NEW CHALLENGES IN LEGAL REGULATION: CERTIFICATION AND LABELING OF ARTIFICIAL INTELLIGENCE SYSTEMS

NOVOS DESAFIOS NA REGULAMENTAÇÃO JURÍDICA: CERTIFICAÇÃO E ROTULAGEM DE SISTEMAS DE INTELIGÊNCIA ARTIFICIAL

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ABSTRACT

Objective: The object of this scientific publication is the peculiarities of the legal regulation of artificial intelligence systems, particularly the need to implement certification and labeling mechanisms to ensure the safe and responsible use of artificial intelligence.

Method: The research method involves a detailed analysis of the regulatory framework, particularly key documents of the European Union, such as the Artificial Intelligence Act, the White Paper on Artificial Intelligence, and others. Based on this analysis, proposals have been developed regarding the need to create an effective control system that will ensure compliance with safety, ethics, and privacy standards in artificial intelligence through the implementation of certification and labeling mechanisms.

Results: In this scientific publication, the authors examine the need for legal regulation of artificial intelligence systems, specifically the implementation of certification and

labeling mechanisms as an essential step for ensuring safety, quality, and trust in such systems. It is argued that certification and labeling allow for the identification of high-risk systems and those subject to voluntary labeling, as well as creating an effective control system to ensure compliance with safety, privacy, and ethics standards.

It is concluded that these procedures represent a compromise between the need for regulation and the promotion of innovation, allowing for the creation of standardized quality criteria without burdensome regulation. At the same time, these mechanisms increase user trust in the technologies, facilitating their adoption and development. The proposed approach to regulating artificial intelligence systems enhances the competitiveness of European enterprises in the global market and aligns with the European Union's strategic goals regarding high standards of quality, ethics, and safety in the development and use of these technologies.

Contribution: It is noted that the growing use of artificial intelligence technologies is accompanied by risks that require appropriate legal regulation. The need for the development of effective control mechanisms for AI systems, taking into account their risks, is identified. The article emphasizes the importance of implementing transparent certification and labeling procedures as mechanisms of legal regulation for AI systems, especially those with high risks. The issue of determining the legal status of such systems is also discussed in order to establish relevant rules for their development, use, and implementation, which can be standardized at national and international levels. It is highlighted that the main goal of establishing regulatory mechanisms is to achieve a balance between the development and innovation in the field of artificial intelligence and the protection of the rights, safety, and interests of individuals and society as a whole. Based on the research findings, two regulatory strategies for AI systems, depending on the level of risk, are proposed to ensure the safety, quality, and trust in AI technologies. The key principles of European policy regarding certification and labeling are presented, and the need for strengthening control over compliance with standards and requirements through these procedures are emphasized.

Keywords: Artificial intelligence; Risks; Legal regulation; Legal status; Certification; Labeling

RESUMO

Objetivo: O objeto desta publicação científica são as peculiaridades da regulamentação jurídica dos sistemas de inteligência artificial, em especial a necessidade de implementação de mecanismos de certificação e rotulagem para garantir o uso seguro e responsável da inteligência artificial.

Método: O método de pesquisa envolve uma análise detalhada do marco regulatório, especialmente dos principais documentos da União Europeia, como o Artificial Intelligence Act, o White Paper on Artificial Intelligence e outros. Com base nessa análise, foram elaboradas propostas sobre a necessidade de criar um sistema de controle eficaz que garanta a conformidade com os padrões de segurança, ética e privacidade da inteligência artificial por meio da implementação de mecanismos de certificação e rotulagem.

Resultados: Nesta publicação científica, os autores examinam a necessidade de regulamentação legal dos sistemas de inteligência artificial, especificamente a implementação de mecanismos de certificação e rotulagem como uma etapa essencial para garantir a segurança, a qualidade e a confiança em tais sistemas.

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Argumenta-se que a certificação e a rotulagem permitem a identificação de sistemas de alto risco e daqueles sujeitos à rotulagem voluntária, além de criar um sistema de controle eficaz para garantir a conformidade com os padrões de segurança, privacidade e ética.

Conclusões: Conclui-se que esses procedimentos representam um meio-termo entre a necessidade de regulamentação e a promoção da inovação, permitindo a criação de critérios de qualidade padronizados sem uma regulamentação onerosa. Ao mesmo tempo, esses mecanismos aumentam a confiança do usuário nas tecnologias, facilitando sua adoção e desenvolvimento. A abordagem proposta para regulamentar os sistemas de inteligência artificial aumenta a competitividade das empresas europeias no mercado global e se alinha às metas estratégicas da União Europeia com relação a altos padrões de qualidade, ética e segurança no desenvolvimento e uso dessas tecnologias.

Contribuição: Observa-se que o uso crescente de tecnologias de inteligência artificial é acompanhado de riscos que exigem regulamentação jurídica adequada. Identifica-se a necessidade do desenvolvimento de mecanismos de controle eficazes para sistemas de IA levando em conta seus riscos. O artigo enfatiza a importância da implementação de procedimentos transparentes de certificação e rotulagem como mecanismos de regulamentação legal para sistemas de IA, especialmente aqueles com altos riscos. A questão da determinação do status legal de tais sistemas também é discutida, a fim de estabelecer regras relevantes para seu desenvolvimento, uso e implementação, que podem ser padronizadas em nível nacional e internacional. Destaca-se que o principal objetivo de estabelecer mecanismos regulatórios é alcançar um equilíbrio entre o desenvolvimento e a inovação no campo da inteligência artificial e a proteção dos direitos, da segurança e dos interesses dos indivíduos e da sociedade como um todo. Com base nos resultados da pesquisa, duas estratégias regulatórias para sistemas de IA dependendo do nível de risco, são propostas para garantir a segurança, a qualidade e a confiança nas tecnologias de IA. São apresentados os princípios fundamentais da política europeia em relação à certificação e à rotulagem, e é enfatizada a necessidade de fortalecer o controle sobre a conformidade com os padrões e requisitos por meio desses procedimentos.

Palavras-chave: Inteligência artificial; Riscos; Regulamentação legal; Status legal; Certificação; Rotulagem

1 INTRODUCTION

The modern world is currently experiencing the fourth industrial revolution, Industry 4.0, where information technologies have become the cornerstone of societal development. The digital revolution is relentlessly transforming various industries, showcasing remarkable adaptability and potential.

Technological innovations have become a critical mechanism for ensuring organizational resilience in the face of unpredictable challenges. This is particularly

evident during crises, whether a global pandemic or armed conflict. By implementing modern digital technologies, not only is the continuity and efficiency of operations ensured, but new opportunities also emerge for development, modernization, and optimization of business processes.

Artificial intelligence is one of the fastest-growing technologies of our time. It is finding increasing applications across various industries, from medicine to transportation, from finance to manufacturing. AI systems can systematize information, process large volumes of data, and deliver accurate results much faster and more efficiently than humans. However, as the use of AI systems expands, so does the risk of negative consequences arising from their use (Tiuria Yu. I., 2022).

For the classification of artificial intelligence systems, a risk-based approach is commonly employed. This approach focuses on assessing the potential consequences and degree of risk associated with the use of such systems. Factors such as the impact of these systems on safety, privacy, rights, and societal aspects for individuals and society at large are taken into account. Risk assessment helps identify AI systems that require particular attention, fostering the need for thorough research and in-depth discussion about their proper legal regulation. This issue poses a significant challenge for the scientific and legal community, as it demands a balanced approach to defining effective mechanisms for controlling these systems.

This issue has been partially explored by researchers such as O.A. Baranov, T.H. Katkova, O.A. Telychko, M.M. Velikanova, and others. Despite the considerable interest of scholars in the legal regulation of artificial intelligence systems, the definition of effective mechanisms for controlling such systems remains a subject of active debate and discussion.

2 METHODS

The purpose of this study is to examine the necessity of legal regulation for artificial intelligence systems through the implementation of certification and labeling mechanisms.

Achieving the study's objective required an in-depth review of the European Union's regulatory framework, particularly a comprehensive analysis of key documents governing the field of artificial intelligence. Specifically, a detailed study of the Artificial

Intelligence Act, the White Paper on Artificial Intelligence, and other foundational acts enabled the identification of principled approaches to certification, labeling, and risk management in the field of digital technologies.

To achieve the purpose of the study, the following methods were employed:

The dialectical method was applied to conduct a systematic analysis of the evolution of legal regulation for artificial intelligence systems. This approach allowed for uncovering internal contradictions and identifying key trends in the development of regulatory mechanisms in the context of ongoing technological transformations.

The methods of analysis and synthesis were used to detail the characteristics of artificial intelligence systems with varying levels of risk, as well as to generalize the results of the analysis of regulatory practices and formulate comprehensive scientific conclusions.

The systemic and structural methods facilitated the examination of certification and labeling as components of an integrated legal regulation system. This approach harmonizes the interests of innovative development with the protection of human rights and freedoms, clearly defining their place and role within the broader context of artificial intelligence regulation.

The comparative legal method enabled a critical assessment of the regulatory mechanisms outlined in European legislation, identifying their potential for adaptation to the national legal system.

The formal logical method ensured consistency and soundness in presenting the study's key provisions and conclusions.

The hermeneutic method facilitated an understanding of the content of European legal acts regulating the procedures for certification and labeling of artificial intelligence systems, as well as their interpretation within the context of enforcement practices.

The dogmatic method was employed to analyze legal acts, including the Artificial Intelligence Act and related regulatory documents, aiming for precise interpretation of legal norms.

A comprehensive approach and the use of these methods enabled an in-depth study of the legal regulation of artificial intelligence through certification and labeling. This approach also allowed for the development of scientifically grounded recommendations to improve the legal framework in this area.

3 RESULTS AND DISCUSSIONS

Considering the key aspects of the Proposal for a Regulation of the European Parliament and of the Council "Laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts» introduced in April 2021, artificial intelligence systems are categorized into two groups: "high-risk systems" and "non-high-risk systems".

Artificial intelligence systems not classified as "high-risk" are employed for tasks that do not directly impact human safety and well-being. These systems typically operate on clear rules and constraints, allowing for straightforward monitoring and oversight of their activities. They are capable of promptly completing tasks and performing useful functions across various fields.

For example, recommendation algorithms suggest products or services based on user preferences, chatbots facilitate automated customer communication, automatic translation systems provide swift text translation, and virtual assistants assist in task organization and information retrieval. Given their limited impact and inherent transparency, these systems pose minimal risks and require less regulatory oversight concerning their operation.

In contrast, high-risk artificial intelligence systems are powerful technological tools that require a cautious approach to their use, as they can significantly impact human safety, rights, and freedoms (Slipeniuk, T., Yankovyi, M., Nikitenko, V., Manzhai, O., Tiuria, Y., 2024). Errors or negligence in their application can lead to serious consequences, particularly in areas such as autonomous vehicles, medical diagnostics, financial services, and law enforcement.

For instance, in the case of autonomous vehicles, incorrect system decisions can provoke accidents and cause harm to individuals. In medical diagnostics, inaccurate or insufficiently substantiated decisions can lead to errors in diagnosing and selecting inappropriate treatment methods. In financial services, improper data processing or the use of incompatible algorithms may result in financial losses for clients. In law enforcement, the hazardous use of artificial intelligence systems can undermine principles of privacy and human rights.

In light of this, to mitigate potential risks, it is crucial to implement appropriate legal regulation and establish oversight mechanisms that ensure the ethical and responsible use of artificial intelligence systems.

At the same time, it is essential to consider that high-risk artificial intelligence systems possess the following characteristics:

1. Autonomous Decision-Making. High-risk AI systems are capable of making decisions independently, without the need for constant human oversight. This autonomy introduces potential risks, as the system may make incorrect decisions or act counterintuitively. Such situations could have serious consequences, necessitating continuous monitoring by developers and regulators throughout the system's lifecycle.

2. High Complexity and Unpredictability. High-risk AI systems are typically built on complex algorithms and models, such as deep neural networks, which are challenging to understand and predict. This complexity makes it difficult to detect potential errors or inappropriate behavior of the system, which can lead to potentially serious consequences.

3. Hazardous Nature. High-risk AI systems can directly impact physical safety, health, rights, and freedoms, with errors or negligence potentially causing severe consequences for society and individuals. For instance, the use of such systems in autonomous vehicles unequivocally affects road safety.

4. Ethical Considerations. Autonomous decision-making AI systems may exhibit bias, discrimination, or violate principles of fairness, leading to negative ethical and social consequences. Therefore, the development and use of such systems must account for ethical aspects. This includes conducting prior testing for compliance with ethical principles and establishing mechanisms to ensure fairness and accountability.

5. Risk Potential. The use of high-risk AI systems may pose threats to security and infringe on fundamental human rights and freedoms, particularly if such systems fall into the hands of malicious actors or are improperly configured. For example, misuse of facial recognition algorithms for mass surveillance or violations of privacy through unlawful collection and use of personal data are potential risks. These systems can also be exploited to manipulate information, spread disinformation, or carry out cyberattacks, causing serious repercussions for individuals, organizations, and society as a whole.

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In light of these risks, it is essential to develop effective mechanisms for protection, cybersecurity, and legal regulation to ensure the reliable and secure operation of high-risk AI systems. Such measures should provide oversight of their use and prevent potential abuses and violations of human rights.

Thus, the use of high-risk artificial intelligence systems should be carried out with consideration of these characteristics and the implementation of specific measures aimed at minimizing potential negative consequences.

Thus, the rapid progress in the development of artificial intelligence systems is accompanied by a number of legal challenges related to their widespread application in various areas of life. This drives the growing relevance of issues such as security, ethics, privacy, responsibility, and legal compliance, which require attention, research, and the development of regulatory mechanisms.

In this context, to ensure the safety and trust in artificial intelligence systems, it is crucial to establish ethical principles for their use, define accountability for their actions, guarantee confidentiality, and protect against potential misuse of these systems. Additionally, creating a mechanism for the verification and assessment of the impact of artificial intelligence on society and individuals is vital.

However, it is important to emphasize that addressing these issues requires close collaboration among all stakeholders, including developers, users, and regulators. Only through their close interaction can effective legal regulation be ensured and a high level of trust in artificial intelligence systems be maintained. At the same time, determining the legal status of AI systems is a key aspect of establishing the appropriate rules for their development, use, and implementation, which could be standardized at both the national and international levels.

The overarching goal of establishing regulatory mechanisms is to ensure a balance between the development and innovation in the field of artificial intelligence and the protection of the rights, safety, and interests of individuals and society as a whole.

According to the definition formulated by the High-Level Expert Group on Artificial Intelligence in the document "A definition of AI: Main capabilities and scientific disciplines", "artificial intelligence systems" are defined as software (and possibly hardware) systems created by humans with a complex purpose, functioning in either a physical or digital environment. They collect data from the surrounding environment,

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interpret this data (whether structured or unstructured) using knowledge, judgment, and information processing, and determine optimal actions to achieve a set goal.

Thus, considering the characteristic features and definition of artificial intelligence systems proposed in this and other European legal documents, it can be concluded that in the European Union, such systems are not granted the status of a legal entity. Therefore, they should be understood as objects.

This is justified as follows: in the European Union legislation, the status of a legal subject is granted to natural and legal persons who have rights and obligations and are direct participants in legal relationships. Considering that artificial intelligence systems, despite their complexity and ability to act independently, are human-made software (and possibly hardware) systems, they cannot be defined as independent subjects of legal relations.

Instead, artificial intelligence systems are viewed as objects of legal relations, subject to legal norms and regulations, but they do not possess independent rights or the ability to participate directly in legal relationships. Their status lies in being objects of established obligations, rights, and responsibilities, with the realization of these rights and obligations dependent on the actions and decisions of the individuals who control and use these systems.

The acceptance of artificial intelligence systems as objects of legal relations creates a perspective for controlling their development, use, and implementation through the application of appropriate regulatory frameworks aimed at certification and product labeling. At the same time, this creates conditions for ensuring the proper quality, safety, and trust in artificial intelligence systems, which, in turn, allows the European Union to establish widely accepted standards and requirements for these systems, helping consumers, developers, and regulators consider their features and societal impact.

The application of certification and labeling can become a powerful tool for legal regulation and an effective mechanism for controlling artificial intelligence systems, promoting transparency, accountability, and adherence to ethical principles in their development, use, and implementation.

Certification is a process of evaluating and confirming the compliance of a product or service with established standards and requirements. This process involves conducting audits, testing, and assessments aimed at determining the degree of compliance with specified criteria (Pikhurets, O., Iasechko, S., Hrekov, Y., & Hrekova,

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M., 2024). At the same time, it ensures the unification of approaches and requirements regarding the quality, safety, and effectiveness of artificial intelligence systems at a level defined by standards and regulatory bodies. On the other hand, labeling allows for the identification and recognition of artificial intelligence systems that meet certain standards and requirements, thereby ensuring their quality and reliability.

In the document "White Paper on Artificial Intelligence: a European approach to excellence and trust", the European Commission proposed two approaches for regulating artificial intelligence systems, based on the implementation of certification and labeling procedures depending on the level of risk.

In the case of "non-risky" systems, which do not fall under the high-risk category, the proposal is to implement a voluntary labeling procedure. According to this approach, interested business entities have the right to voluntarily assess compliance with legal requirements or a specific set of similar requirements specifically established for the purpose of labeling (Kronivets, T., Yakovenko, O., Tymoshenko, Y. et al 2023). After successful evaluation, artificial intelligence systems can be marked with an appropriate quality label confirming their compliance with established standards. Such labeling would characterize products or services using artificial intelligence as trustworthy and in line with certain objective and standardized pan-European benchmarks.

Although the labeling procedure for "non-risky" AI systems is voluntary, if a business entity decides to obtain and use the quality label, it will become mandatory for them. The mandatory nature of the labeling procedure is a way to ensure high standards of quality and safety in the field of artificial intelligence. At the same time, labeling is conditioned by the importance of establishing trust and confidence among users when using artificial intelligence systems.

For high-risk systems, which could significantly impact the rights, freedoms, and safety of individuals, the proposal is to implement a certification procedure. The need for this procedure for such systems is based on the necessity of ensuring a high level of protection for people's rights and freedoms by confirming compliance with defined regulatory standards, general safety product requirements, and specific requirements related to databases, data processing, information assurance, reliability and accuracy, human oversight, remote biometric identification, and more.

The application of certification has several advantages. First, it promotes the unification of approaches to the development and use of artificial intelligence systems,

reducing risks associated with improper use or abuse of such systems. Second, it helps ensure a high standard of safety and quality for products or services, as it is based on established standards and requirements, thus increasing user trust in artificial intelligence systems.

It's important to note that the European Commission recommends not only adhering to the norms established in the General Product Safety Directive (GPSD) but also other relevant legal acts. Depending on the specific characteristics of artificial intelligence systems, these may include: Decision of the European Parliament and of the Council «On a common framework for the marketing of products», EU Regulation 2019/881 "On ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification» and Commission Notice – The 'Blue Guide' on the implementation of EU products rules 2016, and other relevant documents. These regulations help ensure that AI systems comply with broader frameworks concerning safety, cybersecurity, and market requirements, providing a comprehensive regulatory environment for their development and use.

It should be noted that the processes of globalization in Europe and globally, as well as the spread of the free trade concept, have led to the need for harmonization and unification of rules, procedures, and requirements applied to services, products, and cross-border trade. Certification ensures the compatibility and interchangeability of products and their components, uniformity of manufacturing processes, product safety, and contributes to maintaining appropriate quality. The European Council believes that certification significantly contributes to the creation of a standardized technical environment for production in all countries, improving their competitiveness not only on the European Union market but also in external markets, especially in the field of artificial intelligence.

The EU Regulation of July 9, 2008, "The requirements for accreditation and market surveillance relating to the marketing of products" sets out the basic principles and requirements for products marketed within the European Union. This includes ensuring a high level of protection for public rights and interests, such as health, consumer rights, environmental protection, and safety, while guaranteeing the free movement of products. This means that products sold or used in the European Union must meet established normative standards and requirements concerning safety,

quality, health, and other aspects, which must be fulfilled when assessing product compliance, including artificial intelligence systems.

The main goal of certification implementation by the EU member states is to ensure the safety and protection of human life and health, as well as to create conditions for the rational use of all types of resources and to ensure that certified objects meet their intended purpose. Additionally, certification helps eliminate technical barriers to trade and the free movement of products and services within the EU internal market. A widely recognized certification system establishes a common understanding, mutual recognition, and fosters interaction among different sectors, organizations, and countries, leading to the joint development of technologies, collaboration, and the exchange of best practices.

Taking into account the above, the following key principles of European policy regarding the certification of artificial intelligence systems can be identified:

- The agreement among member states to continuously review the technical regulations applied "de jure" or "de facto" on their territory with the aim of removing outdated or unnecessary ones;

- The agreement among member states to ensure mutual recognition of testing results and, where necessary, to establish harmonized rules regarding the activities of certification bodies;

- The agreement to conduct proper preliminary consultations with European Union member states, in accordance with the objectives of EU Directive 2015/1535 of September 9, 2015, which establishes the procedure for providing information in the area of technical regulations, in cases where key national regulatory initiatives or certification procedures negatively impact the functioning of the internal market;

- Expansion of the European Union's practice in technical harmonization, which includes determining the compliance of product technical characteristics with standards, primarily European, but when necessary, national, provided that all required conditions are met, including those related to health and safety;

- Strengthening the role of certification at the European level to promote, on the one hand, the harmonization of European Union legislation, and on the other hand, industrial development, especially in the field of new innovative technologies, which necessitates the introduction of new components into the certification process to improve and modernize the development of standards (e.g., the creation of specialized services, including standardization agencies, special committees, etc.).

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4 CONCLUSIONS

Thus, considering the need for legal regulation of artificial intelligence systems, it is clear that the introduction of certification and labeling mechanisms is a necessary step to ensure the safety, quality, and trust in such systems. Through certification and labeling, it is possible to identify high-risk systems and those subject to voluntary labeling, creating an effective control system to ensure their compliance with safety, privacy, and ethical standards and requirements. This serves as a compromise between the need for imperative regulation and the stimulation of innovation, allowing for the establishment of standardized quality criteria without burdensome regulation. At the same time, these procedures provide users with verified information about products and services using artificial intelligence, increasing user trust in such technologies and fostering their widespread adoption. This approach to legal regulation of artificial intelligence systems serves as a foundation for enhancing the competitiveness of European developers and enterprises in the global market environment. All of this demonstrates the strategic direction of the European Union, aimed at achieving high standards of quality, ethics, and safety in the development, use, and deployment of artificial intelligence systems, as well as protecting the rights and interests of users of these systems.

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