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# Study on the Artificial Intelligence harmonizing regulation

## *Estudo sobre o regulamento harmonizador da Inteligência Artificial*

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**Abstract:** This study examines the Harmonizing Law on the Use and Development of Artificial Intelligence (AI) in the European

Union (EU), focusing on its legislative, social, and economic implications. The research centers on the challenges and opportunities presented by implementing a unified legal framework for AI, based on the European Commission's White Paper and subsequent regulatory proposals.

The relevance of this investigation lies in the growing importance of AI as a strategic vector for the EU's global competitiveness, alongside the need to ensure its development respects fundamental rights and fosters public trust. Balancing technological innovation with the protection of core European values represents a critical challenge reflected in law and public policy.

The adopted method involved a documentary and comparative analysis, reviewing European legal provisions and guidelines, including the White Paper, the proposed AI Regulation, and other relevant norms. Case studies were also considered, particularly on the risks of AI, such as algorithmic discrimination and civil liability.

In conclusion, the Harmonizing Law represents a pivotal step toward balancing the promotion of technological excellence with the safeguarding of fundamental rights in the European Union.

**Keywords:** Artificial Intelligence; Harmonization law; Fundamental Rights; European regulation; AI risks, Sanctions.

**Resumo:** O presente estudo aborda a Lei Harmonizadora sobre a Utilização e o Desenvol-

vimento da Inteligência Artificial (IA) na União Europeia (UE), com especial foco nas suas implicações legislativas, sociais e económicas. O objeto de análise centra-se nos desafios e oportunidades apresentados pela implementação de um quadro legal harmonizado para a IA, tendo como base o Livro Branco da Comissão Europeia e as subsequentes propostas regulamentares.

A relevância desta investigação reside na crescente importância da IA como vetor estratégico para a competitividade global da UE, bem como na necessidade de assegurar que o seu desenvolvimento respeite os direitos fundamentais e promova a confiança pública. Este equilíbrio entre inovação tecnológica e proteção de valores fundamentais europeus constitui um desafio que se reflete diretamente no direito e na política pública.

O método adotado consistiu numa análise documental e comparativa, examinando as disposições legais e diretrizes europeias, incluindo o Livro Branco, o Regulamento de IA proposto, e outras normas aplicáveis. Também foram considerados estudos de caso sobre riscos da IA, especialmente no que tange à discriminação algorítmica e à responsabilidade civil.

Conclui-se que a Lei Harmonizadora é um passo decisivo para o equilíbrio entre a promoção da inovação tecnológica e a salvaguarda dos direitos fundamentais na União Europeia.

**Palavras-chave:** Inteligência Artificial; Lei harmonizadora; Direitos Fundamentais; Regulamentação Europeia; Riscos da IA, Sanções.

### Study on the Artificial Intelligence Harmonising Regulation

The rapid development of Artificial Intelligence (AI) over the last few decades has generated in-depth discussions about its legal, ethical and social implications.

In the European Union, this technological advance has been closely monitored by the European Commission, with the aim of ensuring that AI is used in a safe, transparent way that respects fundamental rights.

Within this context, the current President of the Commission, Ursula Von Der Leyen, has launched the project “A More Ambitious Union”, which sets the development of AI as one of the main objectives of her presidency. (Leyen, 2019, p. 24)

The importance of AI for strengthening the European economy and for competitiveness with other global powers led to the creation of a set of rules to harmonize the development and application of this technology among member states. This movement culminated in the creation of the “White Paper on Artificial Intelligence - A European approach to excellence and trust”, which served as the basis for the Law harmonizing AI in the European Union. (European Commission, 2020, p.27)

The aim of this article is to analyze and discuss the main legal and normative aspects of this legislation, focusing on three central issues: state harmonization or individualization in the development of AI, the risks to the fundamental rights of European citizens, and the mechanisms of accountability for the high risks associated with the development and use of AI.

Firstly, the challenge of legislative harmonization in the development of AI will be addressed, highlighting the importance of a joint approach within the EU to avoid regulatory fragmentation. Next, the fundamental rights affected by the use of AI and the risks of potential human rights violations will be discussed, based on what has been identified by the White Paper. *In Fine*, the liability regime for the high risks of AI will be analyzed, considering the diversity of national legislation and the need for a common legal frame-

work.

### 1. Harmonization or State Individualism in the Development of AI

The first challenge highlighted in the White Paper on AI is the need to harmonize European legislation to regulate the development of this technology. The fragmentation of rules between member states could create a series of obstacles, both in terms of innovation and competitiveness, jeopardizing the European Union’s goal of establishing itself as a global technological power.

AI, as part of the single market, needs a cohesive and efficient regulatory environment. If each member state were to create its own rules, the development of AI would be fragmented, leading to uneven and inefficient results. In addition, the lack of harmonization would make it difficult to take legal responsibility for the risks associated with AI, as different countries could have different legal approaches. (European Commission, 2020, pp. 6-7).

Small and medium-sized enterprises (SMEs) are considered the engine of innovation within the European Union, and the development of AI by SMEs requires a uniform legal environment that encourages growth without creating barriers. One of the main challenges for these companies would be to navigate the different national legislations, which would make it more difficult to make new AI systems available in the European single market. Therefore, the AI harmonizing law chose to adopt a unified approach, in line with the recommendations of the White Paper (European Commission, 2020, pp. 8). This was made explicit in the general provisions of the law, particularly in the articles dealing with the creation of harmonizing rules (Art. 1) and the acceptance of standards to ensure a common legal environment within the Union (Art. 3). The accelerated development of AI brings with it numerous advantages for society, but it also presents substantial challenges for the protection of the fundamental rights guaranteed by the Charter of Fundamental Rights of the European Union (*Charter of Fundamental Rights of the European Union*, 2012)

AI, by its nature, operates on the basis of large volumes of data and algorithms that can directly impact the lives and rights of

citizens, particularly with regard to dignity, privacy and equality.

### 2. Right to Dignity of the Human Person (Article 1 of the CFREU)

The right to dignity is one of the central pillars of the European legal order, being inalienable and inseparable from any other right. In the context of AI, this right can be threatened in various ways, especially when AI systems are used to make automated decisions that negatively affect individuals.

Some examples include:

#### 2.1 Dehumanization

When AI systems are used to replace human judgements in critical areas, such as in criminal justice or in job candidate selection processes, there is a risk that individuals will be treated merely as numbers or data. This violates the fundamental notion of dignity, which presupposes that each person should be treated with respect and consideration for their individuality.

#### 2.2 AI in Public Services

The use of AI in public services, such as health or education, can result in impersonal decisions that profoundly affect the dignity of citizens, especially when automated systems are used to approve or deny essential services.

To mitigate these risks, the Harmonizing Act introduces human oversight measures to ensure that AI systems do not completely replace human intervention, especially in sensitive areas. In Title III, Chapter II, of the AI Act requirements are introduced that high-risk AI systems, such as those used in critical sectors, are monitored by humans, preventing automated decisions from harming individual dignity.

### 3. Right to Private and Family Life and Protection of Personal Data (Articles 7 and 8 of the CFREU)

Privacy is one of the most critical areas affected by the use of AI. AI relies heavily on access to large volumes of data in order to function efficiently, which raises significant concerns regarding respect for privacy and

the protection of personal data.

### 3.1 Potential impacts

- *Mass Monitoring*: AI systems can be used to collect and analyze personal data *en masse*, potentially violating individuals' privacy. Examples include the indiscriminate collection of data from social networks or large-scale digital surveillance by governments or corporations.
- *Biometric Identification*: The use of AI technologies for facial recognition or other forms of biometric identification without the express consent of individuals represents a serious threat to privacy and can lead to real-time surveillance and the erosion of private life.
- *Behavioral Analysis*: AI can be used to monitor people's behavior in invasive ways, such as in workplace surveillance scenarios or online activity monitoring, creating an environment of control and surveillance that infringes on personal privacy.

To deal with these problems, the Harmonization Act imposes strict restrictions on the use of AI for remote biometric identification and introduces transparency obligations for suppliers of AI systems.

People must be informed whenever they are interacting with an AI system, ensuring that their rights to privacy and data protection are respected. In addition, Title II of the Act expressly prohibits the use of AI for real-time biometric identification in public spaces, except in limited cases, serious criminal investigations such as terrorism.

### 4. Right to Non-Discrimination (Article 21 of the CFREU)

Discrimination is one of the biggest concerns related to AI, especially in systems that use *machine learning* and other algorithms that rely on large amounts of historical data. If this data contains prejudices, AI could end up exacerbating and amplifying discrimination that already exists in society (Tolan, 2019, p. 92).

#### 4.1 Main risks

*Access to Opportunities*: AI can be used to decide who does or does not receive a certain op-

*“High-risk AI systems must comply with rigorous standards to prevent discrimination and preserve ethical values with the European market”*

portunity, such as employment or credit. If the algorithm is biased, certain groups can be systematically disadvantaged, violating the right to equality.

To combat discrimination, the Harmonization Act imposes strict requirements on AI systems that assess the social behavior or personality of individuals, prohibiting any form of direct or indirect discrimination (Title II). It also requires AI providers to carry out impact assessments on fundamental rights and ensure that their systems are designed in a fair and inclusive way.

Human supervision is also mandatory in these systems to prevent automated AI-based decisions from perpetuating inequalities.

### 5. Equality between men and women (Article 23 of the CFREU)

Gender equality is another area where AI can have a significant impact. Research has shown that certain AI systems, particularly those used for recruitment or pattern recognition, can contain gender biases that favor one gender over the other.

#### 5.1 Risks observed

*Recruitment systems*: Some companies use AI to filter CVs and identify promising candidates, which can lead to greater inequality in access to predominantly male or female positions by the opposite sex.

*Pattern Analysis*: AI algorithms can also reinforce gender stereotypes, which can lead to prejudiced judgements in areas such as marketing, education and personnel selection (To-

lan, 2019, p. 92).

The White Paper emphasizes the importance of ensuring that AI is not used to reinforce gender inequalities. To this end, the Harmonizing Act includes provisions that prohibit the use of AI in a discriminatory way, ensuring that AI systems are subject to rigorous testing to identify and correct any gender biases before they are implemented on a large scale.

### 5.2 Mitigation and Protection Measures

The Harmonizing Law provides for a series of measures to protect the fundamental rights affected by the use of AI:

*Human Supervision*: The law requires high-risk AI systems to be monitored by human supervisors, who can intervene when necessary to avoid unfair or discriminatory decisions, as well as for cases of accountability.

*Transparency*: The obligation to inform people when they are interacting with AI helps to ensure that citizens can demand that their rights are respected, including by refusing to take part in interactions that do not protect their privacy.

*Impact Assessment*: AI Providers must carry out fundamental rights impact assessments to ensure that their systems do not cause undue harm to European citizens.

*Prohibition of Certain Practices*: Practices involving discrimination, physical or psychological harm, or misuse of personal data are explicitly prohibited by law.

### 6. Accountability for the High Risks of AI

The issue of accountability, legal-civil and/or legal-criminal, for the risks inherent in the use and development of AI was another central concern addressed in the White Paper. The dynamic and autonomous nature of AI creates unique challenges for the attribution of responsibility, especially when systems are developed in one Member State, operate in another and affect citizens of a third State.

The importance of civil liability in the European Union is already recognized by several directives, (European Parliament, 2009, p.21) but the White Paper proposes the creation of a specific framework for AI. This is particularly relevant for systems classified as high risk, as defined in Title III of the harmonizing law.

The legislation proposes a uniform account-

ability regime, which includes human oversight, accuracy, cybersecurity and transparency as core requirements. Suppliers, importers, distributors and users of AI systems have clear obligations with regard to compliance and safety, with hefty penalties provided for non-compliance (up to 30 million Euros or 6 per cent of annual turnover).

### 6.1 Sanctions in the AI Harmonization Law

The sanctions provided for in the European Union's Artificial Intelligence Harmonization Act are one of the central elements in ensuring compliance with the rules established for the development and use of AI systems, especially those with high risks. The idea behind these sanctions is to create a robust system of accountability that discourages illegal or harmful practices, protecting both the fundamental rights of European citizens and the integrity of the European single market. Given the potential social, economic and ethical impact of AI, the sanctions regime is designed to be strict, with fines proportional to the seriousness of the offences committed, especially with regard to the development and implementation of high-risk AI systems.

### 6.2 Scalability of Fines and Offences

The system of sanctions is staggered, taking into account the seriousness of the offence and the potential or actual impact caused by the violation. This creates a flexible and adaptable regime, which takes into account everything from minor compliance failures to more serious offences that jeopardize public safety or violate fundamental rights.

#### -*Serious Offences:*

The most serious infringements, which involve the development and use of AI systems that are prohibited or do not comply with the requirements established by the Harmonization Law, are subject to the strictest sanctions. This includes prohibited practices such as the use of AI to:

- Causing physical or psychological harm to individuals;
- Evaluating the social behavior or personality of individuals without proper consent;
- Using AI in a discriminatory way or in a way that negatively affects vulnerable

groups;

- Implementing biometric identification systems without supervision or an appropriate legal basis.

For such offences, fines can reach up to 30 million Euros or 6 percent of annual turnover, whichever is lower. This level of penalization reflects the seriousness of the violations and the potential catastrophic impact of AI systems that are used to violate fundamental rights or that could cause irreparable damage. But at the same time, it endeavors not to discourage the development of AI in the EU.

#### *Medium Impact Offences*

At the second level of seriousness are offences related to failure to meet compliance obligations. This includes failure to implement adequate security measures, insufficient transparency in the use of AI and failures to provide information to users. These offences jeopardize trust in the use of AI and can result in risks to citizens' privacy and security. For these offences, the penalties can be up to 20 million Euros or up to 4 per cent of annual turnover.

#### *Minor Offences*

Offences involving incorrect or misleading information provided by companies about their AI systems are subject to fines of up to 10 million Euros or up to 2% of annual turnover. Although these offences are considered less serious, they can still undermine the safety and transparency of AI systems, justifying significant sanctions.

In the case of offences committed by EU institutions, bodies or organizations, fines can vary between 250,000 and 500,000 Euros, depending on the nature and seriousness of the offence. Although these amounts are lower than those applied to private entities, they still demonstrate the seriousness with which the European Union treats non-compliance with its own rules.

## 7. Comparison with other sanctioning regimes

The sanctions provided for by the EU's AI Harmonization Act are comparable in scale and rigor to the sanctions provided for by other

regulatory regimes with a major impact on the digital economy and emerging technologies.

### 7.1 General Data Protection Regulation (GDPR)

The sanctioning structure of the AI Harmonization Act closely resembles the fines regime established by the General Data Protection Regulation (GDPR). The GDPR, which also establishes a series of strict obligations for the processing of personal data, provides for fines of up to 20 million Euros or 4 per cent of the company's global annual turnover, depending on the seriousness of the offence (European Parliament, 2016, p.88).

Like the GDPR, the AI Harmonization Act adopts a "*compliance by design*" approach, meaning that compliance with the standards is required from the very beginning of the process of developing and implementing AI systems.

### 7.2 Digital Services Directive (DSA)

The European Union's Digital Services Directive, which aims to regulate large online platforms, also provides for fines proportional to the seriousness of the offence. Fines under the DSA can be as high as 6% of annual turnover, similar to the sanctions under the AI Harmonization Act. The rationale behind these high penalties is to ensure that technology platforms, as well as AI systems, are developed and used ethically and responsibly, minimizing risks for consumers and society as a whole.

## 8. Sanctions as a Compliance Tool

The sanctions provided for by the AI Harmonization Law are not only punitive, but also preventive. The imposition of heavy fines serves as a strong incentive for companies, institutions and public bodies to implement robust compliance mechanisms. At the same time, by having a ceiling of 6 per cent, they serve not to create a default on technological development.

Ongoing supervision, required by Title VIII of the Act, obliges AI providers to document the entire life cycle of their systems, from the development phase to implementation on the market. This post-market monitoring, in addition to the sanctions provided for, creates an environment in which the risk of non-compli-

ance is reduced, encouraging responsible and safe AI practices.

In addition, market surveillance by national and EU authorities plays an essential role in ensuring that sanctions are applied effectively and proportionately. Fines, therefore, are not only a response to violations that have already been committed, but also a way of ensuring that agents involved in the development and use of AI remain compliant with the legislation.

## 9. Conclusion on the Sanctions Regime

The sanctions regime of the AI Act reflects the European Union's commitment to ensuring that AI is developed and used ethically and safely, in line with the EU's core values. By applying strict and staggered sanctions, the law ensures that suppliers, developers, importers and users of AI systems adopt responsible and transparent practices, minimizing risks for citizens and the European market.

The sanctions system has been designed to align with other important regulatory regimes, such as the GDPR and the DSA, ensuring a cohesive and robust approach to the regulation of emerging technologies. In addition, the introduction of post-market surveillance and monitoring mechanisms reinforces the idea that compliance is an ongoing process, not just an initial requirement when launching an AI system onto the market.

By adopting a strict sanctioning regime, the European Union is sending a clear message that the development of AI must be done responsibly and in compliance with fundamental rights, promoting public trust and technological excellence at the same time.

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