies and laws) institutions at the EU level for the development, placement on the market, and use of AI technologies consists of two stages. The first is mapping of normative sources, and the second is selecting and detailing the most important according to their intended scope of application and hierarchical significance.

3.1 Mapping of Normative Sources in the AI Regulatory Framework at the EU Level

Several institutionalization efforts have been made to regulate AI through normative sources by public and private entities at national and supranational levels. This survey focuses specifically on the publications by public entities within the EU. These publications are classified into three main groups: ethical, policy,

40 CARTER, J. Adam. Trust and trustworthiness. *Philosophy and Phenomenological Research,* 2023, vol. 107, no. 2, pp. 379–382.

41 SIGFRIDS (no. 20).

42 Ibid

43 Merriam-Webster. (2024) Excellence. [online]. Available at: <https://www.merriam-webster.com/dictionary/excellence> Accessed: 13.03.2024

44 NIKOLINAKOS (no.21).

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and legal, to establish a structured framework, as illustrated in **Table 1.** They were selected because they are concerned with the essential aspects of AI governance: ethics, strategy, and legality. The timing and objectives of these sources are also critical, serving as key milestones in the evolution of the regulatory framework. This led up to the formulation of the AI Act.

Table1: Outline of the European Union's Regulatory Framework on Artificial Intelligence

Category	Sources
Ethical	Ethics Guidelines for Trustworthy AI[45] Policy and Investment Recommendations for Trustworthy Artificial Intelligence[46] Sectoral Considerations on the Policy and Investment Recommendations for Trustworthy Artificial Intelligence[47]
Policy	Communication: Artificial intelligence for Europe[48] European Commission Staff Working Document: Liability for Emerging Digital Technologies[49] Communication: Building Trust in Human Centric Artificial Intelligence[50] White Paper on Artificial Intelligence: A European approach to excellence and trust[51] Impact Assessment of the Regulation on Artificial intelligence[52] Coordinated Plan on Artificial Intelligence 2021 Review[53]
Legal	General Data Protection Regulation of the EU (GDPR)[54] Proposal for an AI Liability Directive[55] Digital Service Act[56] Digital Market Act[57] Data Governance Act[58] General Product Safety Regulation[59] Data Act[60] Final Draft of The EU AI Act[61]

Source: Table prepared by the authors.

45 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION. Ethics guidelines for trustworthy AI. 2019a.

46 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION. Policy and Investment Recommendations for Trustworthy AI. 2019b.

47 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION. Sectoral Considerations on the Policy and Investment Recommendations for Trustworthy Artificial Intelligence. 2020.

48 EUROPEAN COMMISSION. Artificial Intelligence for Europe. 2018a. COM(2018) 237 final

49 EUROPEAN COMMISSION. European Commission Staff Working Document: Liability for Emerging Digital Technologies. 2018b. COM(2018) 237 final.

50 EUROPEAN COMMISSION. Building trust in human-centric artificial intelligence. 2019. COM(2019) 168 final.

51 EUROPEAN COMMISSION. White Paper on Artificial Intelligence: A European approach to excellence and trust. 2020. COM(2020) 65 final.

52 EUROPEAN COMMISSION (No. 31).

53 EUROPEAN COMMISSION (No. 32).

54 REGULATION (EU) 2016/679 (No. 30).

55 EUROPEAN COMMISSION. Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive). 2022. COM(2022) 496 final.

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The sources from the first 'Ethical' category begin with the *Ethics Guidelines for Trustworthy AI* that introduce this foundational concept for the development, deployment, and use of trustworthy AI. The *Policy and Investment Recommendations for Trustworthy Artificial Intelligence* offer strategies to foster sustainability, economic growth, competitiveness, and inclusivity. The *Sectoral Considerations on the Policy and Investment Recommendations for Trustworthy Artificial Intelligence* details tailored recommendations across various sectors, aimed at enhancing the application of AI in specific fields.

From the second 'Policy' category, the *Communication: Artificial intelligence for Europe* sets the first-ever strategy focusing on the opportunities and challenges posed by AI. The *European Commission Staff Working Document: Liability for Emerging Digital Technologies* identifies the legal challenges that immersive technologies such as AI, Internet of Things (IoT) pose to the existing EU legislation due to their novel technical and operational characteristics. The *White Paper on Artificial Intelligence: A European approach to excellence and trust* sets policy to ensure compliance with European values and fundamental rights, on AI: with the publication of this significant source, the concepts of excellence and trust have prominently emerged. The *Coordinated Plan on Artificial Intelligence 2021 Review* builds on the collaboration between the EC and member states to set out the strategies for the investment, legislative actions, and the alignment of AI policies. The *Impact Assessment of the Regulation on Artificial Intelligence* evaluates the case for action, the objectives, and the effect of different policy options for a European framework for AI.

Finally, from the last 'Legal' category, the *GDPR* is listed as the first initiative in the regulatory framework. It establishes rules for safeguarding the privacy of natural persons in relation to personal data processing, including automated decision-making. The *Proposal for an AI Liability Directive* is intended to define claims related to damage caused by AI systems by modifying the rules for non-contractual civil liability. The *Digital Service Act* aims for a more secure online environment that safeguards users' fundamental rights while ensuring

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56 REGULATION (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a single market for digital services (Digital Services Act) and amending Directive 2000/31/EC, OJ, L277/1, pp. 1–102.

57 REGULATION (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector and amending Directives (EU) 2019/1937 and (EU) 2020/1828 (Digital Markets Act), OJ, L 265/1, pp. 1-66.

58 REGULATION (EU) 2022/863 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act), OJ, L 152/1, pp. 1-44.

59 REGULATION (EU) 2023/988 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and of the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC, OJ, L135/1.

60 REGULATION (EU) 2023/2854 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act), OJ, L.

61 COUNCIL OF THE EUROPEAN UNION (No. 3).The Some

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fair competition among businesses. The *Digital Market Act* aims to increase competition within Europe's digital markets by stopping large corporations from misusing their market dominance and facilitating the entry of new competitors. The *Data Governance Act* targets to increase 'trust' in data sharing, strengthen mechanisms to increase data availability and overcome technical obstacles to its reuse. The *General Product Safety Regulation* aims to tackle the new challenges that digitalization brings to product safety within the EU economy. The *Data Act* represents a wide initiative to address the challenges and capitalize on the possibilities offered by data in the EU, it focuses on equitable access and rights for users, alongside safeguarding personal data protection. Finally, he *Final Draft of EU AI Act* is a pioneering legislation on AI, equipping AI developers, deployers, and users with specific rules and obligations for AI applications. At the same time, this law reduces administrative and financial burdens, benefiting Small and Medium-sized Enterprises.[62]

3.2 Identifying foundational sources

The foundational sources were selected based on their intended application scope and their significance within the regulatory hierarchy: The *Ethics Guidelines for Trustworthy AI*,[63] the *White Paper on Artificial Intelligence: A European Approach to Excellence and Trust,*[64] and the *Final Draft of The EU AI Act*.[65] Their scope is the most comprehensive in this framework given that unlike others, they regulate AI governance directly, rather than dealing with sector-specific recommendations, communication strategies, or investment aims.[66] Their positions are also critical in the regulatory hierarchy,[67] because when examining the timeline of this regulatory framework, the ethics guidelines were published first in 2019, to develop values and ethical principles for the complexities and challenges AI systems poses to society. After that, in 2020, the White Paper was released as a bridge between the

62 JHA, Ashish K., LEAHY, Eoghan. The European Union's Artificial Intelligence Act: An Analysis of Preliminary Perceptions and Responses of Irish SMEs. SHARMA, Sujeet K., et al. (eds). *Transfer, Diffusion and Adoption of Next-Generation Digital Technologies*. Springer Nature Switzerland, 2024, pp. 14–23.

63 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43).

64 EUROPEAN COMMISSION (No. 49).

65 COUNCIL OF THE EUROPEAN UNION (No. 3).

66 (FLORIDI, Luciano. Establishing the Rules for Building Trustworthy Ai. Nature Machine Intelligence, 2019, vol. 1, p. 2; ANDRAŠKO, Jozef, MESARČÍK, Matúš; HAMUĽÁK, Hamuľák, Ondrej. The regulatory intersections between artificial intelligence, data protection and cyber security: Challenges and opportunities for the EU legal framework. *AI & SOCIETY*, 2021, vol. 36, no. 2, pp. 626–627.; RUSCHEMEIER, Hannah. AI as a challenge for legal regulation – the scope of application of the artificial intelligence act proposal. *ERA Forum*, 2023, vol. *23, no.* 3, p. 361.)

67 SIEGMANN, Charlotte, ANDERLJUNG, Markus. The Brussels Effect and Artificial Intelligence: How EU regulation will impact the global AI market. *ArXiv,* 2022, pp. 62–63.; RÁDI, V. Gábor. Comparative Analysis of the AI Regulation of the EU, US and China from a Privacy Perspective. *2023 46th MIPRO ICT and Electronics Convention (MIPRO)*, 2023, pp. 1447–1449.)

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ethics guidelines and the act to transform these principles and values into policies. Finally, the *Final Draft of EU AI Act* was published in 2024, and these policies are seen in the form of law.[68]

3.2.1 'Trustworthiness', 'human-centricity' and 'excellence' – The Incorporation of Ethics and Policies)

The *Ethics Guidelines for Trustworthy AI* systematically present the elements of 'trustworthy AI' in a vertical framework as shown in the **Figure 1**, comprising the characteristic, components, principles, and key requirements to ensure an encompassing approach for the development, deployment, and use of 'trustworthy AI' systems. *The White Paper on Artificial Intelligence: A European Approach to Excellence and 'Trust'* sets policy to ensure compliance with European values and fundamental rights, emphasizing 'human-centricity' and 'ecosystem of excellence'

Figure 1 illustrates an ethical notion of AI, unifying these two sources.

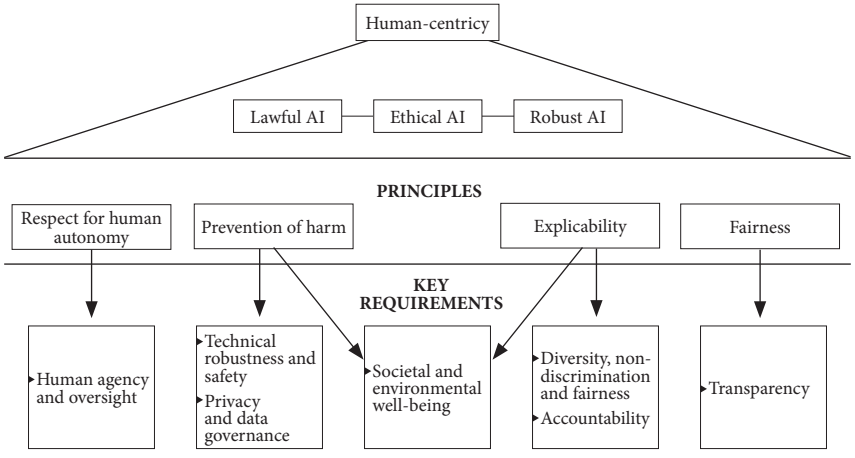

Figure 1: AI trustworthiness, Excellence and Human-Centricity

Source: Figure prepared by the authors.

At the highest level is 'human-centricity' as the ultimate required characteristic of AI, meaning that the technology must enhance human capabilities and decision-making without undermining human autonomy.[69]

68 FLORIDI, Luciano. The European Legislation on AI: A Brief Analysis of its Philosophical Approach. *Philosophy & Technology*, 2021, vol. 34, no. 2, pp. 215–222.

69 (INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 4.; EUROPEAN COMMISSION (No. 49) p. 3, 7.)

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Below are three imperative conditions of trustworthiness: lawfulness, ethicality, and robustness.[70] As pointed out by Joamets & Chochia, lawfulness is the adherence of the systems to all relevant laws and regulations, including, and most importantly, the EU treaties and the EU Charter of Fundamental Rights. Ethical means that AI conforms to values and ethical principles to advance the lives of individuals, and robust AI speaks about the minimization of risks, resilience and reliability of their operations.[71]

Four reiterative principles come next: respect for human autonomy, prevention of harm, fairness, and explicability. These are associated with the five fundamental rights underscored by the Ethics Guidelines which emphasize prioritizing human welfare and adhering to the doctrine of the rule of law.[72] This perspective restates that the development of technology should intrinsically support and reinforce democratic values.[73]

The Ethics Guidelines explain respect for human autonomy as the ability of individuals to make independent choices and control their own lives, specifically in the development and application of technology. Prevention of harm is for safeguarding human dignity, physical and mental integrity, especially under conditions of vulnerability or power asymmetry. Fairness points to the equitable distribution of benefits and costs as well as unbiased objectivity and non-discrimination. Explicability has been loosely equated to transparency of processes and described as articulating the purposes and capabilities of systems and providing justifiable explanations for AI decisions. These must be accessible, reviewable, and appealable to the affected be it directly or indirectly.[74]

Lastly, the Ethics Guidelines mention seven key requirements to realise 'trustworthy AI' in line with the said principles. The first, human agency, is the empowerment of users to have control and influence over AI's decision-making processes. This involves providing users with mechanisms to contest faulty or harmful decisions made by AI systems and to seek redress, thereby ensuring that users can actively participate and make informed decisions in AI-enabled environments.[75] And human oversight refers to the implementation of mechanisms

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70 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 5.

71 JOAMETS, Kristi, CHOCHIA, Archil. Access to Artificial Intelligence for Persons with Disabilities: Legal and Ethical Questions Concerning the Application of Trustworthy Ai. *Acta Baltica Historiae Et Philosophiae Scientiarum*, 2021, vol. 9, no. 1, p. 55.

72 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) pp. 10–11.

73 ANTONOV, Alexander, KERIKMÄE, Tanel. Trustworthy AI as a Future Driver for Competitiveness and Social Change in the EU. In RAMIRO TROITIÑO, David, et al. (eds). *The EU in the 21st Century: Challenges and Opportunities for the European Integration Process*. Springer International Publishing, 2020, p. 148.

74 (INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) pp. 12–13.; ROBBINS, Scott. A Misdirected Principle with a Catch: Explicability for AI. *Minds and Machines*, 2019, vol. 29, no. 4, pp. 495–514.)

75 (INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 16; USMANI, Usman Ahmad, HAPPONEN,

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that ensure human control and supervision over algorithmic systems,[76] this control and supervision can be achieved through three governance mechanisms: Human-In-The-Loop (HITL), Human-On-The-Loop (HOTL), and Human-In-Command (HIC).[77] HITL refers to the direct involvement of human in the AI system's every cycle,[78] HOTL's involvement would be in the design stage and in supervising the AI operation,[79] and HIC is the ability to monitor the actions of the system and determine when and how it should be operated.[80]

Technical robustness and safety indicate that AI systems are durable and dependable. They must operate efficiently in all types of situations without causing unintended harm to humans or the environment.[81] The Ethics Guidelines identify four components of robustness in AI: resilience, safety, accuracy, and reliability with reproducibility. Resilience ensures AI systems can resist and recover from cyber-attacks, while safety measures are in place for system integrity and harm prevention during failures. Accuracy is needed for correct decision-making. Reliability guarantees consistent performance, and reproducibility is the capacity for AI experiments to produce consistent results, validating and deepening the understanding of AI behaviours.[82]

Privacy and data governance is the third; it stipulates that AI systems must operate within an infrastructure that prevents harm and protects individual privacy through extensive data governance. This includes adherence to privacy protocols to not misuse personal data or lead to discrimination during the collection, storage, and processing of data. The integrity and quality of data used in AI must be maintained to avoid biases and errors that could affect the outcomes.

Ari, WATADA, Junzo. Human-Centered Artificial Intelligence: Designing for User Empowerment and Ethical Considerations. *2023 5th International Congress on Human-Computer Interaction, Optimization and Robotic Applications (HORA)*, 2023, pp. 1–3.)

76 KOULU, Riikka. Proceduralizing control and discretion: Human oversight in artificial intelligence policy. *Maastricht Journal of European and Comparative Law*, 2020, vol. 27, no. 6, pp. 726–730.

77 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 16.

78 (ZANZOTTO, Fabio M. Viewpoint: Human-in-the-loop Artificial Intelligence. *Journal of Artificial Intelligence Research*, 219, vol. 64, pp. 243–252.; INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 16.)

79 (NAHAVANDI, Saeid. Trusted Autonomy Between Humans and Robots: Toward Human-on-the-Loop in Robotics and Autonomous Systems. *IEEE Systems, Man, and Cybernetics Magazine*, 2017, vol. 3, no. 1, pp. 10–17.; INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 16.)

80 (INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 16.; JOHNSON, James. Automating the OODA loop in the age of intelligent machines: Reaffirming the role of humans in command-and-control decision-making in the digital age. *Defence Studies*, 2023, vol. 23, no. 1, pp. 43–67.)

81 CHATILA, Raja, et al. Trustworthy AI. In BRAUNSCHWEIG, Bertrand, GHALLAB, Malik (eds). *Reflections on Artificial Intelligence for Humanity.* Springer International Publishing, *2021* pp. 15–17.

82 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) pp. 16–17.

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Furthermore, access to personal data should be controlled, and only qualified personnel should have access to handle sensitive information.[83]

The requirement about societal and environmental well-being is grounded in the EU's commitment to endorse only sustainable and ecological friendly AI development and using this technology to benefit humankind.[84] The Ethics Guidelines outline its three facets: sustainable and environmentally friendly AI, social impact, and society and democracy.[85] The development, deployment, and use of artificial intelligence systems should minimize ecological impact,[86] pay attention to the profound influence on people's social interactions, relationships, and well-being caused by pervasive engagement with AI systems and consider the ways in which this technology may affect individuals' civil and political rights.[87]

Diversity, non-discrimination, and fairness is a requirement for the broad and equitable inclusion in the AI's development and use processes to prevent or minimize discrimination.[88] The Ethics Guidelines also detail its three facets: avoidance of unfair bias, accessibility and universal design, and stakeholder participation. The first could be achieved by removing potential discriminatory data during collection along with the implementation of oversight processes; the second by increasing reach for everyone, regardless of age, gender, abilities, or other similar characteristics, adhering to standards that accommodate the broadest range of users; and the last, is attained through post-training assessment mechanisms.[89]

The accountability requirement does not stand alone. Felzmann et al. emphasize its close link with transparency.[90] The Ethics Guidelines explain accountability by its sub-requirements: auditability, minimisation and reporting of negative impacts, trade-offs and redress. Auditability implies that to evaluate the system's algorithms, data and design is possible. Minimisation and reporting

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83 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 17.

84 MUSIKANSKI, Laura, et al. Artificial Intelligence and Community Well-being: A Proposal for an Emerging Area of Research. *International Journal of Community Well-Being*, 2020, vol. 3, no. 1, pp. 39–55.

85 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 17.

86 VAN WYNSBERGHE, Aimee. Sustainable AI: AI for sustainability and the sustainability of AI. *AI and Ethics*, 2021, vol. 1, no. 3, pp. 213–218.

87 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 17.

88 (MARTÍNEZ RAMIL, Pablo. Is the EU human rights legal framework able to cope with discriminatory AI? *IDP: Revista de Internet, Derecho y Política = Revista d'Internet, Dret i Política*, 2021, no. 34, pp. 3–8.; CACHAT-ROSSET, Gaelle, KLARSFELD, Alain. Diversity, Equity, and Inclusion in Artificial Intelligence: An Evaluation of Guidelines. *Applied Artificial Intelligence*, 2023, vol. 37, no. 1, pp. 2–6.)

89 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 18–19.

90 FELZMANN, Heike, et al. Towards Transparency by Design for Artificial Intelligence. *Science and Engineering Ethics*, 2020, vol. 26 *no.* 6, p. 3338.

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of negative impacts is a mechanism for identifying, assessing, documenting, and reducing potential adverse outcomes of AI systems. Trade-offs refers to ways to handle the conflicts that arise between competing requirements, interests, and values implicated by an AI system. Redress is having a response mechanism for compensating and resolving the wrongs caused by AI.[91]

Transparency, as highlighted by the Ethics Guidelines[92] and discussed by Dignum,[93] centres on the necessity for clarity and openness in AI systems, detailing their data, algorithms, and decision-making processes. It supposes AI explainability— the system's ability to elucidate its decisions in accessible terms (Ras et al., 2022); traceability—comprehensive documentation of inputs, outputs, and data;[94] and effective communication of AI's capabilities and limitations.[95]

Besides emphasizing the need for 'human-centric' AI systems, the white paper highlights support in the pursuit of an 'ecosystem of excellence,' an initiative that aims to stimulate innovation and investment across the EU's value chain, from research to deployment stages. This ecosystem also consists of various components: collaboration and coordination, regulatory and investment-oriented approach, focusing on key sectors, strengthening research and innovation, promotion of 'trustworthy AI', and international cooperation.[96] 'Collaboration and coordination' aim to unify AI efforts across the EU, promoting synergy between Member States, institutions, and stakeholders to enhance efficiency and innovation. 'Regulatory and investment-oriented approach' balances the facilitation of AI adoption with managing associated risks, thereby providing a safe yet fertile ground for AI development. 'Focusing on key sectors' identifies and prioritizes areas where AI can have the most impact, such as healthcare, to ensure targeted and effective advancement. 'Strengthening research and innovation' seeks to establish Europe as a global leader in AI by funding cutting-edge research and fostering a dynamic AI industry. 'Promotion of 'trustworthy AI' ensures that AI development adheres to ethical guidelines and respects fundamental rights, building public 'trust' and acceptance. Lastly, 'international cooperation' extends the EU's AI strategy beyond its borders, aiming to set global standards for ethical AI and promote a worldwide ecosystem that mirrors European values and regulations.

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91 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 18–19.

92 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 16–17.

93 DIGNUM, Virginia. Taking Responsibility. In DIGNUM, Virginia (Ed). *Responsible Artificial Intelligence: How to Develop and Use AI in a Responsible Way*. Springer International Publishing, 2019, p. 54

94 MORA-CANTALLOPS, Marçal, et al. Traceability for Trustworthy AI: A Review of Models and Tools. *Big Data and Cognitive Computing*, 2021, vol. 5, no. 2, pp. 1–3.

95 FELZMANN, Heike, et al. Transparency you can trust: Transparency requirements for artificial intelligence between legal norms and contextual concerns. *Big Data & Society*, 2019, vol. 6, no 1, pp. 1–3.

96 EUROPEAN COMMISSION (No. 49) p. 5–9.

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3.2.2 Legislation (The EU AI Act)

The *Final Draft of The EU AI Act*[97] is setting the most comprehensive law on AI, marking a first-of-its-kind initiative globally. According to Article 1/1 of the Act, the purpose of this regulation is to improve the single market for AI that is 'human-centric' and 'trustworthy', guaranteeing the protection of health, safety, and fundamental rights, as well as supporting democratic values, the rule of law, environmental sustainability, and innovation. The AI Act categorizes AI applications into four levels of risk: minimal, limited, high, and unacceptable.[98] For the minimal risk applications such as spam filters or AI-enabled video games, the AI Act proposes only voluntary codes of conduct.[99] In the limited risk category includes chatbots, emotion recognition and biometric categorization systems, and systems generating 'deepfake' or synthetic content, the AI Act mandates specific transparency requirements such as clear labeling or disclosure that content has been manipulated or created by AI.[100] In this category, the AI Actalso regulates general-purpose AI models, their obligations differentiate from limited risk applications, the AI Act mandates technical documentations, authorised representative, and codes of practices (Article 52a-52e). The high-risk AI systems encompass the applications in the wide range of domains from critical infrastructure to justice administration. They are not banned but the AI Act imposes strict obligations, they must be rigorously evaluated and certified to ensure they meet safety and rights standards before being approved for use.[101] Applications using subliminal techniques or social manipulation categorized at the unacceptable risk level are prohibited.[102]

The AI Act is structured into 12 titles, each addressing different aspects of AI regulation. *Title I* sets the groundwork with general provisions, clarifying the AI Act's purpose, scope, and applicability to both EU-based and external AI system providers and deployers, especially when their system outputs are utilized within the EU. *Title II* identifies specific AI practices deemed to pose an unacceptable risk and thus are prohibited. *Title III* defines high-risk AI systems and establishes criteria for their classification. *Title IV* introduces transparency obligations for both providers and users of AI applications assessed as limited risk. *Title V* promotes innovation through the creation of AI regulatory sandboxes, enabling the development, testing, and validation of AI technologies in a

97 COUNCIL OF THE EUROPEAN UNION (No. 3).

98 NOVELLI (No. 6) pp. 1–2.

99 EDWARDS, Lilian. The EU AI Act: A summary of its significance and scope. Ada Lovelace Institute, 2022, p. 15.

100 VEALE, Michael, BORGESIUS, Frederik Z. Demystifying the Draft EU Artificial Intelligence Act—Analysing the good, the bad, and the unclear elements of the proposed approach. *Computer Law Review International*, 2021, vol. 22, no. 4, pp. 97–112.

101 DE COOMAN, Jerome. Humpty Dumpty and High-Risk AI Systems: The Ratione Materiae Dimension of the Proposal for an EU Artificial Intelligence Act. Market and Competition Law Review, 2022, vol. 6, no. 1, pp. 49–88.

102 EDWARDS (No. 97) pp. 10–13.

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controlled environment. *Title VI* discusses the formation of an AI governance body, including the establishment of the European AI Board and outlining its responsibilities to guarantee consistent application of the AI Act throughout the EU. *Title VII* is dedicated to the creation and upkeep of an EU database for high-risk AI systems, crucial for ensuring their transparency and traceability. *Title VIII* deals with market surveillance and enforcement, elaborating on market monitoring measures, a governance framework, penalties for non-compliance, and the enforcement roles of national competent authorities and the European Commission. *Title IX* regulates codes of conduct for minimal-risk applications. *Title X* specifies requirements for protecting the confidentiality of information acquired under the regulation, safeguarding intellectual property rights, trade secrets, public security, and the integrity of proceedings. *Title XI* explains the European Commission's authority to adopt delegated acts, and *Title XII* includes the final provisions of the AI Act. In addition to the initial 12 titles, the final draft regulates the general-purpose AI models under a new category, designated as Title VIIIA. This title focuses specifically on this category, introducing specific obligations such as maintaining up-to-date technical documentation, assessing and mitigating risks, ensuring cybersecurity, and reporting serious incidents. *Title VIIIA* establishes a framework for the classification of these models based on their high-impact capabilities or significant market influence. Providers of general-purpose AI models are required to comply with stringent oversight and compliance measures to safeguard public interests and fundamental rights.

'Trustworthy AI', 'human-centricity' and 'ecosystem of excellence' as the key categories of the EU AI regulatory framework are encoded within their elements such as 'lawful AI', 'ethical AI' and 'robust AI'. In the next section, they will be used for the documental analysis to assess AI Act's alignment within the AI regulatory framework.

4 Conformity Assessment

The conformity assessment of the AI Act within the EU's AI regulatory framework also consists of two steps: encoding and document analysis. The first looks into terms, expressions and words of the selected/representative sources of the regulatory framework, to decide on what could work as codes, according to frequency laying the grounds for the interpretation. The second step begins with an analytical part, where the frequency of the codes is observed in the AI Act's final text, shedding light on the extent to which the AI Act focuses on these terms by looking at how often they appear within the text which defines the scope of the content analysis.

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4.1 Encoding The Key Elements of the AI Regulatory Framework

The *Ethics Guidelines for Trustworthy AI*[103] and the *White Paper on Artificial Intelligence: A European Approach to Excellence and Trust*[104] were selected as core principled sources of the AI regulatory framework. From these, three grouping categories were proposed to systematize the AI Act's conformity assessment related to the expressions 'Trustworthy AI', 'Human-centricity', and 'Ecosystem of excellence'. **Table 2** shows the terms included.

Table 2: The Categories of AI Regulatory Framework and Encoded Terms

Categories	Encoded Terms
'Trustworthy AI'	'Trustworthy AI', 'Trustworthy artificial intelligence', 'Lawful AI', 'Lawful artificial intelligence', 'Ethical AI', 'Ethical artificial intelligence', 'Robust AI', 'Robust artificial intelligence', 'Human autonomy', 'Prevention of harm', 'Minimizing harm', 'Harm', 'Harmful', 'Fairness', 'Explicability', 'Explainability', 'Human agency', 'Human oversight', 'Robustness', 'Cybersecurity', 'Resilience', 'Safety', 'Accuracy', 'Reliability', 'Privacy', 'Data protection', 'Data governance', 'Data management', 'Societal', 'Society', 'Environment', 'Sustainability', 'Diversity', 'Non-discrimination', 'fairness', 'Accountability', 'Audit', 'Minimization', 'Report', 'Trade-offs', 'Redress', 'Risk', 'Risk management', 'Risk governance', 'Quality management', 'Quality governance', 'Conformity assessment', 'Incident', 'Transparency', 'Explicability', 'Explainability', 'Traceability', 'Record', 'Documentation', 'Database', 'Communication'
'Human-centricity'	'Human-centeredness', 'Human-centricity', 'User-centricity', 'Human-AI interaction', 'HAII', 'Human interface', 'User interface'
'Ecosystem of excellence'	'Ecosystem of excellence', 'Collaboration', 'Coordination', 'Investment', 'Investment-oriented approach', 'Member states', 'Key sector', 'Critical sector', 'Critical infrastructure', 'Research', 'Innovation', 'Sandbox', 'SME', 'Private sector', 'Private actor', 'Private entity', 'International cooperation', 'International collaboration'

Source: Table prepared by the authors.

These three categories are grouping terms for the documental analysis, the terms represent the elements of fitting these categories in the AI regulatory framework. Within 'Trustworthy AI', related its components, principles, and key requirements were encoded. Similarly, within 'Human-centricity' and 'Ecosystem of excellence', their related components and the terms in their explanations were made into codes. The relationship between these terms and the three categories were identified in the previous section.

4.2 Document Analysis and Findings

The interpretative document analysis takes into consideration the frequency of the terms in the AI Act's final text and only in the articles section, it also identifies

103 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43):

104 EUROPEAN COMMISSION (No. 49)

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which articles in they are used as summarized in Table 3. It highlights the relevance of each category for the act, and sets the stage for a deeper content analysis, where the context and implications of these terms are evaluated to understand their alignment with the overarching goals of the regulatory framework.

Looking at the frequency of the terms in the AI Act, the most and least 7 frequent terms are shaded dark and light grey respectively. This shows that the EU AI Act focuses more on 'trustworthy AI', and 'ecosystem of excellence' than on 'human-centricity' in the three categories. However, human-centricity is comprehensively addressed in the *Ethics Guidelines for Trustworthy AI* and the *White Paper on Artificial Intelligence: A European Approach to Excellence and Trust* to characterized AI in the trustworthiness manner.[105]

In the first category, the AI Act places the most emphasis on the terms which represent one principle and some key requirements of trustworthy AI: prevention of harm, technical robustness and safety, privacy and data governance, accountability, and transparency. Conversely, the terms represent the two components and principles of trustworthy AI that are not given attention. These components and principles are lawfulness and robustness, respect for human autonomy, and explicability. When reviewing the articles which focus on prevention of harm, they aim to protect the individuals against unacceptable and high-risk AI systems. The articles establish the obligations to ensure the technical robustness and safety key requirement by mandating robust measurement approaches, technical redundancies, and cybersecurity practices to minimize cyber the risks and create a safe cyber environment.[106] Some of them assert rules to highlighting the key requirement of privacy and data governance through data minimisation,[107] GDPR adherence,[108] specific data management practices.[109] The ten articles set up rules to secure the accountability key requirement with quality oversight,[110]

105 (INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43) p. 4.; EUROPEAN COMMISSION (No. 49) p. 3, 7.)

106 (LIU, Haochen, et al. Trustworthy AI: A Computational Perspective. *ACM Transactions on Intelligent Systems and Technology*, 2022, vol. 14, no. 1, pp. 7–14; MOSKALENKO, Viacheslav, et al. Resilience and Resilient Systems of Artificial Intelligence: Taxonomy, Models and Methods. *Algorithms*, 2023, vol. 16, no. 3, pp. 4–17; 26–34.)

107 BIEGA, Asia J., FINCK, Michèle. Reviving Purpose Limitation and Data Minimisation in Data-Driven Systems. *Technology and Regulation*, 2021, pp. 44–61.

108 LI, Bo, et al. Trustworthy AI: From Principles to Practices. *ACM Computing Surveys*, 2023, vol. 55, no.9, pp. 177:1–177:46

109 VETRÒ, Antonio, TORCHIANO, Marco, MECATI, Mariachiara. A data quality approach to the identification of discrimination risk in automated decision making systems. *Government Information Quarterly*, 2021, vol. 38, no. 4, pp. 1–17.

110 RAJI, Inioluwa Deborah et al. Closing the AI accountability gap: Defining an end-to-end framework for internal algorithmic auditing. Proceedings of the 2020 Conference on Fairness, Accountability, and Transparency, 2020, pp. 34–35.

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Table 3: Frequency Segmentation of Terms in the AI Act Document

Categories	Encoded Terms	Frequency in the entire text	Frequency in the articles	Article
'Trustworthy AI'	'Trustworthy AI', 'Trustworthy artificial intelligence'	10	2	Article 1, 69
	'Lawful AI', 'Lawful artificial intelligence'	0	0	
	'Ethical AI', 'Ethical artificial intelligence'	2	0	
	'Robust AI', 'Robust artificial intelligence'	0	0	
	'Human autonomy'	0	0	
	'Prevention of harm', 'Minimizing harm', 'Harm', 'Harmful'	102	50	Article 1, 5, 6, 7, 71/6-cg
	'Fairness'	5	0	
	'Explicability', 'Explainability'	0	0	
	'Human agency', 'Human oversight'	19	9	Article 14, 29
	'Robustness', 'Cybersecurity', 'Resilience', 'Safety', 'Accuracy', 'Reliability'	211	101	Article 15, 52d
	'Privacy', 'Data protection', 'Data governance', 'Data management'	80	32	Article 10, 52/2, 60/4
	'Societal', 'Society', 'Environment', 'Sustainability',	22	5	Articles 5, 47/1, 54a, 69/2-b, 84/4
	'Diversity', 'Non-discrimination', 'fairness'	23	2	Articles 10, 64
	'Accountability', 'Audit', 'Minimization', 'Report', 'Trade-offs', 'Redress', 'Risk', 'Risk management', 'Risk governance', 'Quality management', 'Quality governance', 'Conformity assessment', 'Incident'	95	76	Article 9, 17, 21, 26, 27, 28, 29, 43, 52ca, 62/2, 62/3
	'Transparency', 'Explicability', 'Explainability', 'Traceability', 'Record', 'Documentation', 'Database', 'Communication'	138	93	Article 11, 12, 13, 18, 20, 52, 52c/1 60/1, 60/2, 61/2, 61/3
'Human-centricity'	'Human-centeredness', 'Human-centricity', 'User-centricity', 'Human-AI interaction', 'HAII', 'Human interface', 'User interface'	1	0	

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Categories	Encoded Terms	Frequency in the entire text	Frequency in the articles	Article
'Ecosystem of excellence'	'Ecosystem of excellence', 'Excellence'	2	2	Article 53
	'Collaboration', 'Coordination', 'Member states'	192	138	Article 53, 55b, 56, 58b
	'Investment', 'Investment-oriented approach'	1	1	
	'Key sector', 'Critical sector', 'Critical infrastructure'	15	4	Article 54
	'Research', 'Innovation', 'Sandbox', 'SME', 'Private sector', 'Private actor', 'Private entity'	215	122	Article 53, 55
	'International cooperation', 'International collaboration'	1	1	Article 2

Source: Table prepared by the authors.

corrective actions,[111] risk reporting,[112] adherence to regulations,[113] authorized representative, risk assessment and mitigation,[114] post-market monitoring, and incident reporting.[115] Lastly, nine articles impose requirement and obligation to safeguard the transparency key requirement through the documentation of training data such as input, output and parameters,[116] the establishment of a database for high-risk AI systems, and the obligation to make clear instructions about the AI system available to the users.[117]

The above suggests that the AI Act's focus on trustworthy AI is suboptimal. It disproportionately concentrates on specific key requirements and merely on one principle associated with trustworthiness. However, the foundational framework proposes a broad concept and the *White Paper on Artificial Intelligence: A European Approach to Excellence and Trust* adopts this concept while highlighting trust as

111 WILLIAMS, Rebecca, et al. From transparency to accountability of intelligent systems: Moving beyond aspirations. Data & Policy, 2022, vol. 4, no. e7, pp. 11.

112 NOVELLI, Claudio, TADDEO, Mariarosaria, FLORIDI, Luciano. Accountability in artificial intelligence: What it is and how it works. *AI & SOCIETY,* 2023, pp. 2–3.

113 Ibid pp. 9–11.

114 HOHMA, Ellen, et al. Investigating accountability for Artificial Intelligence through risk governance: A workshop-based exploratory study. *Frontiers in Psychology*, 2023, vol 14, pp. 1–17.

115 MÖKANDER, Jakob, et al. Conformity Assessments and Post-market Monitoring: A Guide to the Role of Auditing in the Proposed European AI Regulation. *Minds and Machines*, 2022, vol. *32, no.* 2, pp. 248–256.

116 KALE, Amruta. Provenance documentation to enable explainable and trustworthy AI: A literature review. *Data Intelligence*, 2023, vol. 5, no. 1, pp. 139–162.

117 ANDRADA, Gloria, CLOWES, Robert W., SMART, Paul R., Varieties of transparency: Exploring agency within AI systems. *AI & SOCIETY*, 2023, vol. *38, no.* 4, pp. 1325–1327.

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an approach.[118] This supports Laux et al.'s argument on that "*the EU adopted a simplistic conceptualization of trust and is overselling its regulatory ambition*".[119]

In the third category, the AI Act gives the most attention to the terms that represent the two components of the ecosystem of excellence that are collaboration and coordination, and to the strengthening of research and innovation, but the least attention to the investment-oriented approach and international cooperation. The articles 53, 55b, 56, 58b, establishing requirements and obligations are about how to achieve collaboration by building AI regulatory sandboxes at the national and supranational levels as well as setting up AI regulatory governance mechanism at the EU level. In addition, the articles 53 and 56 stress on the research and innovation component. The AI Act, with these articles, endorses controlled environments for innovating, developing, and testing AI systems, benefiting SMEs and startups, in particular.

It may also be said that the AI Act does not equally focus on all components to promote the ecosystem of excellence. While it pays adequate attention to collaboration and coordination, and strengthening research and innovation, it does not address international cooperation, and investment-oriented approach as it would result from adhering to the EU White Paper text more closely. Ecosystem of excellence is part of a wide strategy to ensure that Europe becomes a leading and sovereign region in the context of the data economy and its applications, therefore it is intended to promote innovation and economic growth with focus on trustworthy, safe and ethical AI. Within this envisioned ecosystem, it would be expected that all components are given equal importance to function interdependently. If they are not, the desired conditions would be harder to establish. For instance, while neglecting the international dimension, or if there's an emphasis on innovation without the necessary investments, neither global leadership or sovereignty can be achieved. For this reason, future legislation within the AI Regulatory Framework is needed to prioritize the aspects of the ecosystem of excellence and trustworthy AI that the AI Act has overlooked. These categories represent broad concepts that are essential for a systemic success, which cannot be achieved solely by issuing one legal act.

5 Conclusions

The EU pioneered in issuing the world's first extensive law on the development, use, and placement on the market of AI systems as part of a broader regulatory framework. The AI Act has come to symbolise the EU's ambition for becoming leader to regulate the governance of this technology but being such a recent legislative expression, its fit and match within the system deserves a close examination. The extant literature on the AI Act is limited in scope and mostly based on the first draft published in 2021. To fill in the void of learning about the

118 EUROPEAN COMMISSION (No. 49) p. 9.
119 LAUX (No. 9) p. 3.

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final version while expanding the investigation, this study distinguishes itself by using the final draft published in 2024 to conduct a detailed assessment of the AI Act's conformity within the greater framework. It mapped the AI regulatory landscape, then conducted the assessment through interpretative documental analysis.

The paper approached the mapping with a methodology akin to a partial institutional analysis that included normative sources of the EU AI Regulatory framework with a focus on ethical, policy, and legal foundations, and selected The *Ethics Guidelines for Trustworthy AI* [120] the *White Paper on Artificial Intelligence: A European Approach to Excellence and Trust* (EC, 2020),[121] and the *Final Draft of The EU AI Act* (European Council, 2024).[122] The first two sources' texts were coded, and the codes categorized under 'trustworthy AI', 'human-centricity', and 'ecosystem of excellence'. The categories follow fundamental principles or aspects established in the political discourse and are assigned the codes by extracting terms and topics from their provisions.

Finally, the interpretative document analysis supported an initial assessment indicating that the AI Act concentrates markedly less on ´human-centricity´ than on the other two categories, in spite of the selected sources proclaiming the need for human-centricity at the broadest perspective to characterise AI as trustworthy. In regard to the categories ´trustworthy AI´ and ´ecosystem of excellence', the AI Act stresses on certain elements, for instance the key requirements and components.

The Ethics Guidelines and White Paper on AI initially conceived the elements and requirements intertwined and interrelated to suggest a rather comprehensive balance. In this light and considering that each element and requirement plays an important role building the emerging system, the limitations of the AI Act does not achieve full conformity. The AI Regulatory framework where these the foundation are of high order remains incomplete in aspects so essential as the relationship between humans and machines and the ultimate purpose of these technologies to be implemented and accepted by society widely. It can be claimed that to successfully achieve their intended outcomes, future developments should focus on the overlooked elements of these categories. This must be done by establishing a strong linkage with the AI Act and ensuring that the relationship with each element is systematically presented, and in a manner that concretizes the foundational concepts robustness, legality, ethicality, excellence and human centricity.

120 INDEPENDENT HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE SET UP BY THE EUROPEAN COMMISSION (No. 43).
121 EUROPEAN COMMISSION (No. 49).
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