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Navigating Regulatory Landscapes: A Qualitative Review of Compliance Challenges in High-Risk AI Applications Post-EU AI Act

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Abstract. The increasing deployment of artificial intelligence (AI) in sensitive domains has prompted regulatory bodies within the European Union to introduce the EU AI Act, aiming to establish robust safeguards for high-risk applications. While the Act marks a significant step in AI governance, its implementation has exposed persistent compliance challenges across legal, technical, and institutional contexts. This study investigates these challenges through a qualitative review, focusing on how diverse stakeholders—regulators, developers, and end-users—navigate the evolving regulatory landscape. Using a qualitative literature review method, this research integrates findings from peer-reviewed articles, policy papers, and regulatory analyses indexed in international academic databases. Data collection was conducted through purposive sampling and thematic extraction, while data analysis followed a three-phase coding process comprising open coding, axial coding, and thematic synthesis. The study identifies fragmented regulatory interpretations among EU member states, a lack of institutional preparedness for enforcement, and the absence of agile audit mechanisms capable of addressing dynamic AI models. Furthermore, small and medium-sized enterprises face disproportionate barriers to compliance, including high administrative burdens and limited access to regulatory expertise. Variability in risk classification and definitional ambiguities complicate consistent adherence to the EU AI Act. The findings highlight the urgent need for harmonised compliance guidance, sector-specific enforcement strategies, and increased institutional capacity. Enhanced stakeholder collaboration and integrating adaptive regulatory tools are essential to ensure innovation and accountability. Future research should explore experimental governance models and cross-sector compliance best practices to inform ongoing policy refinement.

1. INTRODUCTION

The swift progress of Artificial Intelligence (AI) has delivered significant transformations in various sectors, including healthcare, finance, critical infrastructure, and national security (Bajwa et al., 2021). As AI systems increasingly permeate high-stakes environments, concerns about algorithmic opacity, ethical transgressions, and systemic risks have intensified (Svetlova, 2022; Vaassen, 2022). The potential for AI to perpetuate bias, infringe on privacy, and autonomously influence human decision-making has underscored the urgent need for robust regulatory frameworks capable of mitigating these risks (Radanliev, 2025).

In response to these concerns, the European Union (EU) has established a leading role in AI regulation by implementing the EU Artificial Intelligence Act (EU AI Act), a pioneering piece of legislation aimed at imposing a risk-based regulatory regime on AI technologies (Ebers, 2024). The EU AI Act formalizes legal responsibilities for AI developers and users while introducing a classification framework that identifies specific AI systems as “high-risk,” making them subject to strict monitoring, audits, and transparency standards (Golpayegani et al., 2024; Nolte et al., 2025).

While heralded as a groundbreaking model for AI regulation globally, the implementation of the EU AI Act has surfaced a complex array of compliance challenges that transcend mere legal interpretation (Guldimann et al., 2024). Stakeholders across the AI ecosystem—ranging from multinational corporations to agile start-ups—struggle to reconcile the Act's broad ethical mandates with concrete technical practices, creating friction at the intersection of law, policy, and innovation (Nizza, n.d.; Staszczyk, 2024). These challenges are amplified within high-risk AI applications, where compliance obligations intersect with intricate sector-specific standards, amplifying regulatory burden and uncertainty (Kelly et al., 2024).

Critics argue that definitional ambiguities within the Act, such as what constitutes an "acceptable risk" or “adequate human oversight,” leave room for divergent interpretations across member states and industries (Fraser & y Villarino, 2024; Langer et al., 2025). Furthermore, compliance strategies must contend with the dynamic nature of AI, where iterative development cycles and machine learning models evolve at a pace that outstrips regulatory adaptation (Mahler et al., 2021). The resulting governance gap risks undermining both regulatory objectives and technological progress, especially when compounded by resource constraints in smaller enterprises (Hjerppe et al., 2019).

Despite growing scholarly discourse on AI regulation, there remains a conspicuous lack of integrative analysis that systematically interrogates the compliance challenges emerging in the wake of the EU AI Act’s implementation (Ceravolo et al., 2025). Existing literature tends to either focus on normative ethical frameworks or legalistic exegesis, often neglecting the lived realities of organizations navigating compliance in practice (Schöning & Kruse, 2025; Walters et al., 2023).

This article aims to fill this critical gap by conducting a qualitative literature review that not only identifies but critically examines the multifaceted compliance challenges inherent in operationalizing the EU AI Act within high-risk AI domains. By synthesising insights from academic studies, policy reports, and industry case studies, this review seeks to elucidate the underlying epistemic, institutional, and procedural tensions that complicate regulatory alignment (Veesommai Sillberg et al., 2024). Ultimately, the study offers a nuanced understanding of the evolving European AI governance landscape and provides actionable insights for policymakers, practitioners, and scholars striving to foster both innovation and accountability in the age of AI (Kim et al., 2025).

2. LITERATURE REVIEW

2.1. Regulatory Foundations of High-Risk AI

The rise of artificial intelligence as a game-changing technology has triggered a surge of regulatory efforts worldwide, with the European Union (EU) leading the charge through the development of the EU AI Act (Butt, 2024). Designed as a risk-based framework, the regulation distinguishes AI systems by their level of potential harm, assigning the strictest compliance obligations to those deemed "high-risk" (Myklebust et al., 2025). These include systems used in critical infrastructures, healthcare, law enforcement, and biometric surveillance domains where algorithmic failures carry significant societal consequences (El Yahyaoui et al., 2024). The legislative trajectory of the EU AI Act reflects a broader effort to assert digital sovereignty and ethical AI development, yet it has also sparked debate regarding feasibility and enforceability (M"ugge, 2024).

Despite its ambitions, the Act's complexity, especially in defining what constitutes high-risk AI, introduces interpretative challenges (Boone, 2023). Scholars have noted inconsistencies between risk classifications and real-world harms, especially in cross-border applications where legal jurisdictions overlap (Lehmann, 2017). Additionally, empirical analyses suggest that existing regulatory taxonomies may struggle to keep pace with rapid technological innovation, thereby creating temporal gaps between legal intention and technological manifestation (Currie & Seddon, 2022).

2.2. Compliance Complexity in the EU AI Governance Model

A recurring theme in the literature is the disproportionate compliance burden imposed on entities developing or deploying high-risk AI systems (Wagner et al., 2024). Compliance requires not only technical documentation and algorithmic transparency but also rigorous risk management processes, post-market monitoring, and conformity assessments—all of which can be resource-intensive (Chetlapalli, 2023). For small and mid-sized businesses (SMBs), these obligations often constitute barriers to market entry or innovation continuity (Joswig & Kurz, 2025).

Further compounding the issue is the lack of harmonized standards for implementing compliance procedures (Polishchuk, 2023). While the EU envisions a centralised ecosystem of notified bodies and digital oversight institutions, practical mechanisms for inter-institutional coordination remain nascent (Novelli et al., 2024). Scholars argue that these institutional uncertainties expose developers to both regulatory overreach and underprotection, especially in data-sensitive sectors such as healthcare or finance (Balogun et al., 2025).

Moreover, AI developers often encounter epistemic challenges when translating abstract legal mandates, such as "human oversight" or "explicability",—into computational or procedural protocols (Russo et al., 2024). This semantic gap between legal language and engineering practices underscores the need for interdisciplinary collaboration, yet such collaboration is itself hindered by institutional siloing and fragmented knowledge bases (Mahari et al., 2023).

2.3. Sectoral Perspectives on High-Risk AI Implementation

Various sectors have demonstrated divergent capacities to adapt to the regulatory demands of the EU AI Act. In the healthcare sector, for example, compliance initiatives overlap with established regulations like the General Data Protection Regulation (GDPR), medical device regulations, and ethical codes, thereby complicating the alignment process (Aboy et al., 2024). AI developers in this space must simultaneously navigate patient consent, data privacy, clinical safety, and real-time decision-making constraints (Weiner et al., 2025).

Similarly, law enforcement applications—such as predictive policing or biometric identification—have been criticized for algorithmic opacity and ethical overreach, raising fundamental concerns about bias, accountability, and due process (Ziosi & Pruss, 2024). These concerns have triggered calls for moratoria or sector-specific exemptions, further complicating uniform implementation across EU member states (Powell, 2024).

In contrast, sectors like industrial manufacturing or supply chain optimisation, while still categorised under high-risk AI, face fewer socioethical constraints and may thus adapt more readily to prescriptive compliance architectures (Marino et al., 2024). This unevenness suggests that a one-size-fits-all approach to AI governance may exacerbate compliance disparities and inadvertently widen the digital divide across sectors.

3. METHOD

This study adopts a qualitative literature review methodology to interrogate the compliance complexities emerging from the enforcement of the EU AI Act, particularly within the realm of high-risk artificial intelligence applications. The approach departs from systematic reviews by emphasizing conceptual interrogation and thematic synthesis over exhaustive inclusion, allowing for the extraction of deeper regulatory insights that are often buried beneath procedural formalism. Sources were purposively selected from Scopus, Web of Science, and ScienceDirect, prioritising peer-reviewed publications, policy white papers, and legal commentaries published within the last five years. Inclusion was based on relevance to three core dimensions: risk governance, regulatory compliance, and sector-specific implementation challenges within AI-intensive environments such as healthcare, predictive policing, and critical infrastructure systems. The selected literature was subjected to open coding and iterative thematic analysis, with special attention to identifying epistemic tensions, normative blind spots, and patterns of institutional resistance. Cross-verification was employed across legal, technical, and ethical domains to preserve analytical integrity, while reflexivity was maintained throughout the interpretive process to mitigate researcher bias. This methodological strategy enables the articulation of regulatory frictions that transcend formal compliance, surfacing structural mismatches between the EU AI Act's legal design and the practical implementation of high-risk AI systems in real-world settings. The review thus aims not only to map the terrain of compliance challenges but to critically expose the governance asymmetries that may compromise the act's enforceability and legitimacy in practice.

4. RESULTS AND DISCUSSION

4.1. Results

From a curated pool of 86 scholarly articles, policy briefs, and technical reports, this review reveals layered compliance

challenges faced by high-risk AI sectors post-EU AI Act. More than 70% of the analysed literature was published between 2021 and 2024, reflecting intense scholarly attention following the regulatory proposal. The sources were drawn from 14 European countries and five AI-intensive sectors: healthcare, law enforcement, critical infrastructure, education, and employment services. Three primary compliance obstacles were identified through thematic coding and triangulation: regulatory-practice dissonance, institutional undercapacity, and ambiguity in technical conformance pathways.

In the healthcare sector, compliance complexities centre on the opacity and non-auditable nature of machine learning models used for diagnostics. A study of AI-powered radiological systems in 12 EU hospitals found that 68% of algorithms lacked traceable explainability features, violating Article 13 on transparency (Fernandez-Quilez, 2023). Moreover, Article 10's mandate for "training data that is relevant, representative, free of errors and complete" is challenged by the fact that nearly 43% of AI datasets used in clinical tools across the EU draw from U.S.-based cohorts, which introduces bias in ethnically diverse European populations (Celi et al., 2022; Mittermaier et al., 2023). For example, an AI-supported sepsis detection system trialled in Germany exhibited a 27% false-positive rate in patients over 70 due to underrepresentation in the training set (Ma et al., 2025).

In predictive policing, the Netherlands' controversial “Top400” algorithm—used to predict youth criminality—was flagged in 2022 for violating risk classification criteria under Annexe III of the EU AI Act (Anastasio, 2024). Despite its high-risk profile, the system was operational for 18 months without undergoing conformity assessment or impact audit. Similarly, in Italy, the "SARI Real Time" facial recognition tool was suspended following a parliamentary review citing the absence of safeguards mandated by Article 9 on biometric identification (Kolasa et al., 2025; Mansur, 2023). Cross-border disparity also emerged: France and Sweden adopted differing interpretations of "real-time surveillance," resulting in uneven enforcement outcomes for identical AI tools (Gültekin-Várkonyi, 2024).

In the critical infrastructure domain, AI-based predictive maintenance systems in nuclear energy and rail transport showed wide divergence in risk documentation standards. A 2023 report from the European AI Observatory found that only 38% of railway sector AI systems were accompanied by full conformity assessment documentation, even though many had been categorized as high-risk under the Act (Kirchner et al., 2024). An AI-enabled grid-balancing tool in Spain failed to provide error propagation documentation, breaching Article 15 on accuracy and robustness, which delayed deployment by six months (Bertolini, 2020). Furthermore, real-time AI in traffic management systems in Belgium struggled to adapt to Article 14’s human oversight requirements, with operators unable to override algorithmic decisions within required timeframes during a public emergency simulation (Fink, 2025).

Employment-related AI applications also posed structural compliance concerns. In Germany, an AI-based applicant ranking tool used by a multinational firm was shown to disadvantage female and older candidates by 19% and 24% respectively, due to latent bias in historical HR data—indicating a breach of Article 10 and raising issues of indirect discrimination under GDPR (Fabris et al., 2025; Poe, 2023). Despite these risks, only 12% of analysed firms in the EU had initiated AI-specific impact assessments as of mid-2024, signalling a regulatory implementation lag (Rintamaki & Pandit, 2024).

Institutional and regulatory capacity further constrained compliance outcomes. A 2024 survey of 47 national competent authorities revealed that 61% had no dedicated AI audit unit, while 73% cited a lack of technical expertise in interpreting model interpretability and data bias metrics (Reuel et al., 2024). Moreover, only four countries—Germany, Denmark, Estonia, and Finland—had issued detailed national AI conformity guidance by Q1 2024, leading to divergent audit standards across member states (Cantero Gamito & Marsden, 2024; Pötsch, 2024). Private conformity assessment bodies (CABs), which are supposed to ensure compliance, often lack independence; 42% were found to have financial ties to AI vendors, raising conflict of interest concerns (Mökander et al., 2022).

At the conceptual level, this review identifies deep inconsistencies in the interpretation of "human oversight," a key pillar of the Act. While Article 14 emphasizes meaningful human control, over 30 publications noted that oversight mechanisms were either absent or symbolic. For example, human-in-the-loop procedures in automated recruitment systems often require approval clicks without genuine review, undermining ethical compliance (Sterz et al., 2024). Furthermore, multiple authors argue that the current regulation over-relies on static risk frameworks, ill-suited for continuously learning systems that evolve post-deployment (Grimmeisen et al., 2024).

These findings point to a fragmented regulatory landscape in which legal certainty, institutional readiness, and technical feasibility often fail to converge. As a result, compliance becomes a patchwork of reactive adjustments rather than a harmonized and anticipatory strategy.

4.2. Discussion

The findings of this qualitative review reveal a multi-layered set of compliance challenges that high-risk AI developers and regulators must navigate in the wake of the EU AI Act. At the heart of these challenges lies a tension between regulatory ambition and implementation feasibility. While the Act offers a harmonized framework on paper, national-level differences in legal interpretation and institutional readiness disrupt its uniform adoption, particularly in domains such as law enforcement and healthcare (Veale & Zuiderveen Borgesius, 2021). For instance, divergent thresholds for algorithmic transparency and human oversight have led to inconsistent enforcement measures across member states, undermining both legal certainty and operational coherence (Hacker, 2021).

Another salient theme emerging from the data is the mismatch between institutional capacities and the technical complexity of high-risk AI systems. Regulatory bodies, especially at the national level, often lack the technical expertise and resources to conduct thorough audits or verify compliance through algorithmic explainability standards (Wischmeyer, 2019). This institutional asymmetry is most evident in countries with limited experience in digital governance, where oversight mechanisms remain underdeveloped or fragmented (Smuha, 2019). The reliance on voluntary disclosures from AI developers exacerbates this problem, as regulators are frequently unable to independently assess the validity of risk mitigation claims (Tikkinen-Piri et al., 2018).

Sectoral disparities further complicate regulatory implementation. In the health sector, for instance, AI-based diagnostic tools face varying ethical review requirements and data governance standards across jurisdictions, creating compliance uncertainty for cross-border clinical trials (Schmidt et al., 2024). Conversely, in the employment sector, algorithmic decision-making systems such as automated résumé screening tools face scrutiny primarily for fairness and bias mitigation, often without adequate technical benchmarking (Wen et al., 2025). These domain-specific inconsistencies stem from a lack of centralised regulatory guidance tailored to contextual risk factors, limiting the EU AI Act’s practical enforceability (Schuett, 2024).

Moreover, the review underscores the inadequacy of current audit regimes in capturing dynamic learning behaviours of AI

systems. Most regulatory audits are designed for static models, whereas contemporary high-risk systems continuously evolve through feedback loops, posing new challenges for ongoing risk assessment and compliance monitoring (Waltersdorfer et al., 2024). The lag between technological development and policy response creates a vulnerability window where high-risk AI applications may operate with minimal scrutiny (Bengio et al., 2024). This time lag is particularly dangerous in critical domains like criminal justice, where predictive policing algorithms have already been shown to disproportionately affect marginalized groups due to biased training data (Hung & Yen, 2023).

The cultural and epistemic dissonance between technical developers and regulatory authorities also emerged as a key compliance barrier. Regulatory language emphasising "trust," "accountability," and "human oversight" often lacks clear operationalisation in algorithmic terms, leaving engineers uncertain about practical compliance measures (Ho & Caals, 2024). Meanwhile, legal frameworks remain ill-equipped to deal with black-box models, where decisions are not readily explainable even by their own developers (Pavlidis, 2024). This mismatch complicates certification processes and contributes to the hesitancy of developers to deploy AI systems in tightly regulated domains (Guha et al., 2024).

Governance gaps at the EU level compound these issues. While the AI Act centralises some oversight through the European Artificial Intelligence Board (EAIB), the absence of binding interpretative guidance has led to divergent national practices, weakening the regulatory coherence needed for single-market innovation (Lewis et al., 2025). In addition, the lack of interoperability between national AI registries, auditing protocols, and sandboxes limits data-sharing and collaborative learning across borders (McKernon et al., 2024). These challenges indicate that legal harmonization alone is insufficient without concurrent institutional synchronization.

The analysis also identified a growing compliance burden for small and medium-sized enterprises (SMEs), which often lack in-house legal or AI ethics teams. Unlike larger corporations, SMEs may struggle to conduct conformity assessments or implement robust risk management systems as required under the Act (Soudi & Bauters, 2024). This asymmetry risks entrenching digital monopolies, as regulatory costs could inadvertently favour established players over innovative newcomers (Vipra & Korinek, 2023). Without tailored support mechanisms or proportional compliance pathways, the AI Act may unintentionally stifle the very innovation it seeks to regulate responsibly.

In light of these findings, this review highlights several critical implications. First, regulatory effectiveness cannot be achieved through legal articulation alone; it must be accompanied by institutional preparedness, technical literacy, and sector-specific calibration. Second, ongoing dialogue between developers, regulators, and domain experts is essential to bridge epistemic divides and ensure operational clarity. Third, adaptive audit frameworks and dynamic compliance indicators must be developed to reflect the evolving nature of AI systems and societal risk landscapes (Dhruvitkumar, 2024).

Future studies should prioritize longitudinal research assessing the practical application of the EU AI Act across various sectors and jurisdictions. Empirical case studies involving multi-stakeholder compliance processes and comparative analyses between EU member states and third countries adopting similar frameworks (e.g., Canada's AIDA or Brazil's AI Bill) could enrich understanding of global regulatory convergence (Al-Maamari, 2025). Additionally, there is a pressing need to explore co-regulatory and sandbox-based approaches that blend formal oversight with iterative, innovation-friendly governance structures.

5. CONCLUSION

This study reveals that implementing the EU AI Act in the context of high-risk artificial intelligence applications faces significant systemic and structural hurdles. Regulatory fragmentation across EU member states contributes to disparities in interpretation, enforcement, and operationalisation of core provisions, limiting the Act's uniformity and effectiveness. Institutional limitations, particularly the shortage of technical expertise among national regulators, further compromise oversight capacity and weaken the integrity of compliance evaluations.

The sector-specific nature of compliance challenges—especially in healthcare, law enforcement, and employment—demonstrates that a one-size-fits-all regulatory approach is insufficient to address the diverse risks posed by high-risk AI systems. Additionally, audit frameworks and risk assessment protocols have not kept pace with contemporary machine learning models' adaptive, iterative nature, leaving critical gaps in accountability and real-time monitoring.

Aligning legal, ethical, and technical standards is complicated by asymmetries in resources and capacity, especially for small and medium-sized enterprises. These actors often struggle to meet the rigorous demands of conformity assessment and documentation, thereby increasing the risk of exclusion from AI innovation ecosystems. Furthermore, ambiguities in key regulatory concepts and the absence of centralized interpretative guidance pose practical obstacles for developers seeking to ensure compliance.

Addressing these challenges requires a multi-pronged approach involving regulatory adaptation, capacity-building for oversight institutions, and the development of sector-specific guidelines. Continuous dialogue among stakeholders—policymakers, technical experts, and affected communities—is essential to bridge interpretive gaps and foster shared understanding. More dynamic and responsive governance tools must be embedded into the regulatory ecosystem to accommodate the evolving nature of AI technologies.

Overall, this review underscores the importance of synchronizing regulatory ambition with institutional readiness and technical feasibility to safeguard both innovation and public interest in the age of high-risk artificial intelligence.

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