THE ADOPTION AND HARMONISATION OF REGULATION (EU) 2024/1689 (AI ACT) AND REGULATION (EU) 2018/1725 (EUDPR): CHALLENGES AND BEST PRACTICES

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Abstract

The adoption of Regulation (EU) 2024/1689 (AI Act) represents a significant advancement in the European Union's regulatory approach to artificial intelligence, aiming to balance technological innovation with the protection of fundamental rights. This paper critically examines the interplay between the AI Act and Regulation (EU) 2018/1725 (EUDPR), highlighting challenges and proposing best practices for their effective harmonization.

The research identifies key intersections and potential conflicts between the two regulations, particularly regarding data processing, transparency, and algorithmic accountability. A primary concern is reconciling the AI Act's rigorous requirements for monitoring and transparency of high-risk AI systems with the EUDPR's strict principles on data minimization and retention. These conflicting mandates present substantial operational and legal challenges for EU institutions, private organizations, and end-users.

Drawing from lessons learned in implementing GDPR and EUDPR, the study provides practical recommendations to enhance compliance, such as the introduction of unified certification frameworks, dedicated support resources for SMEs, and clear interpretative guidelines from supervisory bodies. Additionally, the paper emphasizes the importance of coordinated enforcement mechanisms and flexible regulatory frameworks capable of adapting to rapid technological advancements.

Ultimately, the paper concludes that the EU's distinct regulatory approach, centred on safeguarding fundamental rights and promoting transparent AI technologies, positions Europe as a global pioneer. However, its success depends on effectively managing the harmonization between overlapping regulations. The insights and recommendations presented offer practical pathways for policymakers and stakeholders to navigate the complexities of implementing these regulations, fostering an environment where innovation thrives alongside robust protection of individual rights.

Keywords: *EU AI Act, Data Protection Compliance, Regulatory Harmonization, AI Governance, Fundamental Rights.*

1. Introduction

The European Union has consistently responded to socio-economic challenges through deeper integration and comprehensive legislative frameworks[1], a trend clearly exemplified by the recent adoption of Regulation (EU) 2024/1689 (AI Act). As the first harmonized set of rules governing artificial intelligence systems across the EU, the AI Act represents a landmark development in technology regulation. This paper critically examines the complex interplay between the AI Act and Regulation (EU) 2018/1725 (EUDPR), focusing on the challenges of harmonization and proposing practical approaches to ensure effective implementation of both regulatory frameworks within EU institutions and beyond.

The significance of this research lies in the accelerating deployment of AI technologies across critical sectors such as healthcare, finance, and public administration. These applications generate substantial benefits but simultaneously raise serious concerns regarding transparency, accountability, and fundamental rights protection. As AI systems frequently involve the processing of massive amounts of personal data, including sensitive information, there exists a pressing need to reconcile the AI Act's rigorous requirements for high-risk AI systems with the EUDPR's strict data protection principles, particularly regarding data minimization, purpose limitation, and storage constraints. This reconciliation is crucial not only for legal compliance but also for maintaining the EU's distinct regulatory approach that prioritizes human-centric AI development while fostering technological innovation.

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[1] A. Fuerea, *Manualul Uniunii Europene*, 6th ed., revised and added, Universul Juridic Publishing House, Bucharest, 2016, p. 13.

The legislative journey of the AI Act, culminating in the provisional agreement between the European Parliament and the Council of the European Union in December 2023, underscores the EU's commitment to balanced regulation. In parallel, EUDPR continues to serve as the fundamental legislative framework for data protection within EU institutions, bodies, offices, and agencies. Their intersection creates both opportunities for regulatory synergy and challenges for practical implementation, particularly regarding privacy by design requirements (art. 27 EUDPR) and the supervision mechanisms involving the European Data Protection Supervisor (EDPS).

Methodologically, this paper employs a comprehensive comparative legal analysis of both regulations, identifying key points of intersection and potential conflicts. The research draws on practical implementation challenges faced by organizations required to comply with both frameworks, examining operational constraints experienced by data controllers and AI system providers. This approach is complemented by evaluations of early compliance efforts across different sectors and stakeholder consultations to ensure practical relevance. Through this multifaceted methodology, the paper develops actionable recommendations based on empirical evidence rather than theoretical constructs alone. This research offers a meaningful contribution to the current body of literature by addressing a largely overlooked aspect of European digital governance: the practical harmonization of artificial intelligence regulation and data protection law. While much of the existing scholarship has treated these regulatory frameworks as separate legal domains, there has been limited analysis of how they intersect in operational settings. This study fills that gap by providing an applied perspective that draws on both legal expertise and practical experience in technology implementation. It advances the discussion by proposing concrete mechanisms to reconcile the AI Act's emphasis on transparency and documentation with the EUDPR's strict requirements for data minimization, particularly in the context of high-risk AI systems used within EU institutions.

For the author, this research represents an opportunity to leverage dual expertise in information technology security and EU law, bringing a uniquely applied perspective on regulatory implementation. Drawing from professional experience in implementing IT security measures that comply with data protection requirements while enabling innovative technologies, the paper offers insights at the intersection of legal theory and practical application – a perspective increasingly valuable as technological governance frameworks continue to evolve.

2. Legal and Institutional Framework

2.1. Legal basis and procedure for the adoption of the AI Act

The accelerated evolution of AI-based technologies has led to the need to establish a comprehensive regulatory framework at EU level. In this context, the adoption of Regulation (EU) 2024/1689[2] on harmonized rules on artificial intelligence (*AI Act*) marks a fundamental moment in the history of the regulation of emerging technologies in the European space. This innovative legal instrument establishes a comprehensive regulatory framework for the development and deployment of artificial intelligence systems, aiming to strike a balance between technological progress and the protection of the fundamental rights of European citizens. The emergence of the *AI Act* is the result of a confluence of socio-technological and legal factors. The proliferation of AI-based applications in critical sectors such as health, financial services, and public administration has underscored the necessity for a uniform regulatory framework. This technological expansion, while beneficial for innovation, has given rise to legitimate concerns about the protection of fundamental rights and algorithmic transparency, which required a coherent legislative approach at European level[3]. The critical dimension of the regulation of high-risk artificial intelligence systems was a key catalyst in the process of passing the *AI Act*. Matei-Crăciunescu, M.[4] points out that the absence of specific rules in areas such as recruitment, lending or biometric surveillance could generate significant vulnerabilities in the protection of fundamental rights, including non-discrimination and the protection of personal data.

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[2] The European Parliament and the Council of the European Union. (2018). Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data. Official Journal of the European Union (*https://eur-lex.europa.eu/legal-content/RO/TXT/?uri=CELEX%3A32018R1725*).

[3] M. Barrio Andrés, *European Regulation on Artificial Intelligence*, 2024.

[4] M. Matei-Crăciunescu, *Artificial Intelligence – regulated at European level*, 2024 (*https://www.firon-barnir.com/editorial/mihaela-matei-craciunescu-artificial-intelligence-regulated-at-european-level/*).

In the global context of artificial intelligence regulation, the European Union's approach is distinguished by its emphasis on the protection of fundamental rights and the precautionary principle. Unlike the fragmented model of the United States or China's centralized approach, the European regulatory framework proposes a balanced vision, aligned with the principles enshrined in the GDPR and EUDPR.[5] This alignment demonstrates the EU's strategic consistency in developing a digital ecosystem based on democratic values and fundamental rights. The economic and competitive dimension also played a crucial role in shaping the *AI Act*. In the paper *„Demystifying the Draft EU Artificial Intelligence Act. Computer Law & Security Review"*, Veale and Zuiderveen Borgesius[6] highlight that the architecture of the regulation was designed to incentivise sustainable innovation by introducing risk assessment mechanisms and compliance requirements that do not unduly burden European AI developers. This balanced approach aims to strengthen the EU's position in the global competition for the development of emerging technologies, while maintaining high standards for the protection of citizens' rights. It is important to note that on 6 December 2022, the Council of the European Union adopted its common position on this legislative act. The Council's main objective was to ensure that artificial intelligence systems placed on the EU market are secure and respect fundamental rights and Union values. Ivan Bartoš, Czech Deputy Prime Minister for Digitalisation and Minister for Regional Development, stressed the importance of balancing AI innovation and respecting the fundamental rights of European citizens[7]. Subsequently, on 9 December 2023, the European Parliament and the Council reached a provisional agreement on the AI Act. This regulation aims to protect fundamental rights, democracy, the rule of law and environmental sustainability against the risks associated with AI, while promoting innovation and strengthening Europe's position in this area. The regulation sets out obligations for AI systems, based on their risks and potential impact[8].

In parallel with the EU's efforts, the Council of Europe has developed a draft Framework Convention on Artificial Intelligence, Human Rights, Democracy and the Rule of Law. This project underlines Europe's commitment to regulating AI in a way that protects fundamental values and ensures the responsible use of emerging technologies[9].

The adoption *of AI Act* is based on the EU's need to create a harmonized regulatory framework for regulating the use of artificial intelligence systems. These competences highlight the EU's supranational dimension, enabling it to exercise powers explicitly conferred by Member States in clearly defined policy areas[10]. Thus, the *AI Act* aims to eliminate the fragmentation of national regulations and ensure the application of uniform rules on the development and use of AI in all Member States.

2.1.1. Legislative process and adoption steps

The adoption *of the AI Act* followed the ordinary legislative procedure (co-decision), involving the European Commission, the European Parliament and the Council of the European Union. The European Commission presented the initial proposal in April 2021, based on the principles of protection of fundamental rights, safety and transparency in the use of AI. In December 2022, the Council of the European Union adopted its common position, stressing the importance of regulation that promotes AI in a safe way and in line with the EU's fundamental values. The next step was the interinstitutional negotiations (*trilogues*) between the European Parliament, the Council and the Commission, which were finalized in December 2023 with a provisional agreement on the final text.

The regulation was voted in the plenary session of the European Parliament and the Council of the European Union and entered into force in 2024, thus establishing the first comprehensive regulatory framework dedicated to artificial intelligence at European level.

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[5] J. Chun, C. Schroeder de Witt, K. Elkins, *Comparative Global AI Regulation: Policy Perspectives from the EU, China, and the US*, 2024 (*https://arxiv.org/abs/2410.21279*).

[6] M. Veale, F. Zuiderveen Borgesius, *Demystifying the Draft EU Artificial Intelligence Act*, in Computer Law & Security Review, 43, 105632, 2024.

[7] Council of the European Union (2022, December 6), Artificial Intelligence Act: Council calls for promoting safe AI that respects fundamental rights (*https://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID3972178_code2070340.pdf?abstractid=3896852&mirid=1*).

[8] European Parliament (2023, December 6), Artificial Intelligence Act: Deal on comprehensive rules for trustworthy AI

[9] Council of Europe (2023), Committee on Artificial Intelligence (CAI) - Draft framework convention on artificial intelligence, human rights, democracy and the rule of law.

[10] A. Fuerea, *Dreptul Uniunii Europene – principii, acțiuni, libertăți*, Universul Juridic Publishing House, Bucharest, 2016, p. 23.

2.1.2. Fundamental principles of the AI Act

The AI Act was built on a series of essential principles designed to ensure a balance between innovation and the protection of fundamental rights:

- **risk-based approach** – AI systems are classified according to the risks they pose to citizens' rights and freedoms. Those with unacceptable risk (*e.g.*: AI systems that manipulate human behaviour) are prohibited, and those with high risk (*e.g.*: used in critical infrastructure or law enforcement) are subject to strict compliance requirements[11];

- **transparency and explainability** – AI systems must be developed and implemented in such a way as to allow the decisions they generate to be understood. This principle aims to reduce the risks of algorithmic opacity and discrimination;

- **human oversight and accountability** – AI operators and developers must implement measures that ensure human control over artificial intelligence systems;

- **data protection and compliance with existing legislation** – The AI Act aligns with the General Data Protection Regulation (EU) 2016/679 (GDPR) and Regulation (EU) 2018/1725 (EUDPR), imposing privacy requirements by design and by default for AI systems that process personal data.

2.1.3. AI Act's relationship with international initiatives

The European Union has strengthened its leadership in regulating AI by adopting a governance model that focuses on the protection of fundamental rights. This model is distinct from the approach of the United States, where AI regulation is fragmented and dominated by sectoral initiatives, as well as China, which promotes centralized, state-controlled regulation[12].

In parallel with the *AI Act*, the Council of Europe proposed a draft Framework Convention on Artificial Intelligence, Human Rights, Democracy and the Rule of Law, highlighting the importance of harmonized international standards.

2.1.4. Implementation and applicability of the AI Act

In order to ensure the effective application of the Regulation, *the AI Act* provides:
- establish a European AI Council, which will coordinate implementation at EU level;
- specific obligations for AI developers and users, including technical documentation, auditing and compliance requirements;
- penalties for non-compliance with the regulation, which can reach up to €35 million or 7% of the company's global annual turnover[13].

2.2. Relationship with other EU legal instruments

The Regulation is not an isolated act, but is part of a complex legal ecosystem, having close links with the GDPR, EUDPR, as well as other relevant legislative instruments in the digital, competition and fundamental rights fields. One of the most important pieces of legislation with which the AI Act must be correlated is GDPR, which establishes the general framework for the protection of personal data in the European Union. It imposes clear rules on the collection, processing and use of personal data, rules that also apply to AI systems, in particular those that process sensitive information. From this perspective, the AI Act comes as a complement to the GDPR, imposing additional obligations for AI systems considered to be high-risk. These obligations include increased requirements for transparency, verification and human oversight, given the significant impact that automated decisions can have on European citizens. The relationship between the two regulations is one of interdependence: if the GDPR sets out the general rules on data protection, the AI Act clarifies the specific requirements for emerging technologies that process such data.

In parallel, the AI Act must also be linked to the ePrivacy Regulation, a piece of legislation designed to complement the GDPR by establishing specific rules in the field of digital communications. This regulation has a direct impact on the use of artificial intelligence, in particular with regard to the analysis of online user behavior,

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[11] M. Barrio Andrés, *op. cit.*
[12] J. Chun, C. Schroeder de Witt, K. Elkins, *op. cit.*
[13] M. Veale, F. Zuiderveen Borgesius, *op. cit.*

personalized advertising and the use of data collected through smart devices. The AI Act must therefore be harmonized with the requirements of the ePrivacy Regulation in order to prevent the non-transparent use of algorithms in digital ecosystems and to limit excessive surveillance of users. This interaction is especially crucial in the context of the development of advanced AI models used for behavioral targeting and personalization of online content, where privacy protection must be maintained at the highest standards.

The AI Act also closely interconnects with the Digital Services Act (DSA) and the Digital Markets Act (DMA), two fundamental regulations aimed at regulating digital platforms and major players in the digital economy. The DSA introduces transparency obligations for online platforms, in particular regarding the use of algorithms for content moderation and automated decision-making. On the other hand, the DMA regulates the anti-competitive practices of big tech companies and sets clear rules on the use of data by dominant platforms. Both regulations contain provisions relevant to the AI Act, in particular regarding the explainability of algorithms and the protection of users against opaque or discriminatory practices. Thus, harmonizing the AI Act with the DSA and DMA is essential to ensure coherent digital governance and protect users from potential abuses in the use of AI online[14].

Another key dimension of the AI Act's relationship with EU law is its connection to product safety and technology standardization regulations. In the European Union, products and services involving artificial intelligence must comply with the strict safety requirements laid down in Regulation (EU) 2019/1020 on market surveillance and product compliance. This is particularly relevant for sectors where AI is used in physical devices, such as the automotive industry or robotics. For example, in the case of autonomous vehicles, the AI Act must be compatible with European regulations on road safety and the testing of the software that controls such vehicles. Similarly, in the healthcare sector, the use of AI in diagnostic devices must comply with stringent requirements on patient safety and accuracy of results, which requires an integrated approach of the AI Act with other regulatory standards[15].

Last but not least, the AI Act must be applied in full compliance with the Charter of Fundamental Rights of the European Union, which sets the essential standards for the protection of European citizens' rights. This includes the right to privacy, the protection of personal data, non-discrimination and access to fair justice. The regulation introduces strict obligations for AI systems that could affect these rights, imposing transparency measures and human control over automated decisions. It also ensures that the use of AI in sensitive areas, such as law enforcement or recruitment, respects fundamental EU principles and does not create systemic risks of discrimination or social exclusion[16].

2.3. Institutions and bodies involved in implementation

Responsibility for ensuring the effective enforcement of this regulation is shared between the European Commission, the European Artificial Intelligence Board, the EDPS and the national supervisory authorities of the Member States.

2.3.1. European Commission

The European Commission plays a central role in the implementation of the AI Act, being responsible for the overall coordination of the regulation and the development of the implementing rules. The Commission has the power to issue delegated acts and implementing acts to clarify certain technical aspects of the regulation, such as conformity assessment methods and specific requirements for high-risk AI systems[17] (European Parliament, 2023). The Commission will also play an active role in monitoring the market and regularly assessing the impact of the AI Act, ensuring that regulations are adjusted in line with technological developments. To support the application of the Regulation, the Commission may launch funding and technical support programs for AI developers and users, thereby facilitating compliance with the requirements imposed. This is a measure

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[14] M. Barrio Andrés, *op. cit*.

[15] M. Matei-Crăciunescu, *op. cit.*

[16] M. Veale, F. Zuiderveen Borgesius, *op. cit.*

[17] The European Parliament and the Council of the European Union (2024), Regulation (EU) 2024/1689 on harmonised rules for artificial intelligence (AI Act), art. 97 (*https://eur-lex.europa.eu/legal-content/ro/AUTO/?uri=CELEX%3A32024R1689*).

to prevent strict rules from becoming a barrier to innovation, especially for small and medium-sized enterprises[18].

2.3.2. European Council on Artificial Intelligence (CEIA)

A major novelty brought by the AI Act is the establishment of the European Council for Artificial Intelligence (CEIA), an independent body made up of representatives of the member states and coordinated by the European Commission. This board is responsible for providing technical guidance and ensuring consistency in the application of the regulation at EU level. The main duties of the CEIA include:

- develop common guidelines for the implementation of the AI Act in the Member States;
- issuing opinions and recommendations on the interpretation of the requirements imposed on AI systems;
- coordination of the cooperation mechanism between national supervisory authorities;
- monitoring the social and economic impact of the Regulation and making proposals for its adjustment in the future.

In essence, the CEIA acts as a harmonization mechanism between European legislation and measures adopted at national level, preventing regulatory fragmentation in the application of AI regulations.

2.3.3. European Data Protection Supervisor (EDPS)

EDPS plays a key role in the enforcement of the AI Act, having powers to oversee AI systems that process personal data. This is particularly important given that the AI Act has to be implemented in accordance with EUDPR, which governs data processing in the EU institutions. EDPS is responsible for:

- ensuring compliance between the AI Act and existing data protection legislation;
- issuing guidelines and recommendations for the European institutions using AI;
- investigating cases of breaches of the regulation and imposing administrative sanctions.

In addition, EDPS is working with the CEIA and the European Data Protection Group (EDPB) to ensure a consistent approach between the AI Act and data protection regulations such as the GDPR (European Data Protection Supervisor, 2020).

2.3.4. National supervisory authorities

The implementation of the AI Act at national level falls under the responsibility of national supervisory authorities, which are responsible for monitoring compliance and imposing sanctions for breaches of the regulation. Each Member State must designate an AI competent authority, which will have the following responsibilities:

- accreditation of conformity assessment bodies for AI systems;
- monitoring the market and verifying compliance with the regulation by developers and users;
- collecting and investigating complaints from people affected by AI systems;
- applying sanctions in case of violations, as provided for in the AI Act.

These authorities work directly with CEIA to ensure uniform application of the Regulation in all Member States.

2.3.5. Conformity assessment bodies

In order to verify compliance with the requirements imposed by the AI Act, conformity assessment bodies will be designated, responsible for certifying high-risk AI systems. These bodies are nationally accredited and are required to assess whether an AI system complies with the rules required by the Regulation before it is placed on the market. The main duties of these bodies include:

- auditing AI systems to verify the transparency and accuracy of algorithms;
- issuing certifications for compliant AI systems;
- supervision of compliance with technical requirements by developers and suppliers.

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[18] M. Barrio Andrés, *op. cit.*

This certification process is essential to prevent the misuse of AI systems in critical areas such as law enforcement, health, and critical infrastructure.

3. AI Act – EUDPR Benchmarking

The AI Act introduces a regulatory framework for artificial intelligence systems, setting out specific rules for their use in various fields, while the EUDPR regulates the processing of personal data by the institutions, bodies, offices and agencies of the EU. Comparative analysis between these two regulations is essential to understand how they interact, complement each other and, in some cases, may pose harmonization challenges.

3.1. Scope and general principles

A key distinction between the AI Act and the EUDPR pertains to their respective scopes. The AI Act applies to all artificial intelligence systems placed on the European Union market, regardless of whether their operators are established in the EU or outside it. The regulation aims to regulate the entire lifecycle of an AI system, from development, testing and deployment to use and monitoring. In contrast, the EUDPR has a narrower scope, being intended exclusively for the institutions and bodies of the European Union, laying down rules for the processing of personal data in this specific context.

As regards the general principles, both Regulations place particular emphasis on the protection of fundamental rights. The AI Act imposes obligations on transparency, safety, and human oversight of AI systems, especially for high-risk ones, such as those used in law enforcement, lending, and human resources[19]. On the other hand, the EUDPR is built on principles derived from the GDPR, including legality, fairness, and limitation of the purpose of data processing.

The legal relationship between European regulations, such as the AI Act and the EUDPR, is further guided by the principles of subsidiarity and proportionality, ensuring that regulations are enacted effectively at the appropriate governance level[20]. However, the AI Act also introduces a risk-based approach, classifying AI systems according to their degree of danger to individuals' fundamental rights and freedoms.

3.2. Rights and obligations

From the perspective of rights and obligations, the AI Act and the EUDPR have common objectives, but regulate different aspects. The EUDPR guarantees the fundamental rights of data subjects in relation to the processing of their personal data, giving them the right to access, rectify, delete, oppose and portability of their data. In contrast, the AI Act does not create new data rights, but imposes obligations on operators of AI systems depending on the risk category they fall into. Thus, while the EUDPR strictly regulates the processing of personal data, the AI Act imposes broader requirements on the use of AI technologies, including:

- transparency – users must be informed when interacting with an AI-based system;
- human intervention – AI systems with significant impact must enable human oversight and control;
- safety and robustness – operators must demonstrate that AI systems are safe and do not pose significant risks to users[21].

This difference in approach could create protection gaps, as the EUDPR protects personal data but does not directly regulate the technology that processes it, and the AI Act sets rules for AI but does not introduce specific rights for users.

3.3. Governance and supervisory mechanisms

Both regulations provide for robust supervisory and enforcement mechanisms, but with significant differences. The EUDPR is implemented by the European Data Protection Supervisor (EDPS),[22] which has specific powers over the EU institutions and agencies, overseeing compliance with data protection rules. Instead, the AI Act introduces a new body – the European Council on Artificial Intelligence (CEIA) – that will coordinate the implementation of the regulation and ensure consistency across member states. The AI Act also gives national

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[19] M. Barrio Andrés, *op. cit*.
[20] A. Fuerea, *Dreptul Uniunii Europene, op. cit.*, p. 67.
[21] M. Veale, F. Zuiderveen Borgesius, *op. cit.*
[22] European Data Protection Supervisor (2019). EDPS powers according to Regulation (EU) 2018/1725.

authorities an important role in assessing the compliance of high-risk AI systems and applying penalties for non-compliance.

Another major difference is that the EUDPR provides for direct mechanisms for filing complaints, while the AI Act places a greater emphasis on certification and monitoring. This suggests that the implementation of the AI Act is based more on precautionary compliance, while the EUDPR provides a remediation framework based on individual rights.

3.4. Analysis of sanctioning and remedial mechanisms

The sanctions provided for by the two regulations differ in structure and applicability. The EUDPR adopts a similar model to the GDPR, establishing administrative penalties for data protection breaches. Instead, the AI Act introduces a progressive system of sanctions, depending on the severity of the violations.

According to the AI Act, serious breaches, such as the illegal use of banned AI systems, can attract fines of up to €35 million or 7% of the operator's annual global turnover. For comparison, the EUDPR imposes maximum penalties of up to €500,000 for breaches committed by the EU institutions, reflecting a narrower approach towards private entities.

Another relevant aspect is the remedy mechanism. The EUDPR allows data subjects to lodge complaints with the EDPS or seek compensation for damages suffered due to unlawful data processing. The AI Act, on the other hand, does not provide a direct compensation mechanism, but establishes obligations for developers and users to take preventive measures.

4. Challenges in Regulatory Harmonization

As EU strengthens its regulatory framework on AI, it becomes imperative to identify and resolve any conflicts between these regulations in order to strike a balance between innovation and the protection of fundamental rights.

4.1. Technical and operational aspects

The implementation of the AI Act and its harmonization with the EUDPR involves a number of technical and operational challenges, mainly due to the specific requirements of each regulation. A first essential aspect is the definition and classification of AI systems. The AI Act takes a risk-based approach, establishing categories of systems that are prohibited, high-risk, limited-risk, and minimal-risk. This approach creates technical difficulties in clearly identifying AI systems that require strict compliance and close supervision. On the other hand, the EUDPR regulates the processing of personal data in a general way, without making a risk-based classification. This conceptual difference can lead to confusion as to the applicability of the requirements for AI systems processing personal data[23].

Another technical challenge relates to transparency requirements. While the EUDPR imposes the principle of privacy by design and by default, the AI Act adds additional requirements on the explainability of algorithms and the auditability of automated decisions. Implementing these requirements requires the development of advanced methods for interpreting algorithms, which can be difficult for deep learning models used in AI applications[24].

Moreover, compatibility with existing infrastructure is a major issue. Public and private organizations operating AI systems need to integrate the new requirements of the AI Act into their IT infrastructure, while ensuring compliance with data protection regulations such as EUDPR. This integration may require significant investments in infrastructure upgrades and staff training.

4.2. Potential conflicts between the requirements of the two Regulations

While the AI Act and the EUDPR share common objectives in terms of the protection of fundamental rights, there are also conflicts between their requirements, in particular with regard to the handling of personal data and algorithmic surveillance. A concrete example is the AI Act's algorithm explainability obligation for high-risk AI systems. While this requirement is intended to increase the transparency of automated decisions, it may

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[23] M. Matei-Crăciunescu, *op. cit.*
[24] M. Barrio Andrés, *op. cit.*

conflict with the EUDPR principle of data minimization, which requires that data processing be limited to what is strictly necessary. There are also discrepancies in the duration of storage and access to data used by AI systems. The AI Act imposes strict requirements on the performance monitoring and auditability of AI systems, which may involve the long-term storage of large volumes of data. On the other hand, the EUDPR imposes clear rules on the deletion of data when it is no longer needed. This contradiction creates uncertainties about the retention period of data in AI systems and the rights of users to request their deletion[25].

4.3. Impact on stakeholders

The implementation of the AI Act and its harmonization with the EUDPR will have a significant impact on several categories of stakeholders, including EU institutions, private and public organizations, developers of AI technologies and end-users. For the EU institutions, aligning the two regulations will require adapting internal data protection policies and introducing additional audit and transparency measures. This could lead to bureaucratization and the need for additional resources for compliance management.

For private companies, especially AI start-ups, compliance with both regulations can be costly and complex. The requirements for the transparency of algorithms and compliance with privacy by design principles will require investment in human resources and advanced AI verification technologies. On the other hand, large tech corporations, while better equipped to handle these requirements, will need to adjust their AI development and deployment strategies to avoid the severe penalties imposed by the AI Act[26].

As for end-users, they can benefit from better protection of their rights, but also from greater complexity in interacting with AI systems, which will require more detailed information on their operation and impact.

4.4. Challenges of jurisdiction and territorial enforcement

One of the most sensitive issues in the harmonization of the AI Act and EUDPR is the territorial applicability of these regulations. The AI Act applies to any entity that places an AI system on the EU market, regardless of where it is established. Instead, the EUDPR only applies to the EU institutions and agencies, which creates an area of incomplete overlap between the two regulations. This discrepancy raises problems in terms of the supervision of AI systems developed by non-EU entities. If a non-European company introduces an AI system on the EU market, it must comply with the AI Act, but not necessarily with the EUDPR. This can lead to regulatory gaps in situations where AI systems involve the processing of personal data.

4.5. Issues related to international data transfer

The regulation of international data transfer is another area where harmonization between the AI Act and the EUDPR raises difficulties. While the EUDPR follows the GDPR principles on the transfer of data to third countries, imposing standard contractual clauses and strict protection mechanisms, the AI Act does not contain detailed provisions on this issue. This can create uncertainty for companies using AI systems based on cloud infrastructures located outside the EU. In the absence of clear provisions on data transfers in the AI Act, closer coordination with the EDPS and CEIA will be needed to ensure compliance with data protection principles[27].

5. Best Practices and Recommendations

This chapter analyses specific measures for organizations, implementation guidelines, cooperation mechanisms between authorities and lessons learned from the implementation of *the GDPR/EUDPR,* to ensure a balance between innovation and the protection of fundamental rights.

5.1. Compliance measures for organizations

To comply with the requirements of the AI Act and EUDPR, organizations developing and using AI systems must implement clear compliance measures. Among the most effective measures are:
- Data Protection Impact Assessment (DPIA): The AI Act imposes additional transparency and human

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[25] X. Tracol, Chapter V of Regulation (EU) 2018/1725 on transfers of personal data by Union institutions and bodies to third states and international organizations. ERA Forum, 2021 (*https://link.springer.com/article/10.1007/s12027-021-00679-1*).

[26] M. Veale, F. Zuiderveen Borgesius, *op. cit.*

[27] X. Tracol, *op. cit.*

oversight requirements for high-risk AI systems. Organizations must perform Data Protection Impact Assessment (DPIA) before implementing these systems, thus ensuring compatibility with existing regulations (EUDPR, GDPR); the assessment must include the risks of algorithmic discrimination, decision-making transparency and the impact on fundamental rights.

- Transparency and explainability of AI systems: Organizations must document how AI makes decisions and provide clear explanations to users, especially in the case of systems with a significant impact on their lives (e.g. recruitment, lending, biometric surveillance); Explainability must be implemented in accordance with the privacy by design principle imposed by the EUDPR.[28]

- Human oversight and auditability: High-risk AI systems must allow for human intervention if their decisions are challenged; Organizations must ensure audit and monitoring mechanisms to detect possible errors or algorithmic abuses.

- Accreditation and certification of AI systems: Organisations must obtain certifications for AI systems covered by the AI Act. This involves working with nationally designated conformity assessment bodies[29].

5.2. Implementation guides

To facilitate the implementation of the AI Act and EUDPR, European and national authorities need to provide clear and enforceable guidance. Among the most relevant initiatives are:

- Guidelines issued by the European Data Protection Supervisor (EDPS): EDPS has already published guidance on data protection in AI systems and will need to update these recommendations in line with the requirements of the AI Act; the guidelines must cover issues such as the responsibilities of data controllers, security measures and algorithmic transparency.

- Standardization of technical requirements for AI: Organizations must follow European certification standards, which set clear criteria for the development and use of AI in accordance with the AI Act; The European Commission needs to work with standardization agencies (e.g. CEN, CENELEC) to define minimum technical requirements for AI systems.

- Compliance Support Platforms: The European Commission should develop online platforms to help companies assess the compliance of their AI systems with the AI Act and EUDPR. These platforms could include self-assessment tools, interactive guides and technical documentation templates.

5.3. Mechanisms for cooperation between supervisory authorities

To ensure a consistent application of the AI Act and the EUDPR, cooperation between supervisory authorities is essential. The most important mechanisms include:

- European Council on Artificial Intelligence (CEIA): It must work closely with the European Data Protection Supervisor (EDPS) and the European Data Protection Group (EDPB) to coordinate the application of the AI Act and the EUDPR; a unified approach is needed to avoid discrepancies between AI and data protection regulations.

- Sharing best practices between Member States: National supervisory authorities need to set up mechanisms to exchange information on AI deployment in order to prevent regulatory fragmentation at European level; it is recommended to create a European register of high-risk AI systems that is accessible to competent authorities.

- Harmonization of sanctions and corrective measures: Clear rules need to be laid down on cooperation between national authorities in investigating and sanctioning infringements; currently, the AI Act provides for penalties of up to €35 million or 7% of global turnover, and the EUDPR imposes penalties of up to €500,000. Clarification is needed on the applicability of these sanctions to cases of AI misuse.

5.4. Case studies and lessons learned from GDPR/EUDPR implementation

Experience implementing GDPR and EUDPR can provide valuable lessons for the application of the AI Act. Some relevant examples include:

- GDPR Implementation in Large Companies vs. SMEs: Large companies were able to comply faster due

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[28] M. Barrio Andrés, *op. cit*.
[29] M. Veale, F. Zuiderveen Borgesius, *op. cit.*

to the resources available, but SMEs faced difficulties due to the complexity of compliance requirements; an important lesson for the AI Act is the need for dedicated support resources for SMEs[30].

- The case of Google Analytics and international data transfer: The decisions of the European authorities on the use of Google Analytics have shown the difficulties regarding the international transfer of data under the GDPR; For the AI Act, the rules on the use of AI based on cloud infrastructures located outside the EU need to be clarified[31].

- The impact of GDPR fines on companies in the EU: Fines imposed on large companies (*e.g.*: Meta, Amazon) have led to greater compliance with the GDPR; a similar mechanism could be used to encourage compliance with the AI Act, but penalties must be proportionate and adapted to the technological context.

6. Conclusions and Perspectives

A fundamental question that arises at the end of this analysis is: How can the European Union strike a balance between the development of artificial intelligence and the protection of citizens' fundamental rights? This is not just a theoretical question, but a practical one, which directly affects the European institutions, private companies and end-users of AI-based technologies. As artificial intelligence systems become increasingly integrated into economic and social processes, the associated risks – from decision-making opacity to privacy violations – become increasingly evident. In this context, EU adopted Regulation (EU) 2024/1689 (AI Act), seeking to establish a legal framework to ensure a controlled and responsible development of artificial intelligence. But this regulation does not exist in isolation. One of its main points of intersection is with EUDPR, which governs data protection in the European Union institutions and agencies. Although the two regulations share common fundamental values, the present analysis has shown that there are multiple challenges in harmonizing their requirements. On the one hand, the AI Act imposes clear standards of transparency and auditability for AI systems, but on the other hand, the EUDPR limits data processing to what is strictly necessary, raising questions about the compliance of these two legal frameworks.

6.1. What are the main findings?

First, the adoption of the AI Act is a necessary step for the regulation of emerging technologies, providing a single legal framework that classifies AI systems according to risk and imposes strict requirements for those that can have a significant impact on the rights and freedoms of European citizens. The EU thus differentiates itself from other jurisdictions, such as the USA, which adopts a more fragmented approach, or China, which implements centralized oversight of AI.

Second, the interaction between the AI Act and the EUDPR is complex, as the two regulations were not designed in a synchronized manner. The AI Act is focused on the control of AI from the perspective of the risks it generates, while the EUDPR is focused on the protection of personal data. This difference creates challenges in enforcement, in particular with regard to algorithmic transparency and data storage.

There are also significant risks of overlap and conflicts between the two regulations. For example, the AI Act states that certain AI systems must be constantly audited and monitored to prevent risks, which involves storing large volumes of data, sometimes for long periods. On the other hand, the EUDPR imposes strict rules on minimizing data and deleting it after it has served its purpose. This conflict requires legislative clarifications and adjustments to ensure the effective application of both regulations.

In addition, the implementation of the AI Act will have a significant impact on all stakeholders involved. EU institutions will have to adapt their internal policies to comply with strict AI requirements, companies will be forced to reassess their strategies for developing and using AI technologies, and end-users will need to be better informed about how AI influences their daily lives.

6.2. What measures can enhance the harmonization between the AI Act and the EUDPR?

In order for these two rules to coexist effectively and provide real protection of fundamental rights, the EU must consider the following measures:

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[30] Deloitte, Deloitte's view on the implementation of Regulation (EU) 2018/1725, 2018, *https://www.deloitte.com/be/en/services/risk-advisory/research/gdpr-for-eu-institutions.html*.

[31] X. Tracol, *op. cit.*

- Clarifying the relationship between the AI Act and the EUDPR through official guidelines that provide clear interpretations of how the requirements of the two regulations complement each other. This is essential to avoid legal ambiguities and to provide a clear direction for institutions and companies.

- Flexibility of compliance mechanisms to allow SMEs and start-ups to comply with the AI Act without being burdened by excessive bureaucratic requirements. Implementing digital compliance support platforms could facilitate this process.

- Create a unified certification framework that includes both the requirements of the AI Act and the data protection rules imposed by the EUDPR. Thus, an AI system that is certified for use in the EU should also comply with data protection standards.

- Strengthening cooperation mechanisms between supervisory authorities, in particular between the CEIA and the EDPS. Cooperation between these institutions will be essential to ensure uniform application of the regulations.

- Monitoring the impact of the AI Act on innovation and regularly adjusting regulations according to technological developments. Regulations need to be flexible enough not to hinder the development of AI in Europe.

6.3. What are the future prospects for AI regulation in the EU?

The future of AI regulation in the EU will be marked by several strategic directions:

- Possible revisions of the AI Act depending on technological developments and its impact on the European market. As generative AI and other emerging technologies become increasingly sophisticated, the European Union will need to adapt regulations to meet new challenges.

- Expanding international cooperation in the field of AI, in particular through common standards with other important jurisdictions such as the US and Japan. This could lead to the creation of a global framework for regulating AI.

- Adopt ethical standards for AI, complementary to legal requirements, to ensure that AI systems not only comply with the law, but also with the ethical principles of a democratic society.

Accelerated technological developments in recent years have placed the EU in a decisive position when it comes to regulating artificial intelligence. The adoption of the AI Act is more than a legislative response to today's technological challenges – it is a statement of principles and values that will guide the development of the European digital society in the decades to come. Beyond the regulatory framework, the effective implementation of this regulation requires an unprecedented mobilization of institutional resources and a profound transformation of the way organizations approach technological innovation. The challenges are not only of a technical or legal nature, but relate to the very ability of European society to maintain its identity and fundamental values in an era of accelerated digital transformation.

The regulation of artificial intelligence through the AI Act is an ambitious social and legal experiment. Europe aims to demonstrate that technological innovation can coexist with the protection of fundamental rights that economic progress must not come at the expense of democratic values. The success of this approach will depend on the Regulation's ability to respond to emerging challenges and adapt to the realities of an ever-evolving technology. European society is facing fundamental questions about the nature of technological progress and its impact on everyday life. The AI Act does not provide definitive answers, but rather a framework of principles and values to guide the development and implementation of AI-based technologies. The real challenge is to translate these principles into concrete practices that serve the public interest and protect individual rights. The future will show whether this distinct European approach to AI regulation will become a global model or remain a regional exception. What is certain is that through the AI Act, Europe has assumed the role of a pioneer in defining an ethical and legal framework for the era of artificial intelligence, and the success or failure of this initiative will profoundly influence the way in which global society will address the technological challenges of the future.

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