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Abstract

This thesis presents a comprehensive analysis of the European Union's regulatory framework for artificial intelligence. As AI technologies become increasingly integral to various sectors, the necessity for a clear regulatory structure to address the associated ethical, legal, and societal challenges is becoming essential. The European Union has positioned itself as a global leader in AI governance, aiming to create a balanced environment that fosters innovation while safeguarding fundamental rights and ethical standards. The thesis examines the evolution of AI regulation within the EU, highlighting legislative instruments such as the General Data Protection Regulation and the recently adopted Artificial Intelligence Act. It explores the core principles underpinning the EU's regulatory approach, including transparency, accountability, human-centricity, and risk-based regulation, and how these principles are integrated in legislative measures. A thorough analysis of the regulatory texts and related policy documents is conducted to explore the EU's strategic objectives and regulatory mechanisms. The research identifies and discusses key regulatory themes, such as data protection, algorithmic transparency, bias mitigation, and the delineation of high-risk AI applications. Additionally, it investigates the implications of these regulations for AI development and deployment within the EU. Comparative analysis with non-EU regulatory frameworks is also incorporated to contextualize the EU's approach within the global AI governance ecosystem. Findings suggest that the EU's regulatory framework for AI is both comprehensive and pioneering, setting a high standard for ethical AI governance. However, the dynamic nature of AI technology necessitates ongoing regulatory adaptation and refinement. The study concludes with recommendations for enhancing the regulatory framework to ensure it remains responsive to technological advancements and continues to uphold the EU's commitment to ethical and responsible AI.

Deutscher Abstract

Diese Arbeit präsentiert eine umfassende Analyse des Regulierungsrahmens der Europäischen Union für künstliche Intelligenz (KI). Da KI-Technologien in verschiedenen Sektoren immer wichtiger werden, ist eine klare Regulierungsstruktur zur Bewältigung der damit verbundenen ethischen, rechtlichen und gesellschaftlichen Herausforderungen unerlässlich. Die Europäische Union hat sich als weltweit führender Gesetzgeber in der KI-Governance positioniert und strebt danach, ein ausgewogenes Umfeld zu schaffen, das Innovationen fördert und gleichzeitig Grundrechte und ethische Standards schützt. Die Arbeit untersucht die Entwicklung der KI-Regulierung innerhalb der EU und hebt Gesetzgebungsinstrumente wie die Datenschutz-Grundverordnung (DSGVO) und das Gesetz über künstliche Intelligenz hervor. Sie untersucht die Grundprinzipien, die dem Regulierungsansatz der EU zugrunde liegen, darunter Transparenz, Rechenschaftspflicht, Menschenzentriertheit und risikobasierte Regulierung, und wie diese Prinzipien in Gesetzgebungsmaßnahmen integriert werden. Es wird eine gründliche Analyse der Regulierungstexte und der zugehörigen politischen Dokumente durchgeführt, um die strategischen Ziele und Regulierungsmechanismen der EU zu untersuchen. Die Forschung identifiziert und diskutiert wichtige Regulierungsthemen wie Datenschutz, algorithmische Transparenz, Minderung von Voreingenommenheit und die Abgrenzung von KI-Anwendungen mit hohem Risiko. Darüber hinaus werden die Auswirkungen dieser Vorschriften auf die Entwicklung und den Einsatz von KI in der EU untersucht. Eine vergleichende Analyse mit nicht-EU-Regulierungsrahmen wird ebenfalls durchgeführt, um den Ansatz der EU im globalen KI-Governance-Ökosystem zu kontextualisieren. Die Ergebnisse deuten darauf hin, dass der EU-Regulierungsrahmen für KI sowohl umfassend als auch wegweisend ist und einen hohen Standard für eine ethische KI-Governance setzt. Die dynamische Natur der KI-Technologie erfordert jedoch eine kontinuierliche Anpassung und Verfeinerung der Vorschriften. Die Studie schließt mit Empfehlungen zur Verbesserung des Regulierungsrahmens, um sicherzustellen, dass er weiterhin auf technologische Fortschritte reagiert und das Engagement der EU für eine ethische und verantwortungsvolle KI aufrechterhält.

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Table of Abbreviations

AI	The Artificial Intelligence
AI Act	The Artificial Intelligence Act
AI HLEG	The high-level expert group on artificial intelligence
ECJ	The European Court of Justice
EU	The European Union
UN	The United Nations
UNESCO	The United Nations Educational, Scientific and Cultural Organization
US	The United States of America
OSCE	The Organization for Security and Co-operation in Europe
SME	The Small and medium-sized enterprises
TEU	The Treaty on European Union
TFEU	The Treaty on the Functioning of the European Union

Introduction

Over the past decade, AI has become the most discussed topic across the world. This technology is capable of performing tasks and making decisions without human intervention¹ and offers significant opportunities for progress in various fields. Today, AI is increasingly applied in healthcare, education, finance, transportation, and even legal services. For instance, legal professionals use AI to quickly find legislation or analyse databases like LexisNexis and Westlaw what makes legal services more cost-effective for clients². Additionally, people are actively using AI tools like famous ChatGPT to assist with writing, research, and everyday tasks³.

However, the rapid growth of AI and its integration into everyday life of people also presents challenges for the society, particularly in developing a regulatory framework for its use. Regulators worldwide are now crafting policies that balance innovation with ethical and societal considerations. The EU became a leader⁴ of this effort with its comprehensive approach in AI regulation, aiming to establish a revolutionary framework that ensures the safe and beneficial use of AI technologies while protecting fundamental human rights⁵.

This thesis aims to provide a comprehensive analysis of the EU's regulatory framework for AI, focusing on the EU AI Act⁶. It seeks to examine the historical development of AI regulations within the EU, the legal foundations underpinning these efforts, and the specific provisions of the AI Act. Furthermore, it will evaluate the criteria for assessing high-risk AI systems and conduct a comparative analysis with national AI initiatives within EU member states and other countries. By addressing the challenges and critiques of the current AI regulatory framework,

¹ Glover E, "What Is Artificial Intelligence (AI)?" (*Built In*, March 11, 2019) <<https://builtin.com/artificial-intelligence>>

² Hartman E, "How AI Is Revolutionizing the Practice of Law" (*Harris Sliwoski LLP*, April 3, 2024) <<https://harris-sliwoski.com/blog/how-ai-is-revolutionizing-the-practice-of-law/>>

³ Somanathan S, "ChatGPT Statistics in 2024: User Growth and Development" (*ClickUp*, May 15, 2024) <<https://clickup.com/blog/chatgpt-statistics/>>

⁴ European Parliament, "EU AI Act: First Regulation on Artificial Intelligence" (*Topics | European Parliament*, June 8, 2023) <<https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence>>

⁵ European Parliament, "European Approach to Artificial Intelligence" (*Topics | European Parliament*, May 28, 2024) <<https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence>>

⁶ REGULATION (EU) 2024/... OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of ... laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) [2024] (the 'AI Act')

this thesis aims to offer insights into the global implications and future prospects of AI regulation in the EU.

The primary research questions guiding this thesis are:

1. How has the historical development of AI regulation evolved within the EU?
2. What are the legal foundations and key provisions of the EU AI Act?
3. How are high-risk AI systems assessed, and what are the criteria and impact assessments involved?
4. How does the EU's approach compare with national AI initiatives within and outside the EU?
5. What are the main challenges and critiques of the EU AI regulatory framework?
6. What are the future prospects and recommendations of the EU's AI regulation?

This thesis is structured as follows:

Chapter 1: Historical Development

This chapter provides an overview of the early developments in AI technology and the evolution of AI regulation globally. It will disclose the milestones in EU AI policy, highlighting significant directives, regulations, and initiatives. This chapter will also discuss key historical case studies will be examined to show the progression and context of AI regulation in the EU, setting the stage for understanding the current framework.

Chapter 2: Legal Foundations for AI Regulation in the EU

This section explores the EU's legal framework, examining the treaties and charters that form the basis for AI regulation. It will dive into the principles underpinning AI regulation, such as transparency, accountability, and human-centricity. The intersection of AI regulation with other areas of EU law, including data protection, consumer protection, and competition law, will also be discussed to provide a comprehensive legal context.

Chapter 3: The EU AI Act: Key Provisions

This chapter provides for an in-depth analysis of the AI Act, focusing on the risk-based classification of AI systems. The chapter will detail the requirements for high-risk AI systems, including compliance obligations for providers and users. In order to understand AI Act's

practical implications this chapter will also examine enforcement mechanisms, such as oversight by regulatory bodies and penalties for non-compliance.

Chapter 4: Assessing High-Risk AI Systems: Criteria and Impact Assessments

This chapter examines the definition and criteria for high-risk AI systems, importance of high-risk AI systems' regulation, their identification and categorization. It will cover risk assessment methodologies, sector-specific considerations, and the impact of high-risk AI on various industries.

Chapter 5: Comparative Analysis with National AI Initiatives

A comparative analysis of AI regulation in major EU member states and non-EU countries will be conducted in this chapter. It will highlight best practices and innovative approaches from different jurisdictions and show how these practices can inform and improve the EU legal framework.

Chapter 6: Challenges and Critiques of the EU AI Regulatory Framework

This section discovers the practical implementation challenges of the EU AI regulatory framework. It will also explore regulatory gaps and potential unintended consequences of the AI Act providing a balanced view of the framework's strengths and weaknesses.

Chapter 7: Future Prospects and Recommendations

The final chapter discusses anticipated developments in AI technology and future regulatory trends in the EU regulatory framework. It will discuss recommendations for policymakers to address emerging challenges and opportunities in AI governance. The chapter aims to provide forward-looking thoughts, contributing to the future of AI regulation and its potential evolution.

Through this structured approach, the thesis aims to provide a comprehensive analysis of the EU's regulatory framework for AI contributing to the broader discussion on AI governance and policy.

I. Historical development

1.1. Early Developments in AI technology

The concept of AI emerged in the first half of the 20th century when scientists began exploring the possibility of creating machines that could think and solve problems independently, mimicking human intelligence⁷. Early developers include Alan Turing, a British mathematician who suggested in his paper “Computing Machinery and Intelligence” that machines could use available information to solve problems and make decisions in the same way humans do⁸. However, to achieve this, machines needed to undergo fundamental changes. Before 1949, computers could not store information, meaning they could not remember commands, and computing was extremely expensive and not widely used as nowadays⁹.

Later in 1950’s the first program designed to mimic the problem-solving skills of a human was developed by Allen Newell, Cliff Shaw and Herbert Simon and called the “Logic Theorist”¹⁰. It was presented at the Dartmouth Summer Research Project on Artificial Intelligence (DSRPAI) in 1956, hosted by the professor at Dartmouth College - John McCarthy ¹¹. The DSRPAI conference is often cited as the birth of AI as a field of study¹². Top researchers from various disciplines came together for open-ended discussions on AI, during which John McCarthy coined the term “Artificial Intelligence” defining it as “the science and engineering of making intelligent machines, especially intelligent computer programs”¹³. By the end of the conference all participants agreed that AI was achievable opening the way for further developments. Later in the 1970s, it became easier and more cost-effective for computer technology to store larger amounts of information and analyse it more quickly¹⁴. However, AI still was not possible at that time as computers could not store enough information and process it fast enough to exhibit any intelligence¹⁵.

⁷ Anyoha R, “The History of Artificial Intelligence” (*Science in the News*, August 28, 2017) <<https://sitn.hms.harvard.edu/flash/2017/history-artificial-intelligence/>>

⁸ Turing A. M., “Computing Machinery and Intelligence” (1950) 49 *Mind* 433-460

⁹ Anyoha R, “The History of Artificial Intelligence” (*Science in the News*, August 28, 2017) <<https://sitn.hms.harvard.edu/flash/2017/history-artificial-intelligence/>>

¹⁰ Ibid

¹¹ Ibid

¹² Ibid

¹³ McCarthy JJ, Minsky ML and Rochester N, “Artificial Intelligence” (March 3, 2010) <https://www.researchgate.net/publication/41667499_Artificial_Intelligence>

¹⁴ Anyoha R, “The History of Artificial Intelligence” (*Science in the News*, August 28, 2017) <<https://sitn.hms.harvard.edu/flash/2017/history-artificial-intelligence/>>

¹⁵ Ibid

AI has achieved many landmark goals only with the progress of technology from the late 20th century to the present. For example, in 1997 world chess champion and grand master Gary Kasparov was defeated by IBM's Deep Blue, a computer program designed to play chess¹⁶. This marked the first time a world chess champion lost to a computer, representing a significant advancement in AI decision-making capabilities. Since then, AI has evolved to include speech recognition software, robots capable of recognizing and displaying emotions, and, most notably for the ordinary people - ChatGPT launched by OpenAI on 30 November 2022¹⁷. As the first AI chatbot compose various written content, including articles, social media posts, essays, code, and emails.

To conclude, the journey of AI technology from its early conceptual stages to modern advancements has been shaped by key events such as DSRPAI conference and foundational works of many scientists as well as technological progress has enabled significant achievements in the AI's technology remarkable evolution and potential.

1.2. Evolution of AI regulation globally

As AI technology has advanced, it has become important for countries around the world to create rules to manage its impact. Legislators around the world always try to keep up with development of technology and the regulation of AI is no exception. During the 1980s and 1990s, countries like Japan and the US heavily invested in AI research and development, achieving significant technological breakthroughs¹⁸. This rapid advancement highlighted the necessity of regulatory framework that could address AI's ethical, legal, and societal implications. However, initial regulatory measures were largely ad hoc and focusing on specific issues such as data privacy and cybersecurity, without providing comprehensive oversight of AI technologies. For example, in 2001 the Tampa Police Department implemented a facial recognition system the Face-IT system developed by Visionics Corporation in the US¹⁹. This system was used to scan faces in crowds at the Super Bowl in 2001 to search for wanted

¹⁶ Sullivan M, "Deep Blue Defeats Garry Kasparov in Chess Match" (*History*, November 16, 2009) <<https://www.history.com/this-day-in-history/deep-blue-defeats-garry-kasparov-in-chess-match>>

¹⁷ OpenAI, "Introducing ChatGPT" <<https://openai.com/index/chatgpt/>>

¹⁸ University of Washington, "The History of Artificial Intelligence" (2006), page 22

¹⁹ Canedy D, "Tampa Scans the Faces in Its Crowds for Criminals" *The New York Times* (July 4, 2001) <<https://www.nytimes.com/2001/07/04/us/tampa-scans-the-faces-in-its-crowds-for-criminals.html>>

criminals. The deployment of this technology raised significant privacy concerns as there was no legal framework specifically addressing the use of facial recognition by police at that time²⁰.

At the beginning of 21st century, it became clear that ethical considerations should be included in AI rules and lead to more comprehensive approach. This period marked the beginning of more structured efforts to regulate AI. For example, in the US there is no special federal regulation framework that is comprehensive for AI specifically which means that AI regulation is not unified²¹. However, to address some of the AI challenges there are several sector-specific AI related agencies and organizations such as the Federal Trade Commission²² that targets the consumer protection issue regarding AI use in applications and the National Highway Traffic Safety Administration²³ that regulates aspects of AI powered technologies, specifically in autonomous cars.

Another example, China is resolute in its efforts to regulate AI and aims to establish itself as the foremost AI innovation hub centre by 2030²⁴. The Chinese Cybersecurity Law and the New Generation AI development plan offer provisions for safeguarding data and ensuring cybersecurity in the field of AI with a particular focus on adhering to regulations and implementing timely risk management strategies²⁵. China recognizes the importance of making AI ethical and secure for the people that use it.

It is noteworthy that the international organizations such as the OECD and the UN are also actively engaged in the development of regulatory frameworks for AI²⁶. The OECD establishes principles for AI including transparency, responsibility and inclusion to guide its development

²⁰ Ibid

²¹ Savio J, "AI Regulations Around the World" (*Spiceworks*, April 30, 2024) <<https://www.spiceworks.com/tech/artificial-intelligence/articles/ai-regulations-around-the-world/>>

²² Ibid

²³ Ibid

²⁴ Xinhua, "China Accelerates AI Development to Build AI Innovation Center" (April 6, 2024) <https://english.www.gov.cn/news/202404/06/content_WS6610834dc6d0868f4e8e5c57.html>

²⁵ Savio J, "AI Regulations Around the World" (*Spiceworks*, April 30, 2024) <<https://www.spiceworks.com/tech/artificial-intelligence/articles/ai-regulations-around-the-world/>>

²⁶ OECD, "Recommendation of the Council on Artificial Intelligence" (2019)

and application²⁷. The UN Sustainable Development goals emphasize the significance of utilizing AI to achieve worldwide advantages and sustainability²⁸.

However, truly revolutionary in the field of AI regulation is of course the EU. The EU has adopted a proactive approach to AI legislation, driven by measures like the GDPR²⁹ and the first-ever AI Act. Since AI systems depend on the gathering and use of personal data, the EU claims that strict regulations must be implemented in order to protect and preserve individual privacy. Furthermore, the EU wants to stop AI systems from operating without human oversight³⁰. The European Union aims to be at the forefront of AI deployment innovation and competitiveness by enforcing ethical standards³¹.

1.3. Milestones in EU AI Policy

Overall, the EU is a leader in developing comprehensive regulatory frameworks for emerging technologies such as GDPR or Digital services Act³². This leadership did not bypass AI as 2010's which can be marked as the beginning of AI regulation journey in the EU. Key milestones include the European Commission's publication of the "Digitising European Industry" strategy in 2016 which emphasized the importance of AI and digital transformation³³.

In April 2018, the European Commission has published its AI strategy for Europe³⁴ outlining a three prolonged approach as follows:

²⁷ Ibid

²⁸ United Nations Sustainable Development Group, "Harnessing Artificial Intelligence for Sustainable Development Goals" (May 8, 2024) <<https://unsdg.un.org/latest/announcements/harnessing-artificial-intelligence-sustainable-development-goals-sdgs>>

²⁹ 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, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L 119/1 (the GDPR)

³⁰ Savio J, "AI Regulations Around the World" (*Spiceworks*, April 30, 2024) <<https://www.spiceworks.com/tech/artificial-intelligence/articles/ai-regulations-around-the-world/>>

³¹ Ibid

³² European Parliament, "European Approach to Artificial Intelligence" (*Topics | European Parliament*, May 28, 2024) <<https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence>>

³³ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee Regions Digitising European Industry Reaping the full benefits of a Digital Single Market [2016] COM(2016) 180 final

³⁴ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee Regions Artificial Intelligence for Europe [2018] COM(2018) 237 final

- “Boost the EU's technological and industrial capacity and AI uptake across the economy, both by the private and public sectors. This includes investments in research and innovation and better access to data.
- Prepare for socio-economic changes brought about by AI by encouraging the modernisation of education and training systems, nurturing talent, anticipating changes in the labour market, supporting labour market transitions and adaptation of social protection systems.
- Ensure an appropriate ethical and legal framework, based on the Union's values and in line with the Charter of Fundamental Rights of the EU. This includes forthcoming guidance on existing product liability rules, a detailed analysis of emerging challenges, and cooperation with stakeholders, through a European AI Alliance, for the development of AI ethics guidelines.”³⁵

Later that year, the European Commission established the High-Level Expert Group on Artificial Intelligence (AI HLEG) to provide recommendations on AI policy and ethics. In 2019 the AI HLEG published Ethics Guidelines for Trustworthy AI which became a key document, advocating for AI systems that are lawful, ethical, and robust³⁶.

The establishment of the European AI Alliance as a multi-stakeholder forum demonstrated the EU's commitment and dedication to open and inclusive policymaking. Since its start in 2018 it has engaged around 6,000 stakeholders across Europe through regular events such as public consultations and online forum exchanges³⁷.

In February 2020, the European Commission published its White Paper on AI, which proposed a regulatory framework designed to promote both excellence and trust in AI³⁸. This document

³⁵ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Artificial Intelligence for Europe [2018] COM(2018) 237 final, page 1

³⁶ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Fostering a European approach to Artificial Intelligence [2021] COM(2021) 205 final

³⁷ European Commission, “The European AI Alliance” <<https://digital-strategy.ec.europa.eu/en/policies/european-ai-alliance>>

³⁸ European Commission, White Paper on Artificial Intelligence: a European approach to excellence and trust [2020] COM(2020) 65 final

set the foundation for the AI Act, which seeks to establish a uniform regulatory landscape throughout the EU.

In April 2021, the European Commission introduced a comprehensive AI package aimed at advancing a European approach to AI. This initiative highlighted the EU's commitment to establishing itself as a leader in both the ethical and innovative advancement of AI technologies. A key component of this package is the Communication on fostering a European approach to AI. This document set strategic priorities and objectives for AI development within the EU, focusing on the need for AI systems to be human-centric, trustworthy, and aligned with European values and fundamental rights. By promoting these principles, the European Commission seeks to build public trust and drive the adoption of AI across various sectors. As another part of the AI package, the European Commission also presented a review of the Coordinated Plan on AI. This updated plan, developed together with EU Member States, was aimed on improving collaboration and uniformity in AI policies throughout Europe³⁹. It seeks to synchronize efforts, exchange best practices, and guarantee that AI developments are inclusive and advantageous for all Member States, thereby promoting united and yet competitive European AI environment⁴⁰. However, the most important part of the European Commission's AI package included the proposal for the AI Act. The AI Act is a significant part of the package, designed to provide a legal framework for the safe and ethical deployment of AI across the EU. According to recent news, the Council of the EU approved the AI Act on 21 May 2024 thereby giving final green light to the first worldwide rules⁴¹. Through these coordinated efforts, the European Commission's AI package of April 2021 aimed to create a balanced and forward-looking regulatory environment that supports the responsible development of AI technologies across Europe.

³⁹ European Parliament, “European Approach to Artificial Intelligence” (*Topics | European Parliament*, May 28, 2024) <<https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence>>

⁴⁰ Ibid

⁴¹ European Council, “Timeline – Artificial Intelligence” <<https://www.consilium.europa.eu/en/policies/artificial-intelligence/timeline-artificial-intelligence/>>

Presumably in August 2024, the AI Act will be published in the EU Official Journal and go into effect 20 days later⁴². With some exceptions for particular sections, it will take effect two years after it is put into effect⁴³.

1.4. Key historical case studies

Several historical case studies highlight the EU's evolving approach to AI regulation. One of the examples is the GDPR implemented in 2018. While not being the AI specific regulation, the GDPR introduced global standard for data protection and privacy which impacted AI systems that process personal data. AI regulatory initiatives are influenced by the GDPR's principles of transparency, accountability and user consent. As stated in the European Parliamentary Research Service's study "The impact of the General Data Protection (GDPR) on artificial intelligence" there is a tension between data protection principles and AI such as: purpose limitation, data minimisation, special treatment of "sensitive data" and the limitation on automated decisions⁴⁴.

Another case study is the regulation of autonomous vehicles, where AI is considered as the main tool and plays crucial role for assisted, automated and autonomous driving⁴⁵. The EU has been a key player in global efforts to set safety and ethical standards for self-driving cars. Through initiatives like the European New Car Assessment Programme (Euro NCAP) and the Horizon 2020⁴⁶ research projects, the EU has helped establish safety benchmarks and drive innovation in the autonomous vehicle industry. For example, Horizon 2020 provides significant financial support and encourages collaboration among researchers, industries, and policymakers to leverage AI's potential in enhancing transportation systems, promoting sustainable development, and raising vehicular safety standards⁴⁷.

⁴² Spies A, "The EU AI Act Is Coming – With Numerous Legal Consequences" (*Morgan Lewis Newsletter*, June 27, 2024) <<https://www.morganlewis.com/pubs/2024/06/the-eu-ai-act-is-coming-with-numerous-legal-consequences>>

⁴³ Council of the EU, "Artificial Intelligence (AI) Act: Council Gives Final Green Light to the First Worldwide Rules on AI" (*Press Release*, May 21, 2024) <<https://www.consilium.europa.eu/en/press/press-releases/2024/05/21/artificial-intelligence-ai-act-council-gives-final-green-light-to-the-first-worldwide-rules-on-ai/>>

⁴⁴ European Parliament, "The impact of the General Data Protection Regulation on artificial intelligence" (2020) page 62

⁴⁵ Löfing N, "Impact of the EU's AI Act Proposal on Automated and Autonomous Vehicles" (*Bird & Bird*, April 12, 2023) <<https://www.twobirds.com/en/insights/2023/global/impact-of-the-eus-ai-act-proposal-on-automated-and-autonomous-vehicles>>

⁴⁶ European Commission, "Horizon 2020" (*Research and innovation*) <https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-2020_en>

⁴⁷ Ibid

The EU's strategy for AI regulation, illustrated by laws like the GDPR and initiatives in autonomous vehicle regulation, show its dedication to balancing innovation with safety and ethical standards. While the GDPR has set a global standard for data protection that deeply influences AI development, it also introduces challenges around the limitations on data usage that are typical with AI systems. At the same time, the EU's involvement in autonomous vehicle regulations through programs like Euro NCAP and Horizon 2020 emphasizes its commitment to setting global safety benchmarks and encouraging collaborative innovation. These examples highlight how the EU manages to encourage the potential of AI while maintaining a strong focus on regulatory compliance and the protection of public interest and data privacy.

II. Legal foundations for AI regulation in the EU

2.1. EU legal framework and AI Act

The EU is leading the way in regulating AI with a comprehensive legal framework. Central to this effort is the AI Act, which aims to set clear rules for AI development and use across Europe. To understand the place of AI Act it is important to understand the hierarchy of legislative acts in the EU. The EU's legal system is truly unique, and complex consisted of various treaties, regulations and directives that form the foundation of its legislative and regulatory activities.

Sources of the EU law can be divided on two major categories as Primary EU law and Secondary EU law⁴⁸. Primary EU law is made and enacted by the Member States but applied with supranational elements. It includes the European treaties and general principles of EU law⁴⁹. The European treaties include founding treaties e.g. TFEU⁵⁰ and TEU⁵¹, Charter of Fundamental rights of the EU, amending treaties and accession treaties. General principles of EU law include legal principles adopted by the ECJ such as rule of law, supremacy rule, doctrine of direct effect of EU law and etc. According to article 288 of the TFEU secondary sources of EU law include regulations, directive, decisions, recommendations and opinions⁵².

⁴⁸ European Commission, "Types of EU Law" <https://commission.europa.eu/law/law-making-process/types-eu-law_en>

⁴⁹ Ibid

⁵⁰ Consolidated version of the Treaty on the Functioning of the European Union [2012] OJ C 326 (TFEU)

⁵¹ Consolidated version of the Treaty on European Union [2012] OJ C326/13 (TEU).

⁵² TFEU, article 288(1)

By Article 1 of the AI Act, the AI Act is considered as regulation of the EU meaning that it is binding and entirely and directly applicable in all Member States⁵³ and will directly apply rights and obligations on individuals. This hierarchical structure ensures that there is a clear order and coherence in how laws are created, implemented, and interpreted across the EU, aiming to maintain legal consistency and uphold the principles of EU treaties.

2.2. Relevant treaties and charters

The regulation of AI in the EU draws upon several critical treaties and charters that establish fundamental rights and principles.

First of all, the TFEU outlines the competencies of the EU and the legislative processes for adopting regulations and directives. Articles relevant to AI regulation include those on the internal market (Articles 26-27), consumer protection (Article 169), and the digital single market (Article 114). These provisions enable the EU to create a regulatory environment for AI that promotes innovation while ensuring market efficiency and consumer safety.

Secondly, the Charter of Fundamental Rights of the EU⁵⁴ safeguards fundamental rights and freedoms that must be upheld in AI development and deployment. Important provisions include the right to privacy and data protection (Articles 7 and 8), non-discrimination (Article 21), and the right to an effective remedy (Article 47). These rights ensure that AI technologies are developed in a manner that respects individual freedoms and promotes equality.

As mentioned before, although not specifically aimed at AI, the GDPR is a cornerstone of EU data protection law that significantly influences AI systems that process personal data. It sets principles such as lawfulness, fairness, transparency, data minimization, and accountability, which are critical to AI governance. The GDPR's requirements ensure that AI applications handling personal data operate within a framework that prioritizes user rights and data security.

In summary, the EU's approach to regulating AI is built on a foundation of essential treaties and charters that establish key rights and principles for the EU. The TFEU, the Charter of

⁵³ AI Act, Article 1

⁵⁴ Charter of Fundamental Rights of the EU [2000] (2000/C 364/01)

Fundamental Rights, and the GDPR all play crucial roles in shaping a regulatory environment that promotes innovation while safeguarding consumer rights, privacy, and equality. This comprehensive framework ensures that AI technologies are developed and deployed in a manner that is ethical, transparent, and aligned with the EU's core values, thereby fostering public trust and driving sustainable advancement in the AI sector.

2.3. Principles underpinning AI regulation

As stated on European Commission's website the aim of the new rules is to: "foster trustworthy AI in Europe and beyond, by ensuring that AI systems respect fundamental principles of the EU"⁵⁵. To ensure that AI development aligns with the EU's values and objectives, several principles underpin the EU's approach to AI regulation like ethics and human rights, transparency and accountability, safety and security, innovation and competitiveness⁵⁶.

Firstly, the EU emphasizes the ethical development of AI, ensuring that AI systems respect human dignity, privacy and other fundamental rights⁵⁷. It is clearly stated in the guidelines and recommendations from AI HLEG that AI should be trustworthy by being lawful – respecting all applicable laws and regulations, ethical – respecting ethical principles and values and robust – both from technical perspective while taking into account its social environment⁵⁸. As there are concerns on how AI systems handle personal data the AI Act implements strict measures to protect individual's privacy, with guidelines around processing data lawfully, fairly and transparently⁵⁹.

Secondly, the EU states that AI systems must operate transparently and allowing users and stakeholders to understand how decisions are made⁶⁰. The EU recognizes that the AI systems should assist human capabilities rather than replace them. In order to achieve it AI systems must be designed allowing humans to make informed decisions and intervene when necessary.

⁵⁵ European Parliament, "European Approach to Artificial Intelligence" (*Topics | European Parliament*, May 28, 2024) <<https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence>>

⁵⁶ European Commission, "AI Act" <<https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai#:~:text=The%20AI%20Act%20is%20the%20first%20Dever%20comprehensive%20legal%20framework,powerful%20and%20impactful%20AI%20models.>>

⁵⁷ Ibid

⁵⁸ AI HLEG, "Ethics Guidelines for Trustworthy AI" (2019) page 14

⁵⁹ Ibid, page 17

⁶⁰ AI Act, Article 13

AI systems should possess transparency and comprehensibility, offering explicit justifications for their behaviours and recommendations.⁶¹ AI systems' actions should be under control of individuals and organizations holding them to ensure accountability.

Thirdly, AI should be aligned with principles of safety and security⁶². The EU emphasizes that risks associated with AI should be mitigated. Such risks include biases, errors and cybersecurity threats. To mitigate those risks the EU developed categorized AI systems based on their potential impact, with stricter requirements for high-risk applications. Furthermore, using AI systems necessitates adopting rigorous testing and validation procedures, taking a proactive approach to identifying and managing risks, and having confidence that AI systems work as intended, preventing or posing little harm to people or society⁶³.

Lastly, while prioritizing ethical and safety considerations, the EU also aims to foster innovation and maintain its competitiveness in the global AI landscape⁶⁴. Regulatory frameworks should be designed to be flexible and adaptive, supporting technological advancements and market growth. As stated in press release of the Council of the EU: "The AI Act provides for an innovation-friendly legal framework and aims to promote evidence-based regulatory learning. The new law foresees that AI regulatory sandboxes, enabling a controlled environment for the development, testing and validation of innovative AI systems, should also allow for testing of innovative AI systems in real world conditions"⁶⁵.

To sum up, the EU's approach to regulating AI focuses on creating trustworthy AI systems that respect its core values. The framework emphasizes ethics, transparency, safety, and innovation. It ensures AI respects human dignity and privacy, operates transparently, and holds accountability, with strict data protection measures. The EU also addresses safety by mitigating risks like biases and cybersecurity threats, categorizing AI based on impact and requiring testing. Additionally, the EU fosters innovation and competitiveness with flexible regulations and AI testing environments, aiming to balance technological progress with fundamental rights protection.

⁶¹ AI Act, Article 13

⁶² AI HLEG, "Ethics Guidelines for Trustworthy" (2019) page 16

⁶³ Ibid, page 22

⁶⁴ Ibid, page 9

⁶⁵ European Council, "Artificial intelligence (AI) act: Council gives final green light to the first worldwide rules on AI" <<https://www.consilium.europa.eu/en/press/press-releases/2024/05/21/artificial-intelligence-ai-act-council-gives-final-green-light-to-the-first-worldwide-rules-on-ai/>>

2.4. Intersection with other areas of EU Law

In order to act like one mechanism, the EU requires harmonized legislation. As a result, AI Act intersects with various areas of law including data protection, consumer protection, competition law and product liability.

One of the major roles in regulating AI systems is played by GDPR as we are talking about processing of the personal data. It is worth to mention that the GDPR is a technology-neutral regulation⁶⁶. The definition of “processing” under the GDPR⁶⁷ is broad and it is evident that the GDPR applies to AI systems to the extent that personal data is present somewhere in the lifecycle of an AI system. While AI is not explicitly mentioned in the GDPR under article 22 the automated decision-making framework serves as a form of indirect control over the use of AI systems on the basis that AI systems are used to take automated decisions that impact individuals. Compliance with data protection principles is essential for ensuring the lawful use of AI technologies⁶⁸.

Another intersection is consumer laws and protection. As AI systems are used in consumer products and services they must comply with EU consumer protection laws, ensuring they are safe, reliable and do not deceive consumers. The Consumer Protection Cooperation Regulation⁶⁹ enhances cross-border cooperation to enforce these laws. Customers can undoubtedly gain from AI technologies, which give them access to new application features and make it easier for them to find deals that suit their needs. However, consumer groups like the European Consumer Organization and the European Consumer Centers Network (ECC-Net) are also voicing concerns about issues including unfair business practices and privacy protection⁷⁰. ECC-Net highlights the following considerations for using AI systems:

⁶⁶ GDPR, Recital 15

⁶⁷ GDPR, Article 4 (2)

⁶⁸ European Parliament, “The impact of the General Data Protection Regulation on artificial intelligence” (2020) page V

⁶⁹ Regulation (EU) 2017/2394 of the European Parliament and of the Council of 12 December 2017 on cooperation between national authorities responsible for the enforcement of consumer protection laws and repealing Regulation (EC) No 2006/2004 [2017] OJ L 345/1

⁷⁰ European Consumer Centers Network, “Artificial Intelligence: How Do We Protect Consumer Rights in AI Applications?” <<https://www.eccnet.eu/news/artificial-intelligence-how-do-we-protect-consumer-rights-ai-applications>>

- “Consumers should always have the right to information. They should be made aware when an algorithm is using their personal information to provide offers for goods and services, uses this data to make a decision or reports this data to third parties. Personal information could include data on purchasing behaviour, or data related to the consumer’s health, emotions or finances.
- Consumers should always be allowed to request human intervention if they are unsatisfied with the outcome of an AI-based complaint handling system.
- Resources such as full documentation, tests, datasets and data prediction tools should be made more available and accessible. This is needed for an evidence-based assessment of the algorithm.
- Deployers and users should collaborate in conducting a fundamental rights and consumer rights impact assessment.
- Legislation measures need frequent adaptation, given the quick evolving of technology and use cases, which pose new challenges.
- Codes of conduct may be useful for self-regulation in fields which are not yet regulated by norms.
- Awareness campaigns should address consumers, companies and policy makers.”⁷¹

The AI Act also intersects with competition law of the EU. The EU's competition law framework, including antitrust rules and merger control, ensures that AI advancements do not lead to monopolistic practices or unfair market dominance. The EU's AI Act introduces standardized regulations for AI technologies across the EU by which creates a fair playing field that prevents larger companies from dominating the market through exclusive practices⁷². It tackles potential anti-competitive actions by controlling how data is accessed and used which is essential for training AI systems. Large companies are often at risk of monopolizing data and must follow strict rules about transparency and how they handle data to ensure that smaller companies can also innovate and compete freely⁷³. Additionally, the AI Act supports competition by promoting interoperability and data portability⁷⁴, which helps prevent

⁷¹ European Consumer Centers Network, “Artificial Intelligence: How Do We Protect Consumer Rights in AI Applications?” <<https://www.eccnet.eu/news/artificial-intelligence-how-do-we-protect-consumer-rights-ai-applications>>, page 1

⁷² Ditsche J and others, “European AI Act: Opportunities and Challenges” (*Roland Berger GmbH*, May 8, 2024) <<https://www.rolandberger.com/en/Insights/Publications/European-AI-Act-Opportunities-and-challenges.html>>

⁷³ European Data Protection Supervisor, “Privacy and competitiveness in the digital age of big data: The Interplay between data protection, competition and consumer protection in the Digital Economy” (March 2014) page 14

⁷⁴ AI Act, Section 3

consumers from being locked into one provider and have more choices on the specific market. These measures ensure that the AI Act not only upholds safety and ethics in AI but also fosters a competitive, diverse market environment⁷⁵.

Lastly, AI systems must follow EU product liability rules, especially those built into physical products. The Product Liability Directive⁷⁶ sets the standards for when manufacturers are responsible for damage caused by defects in their products, and this includes products that use AI. As AI technology advances and becomes more common in consumer products, it is crucial that these products meet high safety standards to avoid causing harm and incurring legal liability⁷⁷.

In summary, it is really important for the EU to ensure that AI regulation is deeply interconnected with its legal framework and respects fundamental rights, data protection, consumer protection, competition law, and product liability. By integrating these various legal areas, the EU aims to create a comprehensive regulatory environment that promotes ethical AI development, protects fundamental rights, and fosters innovation.

III. The EU AI Act: Key provisions

3.1. Overview of the AI Act

The EU AI Act represents a landmark effort to create a unified regulatory framework for AI across the EU. The EU understands the importance of AI in high-technology age and the benefits AI can bring in such sectors as healthcare, transport, manufacturing and sustainable energy and etc⁷⁸.

As stated in the final version of AI Act: “the purpose of this Regulation is to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy

⁷⁵ De Moncuit A and others, “AI Challenges in Competition Law: How Are Regulators Responding?” (*PLC Magazine*, April 2024) <https://www.mayerbrown.com/-/media/files/perspectives-events/publications/2024/04/ai-challenges-in-competition-law_mar24.pdf%3Frev=-1>

⁷⁶ 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 [1999] OJ L 210/29

⁷⁷ AI Act, Article 1(1)

⁷⁸ European Parliament, “European Approach to Artificial Intelligence” (*Topics | European Parliament*, May 28, 2024) <<https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence>>

AI, while guaranteeing a high level of protection of health, safety, fundamental rights enshrined in the Charter, including democracy, the rule of law and environmental protection, against harmful effects of AI systems in the Union and supporting innovation”⁷⁹. The EU’s priority can be understood as ensuring that AI systems used in the EU are safe, transparent, traceable, non-discriminatory and environmentally friendly. To avoid negative effects, people should supervise AI systems rather than relying solely on automation. The European Parliament also aimed to define AI in a uniform, technology-neutral manner that would be applicable to future AI systems.

The AI Act will apply to both providers and deployers (users) of in-scope AI systems that are used in or produces an effect in the EU no matter of their place of establishment. This means the providers or deployers of AI systems in third countries will have to comply with the AI Act if the output of the system is used in the EU. By article 3 of AI Act provide means “a natural or legal person, public authority, agency or other body that develops an AI system or a general purpose AI model or that has an AI system pr a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge” at the time deployer means “a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of personal non-professional activity”⁸⁰.

The EU identifies AI system as following: “AI system means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input to receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments”⁸¹. The AI Act will not be applicable to AI systems used exclusively for military or defence purposes, used solely for the purpose of research and innovation and used by people for non-professional reasons⁸². In addition to that certain systems will be banned under the AI Act, including ones used for emotion recognition in the workplace, for untargeted scraping of facial images from the CCTV footage or the internet to create facial recognition databases⁸³. However, using AI systems to conduct remote biometric

⁷⁹ AI Act, Article 1(1)

⁸⁰ AI Act, Article 3

⁸¹ AI Act, Article 3(1)

⁸² AI Act, Article 2(3)

⁸³ AI Act, Recital 18

identification in public will be allowed when strictly necessary for law enforcement purposes⁸⁴. For such systems certain safeguards will be put in place such as limiting the use of these systems to conducting searches for people suspected of the most serious crimes⁸⁵.

The AI Act differs AI systems depending on the risk level posed i.e. risk-based approach and establish different obligations for providers and deployers in accordance with it. Transparency obligations for example will be lighter for limited risk AI systems and will include informing users that the content they are engaging with is AI generated⁸⁶. At the same time for high-risk AI systems citizens will have a right to receive explanations about decisions that affect their rights⁸⁷. The high-risk AI systems and rights and obligations of providers and deployers will be explored more in the next chapters.

Like the GDPR the fines for non-compliance with obligations set by AI Act will be calculated as a percentage of the liable party's global annual turnover in the previous financial year, or a fixed sum, whichever is higher:

- 35 million euro or 7% for violations which involve the use of banned AI applications.
- 15 million euro or 3% for violations of the AI Act's obligations; and
- 7.5 million euro or 1.5% for the supply of incorrect information⁸⁸

This is aimed at ensuring that AI entities take the regulations seriously and implement necessary compliance measures.

Nevertheless, AI Act is also aimed on support of innovation and SMEs⁸⁹. National level regulatory sandboxes and real-world testing must be created and made available to start-ups and SMEs so they may grow and equip creative artificial intelligence before it finds application on the market. The AI Act offers support to SMEs through advice, financial aid, and exemptions for free and open-source AI components which are publicly available tools like libraries, and models with accessible source code that anyone can use, modify, and distribute⁹⁰. The AI Act also creates regulatory sandboxes to provide a risk-free testing environment, and

⁸⁴ AI Act, Annex III

⁸⁵ AI Act, Article 26(10)

⁸⁶ AI Act, Article 50

⁸⁷ AI Act, Article 86(1)

⁸⁸ AI Act, Article 99

⁸⁹ AI Act, Recital 143

⁹⁰ Ibid

SMEs will receive priority access and privilege in compliance requirements for high-risk AI systems⁹¹.

To conclude the AI Act marks a significant step towards establishing a comprehensive regulatory framework for AI across the EU. The AI Act aims to ensure that AI systems are used responsibly and ethically, while also fostering innovation and supporting businesses. The AI systems are divided based on the risk approach and because of that imply different rights and obligations for providers and deployers. The AI Act applies to both EU and non-EU providers and users, reflecting its broad scope and the EU's commitment to a high standard of AI governance.

3.2. Risk-based classification of AI Systems

As mentioned above the AI Act categorizes AI systems into four risk levels to ensure that the level of regulatory oversight matches the potential risk they pose to safety and fundamental rights, ranging from minimal risk to unacceptable risk.

Firstly, minimal or no risk AI systems are largely exempt from specific regulatory requirements. These include applications like AI-powered spam filters and video games⁹². Developers and deployers of these systems enjoy greater flexibility in innovation and use and at the same time face a minimal regulatory burden⁹³. This category allows for rapid development and deployment with basic obligations primarily cantered around ensuring transparency and providing adequate information to users about how the systems operate⁹⁴.

Secondly, limited-risk AI systems are subjected to a moderate level of regulatory oversight due to their potential impacts on public safety and individual rights, though these impacts are considered less severe than those posed by high-risk AI systems⁹⁵. Examples of limited-risk AI systems include chatbots and AI-driven customer service applications. Developers and

⁹¹ Irr C, "AI Regulation in Focus: Balancing Innovation and Governance in the EU and UK" (*ACT | The App Association*, February 29, 2024) <<https://actonline.org/2024/02/29/ai-regulation-in-focus-balancing-innovation-and-governance-in-the-eu-and-uk/>>

⁹² European Parliament, "EU AI Act: First Regulation on Artificial Intelligence" (*Topics | European Parliament*, June 8, 2023) <<https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence>>

⁹³ Ibid

⁹⁴ Ibid

⁹⁵ Ibid

deployers of these systems enjoy a certain degree of flexibility, but they face more significant obligations compared to minimal risk AI applications. Developers of limited-risk AI systems, like chatbots, must make it clear to users that they are interacting with AI and not humans⁹⁶. This transparency helps build trust and sets the right expectations. They have the right to sell and use these AI systems throughout the EU if they follow these transparency rules. The goal of these regulations is to balance the growth of technology and business with the need to protect consumers, ensuring that these AI systems do not mislead users about their true nature⁹⁷. This regulatory setup encourages innovation while also protecting the rights and trust of users in AI technology.

Thirdly and most importantly, high-risk AI systems are subject to stringent requirements due to their significant impact on critical areas such as health, safety, and fundamental rights⁹⁸. This category encompasses AI applications in critical infrastructure e.g., transportation, education, employment, essential public and private services, law enforcement, migration, and justice⁹⁹. High-risk systems must comply with specific obligations related to data governance, documentation and traceability, transparency, human oversight, and robustness and accuracy as they may lead to violation of rights to human dignity, respect for private and family life, protection of personal data, freedom of expression and information, freedom of assembly and of association etc. In the next chapter high-risk AI systems will be examined more closely.

Lastly, AI systems that pose an unacceptable risk to people's rights and safety are prohibited outright. This category includes systems that manipulate human behaviour to the detriment of users or exploit vulnerabilities of specific groups (e.g., children). Examples include AI used for social scoring by governments, akin to practices seen in some non-EU countries¹⁰⁰. Such AI systems may lead to discriminatory outcomes and the exclusion of certain groups¹⁰¹.

By categorizing AI systems based on risk, the AI Act aims to ensure that appropriate safety measures are applied according to the potential impact of each system. This clarity fosters

⁹⁶ AI Act, Article 50(1)

⁹⁷ AI Act, Recital 74

⁹⁸ AI Act, Article 6

⁹⁹ AI Act, Annex III

¹⁰⁰ European Parliament, "EU AI Act: First Regulation on Artificial Intelligence" (*Topics | European Parliament*, June 8, 2023) <<https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence>>

¹⁰¹ Ibid

compliance and helps ensure that AI systems are developed and deployed responsibly. The risk-based approach allows for a balanced regulatory framework that does not slow down innovation. Low-risk AI systems for example face fewer regulatory obligations, encouraging innovation and the development of new AI technologies without unnecessary burdens¹⁰².

Overall, the categorization of AI systems into four risk levels in the AI Act is designed to provide a structured and proportionate regulatory approach that balances safety, innovation, consumer protection, and ethical considerations in the development and deployment of AI technologies.

3.3. Obligations for providers and users

As mentioned before, the AI Act categorizes AI systems according to their potential risk levels and implies specific obligations and rights for both AI providers and users. For example, under the AI Act AI providers are subject to different levels of regulatory requirements depending on how risky their AI systems are. For AI systems that pose high risks, providers must carry out detailed risk assessments and take steps to reduce these risks throughout the system's entire life¹⁰³. They also need to follow strict rules to make sure the data used to train, validate, and test the systems is fair and accurately represents different groups of people¹⁰⁴. Additionally, providers must be clear about what the AI can do, what it is meant for, its limitations and they must oversee the AI closely to step in if something goes wrong¹⁰⁵. They are also required to keep detailed records of how the AI operates, including the algorithms used and the sources of data to help with audits and ensure they are complying with regulations¹⁰⁶. Despite the strict rules, the AI Act also provides several benefits for AI providers to support innovation and business growth. Providers who follow the AI Act's regulations are allowed to sell and use their AI technologies throughout the entire EU, giving them a broad market to work with¹⁰⁷. Additionally, the AI Act protects the intellectual property rights of AI developers, allowing them to keep their innovations secure while they comply with the regulatory demands¹⁰⁸. This helps encourage the development and spread of new AI technologies across the EU.

¹⁰² Ibid

¹⁰³ AI Act, Article 73

¹⁰⁴ AI Act, Annex VII (4.6)

¹⁰⁵ AI Act, Article 13

¹⁰⁶ AI Act, Article 12

¹⁰⁷ AI Act, Article 2(1)

¹⁰⁸ AI Act, Recital 87

Talking about deployers, both businesses and individuals, must follow the rules set by the providers when using AI systems. This means they need to use the AI only for its intended purposes and follow the manufacturer's instructions closely¹⁰⁹. Users are also responsible for keeping an eye on how the AI is performing and must report any problems or unusual behaviour to the providers or the appropriate authorities¹¹⁰. This ensures that any issues are dealt with quickly. The AI Act ensures that users of AI, especially those using high-risk applications, are fully informed about how the systems work and the decisions they make¹¹¹. Users have the right to detailed information about these AI systems and can also understand the reasoning behind their actions¹¹². Additionally, if an AI system causes any harm, the AI Act gives users ways to address this, including the right to file complaints and seek compensation¹¹³. This helps protect consumers by ensuring they have recourse in case something goes wrong.

To sum up, the EU's AI Act classifies AI systems by risk levels, outlining specific rules for AI providers and users. Providers of high-risk AI systems must conduct thorough assessments, ensure their data is fair, and keep detailed records. Although strict, these rules also allow compliant providers to access the entire EU market and protect their inventions. Users must follow provider instructions and monitor the AI systems, reporting any issues. They are also entitled to detailed information about the AI systems they use and can seek redress if harmed. Overall, the AI Act aims to create a safe and innovative environment for AI across the EU, balancing rigorous safety requirements with support for technological advancement.

3.4. Enforcement and Penalties

A crucial aspect of any regulatory framework is its enforcement mechanism and the penalties for non-compliance. These components are essential to ensure that the regulations are not merely guidelines but enforceable standards that uphold the integrity of the legal framework. The enforcement mechanisms and penalty structures outlined in the EU AI Act, highlighting their role in ensuring compliance and safeguarding public interest.

The EU AI Act establishes a comprehensive set of enforcement mechanisms designed to monitor compliance and address violations. Central to this framework is the designation of

¹⁰⁹ AI Act, Recital 96

¹¹⁰ AI Act, Recital 91

¹¹¹ AI Act, Recital 93

¹¹² AI Act, Annex IV (3)

¹¹³ AI Act, Article 89

national supervisory authorities responsible for the oversight and enforcement of AI regulations within each member state¹¹⁴. These authorities are tasked with conducting inspections, investigating complaints, and ensuring that AI providers and users adhere to the legal requirements set forth in the AI Act.

To facilitate effective enforcement, the AI Act also calls for cooperation between national authorities and the establishment of a European AI Board¹¹⁵. This Board is envisioned to harmonize enforcement practices across the EU and provide guidance on complex or significant matters concerning AI regulation¹¹⁶. This coordinated approach is crucial given the cross-border nature of AI technologies and the need for a unified regulatory response within the single market.

The AI Act introduces a tiered penalty structure that reflects the severity of the infringement, and the level of risk associated with the AI system involved. Penalties for non-compliance are designed to be dissuasive and proportionate to the nature of the violation:

1. For minor infringements, such as failure to comply with administrative requirements, the penalties may include fines up to 1% of a company's total worldwide annual turnover of the preceding financial year or up to 7,5 million euro, whichever is higher¹¹⁷.
2. For more significant infringements, particularly those involving non-compliance with data handling or transparency obligations for high-risk AI systems, fines can reach up to 3% of the total worldwide annual turnover or 15 million euro, whichever is higher¹¹⁸.
3. In cases of extreme non-compliance, such as deploying or operating prohibited AI practices (e.g., manipulative or exploitative applications), the penalties can be as severe as 7% of total worldwide annual turnover or 35 million euro, whichever is greater¹¹⁹.

The enforcement mechanisms and penalties outlined in the EU AI Act are foundational to the effectiveness of the regulatory framework. By establishing national authorities and fostering cooperation across member states, the EU aims to ensure consistent and effective enforcement of AI regulations. The tiered penalty structure acts as a strong obstacle against non-compliance,

¹¹⁴ AI Act, Article 74(8)

¹¹⁵ AI Act, Recital 20

¹¹⁶ AI Act, Recital 53

¹¹⁷ AI Act, Article 99(5)

¹¹⁸ AI Act, Article 99(4)

¹¹⁹ AI Act, Article 99(3)

ensuring that AI developers and providers prioritize loyalty to legal standards. Together, these measures strengthen the governance of AI technologies, promoting a safe, ethical, and innovative digital future within the EU. The success of these enforcement strategies will be critical in maintaining public trust in AI and supporting the EU's position as a global leader in AI regulation.

IV. Assessing high-risk AI systems: Criteria and Impact assessments

4.1. Definition and criteria for high-risk AI

The AI Act defines AI systems as high risk if they pose significant threats to health, safety, and fundamental rights. According to the article 6 of AI Act:

“1. Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be high-risk where both of the following conditions are fulfilled:

- a) the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;
- b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.

2. In addition to the high-risk AI systems referred to in paragraph 1, AI systems referred to in Annex III shall be high-risk.”¹²⁰

The AI Act indicates three primary criteria for designating AI systems as “high-risk”:

1. **Intrinsic Nature of the AI System:** This criterion focuses on AI systems that inherently pose significant risks due to the nature of their functionality or the impact they might have on people¹²¹. For example, an AI system designed to perform

¹²⁰ AI Act, Article 6(1)

¹²¹ AI Act, Article 6(3)

surgical operations autonomously would be considered high-risk by virtue of its nature because its primary function directly affects critical aspects of human health.

2. **Safety Component Role:** Under this criterion, an AI system is designated as high-risk if it acts as a safety component within a broader product or system¹²². The AI's role is crucial in ensuring the safety of the overall product's operation. For example, an AI algorithm that controls braking in an automated vehicle or manages the safe operation of industrial machinery would fall under this category. The failure of such an AI system could lead to significant risks to health and safety.
3. **Categorical Listing:** The AI Act explicitly lists certain types of AI applications that are considered high-risk, regardless of the specific context in which they are used¹²³. This category includes AI systems used in critical infrastructure, employment and workers management, essential private and public services, law enforcement, migration management, and the administration of justice and democratic processes. Systems falling under this category are predefined because their application areas are sensitive and have profound implications for rights and freedoms.¹²⁴

AI systems in critical sectors such as healthcare, transportation, energy, and public services are considered high-risk due to the severe consequences their failure or misuse might entail. The intended purpose of the AI system significantly influences its risk level. For example, AI used in medical devices, autonomous vehicles, and employment decision-making processes are classified as high-risk because of their potential impact on human lives and livelihoods. Furthermore, AI systems that affect fundamental rights, such as privacy, freedom of expression, and non-discrimination are also perceived as high-risk. This includes systems involved in biometric identification, critical infrastructure management and legal decision-making as stated in Annex III of the AI Act¹²⁵. The degree of autonomy of the AI system and the level of human oversight available also contribute to its risk classification, with fully autonomous systems having minimal human intervention being more likely to be classified as high-risk.

Many AI systems will not fall under the regulatory framework established by the EU AI Act. For instance, broad exceptions apply to AI systems used exclusively for military, defence, or

¹²² AI Act, Article 6(1)

¹²³ AI Act, Article 6(2)

¹²⁴ AI Act, Article 6(2)

¹²⁵ AI Act, Annex III

national security purposes, irrespective of the entity involved¹²⁶. Additionally, AI systems and models developed and deployed solely for scientific research and development, as well as those involved in research, testing, and development prior to market placement or service initiation, are exempt¹²⁷. Individuals using AI systems purely for personal, non-professional activities are also excluded from the regulatory scope.

Further exceptions apply to AI systems that might otherwise be classified as high-risk under the AI Act. These systems will not be considered high-risk if they do not pose a significant risk to health, safety, or fundamental rights, and do not materially influence decision-making outcomes. Specifically, AI systems are deemed not to pose significant harm if they meet at least one of the following criteria: performing a narrow procedural task, improving the result of a previously completed human activity, detecting decision-making patterns without replacing or influencing the prior human assessment, or performing a preparatory task relevant to potential high-risk uses listed in the AI Act.

4.2. Risk assessment methodologies

The AI Act outlines several methodologies for assessing the risks associated with high-risk AI systems to ensure compliance and mitigate potential harms.

Firstly, technical documentation plays a crucial role in ensuring transparency and accountability in the development and deployment of high-risk AI systems¹²⁸. It includes detailed descriptions of the AI system's architecture, functionalities, algorithms used, and the methodologies employed for training, validation, and testing. This documentation is essential for regulators, auditors, and stakeholders to understand how the AI system operates, its intended use cases, and potential implications. It also facilitates compliance with regulatory requirements by providing a clear record of the AI system's design, performance characteristics, and data processing practices. Comprehensive technical documentation enables thorough assessments of AI system safety, accuracy, and cybersecurity measures, ensuring that the system meets regulatory standards and ethical guidelines throughout its lifecycle.

¹²⁶ AI Act, Recital 24

¹²⁷ AI Act, Recital 25

¹²⁸ AI Act, Recital 66

Secondly, the conformity assessment process is a systematic evaluation of a high-risk AI system to determine its compliance with regulatory requirements and applicable standards¹²⁹. It involves testing, verification, and validation activities conducted by accredited third-party organizations known as notified bodies. These assessments verify that the AI system operates safely, reliably, and effectively under anticipated conditions, without posing significant risks to individuals, public safety, or fundamental rights. Conformity assessments encompass a range of criteria including technical performance, cybersecurity safeguards, data protection measures, and adherence to ethical principles. By undergoing a conformity assessment, AI system providers demonstrate their commitment to ensuring the integrity and trustworthiness of their technologies, thereby fostering confidence among users, consumers, and regulatory authorities.

Thirdly, risk management system is essential for identifying, assessing, mitigating, and monitoring risks associated with high-risk AI systems throughout their lifecycle¹³⁰. Providers are required to implement structured processes and procedures to systematically analyse potential hazards, vulnerabilities, and consequences related to the AI system's deployment and operation. Risk management activities include conducting comprehensive risk assessments, defining risk acceptance criteria, implementing risk mitigation measures, and establishing mechanisms for continuous monitoring and review¹³¹. Effective risk management ensures that risks are managed proactively, minimizing the likelihood of adverse outcomes such as safety incidents, privacy breaches, or unintended biases. It also supports compliance with regulatory requirements by demonstrating a systematic approach to risk prevention and mitigation tailored to the specific characteristics and applications of the AI system.

In addition, human oversight mechanisms are critical for ensuring the responsible and ethical deployment of high-risk AI systems¹³². These mechanisms enable human intervention in AI decision-making processes, particularly in complex, ambiguous, or critical situations where human judgment is essential. Human oversight ensures accountability by allowing individuals to understand and challenge AI-generated decisions, ensuring that they align with legal, ethical, and societal norms¹³³. Transparency measures complement human oversight by providing clear

¹²⁹ AI Act, Recital 51

¹³⁰ AI Act, Article 8(1)

¹³¹ AI Act, Recital 66

¹³² AI Act, Recital 73

¹³³ Ibid

explanations of how AI systems reach their conclusions, including the data used, algorithms applied, and reasoning processes involved. Transparent AI systems empower users, stakeholders, and affected individuals to assess the fairness, reliability, and ethical implications of AI-driven decisions, fostering trust and confidence in AI technologies¹³⁴.

It is worth to mention that, testing and validation are also essential stages in the development and deployment of high-risk AI systems to verify their functionality, performance, and safety under real-world conditions¹³⁵. Testing involves conducting controlled experiments and simulations to assess the AI system's accuracy, robustness, scalability, and reliability across diverse scenarios and use cases¹³⁶. Validation ensures that the AI system achieves consistent, reliable results without unintended biases or adverse impacts on individuals or society. Rigorous testing and validation processes help identify potential issues, weaknesses, or vulnerabilities early in the AI system's lifecycle, enabling providers to implement corrective actions, optimizations, or improvements to enhance system performance and mitigate risks¹³⁷. By demonstrating robust testing and validation practices, AI system providers enhance confidence in their technologies' reliability, effectiveness, and suitability for intended applications.

Moreover, effective data governance practices are essential for ensuring the integrity, relevance, and ethical use of data throughout the lifecycle of high-risk AI systems¹³⁸. Providers must establish and maintain stringent data management policies and procedures to govern data collection, storage, processing, sharing, and disposal in compliance with regulatory requirements and ethical standards¹³⁹. Data governance encompasses measures to ensure data accuracy, completeness, and consistency, preventing biases, inaccuracies, or unauthorized access that could adversely affect AI system performance or outcomes. Quality assurance processes, data validation techniques, and transparency in data sourcing and usage enhance the reliability and trustworthiness of AI-driven insights and decisions¹⁴⁰. By prioritizing data governance, AI system providers promote accountability, fairness, and compliance with data

¹³⁴ AI Act, Article 13

¹³⁵ AI Act, Recital 139

¹³⁶ AI Act, Article 57

¹³⁷ Ibid

¹³⁸ AI Act, Article 10

¹³⁹ Ibid

¹⁴⁰ AI Act, Article 17(1)

protection principles, thereby safeguarding individuals' rights and promoting ethical AI practices.

Lastly, continuous monitoring and reporting are essential for proactive risk management and compliance with regulatory obligations throughout the operational lifecycle of high-risk AI systems¹⁴¹. Providers must establish robust monitoring mechanisms to track the AI system's performance, detect emerging risks or anomalies, and ensure ongoing compliance with regulatory requirements and ethical guidelines¹⁴². Continuous monitoring involves real-time or periodic assessments of AI system operations, data inputs, outputs and performance metrics to identify potential issues, deviations or adverse impacts¹⁴³. Prompt reporting of incidents, non-compliance events, or significant changes to the AI system to relevant authorities facilitates transparency, accountability, and timely corrective actions¹⁴⁴. By maintaining rigorous monitoring and reporting practices, AI system providers demonstrate their commitment to operational excellence, risk mitigation, and ethical governance, thereby enhancing trust, accountability, and societal acceptance of AI technologies.

These methodologies collectively form a comprehensive framework for assessing, managing, and mitigating risks associated with high-risk AI systems, promoting responsible innovation and ethical deployment across diverse sectors and applications. By adhering to these methodologies, AI system providers contribute to building trust, ensuring regulatory compliance, and fostering sustainable development of AI technologies that benefit individuals, organizations, and society as a whole.

4.3. Impact on fundamental rights

The AI Act places significant emphasis on the protection of fundamental rights in the use of AI systems. It acknowledges the impact AI technologies can have on individual rights and freedoms and thus incorporates several provisions to safeguard these rights. This section discloses impact of AI Act on fundamental rights.

¹⁴¹ AI Act, Article 88

¹⁴² AI Act, Article 89

¹⁴³ Ibid

¹⁴⁴ AI Act, Article 73

For example, a Data Protection Impact Assessment (DPIA)¹⁴⁵ is necessary whenever the processing of personal data is expected to significantly threaten individual rights and freedoms. According to the AI Act, those deploying high-risk AI systems must carry out a DPIA and submit a summary of this assessment to the relevant national authority¹⁴⁶.

The DPIA must include the information outlined in Article 13 of the AI Act in addition to what is required by Article 35 of the GDPR¹⁴⁷:

- Identification and contact details of the provider or their authorized representative.
- Description of the characteristics, capabilities, and performance limitations of the high-risk AI system, covering its purpose, level of accuracy (including metrics, robustness, and cybersecurity considerations that may impact it), and potential risks to health, safety, or fundamental rights.
- Technical specifications and characteristics of the AI system sufficient to explain its outputs.
- Target individuals for whom the system is intended.
- Specifications regarding input data, including details on training, validation, and testing datasets used.
- Information enabling deployers to interpret and use the system's outputs appropriately.
- Details of any changes made to the AI system and its performance.
- Human oversight measures as defined in Article 14.
- Computational and hardware resources required, expected system lifetime, and maintenance measures to ensure proper functioning, including software updates.
- Description of mechanisms for collecting, storing, and interpreting logs in accordance with Article 12.¹⁴⁸

Deployers may also need to conduct a Fundamental Rights Impact Assessment (FRIA) under the AI Act and report findings to the national authority¹⁴⁹. This requirement applies to public bodies, private entities offering public services, and operators of high-risk systems. The FRIA should cover:

¹⁴⁵ AI Act, Annex VIII, Section C, 5

¹⁴⁶ Ibid

¹⁴⁷ GDPR, Article 35

¹⁴⁸ AI Act, Article 13

¹⁴⁹ AI Act, Annex VIII, Section C, 4

- Description of the processes involving the system's use.
- Timeframe and frequency of intended system use.
- Individuals and groups affected by the system.
- Description of human oversight measures.
- Specific risk assessment and corresponding mitigation measures.¹⁵⁰

In practice, both DPIA and FRIA requirements can be combined into a single consolidated document that meets the criteria of both the GDPR and the AI Act, thereby streamlining administrative processes.

V. Comparative analysis with national AI initiatives

5.1. Overview of AI regulation in major EU member states

The regulatory framework for AI in major EU member states is influenced both by EU legislation, such as the AI Act, and individual national laws that are aimed to specific needs and concerns within each country. This chapter provides for the analysis of major EU member states' AI approach.

Starting with Germany which is a leader in AI regulation, focused mainly on ethical guidelines and the development of AI that aligns with European values of privacy and data protection. The German government has also invested significantly in AI research and development, aiming to ensure that AI technology supports economic growth while adhering to stringent ethical standards. Germany's AI strategy launched in 2018 focuses on fostering innovation, securing skilled labour, and ensuring ethical, human-centric development of AI which aligns with the EU's view¹⁵¹. The government plans to invest billions of euros into AI research and development, emphasizing both technological advancements and ethical considerations. Germany emphasizes adherence to GDPR and has incorporated AI-specific considerations into various sectoral regulations, especially concerning autonomous driving and healthcare¹⁵².

At the same time, France has been proactive in its approach to AI, emphasizing both the opportunities and challenges posed by AI technologies. France's AI strategy announced by

¹⁵⁰ AI Act, Article 27

¹⁵¹ European Commission, "Germany AI Strategy Report" (*AI Watch*, September 1, 2021) <https://ai-watch.ec.europa.eu/countries/germany/germany-ai-strategy-report_en>

¹⁵² Ibid

President Macron in 2018 includes significant investment in research, development of a data policy that facilitates AI innovation while protecting individuals' privacy, and a push to make France a leader in AI ethics¹⁵³. The French strategy includes fostering innovation through public and private sector collaboration and ensuring that AI development is inclusive and ethical. France has also been a strong advocate for creating a European AI regulatory framework that balances innovation with fundamental rights. France aligns closely with EU directives and has taken steps to implement AI-specific guidance within its data protection framework, guided by the French data protection authority - La Commission Nationale de l'Informatique et des Libertés (CNIL)¹⁵⁴.

Finally, Spain has been working on developing a national AI strategy that aligns with its digital and economic policies. Spain's AI strategy as a part of the broader Digital Spain 2025¹⁵⁵ initiative aims to accelerate AI deployment across the economy, boost AI research, and ensure ethical AI development. The focus is on leveraging AI to enhance economic growth, improve public sector efficiency, and address social challenges. Spain also stresses the importance of ethical considerations and the responsible use of AI and has begun integrating AI regulations into its broader digital strategy, with a strong focus on ethical standards and enhancing transparency in AI applications¹⁵⁶.

Each of the countries mentioned above tailors its approach to the unique opportunities and challenges presented by AI reflecting national priorities and cultural values while aligning with EU-wide regulations such as the GDPR and the forthcoming AI Act. This diverse regulatory approach helps to foster environments that are favourable to innovation while ensuring that AI development remains aligned with broader societal values and norms.

5.2. Comparative analysis with non-EU countries

To understand tendencies of AI regulation worldwide it is also important to compare AI regulation between the EU and non-EU countries and to reveal contrasting approaches driven by geopolitical dynamics, economic imperatives, and technological capabilities.

¹⁵³ European Commission, "France AI Strategy Report" (*AI Watch*, September 1, 2021) <https://ai-watch.ec.europa.eu/countries/france/france-ai-strategy-report_en>

¹⁵⁴ Ibid

¹⁵⁵ European Commission, "Spain AI Strategy Report" (*AI Watch*, September 1, 2021) <https://ai-watch.ec.europa.eu/countries/spain/spain-ai-strategy-report_en>

¹⁵⁶ Ibid

For example, China's national strategy, as outlined in its "Next Generation Artificial Intelligence Development Plan" seeks to make the country a world leader in AI by 2030¹⁵⁷. This strategy is comprehensive and state-driven, targeting advancements in AI capabilities across various sectors including healthcare, education, defence, and manufacturing. China's AI regulatory framework is rapidly evolving. Initially focused primarily on promoting growth and innovation, recent developments have seen a shift toward more robust regulations, particularly concerning data security and the ethical implications of AI¹⁵⁸. This includes the Cybersecurity Law, the Data Security Law, and the Personal Information Protection Law, which impose strict requirements on data collection, processing, and cross-border data transfer¹⁵⁹. These laws are part of China's broader strategy to control the AI ecosystem while safeguarding national security and social order.

At the same time the US lacks a singular national AI strategy but has several initiatives spread across various federal agencies¹⁶⁰. The approach is fragmented but highly driven by private sector innovation with significant investments in AI research and development. The US government has initiated programs like the American AI Initiative and National AI Research Resource Task Force to promote AI in public sectors, enhance AI research and establish ethical guidelines for AI deployment¹⁶¹. As was mentioned before the regulatory approach in the US is sector-specific rather than holistic. There is no comprehensive national AI policy but instead, regulations are applied based on specific applications and industries. This includes guidelines from the Federal Trade Commission on AI and consumer protection¹⁶², Department of Transportation regulations on autonomous vehicles¹⁶³, and health-related AI regulations under

¹⁵⁷ Perplexity, "China's Strategic Initiatives in Artificial Intelligence (AI): Policies, Developments, and Economic Impact" (*Perplexity*, May 21, 2024) <https://www.perplexity.ai/page/china-s-strategic-initiatives-a61GjWoJSZudk6x2W_LxvQ>

¹⁵⁸ Ibid

¹⁵⁹ Ibid

¹⁶⁰ Select Committee on Artificial Intelligence of the National Science and Technology Council, "National Artificial Intelligence Research and Development Strategic Plan 2023 Update" (May 2023) page II

¹⁶¹ Ibid, page 12

¹⁶² Federal Trade Commission, "Using Artificial Intelligence and Algorithms" (April 8, 2020) <<https://www.ftc.gov/news-events/blogs/business-blog/2020/04/using-artificial-intelligence-algorithms>>

¹⁶³ U.S Department of Transportation, "Automated Vehicles Comprehensive Plan" (January 2021) https://www.transportation.gov/sites/dot.gov/files/2021-01/USDOT_AVCP.pdf page 15

the Food and Drug Administration¹⁶⁴. Data privacy laws also vary by state, with California's Consumer Privacy Act¹⁶⁵ being one of the most developed.

Following Brexit, the UK updated its national AI strategy to emphasize leadership in ethical AI, focusing on sectors like healthcare and security. The strategy aims to leverage AI for economic growth and societal benefits, with substantial investments in AI research and infrastructure¹⁶⁶. The UK government has also initiated AI-specific programs to support startups and innovation hubs, aiming to create a conducive environment for AI development¹⁶⁷. While maintaining strong adherence to GDPR-like standards for data protection, the UK is actively working on its regulatory framework that could potentially diverge from EU norms to foster a more flexible regulatory environment¹⁶⁸. The UK focuses on creating frameworks that support the safe and ethical use of AI, emphasizing transparency, accountability, and public trust.

These diverse approaches highlight the varying priorities and strategies across major global players, from state-driven initiatives in China, market-driven approaches in the USA and ethical leadership in the UK comparing to regulatory framework in the EU. Each region adapts its AI policies to reflect its socio-economic objectives and cultural values.

5.3. Lessons for the EU AI Framework

As the EU seeks to improve its AI regulatory framework, there are valuable lessons to be learned from the regulatory experiences of the US, China, the UK and other global practices. These lessons can inform the EU's approach to create a dynamic, inclusive, and effective AI governance model.

China's centralized approach to AI development, focused on alignment with national priorities and rigorous data governance, offers several elements and practices that could benefit the EU. By adopting a similar centralized control, the EU could achieve greater consistency and efficiency in AI regulations across its member states. Additionally, China's stringent data

¹⁶⁴ The U.S. Food and Drug Administration, "Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together" (March 15, 2024) <<https://www.fda.gov/media/177030/download?attachment>>

¹⁶⁵ California Consumer Privacy Act of 2018 (CCPA)

¹⁶⁶ Secretary of State for Digital, Culture, Media and Sport by Command of Her Majesty, "National AI Strategy" (2021) page 7

¹⁶⁷ Ibid, page 28

¹⁶⁸ Ibid, page 53

governance measures, which ensure data security and ethical handling, could serve as a model for the EU to strengthen its own data protection frameworks¹⁶⁹. Moreover, China's commitment to embedding ethical considerations into AI systems could inspire the EU to develop comprehensive ethical guidelines covering fairness, accountability, and transparency¹⁷⁰. Integrating these elements into its regulatory framework could enhance the EU's effectiveness in managing AI technologies and reinforce its leadership in global ethical AI governance.

The US shows market-driven regulatory approach that fosters rapid technological advancements and innovation. This sector-specific regulations allows for tailored governance that meets the unique needs and risks associated with different AI applications. The EU could benefit from adopting a similar model, which would allow for more flexible and adaptive legislation. Additionally, the strong public-private partnerships evident in the US promote a thriving ecosystem for AI development, something the EU could strengthen to drive innovation and commercialization of AI technologies¹⁷¹.

The UK's focus on ethical AI and its implementation of advisory bodies to oversee AI ethics is also particularly instructive. The UK's use of regulatory sandboxes to test AI in controlled environments is an innovative practice that the EU could expand, facilitating safe innovation¹⁷². The UK's public engagement strategies¹⁷³, which include the public in AI discussions and policymaking, could also be adopted by the EU to enhance transparency and public trust in AI systems.

To conclude, by integrating these diverse insights from around the world, the EU can enhance its AI regulatory framework to be more robust, adaptable, and capable of fostering an environment that promotes safe, ethical, and innovative AI development. This holistic approach will not only align with the EU's technological and ethical standards but also position it as a global leader in AI governance.

VI. Challenges and critiques of the EU AI regulatory framework

¹⁶⁹ Perplexity, "China's Strategic Initiatives in Artificial Intelligence (AI): Policies, Developments, and Economic Impact" (*Perplexity*, May 21, 2024) <https://www.perplexity.ai/page/china-s-strategic-initiatives-a61GjWoJSZudk6x2W_LxvQ>

¹⁷⁰ Ibid

¹⁷¹ Select Committee on Artificial Intelligence of the National Science and Technology Council, "National Artificial intelligence Research and Development Strategic Plan 2023 Update" (May 2023) page 8

¹⁷² Secretary of State for Digital, Culture, Media and Sport by Command of Her Majesty, "National AI Strategy" (2021) page 50

¹⁷³ Ibid, page 42

6.1. Practical implementation challenges

The EU's ambitious approach to AI regulation i.e. the AI Act aims to standardize the deployment and management of AI technologies across its member states. However, the practical implementation of such a comprehensive regulatory framework presents several challenges including the diversity of the AI applications, the rapid pace of technological change, and the varying capabilities of member states to enforce these regulations.

One of the foremost challenges in implementing the EU AI regulatory framework is the diversity within the AI ecosystem¹⁷⁴. AI technologies range from simple algorithms used in everyday applications to complex systems that drive critical infrastructures and implement decision-making processes. This variability complicates the application of a uniform regulatory approach. As mentioned before, the AI Act categorizes AI systems based on risk, but the dynamic nature of AI applications means that these categories need constant updates and revisions¹⁷⁵. Ensuring that the regulatory framework remains relevant and effective as AI technologies evolve requires a flexible and responsive regulatory mechanism, which can be difficult to maintain across 27 member states with different technological level of development¹⁷⁶.

The rapid pace of technological advancement in AI presents another significant challenge. The AI development is highly dynamic, with new methodologies, capabilities, and applications emerging at a fast pace every day. Regulatory frameworks traditionally are behind technological developments and there is a risk that by the time regulations are drafted, debated, and implemented, the technology landscape may be completely different. This lag can become an obstacle for innovation and make it difficult for EU regulations to keep pace with global technological standards, potentially putting European AI industries at a competitive disadvantage.

As mentioned above, the EU consists of member states with varying levels of technological advancement and regulatory capabilities. Implementing a uniform AI regulatory framework

¹⁷⁴ Vainionpää F and others, "A Review of Challenges and Criticisms of the European Artificial Intelligence Act (AIA)" (December 1, 2023), page 12

¹⁷⁵ Ibid, page 13

¹⁷⁶ The World Bank, "Transformative technologies (AI) challenges and principles of regulation" (May 8, 2024) <<https://digitalregulation.org/3004297-2/>>

across such a diverse economies and technological infrastructures is challenging. Some member states may lack the technical expertise, resources, or infrastructure to effectively enforce the AI regulations. This disparity can lead to uneven application of the legislation, where some countries might implement and enforce regulations more rigorously than others, leading to a fragmented digital single market¹⁷⁷.

AI technologies often operate across borders, processing data from multiple jurisdictions. The GDPR adds layers of complexity to the regulation of AI. Ensuring that AI systems comply with these regulations while operating internationally requires extensive coordination and cooperation with non-EU countries. Moreover, the EU's approach to data privacy and AI regulation might differ significantly from those of other major players like the US and China, potentially leading to conflicts and challenges in international AI projects and data flows¹⁷⁸.

To sum up, practical implementation of the EU AI regulatory framework faces significant challenges such as the diversity of AI applications, the rapid pace of technological advancements, and the varied capabilities of the EU member states. Furthermore, the international nature of AI technologies will require cross-border cooperation, which may become a challenge due to differing regulatory standards. Addressing these challenges requires a dynamic regulatory approach that can adapt to technological changes together with strong support systems for less technologically advanced member states to ensure united enforcement. Only by addressing these variety of challenges can the EU hope to successfully implement a regulatory framework that harnesses the benefits of AI while safeguarding the rights and safety of its citizens.

6.2.Criticisms from various stakeholders

The EU AI Regulatory framework has faced various criticisms from multiple stakeholders across the EU. These criticisms typically include the framework's potential impact on innovation, its practical enforceability, and the balance it seeks between regulation and technological freedom.

¹⁷⁷ Caroli L, "Will the EU AI Act work? Lessons learned from past legislative initiatives, future challenges" (*IAPP*, April 17, 2024) <<https://iapp.org/news/a/will-the-eu-ai-act-work-lessons-learned-from-past-legislative-initiatives-future-challenges>>

¹⁷⁸ Ibid

One of the most vocal criticisms comes from the technology sector, particularly startups and SME, which argue that the stringent regulations imposed by the AI Act could slow down the innovation¹⁷⁹. They mark that the heavy regulatory burden not only places significant financial pressure on small companies but also delays the time to market for new AI innovations. This could potentially slow down the competitiveness of European AI firms against global counterparts, particularly those in less regulated markets like the US and China¹⁸⁰.

Legal experts and academic circles have pointed out that the AI Act while being comprehensive suffers from vagueness in its definitions and classifications¹⁸¹. The categorization of AI systems according to risk is seen as overly broad, leading challenges for the interpretation that could result in inconsistent application across member states¹⁸². It complicates compliance for AI developers, who require clear and precise guidelines to navigate the regulatory landscape effectively.

From an economic perspective, there is significant concern about the compliance costs associated with the AI Act¹⁸³. Representatives from the industry argue that the need to conduct extensive conformity assessments, maintain detailed documentation, and stick to strict compliance requirements could disproportionately affect smaller market players, potentially leading to market consolidation where only large corporations can afford to operate¹⁸⁴. This could reduce diversity in the AI market, ultimately impacting innovation and market dynamics.

Specifically focusing on SMEs and startups, these entities often lack the resources to manage comprehensive risk assessment and mitigation strategies that are mandated for high-risk AI applications. The framework's one-size-fits-all approach is seen as not sufficiently accommodating the varied capabilities and resources of different-sized entities within the industry¹⁸⁵.

¹⁷⁹ Ibid

¹⁸⁰ Pernot-Leplay E, "The AI Regulation Dilemma: A China, EU & U.S. Comparison" (*Emmanuel Pernot-Leplay*, December 27, 2023) <<https://pernot-leplay.com/ai-regulation-china-eu-us-comparison/>>

¹⁸¹ Labuz M, "Regulating Deep Fakes in the Artificial Intelligence Act" (October 27, 2023) <<https://www.acigjournal.com/pdf-184302-105060?filename=Regulating%20Deep%20Fakes%20in.pdf>> page 28

¹⁸² Ibid, page 25

¹⁸³ Renda A, "Clarifying the Costs for the EU's AI Act" (*CEPS*, September 24, 2021) <<https://www.ceps.eu/clarifying-the-costs-for-the-eus-ai-act/>>

¹⁸⁴ Ibid

¹⁸⁵ Turgay S and Aydın A, "Risk Mitigation for SMEs: A Step-by-Step Guide to Implementing an Effective Framework" (August 25, 2023)

Critics also argue that the EU's AI regulatory framework could isolate European AI development from the global market¹⁸⁶. By imposing stricter regulations than those seen in other major economies, the EU risks creating a market that is less attractive for international investment and collaboration. This isolation could be an obstacle for European entities' ability to engage in international research and development projects, limiting their exposure to global innovations and ideas¹⁸⁷.

While the EU's AI regulatory framework sets a global precedent in terms of its comprehensive approach to regulating AI technologies, it faces significant criticisms concerning its impact on innovation, vagueness in legal texts, high compliance costs, and potential global isolation. Addressing these concerns requires a precise balance between enforcing safety and ethical standards and maintaining a vibrant, competitive, and innovative AI sector. For the EU to succeed in its regulatory ambitions, it must consider these criticisms seriously, adapting its approach to foster an environment where safety, innovation, and economic viability coexist. Only then the framework can serve as a truly effective model for AI governance both within and outside the EU.

6.3. Analysis of regulatory gaps

A thorough analysis reveals several gaps within the EU AI regulatory framework. Despite its ambitious scope, the framework exhibits certain regulatory gaps that may impact its effectiveness and efficiency.

One of the most significant gaps in the EU AI regulatory framework is its potential inability to keep pace with the rapid advancements in AI technology¹⁸⁸. AI is a fast-evolving field, with new technologies and applications emerging at a speed that can outpace legislative processes. The framework's current structure may not be flexible enough to accommodate unforeseen

<https://www.researchgate.net/publication/373392193_Risk_Mitigation_for_SMEs_A_Step-by-Step_Guide_to_Implementing_an_Effective_Framework>

¹⁸⁶ Krasodonski A, "The EU's New AI Act Could Have Global Impact" (*Chatham House – International Affairs Think Tank*, March 13, 2024) <<https://www.chathamhouse.org/2024/03/eus-new-ai-act-could-have-global-impact>>

¹⁸⁷ Ibid

¹⁸⁸ Wheeler T, "The Three Challenges of AI Regulation" (*Brookings*, June 15, 2023) <<https://www.brookings.edu/articles/the-three-challenges-of-ai-regulation/>>

developments or the swift evolution of AI capabilities, leading to regulations that could quickly become outdated or irrelevant¹⁸⁹.

The EU composed of various sovereign states each with its own legal system and enforcement mechanisms faces challenges in applying and enforcing AI regulations consistently across different jurisdictions¹⁹⁰. This inconsistency could result in regulatory arbitrage, where AI developers might choose to operate in member states with less stringent enforcement to avoid tougher regulations¹⁹¹. Achieving uniform enforcement throughout the EU is crucial for the success of the regulatory framework but remains complex due to differences in national capabilities and interpretations of the rules.

Additionally, as mentioned before the framework has been criticized for its vague and sometimes ambiguous definitions of key AI-related terms¹⁹². This lack of clarity can lead to different interpretations of what compliance entails, complicating the responsibilities of both AI developers and regulatory bodies¹⁹³. Without clear definitions, companies may find it difficult to ensure their AI systems fully comply with regulations, potentially resulting in unintentional non-compliance or hindering innovation due to legal uncertainties.

The EU's AI regulatory framework represents a significant step forward in the global governance of AI. However, it is not without its gaps, which could potentially undermine its effectiveness. Addressing these gaps requires a dynamic regulatory approach that can adapt to the fast-paced evolution of AI technologies, more precise legal definitions, stronger measures for cross-border enforcement, and enhanced protections for low-risk AI applications. By closing these gaps, the EU can ensure that its AI framework not only protects citizens but also fosters a healthy, innovative AI ecosystem that can thrive both within and beyond its borders.

VII. Future prospects and recommendations

7.1. Future regulatory trends

¹⁸⁹ Ibid

¹⁹⁰ Ibid

¹⁹¹ Ibid

¹⁹² Nordström M, "AI under Great Uncertainty: Implications and Decision Strategies for Public Policy" (September 7, 2021) page 1706

¹⁹³ Ibid, page 1706

As the EU navigates the evolving landscape of AI, its regulatory framework aims to ensure safe, transparent, and ethical deployment of AI technologies. Given the rapid development of AI and its significant societal impacts, the framework must continually adapt. It is expected to shift towards more dynamic and scalable regulations that can adjust to new technological developments, making the regulations more flexible and responsive to changes¹⁹⁴.

The EU also anticipates greater international cooperation and the harmonization of standards to manage AI's global nature¹⁹⁵. This includes active participation in global forums to establish universal AI norms, ensuring consistent regulations across borders and preventing companies from exploiting less stringent regulations in other regions¹⁹⁶.

Ethics remains a central focus, with future regulations expected to emphasize the design and deployment of AI systems that uphold human rights, privacy, and non-discrimination. Additionally, the concept of human oversight may expand to ensure AI systems incorporate meaningful human control, particularly in critical sectors like healthcare and law enforcement.

The EU may also introduce sector-specific regulations to address the unique risks in fields like healthcare, autonomous vehicles, and financial services, ensuring that safeguards are stringent without hindering innovation in less critical applications¹⁹⁷. Moreover, as AI systems increasingly make autonomous decisions, there may be a need to revise liability frameworks to clearly define accountability when AI systems cause harm¹⁹⁸.

In conclusion, the EU's AI regulatory framework is set to evolve significantly, adopting flexible regulations, fostering global cooperation, focusing on ethical AI development, tailoring regulations to specific sectors, and updating liability standards. These changes aim not only to protect citizens but also to create an environment where AI can prosper and positively contribute to society, shaping the future of AI in a beneficial and sustainable way.

¹⁹⁴ Rodríguez Ovejero J.M., "The Future of AI Regulation in Europe" (*Frontier Economics*) <<https://www.frontier-economics.com/uk/en/news-and-insights/articles/article-i7081-the-future-of-ai-regulation-in-europe/>>

¹⁹⁵ Cha S, "Towards an International Regulatory Framework for AI Safety: Lessons from the IAEA's Nuclear Safety Regulations" (*Humanities and Social Sciences Communications*, July 10, 2024) page 6

¹⁹⁶ Ibid, page 6

¹⁹⁷ Lölfling N, "Impact of the EU's AI Act Proposal on Automated and Autonomous Vehicles" (*Bird & Bird*, April 12, 2023) <<https://www.twobirds.com/en/insights/2023/global/impact-of-the-eus-ai-act-proposal-on-automated-and-autonomous-vehicles>>

¹⁹⁸ Ibid

7.2. Recommendations for policymakers

As the EU continues to refine its approach to regulating AI, the rapid pace of technological advancement poses unique challenges. The EU's regulatory framework must not only protect citizens but also encourage innovation and maintain competitiveness on the global stage.

To address the dynamic nature of AI technology, it is crucial that the EU's regulatory framework incorporates flexibility and adaptability. The introduction of mechanisms such as “sunset clauses”, which mandate the periodic review and expiration of regulations unless they are explicitly renewed, can ensure that the legal environment keeps pace with technological developments¹⁹⁹. Additionally, the framework should be adaptable, allowing for quick updates and modifications in response to new technological challenges and opportunities²⁰⁰. This approach will help prevent the regulations from becoming obsolete and ensure they continue to effectively address the evolving landscape of AI technologies.

Given the global nature of AI development and deployment, the EU should prioritize international collaboration to achieve harmonization of AI regulations²⁰¹. By engaging in dialogues with other international bodies and countries to establish common standards and norms, the EU can facilitate cross-border AI development and simplify compliance for multinational enterprises²⁰². This strategy not only prevents regulatory fragmentation but also enhances the global competitiveness of EU-based AI companies by ensuring that AI technologies developed within the EU are compliant with international standards, thereby expanding their market access²⁰³.

Supporting research and innovation in AI especially in areas such as ethical AI and technologies that enhance transparency and accountability is essential²⁰⁴. The EU can drive advancements in these fields through increased funding and the establishment of public-private partnerships and innovation hubs²⁰⁵. This support not only positions the EU as a leader in

¹⁹⁹ Bildt C and others, “Spotlight Series on Global AI Policy -- Part I: European Union” (*Inside Global Tech*, October 4, 2023) <<https://www.insideglobaltech.com/2023/10/04/spotlight-series-on-global-ai-policy-part-i-european-union/>>

²⁰⁰ Ibid

²⁰¹ Ibid

²⁰² Ibid

²⁰³ Ibid

²⁰⁴ European Commission, White Paper on Artificial Intelligence: a European approach to excellence and trust [2020] COM(2020) 65 final

²⁰⁵ Ibid

ethical AI development but also stimulates economic growth and technological leadership within the region.

To ensure that AI regulations align with societal values and public interests, policymakers must enhance efforts to engage the public in AI-related discussions. Furthermore, investing in AI education and literacy programs can increase public understanding and acceptance of AI technologies²⁰⁶. An informed and educated public is crucial for fostering an environment where AI can be both accepted and critically evaluated, ensuring that AI development is guided by the needs and values of society²⁰⁷.

The application of AI across various sectors—each with its own set of risks and requirements—necessitates the development of sector-specific regulatory guidelines²⁰⁸. Tailoring regulations to the specific needs and challenges of sectors such as healthcare, automotive, or finance ensures that safeguards are both appropriate and effective, facilitating innovation while protecting the public from potential harms associated with AI technologies²⁰⁹.

As AI systems increasingly perform complex tasks autonomously, updating liability and accountability frameworks to define clear responsibilities when AI systems fail, or cause harm is imperative²¹⁰. This includes considering new legal categories for autonomous AI systems and ensuring that victims of AI-related incidents have clear avenues for redress.

The recommendations provided aim to create a robust, flexible, and forward-looking regulatory environment that not only protects EU citizens but also promotes a thriving, innovative AI ecosystem. By adopting these strategies, EU policymakers can ensure that the region remains at the forefront of ethical AI development and deployment, effectively balancing the benefits of AI with the need for oversight and public accountability.

²⁰⁶ Mantovani B, “Why AI Literacy Is Essential for Public Administration” (*Eipa*, May 21, 2024) <<https://www.eipa.eu/blog/ai-literacy-for-public-administration/>>

²⁰⁷ Ibid

²⁰⁸ Ross J, “Beyond the Black Box: Tailoring AI Regulation in Healthcare” (*Applied Clinical Trials*, April 30, 2024) <<https://www.appliedclinicaltrialsonline.com/view/beyond-the-black-box-tailoring-ai-regulation-in-healthcare>>

²⁰⁹ Ibid

²¹⁰ Mack O and others, “Legal Tech: Liability and Responsibility in the Age of AI” (*ACC Docket*, April 9, 2024) <<https://docket.acc.com/legal-tech-liability-and-responsibility-age-ai>>

7.3. Enhancing cooperation with international partners

As the EU leads the way in regulating AI there is a growing need to work more closely with international partners. This collaboration is crucial not just for aligning regulatory standards but also for driving innovation and promoting ethical AI practices globally²¹¹. AI technology crosses international borders, making it important for the EU's regulations to be recognized and effective outside its own territory. Working together with other countries can help standardize rules, making it easier for companies to operate internationally while adhering to privacy, security, and ethical standards²¹².

To boost international cooperation, the EU could engage in several strategic actions. One effective approach is forming formal agreements with other nations and international organizations²¹³. These agreements create a structured framework that encourages a unified approach to AI regulation, promoting mutual understanding and a committed collaborative effort.

Another key strategy involves the EU's active participation in international AI forums and organizations like the OECD or UNESCO²¹⁴. By engaging in these global platforms, the EU can influence the development of worldwide AI policies that reflect shared values of ethical AI use²¹⁵. This not only helps in shaping a consistent global regulatory landscape but also allows the EU to promote its principles on a larger stage, potentially leading to broader adoption.

Additionally, the formation of strategic partnerships and alliances focused on AI can lead to deeper collaboration on specific challenges²¹⁶. These partnerships can target areas such as combating AI bias, enhancing cybersecurity measures in AI systems, and developing global ethical standards²¹⁷. By leveraging collective expertise and resources, the EU can facilitate the

²¹¹ Panait C and others “Striking the Balance between Innovation and Regulation in AI – Is Europe Leading the Way or Lagging Behind?” (October 25, 2021) <https://www.researchgate.net/publication/357992486_Striking_the_balance_between_innovation_and_regulation_in_AI_-_is_Europe_leading_the_way_or_lagging_behind>

²¹² Ibid

²¹³ Ibid

²¹⁴ UNESCO, “Artificial Intelligence: Partnership between UNESCO and the EU to Speed up the Implementation of Ethical Rules” (June 28, 2023) <<https://www.unesco.org/en/articles/artificial-intelligence-partnership-between-unesco-and-eu-speed-implementation-ethical-rules>>

²¹⁵ Ibid

²¹⁶ Kondu R, “AI Risks: Exploring the Critical Challenges of Artificial Intelligence” (*Lakera – Protecting AI teams that disrupt the world.*) <<https://www.lakera.ai/blog/risks-of-ai>>

²¹⁷ Ibid

development of robust and universally accepted AI solutions that adhere to high ethical standards.

Lastly, working towards harmonizing regulatory frameworks is crucial. The EU can collaborate with other regions to develop a set of minimum universal standards for AI, particularly focusing on critical issues like data privacy, algorithmic transparency, and accountability²¹⁸. This effort to harmonize regulations can reduce barriers to technology transfer and market entry, making it simpler for AI companies to operate internationally under a common set of rules²¹⁹.

By implementing these strategies, the EU can enhance its international cooperation in AI regulation, leading to more consistent global standards, fostering trust in AI technologies, and accelerating the pace of ethical AI innovation. This commitment to robust, ethical, and transparent AI regulation, supported by enhanced international collaboration, not only protects European citizens but also contributes to a safe and ethical global digital ecosystem. This approach solidifies the EU's position as a global leader in the regulation of emerging technologies.

Conclusion

The EU's AI Act represents a significant milestone in the regulation of AI, aiming to foster trust, transparency, and accountability in the development and deployment of AI technologies. Through a comprehensive framework that addresses ethical considerations, promotes innovation, and strengthens regulatory oversight, the AI Act seeks to ensure that AI systems are developed and used responsibly to benefit individuals and society as a whole.

Throughout this master thesis, we have examined various aspects of the EU AI regulatory framework, including its historical development, legal foundations, key provisions, assessment criteria for high-risk AI systems, stakeholder perspectives, comparative analysis with national initiatives, challenges, and future prospects. Each component contributes to a nuanced understanding of the opportunities and challenges associated with regulating AI in the EU.

²¹⁸ Atticus Education, "European Union's 2024 AI Laws: A Global Milestone" (*European Union AI Laws: A Global Milestone*, March 22, 2024) <<https://www.atticuseducation.ae/european-unions-2024-ai-laws/>>

²¹⁹ Ibid

While the AI Act represents a significant step forward in promoting ethical AI development and protecting fundamental rights, it also faces several challenges and critiques. Concerns about its potential impact on innovation, enforcement complexities, adequacy in addressing ethical issues, and the balance between regulation and flexibility highlight the need for continuous refinement and adaptation.

Looking ahead, it is essential to advance ethical AI development, foster innovation and competitiveness, strengthen regulatory frameworks, and empower stakeholder engagement. By addressing these priorities, policymakers can navigate the complexities of AI governance and harness the transformative potential of AI technologies for the benefit of society.

As AI continues to evolve and shape our world, the EU's commitment to responsible AI regulation serves as a guiding beacon for other regions and nations. By working collaboratively and adopting a proactive approach to AI governance, we can build a future where AI technologies contribute to a more equitable, sustainable, and inclusive society for generations to come.

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