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# Regulation of Artificial Intelligence: A Systematic Literature Review

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**Abstract: Objectives:** This study aims to examine the different approaches used to regulate artificial intelligence through a systematic and bibliometric analysis of the literature. **Prior Work:** Governments and industry concur that there is an urgent need for artificial intelligence (AI) regulation. The European Union, the United States of America and China have already pioneered in the regulation of AI with different regulatory approaches. However, there remains no clearly defined method of how AI can be regulated comprehensively. **Approach:** A total of 38 articles published between 2019-2024 extracted from the Scopus and Clarivate Web of Science databases were selected for analysis following the PRISMA protocol. The review combined bibliometric and systematic review. **Results:** The study established risk-based, management-based, rights-based, systemic market safety, tort liability, single unified law and ethics as major approaches used to regulate AI. Economic and political concerns remain barriers to effective regulation as governments and jurisdictions aim to become centers of innovation. **Implications:** A universal and unified regulation of AI which extends from ethical standards enforced by professional bodies to actual enforceable law is required to avoid law lacunas. **Value:** Major AI regulatory approaches were examined, and trends and gaps in the regulation of AI literature were identified.

Keywords: risk-based regulation; artificial intelligence ethics; innovation; machine learning

JEL Classification: K1

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# 1. Introduction

The Artificial Intelligence (AI) has been widely adopted in various sectors and has become an important part of human lifestyle. AI has the potential to revolutionize the economy by enhancing efficiency, digitalizing monotonous work and improving decision-making. However, the transparency, security, data privacy, accountability and safety related to its use are of concern. As AI systems become more autonomous and universal regulators, governments, industries and society face the pressing challenge of establishing a regulatory framework that promotes innovation while mitigating risk.

Discussions of AI regulation began in 2015 after a decade of disruptive innovations powered by AI. Regulators around the globe are working on developing AI regulations which seek to facilitate innovations while at the same time ensuring safety and systemic stability. The United States of America, the European Union, China and South Korea pioneered the regulation of AI (Park & Kwon, 2023). Table 1 shows an overview of AI legislation and regulation by country. Nevertheless, the discussions on how to regulate AI has proven to be contentious and it is still unclear how AI should be regulated. Hence reviewing the perceptions of literature on the current regulation and future suggestions is crucial for developing a comprehensive AI regulation. In this context, the study reviews the prerequisites for valid artificial intelligence regulation, and legislative measures through a bibliometric and systematic literature review of previous research.

Nation (state)	Title of the Act (bill)	Legislative
		date
U.S.A	Executive Order 13960: Promoting the Use of	2020.12
(Federation)	Trustworthy Artificial Intelligence in the Federal	(enacted)
	Government (Executive Order 13960)	
U.S.A	National Artificial Intelligence Initiative Act of 2020	2021.01
(Federation)	(Federation) (NAIIA)	
U.S.A	Algorithmic Accountability Act of 2022(AAA)	2022.03
(Federation)		
U.S.A	An Act establishing a commission on automated	2022.03
(Massachusetts)	decision-making by government in the commonwealth	
U.S.A	U.S.A Chapter 43.386 RCW Facial Recognition	
(Washington)		(enacted)
U.S.A (New	S. 1402: An Act concerning discrimination and	2022.02
Jersey	automated decision systems and supplementing	

 Table 1. Overview of AI legislation and regulations by country

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		1
U.S.A (Illinois)	Artificial Intelligence Video Interview Act	2019.08
		(enacted)
		(chaeteu)
European Union	Proposal for a Regulation laying down harmonized	2021.04
1	rules on artificial intelligence Artificial Intelligence	
	A (AT A )	
	Act (AI Act)	
South Korea	Act on Algorithms and Artificial Intelligence (AAAI)	2022.11
	Act on the Development of Artificial Intelligence and	2022.07
	the Establishment of Trust in AI (ADAIETAI)	
China (Shenzhen)	Regulations for the Promotion of the Artificial	2022.08
	Intelligence Industry in the Shenzhen Special	(enacted)
	Economic Zone (RPAIIS)	

Source: Park and Kwon (2023)

The constantly evolving, complex nature of AI makes it difficult to define, regulate and develop a comprehensive law (Ruschemeier, 2023). A review of previous AI standards confirmed that the risks entities incur cannot be fully controlled via the current legal control (Park & Kwon, 2023). Ruschemeier (2023) documents the lack of a standard definition as a challenge to regulating AI. The term is highly ambiguous, therefore there is no standard or generalizable definition of AI across disciplines. A standard definition of AI is a prerequisite to meet the legal principles of legal certainty and the protection of legitimate expectations (Ruschemeier, 2023). This study defines AI as the simulation of human intelligence in machines that are programmed to think and act like humans. It involves the development of algorithms and computer programs that can perform tasks that typically require human intelligence.

The cornerstone of AI regulation's theoretical framework is based on socioeconomic and political reasons. Paul (2023) and Valenzuela-Fernández, Ocaña-Fernández, Sánchez, Apaza, Zubieta-Romero and Uribe-Hernández (2023) argued that the current AI regulations were developed based on economic and political backgrounds where apart from creating a safe and sound operating environment, governments seek to compete for AI innovation and to become centres for innovation.

# 2. Material and Methods

This study adopted a bibliometric and systemic review of the literature to address research questions. Systematic reviews are important to identify literature gaps and limitations in the conduct of previous studies that might be addressed in the current and future studies. This systematic review differs from traditional narrative reviews by adopting a replicable, scientific and transparent process. The two methods complement each other to map scientifically the evaluation of knowledge in a field, through a triangulation of both qualitative and quantitative methods.

### 2.1. Research Questions

A crucial step in conducting systematic literature is the formulation of research questions. Research questions should be formulated by a panel of experts and should be Feasible, Interesting, Novel, Ethical, and Relevant (Cummings et al., 2007). The study aims to focus on the following research questions;

- 1) How does the extant literature perceive about the regulation of AI?
- 2) What are the identified approaches used to regulate AI?
- 3) What benefits and challenges are posed?
- 4) Which best practices may be deduced in the development of regulation of AI?

### 2.2. Inclusion and Exclusion Criteria

The systematic search of literature was conducted using two databases, the Scopus and the Web of Science databases from 2019-2024. The two databases were selected based on their diverse literature from a broader range of journals, which improves the quality of data. An advanced search using the keywords "AI regulation" "Artificial intelligence regulation" and "machine learning regulation" was conducted in December 2024 and a total of 116 articles from Web of Science (51) and Scopus database (65) were obtained. A filtering process involving the sorting of article data and the reading of abstracts was conducted. Duplicates, articles which were out of scope and those which were not in English language were removed. Only a total of 38 articles qualified for inclusion.

### 2.3. Data Analysis

Data analysis was conducted by Vosviewer software and Excel. Vosviewer software was used to conduct bibliometric analysis and scientific literature mapping, whilst Excel was used for content and qualitative thematic analysis. Bibliometric analysis applies statistical methods to conduct performance analysis and science mapping which provide data about the volume, spatial representation, relationship and impact of research through the use of a wide range of techniques. The study used co-occurrence of keywords, co-citations and data descriptives as indicators for bibliometric analysis. This analysis was triangulated by content and thematic analysis conducted to determine the major themes guiding the regulation of AI.

# 3. Results

## **3.1. Bibliometric Descriptive Statistics**

The literature relating to the regulation of AI analyzed in this study covers a timespan from 2019 to 2024 and draws literature from 33 sources, yielding insights from 38 documents. The current literature has an average citation rate of 18.52 and 35 articles have at least one citation showing a significant contribution of the articles to the body of knowledge. Collaboration of authors was highly concentrated within the same country, with 117 authors contributing, and 11 single-authored documents. Table 2 shows the descriptive statistics of the papers used in systematic literature review.

Main information about data	
Timespan	2019-2024
Sources (Journals)	33
Documents	38
Average citation per document	18.52
Document content	
Author's Keywords	256
Authors	
Authors	117
Authors collaboration	
Single-authored docs	11

Table 2. Descriptive statistics of the papers

Source: Authors compilation 2024

### **3.2.** Contribution According to Country

The United Kingdom, China, Germany, Italy, Ukraine, the United States of America and Russia emerged as the highest contributors to the regulation of AI literature. However, there is a poor representation of developing nations in the literature under study, especially from the African context. Considering the fast and universal adoption of AI systems there is an urgent need for AI regulation research from various perspectives and jurisdictions. Figure 1 shows country contribution to AI regulation research.

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Figure 1. Country contribution (Author's compilation, 2024)

A research specialty can be identified by the specific associations recognized between its keywords (Kamewor, Kwateng & Mensah, 2024). Hence a keyword co-occurrence analysis was conducted to ascertain the main topics and trends in the regulation of AI literature. Only keywords that occurred at least three (3) times were considered for analysis. A total of thirty-five (35) keywords were mentioned more than three times (Figure 2). Trends in the current AI regulation literature show an emphasis on artificial intelligence, trustworthy AI, AI ethics, AI definition, deep learning, privacy, human rights, economic and social effects and laws and regulations of AI as shown in Figure 2. Hence AI regulation is an interplay of social, economic and ethical considerations. The EU AI regulation emerged as the most cited regulatory framework of AI.



Figure 2. Co-occurrence of keywords (Author's compilation, 2024)

# 3.3. Thematic Analysis

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A comprehensive qualitative thematic analysis was conducted to identify and examine the approaches to regulating AI. Themes were assigned to articles after reading the full article. The unified law (n = 4, 11%), rights-based (n = 3, 8%), AI ethics ((n = 5, 13%) and risk-based approach (n = 3, 8%) to AI regulations emerged as the major themes in the regulation of AI literature. A significant portion of the literature (n = 6, 16%) documents the challenges related to the regulation of AI. Data privacy challenges and regulations also emerged as a crucial theme in the regulation of AI. This next section will examine the identified themes in detail.

# 4. Discussion of Results on the Approaches to AI Regulation

# 4.1. Theme One: Risk Based Approach to AI Regulation

The literature documents the Risk-Based Approach (RBA) to regulating AI as the most dominant way of regulating AI. The RBA was popularised by the European Union when they adopted the RBA in their AI Act. The EU legally implemented the AI Act into law in March 2024 which was initially proposed in March 2021. In the RBA of the EU AI Act, AI risk is subdivided into four categories of risk criticality namely minimal risk, limited risk, high risk and unacceptable risk. First,

AI systems that create an unacceptable risk are banned whilst low-risk AI systems are subject to various transparency obligations, and the adoption of codes of conduct. Secondly, the Act puts more emphasis on high-risk al which are required to establish and operate a risk management system, establish a data and data governance management system, prepare technical documents containing legal requirements and compliance before market launch, provide information to users and ensure transparency, human oversight of AI systems, fulfil cybersecurity measures obligations, establish quality management system, fulfil conformity assessment, and post-market monitoring obligations aftermarket launch shall be fulfilled (Lim, Park & Kim, 2022; Finocchiaro, 2023). Although the approach was frequently mentioned by literature and regarded as comprehensive, most authors criticise the approach based on its applicability challenges in specialised sectors like the health and financial sector.

### 4.2. Theme Two: Management Based Approach to AI Regulation

Crum and Coglianese (2024) argued for a management-based regulation of AI systems approach which seeks to increase human oversight on the development, training and use of AI systems to minimize risk. The approach requires regulated entities to engage in internal managerial steps to identify risks, establish measures to reduce or control them, and then audit to ensure that the selected measures are followed as well as that risks are kept under control. Crum and Coglianese (2024) contended that the approach reduces the risk associated with a lack of interpretability, lack of explainability and misalignment with human intuition. Training of AI models involves a range of methods which usually provide autonomy to continuously learn from newly added data, other models, generated new data or real-time online data. Through deep learning, a crucial subset of artificial intelligence computer programs learns a task without being explicitly programmed. However, algorithms based on deep learning cannot explain the rationale for decisions made (Chia, 2019). The MBR of AI advocates for the use of supervised and reinforcement learning which involves human guidance in the training of AI systems. The MBR of AI has already been adopted in the EU AI act, United States AI regulations and the International Standards Organisation (ISO).

# **4.3.** Theme Three: Effectiveness and Rights Based Approach to AI Regulation in the Health Sector

In the heath sector the use of machine Learning and Deep Learning models is gaining momentum as AI is being used for medical diagnostics and treatment planning. However, Ploug and Holm (2023) argued that some AI systems are biased and produce morally unjustified differential treatment of patients. Literature

concurs that AI health systems can at most be equivalent but not superior to human doctors. The authors argued for a risk-based approach supplemented by a rightbased approach where patients being subjected to AI-supported diagnostics and treatment planning have a right to a second opinion. A right to a second opinion is a well-adopted traditional norm where patients are allowed to consult or referred to another medical practitioner. Ploug and Holm (2023) argued that the widely adopted risk-based approach promulgated by the European Union is inadequate for AI regulation in the health sector. The authors further argued that due to data sharing restrictions and the need for patient data, the data used in developing and training AI system models are usually inadequate and not a true representation of the presented population, which leads to AI diagnosis and treatment harm.

In the same vein, Zoellick, Drexler and Drexler (2024) concluded that AI systems must not substitute human medical expertise but play a supportive role due to instances where AI tools provide diagnoses that conflict with human medical expertise. The authors categorized the application of AI in health systems into three categories. First AI tools can be used to avail a second opinion in outpatient care hence complementing the initial human assessment and reducing diagnostic errors in the process. Second, AI systems can perform initial diagnosis for patient categorization and prioritization, where the AI system conducts an initial assessment to categorize patients flagging those with higher risks for immediate attention. Third, patient self-monitoring where patients use AI smartphone apps to diagnose and self-monitor their health for health literacy and seek further assistance by professional doctors if a serious condition is identified. In all these circumstances the authors advocated for a complimentary role instead of an autonomous role. Zoellick, Drexler and Drexler (2024) further argued that the newly introduced RBA AI regulation emphasizes on ensuring AI systems harmlessness, however, the licensing for medication follows the framework of effectiveness ensuring a safe clinical dose, assessment of side effects and efficacy, and ultimately demonstration of effectiveness. Based on various opinions provided by scholars, there is an urgent need for regulation of AI in the health sector to protect individuals from harm. Where AI systems are used patients should have a right to a second opinion, and should be given a choice to agree or disagree with the use of AI systems in their diagnosis procedure without facing negative consequences, AI systems should not replace human medical expertise and diagnosis should be supported by clinical evidence.

### 4.4. Theme Four: Market Safety Regulation

Lee (2020) argued for market safety regulation in the financial industry to address systemic risk caused by AI. The authors documented that algorithmic trading and peer-to-peer trading platforms can cause systematic risk and market manipulations

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which are capable of destabilizing the financial system. The literature documents previous instances where high-frequency algorithm trading caused market crashes through sudden withdrawal of stocks. Heading behaviours and reduction in liquidity are other systematic challenges brought by the use of AI in trading.

The financial industry is heavily regulated and is hinged on three main pillars, systemic regulation, prudential regulation and conduct of business regulation (Gumbo, Njerekai, Murungu & Damabaza, 2020), where Systemic Regulation ensures financial system safety and soundness, prudential regulation is mainly concerned with consumer protection and conduct of business regulation is mainly focused on how banks and financial institutions conduct their business. The destabilization of financial markets through Al systems calls for regulation with more emphasis on systemic stability than risk management. A risk-based approach which has more emphasis on managing risk does not effectively regulate highly sensitive sectors like the financial sector which is highly contagious and paramount to every economy. Previous bank runs, which paralyzed the global financial sector. Regulation should also enforce Investor protection, which is a common standard requirement in the financial sector Lee (2020).

### 4.5. Theme Five: Regulation with Tort Liability

Chamberlain (2022) advocated for some basic principles of tort law to be implemented in the risk-based AI regulation. Considering that some fundamental principles of tort law like fault-based liability, strict liability, negligence and assumption of risk are commonly applied in risk-based law and have been in operation for the past decades, imbedding them in the new regulations will allow a uniform application of regulations. In the same vein Brown, Truby and Ibrahim (2022) called for a unified integration of civil liability, strict liability and fault liability in AI regulations. The authors noted that these regulations are usually separated from AI regulations hence creating lacunas in AI regulation systems.

# 4.6. Theme Six: Single Regulatory Legal Act/Unified Law to Regulate All Artificial Intelligence

Although the EU AI Act is considered a coordinated and horizontal approach to AI regulation, Brown, Truby and Ibrahim (2022) contrasted that the EU failed to create synergies between the General Data Protection Regulation (GDPR) and AI Regulation Act hence creating a lacuna in the regulatory of AI. Mishina, Shikula and Afanasyeva (2020) advocated for a single regulatory legal act to govern AI where the regulation can consist of two parts; the general and the special part. First, the general part should set out the general legislative requirements applicable to all 42

sectors horizontally like the goals, principles, main provisions of the legal regulation of AI, definitions, certification and public control mechanisms. Secondly, the special part extends regulation to specific sectors or sections where one should adhere to the rule on the priority of a special rule over a general rule. The literature documents the fragmentation of law related to AI across the world. Civil liability, ethical aspects, and IPRs should be integrated into AI regulations (Brown, Truby & Ibrahim, 2022).

# **4.7.** Theme Seven: AI Regulatory Bodies, Technical Committees of Standardisation and Testing Laboratories

Mishina, Shikula and Afanasyeva (2020) argued that to enhance the regulation of AI, a certification process should include technical committees for standardization, certification bodies, as well as testing laboratories, in which the capabilities of developed technologies are directly evaluated. In the same vein, Bradley (2022) categorized regulatory approaches into rights-based, sectorial based and standardsbased approaches. The author noted a renewed attention to technical and professional standards in the regulation of AI. Crum and Coglianese (2024) also noted the influence of the International Standard Organisation (ISO) in the formulation of AI regulatory standards. AI regulatory frameworks must comprise the regulation of the people developing the algorithms and training the algorithms with data to promote ethical programming (Brown, Truby & Ibrahim, 2022). The EU AI Act also advocated for the use of regulatory sandboxes as regulatory laboratories for testing the AI system. Regulatory sandboxes create a mutual learning environment for both the innovators and the regulators to learn about the applicable regulations and innovations respectively. Hence facilitating a wellinformed regulatory system.

# 4.8. Theme Eight: Progressive Legislative Model

A unified law may not be an effective practical application when dealing with AI's evolving nature and uncertainty. Literature documents the progressive and sectorial nature of legislation applied in the USA, as a fundamental step in regulating AI. well before the adoption of a common and comprehensive national law, an observation of the impacts of the law in independent sectors or states provides leeway for regulators to assess the consequences and effectiveness of the law. However sectorial and individual state laws can lead to an uneven application of law and difficulty in responding to what occur in unregulated fields (Park & Kwon, 2023). In the health sector, the regulation of AI software as a medical device is

more recent and needs more analysis to be effectively regulated (Penteado, Fornazin, Castro & Rachid, 2022; Giansanti, 2022).

### 4.9. Theme Nine: Sustainability Regulation

The current AI regulations lack explicit attention to the environmental aspect and social inclusion (Pecchia1, Maccaro, Matarrese, Folkvord & Fico, 2024). Generally, the training of AI algorithms has a significant carbon dioxide emission footprint whilst the sharing and storing of massive data is energy-intensive. Resultantly the corresponding hardware and cooling systems to support AI models have a high probability of compromising sustainable environmental regulation. Hence the need for regulators to consider sustainability in the regulation of AI, ensuring that AI systems are green and their production is aligned with net-zero emissions targets. Concerning the sustainable development goals, diversity and inclusivity should be facilitated, AI systems should be inclusive and non-discriminatory. Penteado, Fornazin, Castro and Rachid (2022) noted a lack of adequate literature on the environmental impact of the increasing amount of electricity used to train deep learning models.

### 4.10. Theme Ten: Digital Ethics and Self-Regulation

Literature documents moral and ethical principles as a basis for AI regulation (Khisamova, Begishev & Gaifutdinov, 2019). Adoption of standard ethical and moral standards by AI experts and users like the programmers, IT specialists, scientists, lawyers, economists and entrepreneurs will ultimately ensure self-regulation of the industry. In the same vein Brown, Truby and Ibrahim (2022) argued that AI ethics can pave the way for the development of a more effective AI regulation, complementing the practical analysis of AI consequences and making AI guidelines more effective, proactive, and action-inspiring. Although moral suasion is not always an effective way of enforcing law, it is a standard method of enforcing moral standards and values. Natorski (2024) documented the success of Ethics of Artificial Intelligence adopted by 193 UNESCO member states in 2021 as a global move to effective regulation of AI, in the same vein Khisamova, Begishev and Gaifutdinov (2019) advocated for the introduction of uniform ethical principles for AI developers and users of systems.

# 4.11. Theme Eleven: Intellectual Property Law for AI

Literature argues that AI works should be copyrighted because AI is considered a tool of human authors used in the creation of work. However, Albakjaji (2024) noted a dilemma in the Intellectual Property of AI in Saudi Arabia regulations as 44

the current regulations do not fully account for AI works' unique properties. AI machines can develop subject matter namely artwork, build an object, write a piece of literature and develop a new brand name and such innovations should be fully protected by IP. Vasilevskaya and Poduzova (2022) argued for AI's works to be included in the list of protected intellectual property of the Civil Code of the Russian Federation.

### 4.12. Challenges

The literature documents data privacy, transparency, evolving nature of AI and political concerns as major challenges to AI regulation. Data constitutes the backbone of AI systems, hence the need for open data sharing across jurisdictions, however, this violates data privacy regulations and the rights of individuals concerned. Transparency relates to trust in AI technologies facilitated by explainability, traceability, and communication. There exists a heated debate on the explainability of AI algorithms which use deep learning systems which can learn and make independent decisions without providing a standard justification for the decisions. This poses a serious challenge to regulators since the decision-making process is unexplainable. The literature documents the importance of developers of AI systems to provide the means for humans to understand and trace the outputs of the system (Schedl, Gómez & Lex, 2022). Previous incidents record algorithmic biases and discriminatory behaviours in decision making which pose harm to AI system users, especially in the health sector. Hence the need for traceability to keep track of the behaviour of a system, explainability and detailed documentation of the system development process, limitations and capabilities. Fairness, nondiscrimination and diversity also emerged as major issues to be considered when regulating AI.

# 5. Conclusion

This study explored the approaches to AI regulation and recommended best practices to regulate AI. Risk-based, management-based, rights-based, systemic market safety, tort liability, single unified law and ethics emerged as major approaches to regulate AI. Economic and political concerns remain barriers to effective regulation as governments and jurisdictions aim to become innovation centres. Data privacy, transparency and the evolving nature of AI need to be considered when developing AI regulations. The debate on the regulation of AI is decreasing in literature, however, there remain literature gaps in data privacy regulation in contrast to open data sharing since data is fundamental to the training of quality AI systems. Literature gaps also exist on the development of unified, comprehensive multi-faceted AI regulations which cater for both general and specific sector laws. The study recommends a universal and unified regulation of AI which extends from ethical standards enforced by professional bodies to actual enforceable comprehensive law to avoid law lacunas. Literature from developing nations is also crucial in the development of effective regulatory solutions.

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