Uncertainty as a Primary Barrier for Trustworthy AI Under the EU AI Act: German SME Perspectives

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The European Union's AI regulation, the EU AI Act, represents a significant shift from voluntary ethical frameworks to binding regulation, presenting implementation challenges particularly for resource-limited SMEs. Our mixed-methods research examined the EU AI Act's impact on SMEs through surveys of German AI SMEs ($N = 21$) and interviews with AI SMEs and industry stakeholders ($N = 13$). In this extended abstract, we summarize our motivation and methods, and focus on providing results from the interviews. Our findings reveal that company size and compliance experience significantly affect estimated implementation capabilities. SMEs face considerable resource constraints across time, finances, and staffing. Implementation uncertainties – including definitional ambiguity, unclear scope, and insufficient guidance – drive strategic responses: delaying compliance efforts, modifying products to reduce regulatory burden, and frequently seeking external compliance expertise and certification. These results indicate that uncertainty emerges as the primary implementation barrier. Researchers can help reduce uncertainty by developing best-practice guidelines that support the AI Act's trustworthy AI objectives. We conclude with recommendations for policymakers and researchers.

Keywords: AI Regulation, EU AI Act, Trustworthy AI, SME, Standardization, Harmonized Standards, Certification

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1 Introduction

The European Union Artificial Intelligence Act (AI Act) represents a milestone in AI governance as it creates the world's first comprehensive legal framework for artificial intelligence systems [8]. This regulation marks a decisive transition from voluntary ethical guidelines to binding legal requirements. Prior work [e.g., 12] has identified the limited effectiveness of ethical principles such as fairness, accountability and transparency [18] in actual decision-making processes, despite their broad adoption by industry leaders [10, 25, 32] and international organizations [1, 16, 30]. Further research observed that these frameworks often functioned as "ethics washing" [37],

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that they lacked implementation methods [26] and that they remained "meaningless, isolated and toothless" when they came into conflict with commercial interests [29]. The core aim of the AI Act is to ensure the development and deployment of trustworthy AI by protecting EU citizens from risks to their health, safety and fundamental rights, while promoting innovation [8]. This regulatory approach stems from the recognition that AI is a transformative technology [11] that, while offering significant benefits, can also pose significant risks [14] in areas such as healthcare [28], law enforcement [3], education [24], financial services [35], and recruitment [15].

The timetable for the implementation of the AI Act, which came into force in August 2024, makes it urgent for the industry to adapt. The obligations for high-risk AI systems will take effect within 24 months of the AI Act coming into force [8]. Harmonized European Standards that will support compliance with the AI Act are currently under development. Given the recent adoption of the regulation, discourse in academia as well as industry best practices for practical implementation are still emerging.

For this reason, this study captures an interesting point in time when the regulation exists but detailed implementation guidance is not yet available. This study provides unique insights into the industry's initial reactions and the challenges, particularly for small and medium-sized enterprises (SMEs),[1] which have to balance limited resources between increasingly complex compliance requirements requested by legally binding regulations and core business activities. Compared to larger companies, they typically do not have dedicated compliance teams at their disposal. Our research can be situated in the realm of prior studies on the impact of technology regulation on companies, including initial responses of SMEs to the EU AI Act (conducted before the publication of the final legal AI Act text) [e.g., 17, 22], the impact of the GDPR on SMEs [e.g., 7, 13, 34] or the impact of regulation outside the EU on businesses also operating, e.g., in the Chinese market [e.g., 4, 5].

Our research poses three research questions: (1) How aware and informed are SMEs about the EU AI Act and how do their current practices align with its requirements? (2) What challenges do SMEs face in implementing the EU AI Act and what strategies are they developing to address these challenges? (3) What impact of the EU AI Act do SMEs anticipate on their business and the broader European AI industry? Using a mixed methods approach, we address these questions by combining an exploratory survey of AI SMEs located in Germany with semi-structured in-depth interviews with both representatives from German AI SMEs and industry experts. In this extended abstract, we describe our research approach and focus on summarizing the results from the semi-structured interviews.

This research makes the following contributions to the field: First, we capture the current state of AI Act awareness of SMEs and their practical alignment with the requirements of the AI Act at a unique point in time, approximately six months after entering into force, but before detailed implementation guidance became available. Second, we identify key operational challenges faced by SMEs, focusing on concrete implementation issues rather than abstract policy implications. Our findings highlight uncertainty as an overarching fundamental barrier that threatens the EU AI Act's effectiveness in establishing trustworthy AI.

2 Methods

We employed a sequential mixed methods design (quan→QUAL) [6, 21, 27], where an initial exploratory survey of SMEs informed subsequent semi-structured in-depth interviews with SME representatives and industry experts. In general, quan→QUAL research designs emphasize qualitative data collection and analysis [6].

[1] For this work, we adopted the official EU definition of SMEs from https://singlemarket-economy.ec.europa.eu/smes/sme-definition_en.

Exploratory Survey and Interview Design. We structured our survey following Kasunic's systematic seven-stage methodology [20], organizing it into four key components: (1) company demographics, (2) guided AI system risk classification, (3) evaluation of essential requirements through 5-point Likert scales [19], and (4) open-ended questions about AI governance and anticipated challenges. The risk classification was a simplified assessment adapted from [9]. The requirements evaluation examined six previously identified clusters of AI Act topics based on Articles 9-15 of the AI Act (technical system fundamentals, deployment guidelines, data, risk management, performance evaluation, and human oversight) across four dimensions of analysis (technical expertise availability, cost and time impact, external support needs, and perceived importance). Some concluding questions were adapted from [2].

Following guidelines by Taherdoost [36], the interview guideline was designed to investigate the alignment of current practices with AI Act requirements, key challenges, and compliance strategies identified in the preceding survey phase. All interviews were conducted virtually through Zoom (eleven in German and two in English), recorded with participant consent, machine-transcribed, and subsequently validated through manual review.

Data Analysis. Quantitative data from the survey ($N = 21$) were processed with descriptive statistical analysis [21]. For qualitative responses to open-ended questions, we employed an inductive content analysis methodology [23], which involved comprehensive coding procedures and systematic category formulation with inter-coder validation involving two researchers to ensure analytical rigor [33]. Interview transcripts ($N = 13$) were analyzed using MAXQDA 2022 following Mayring and Fenzl's qualitative content analysis approach [23]. Our categorization framework emerged through an inductive approach. Applying the two-stage validation approach from Rädiker and Kuckartz [33], we conducted an initial revision of the category system after analyzing 25% of the data (three interviews), where a second researcher reviewed the initial codings. We collaboratively refined the coding structure based on these assessments. Upon completion of the full coding process, we conducted an inter-coder reliability assessment and performed both qualitative and quantitative examinations of the resulting category framework.

Participants. Following a criterion sampling approach [31], potential survey participants were identified through three major German AI startup and SME databases,[2] yielding 462 eligible companies. We contacted all 462 SMEs twice via email and reminded them with a follow-up email after two weeks. Additionally, we asked start-up hubs to distribute the survey link. The survey sample was dominated by small enterprises, both startups and established businesses, with 52% being micro enterprises (<10 employees), and the remaining companies having up to 250 employees. Most respondents indicated limited familiarity with the EU AI Act, describing their knowledge as moderate or less. Regarding risk profiles, most participants (62%) reported developing low-risk AI systems, while 24% developed high-risk applications, 10% created systems with unacceptable risk, and one participant did not provide risk classification information. The interview sample consisted of nine SME representatives and four experts, recruited through purposeful selection [31] from a variety of industry sectors. Initial survey insights about sector-specific challenges and existing regulatory knowledge motivated this approach, aligning with the horizontal nature of the EU AI Act. Among the SME participants, four developed low-risk AI systems, four developed high-risk AI systems, and one developed both low- and high-risk AI systems. Regarding AI operator roles, eight companies were classified as providers while one operated as a deployer.

[2]Lernende Systeme: https://www.plattform-lernende-systeme.de/startseite.html, AI+MUNICH Start-ups: https://www.munich-ecosystem.de/ai-munich, and AI Startup Landscape: https://www.appliedai-institute.de/hub/2024-ai-german-startup-landscape

Limitations. This study captures a specific moment approximately six months after the AI Act's entry into force, before the release of harmonized European Standards. The relatively small sample size ($N = 21$ for survey, $N = 13$ for interviews) limits broad generalizability across the diverse European SME landscape. We acknowledge potential self-selection bias, as participants may represent SMEs with greater awareness of or interest in the AI Act, potentially excluding businesses that had not yet begun considering regulatory compliance. To partially mitigate this bias, we included interviews with industry experts not directly affected by the AI Act's obligations, who largely confirmed the challenges identified by SMEs. Future research should expand the geographic scope and conduct longitudinal studies to track how SME responses evolve as implementation guidance becomes available.

3 Results

In the following, we highlight the results from the interviews and substantiate them in part with results from the survey study. Based on the interviews, we identified nine main themes clustering 29 codes and 67 subcodes focused on SMEs' practices, challenges, and strategies for AI Act compliance. The nine main themes are:

- **Technical and Development Practices** highlighted current software development approaches, revealing that while all interviewed startups employ standard version control and project management tools, none have implemented AI-specific documentation methods such as model cards or datasheets. Multiple interviewees highlighted the tension between fast-paced, iterative AI development practices and the slower compliance processes required by the AI Act. In smaller teams, formal documentation often seems less crucial, contributing to minimal documentation practices.
- **Management and Compliance Practices** provided evidence for varying levels of risk and quality management maturity across companies, with more sophisticated systems found in regulated sectors like healthcare. Our survey found that approximately half of the companies reported prior experience with standard certifications, with SMEs expressing positive experiences with ISO standards due to their adaptability to different company sizes and support for iterative improvement approaches.
- **Implementation Challenges** emerged as a critical concern across all participants, with resource constraints manifesting across four dimensions: financial resources (74% of survey respondents expect significant cost increases), time constraints (described as unrealistic implementation time frames in interviews), technical expertise gaps (57% of surveyed companies reported insufficient expertise for data requirements, 67% for risk management), and human resources (76% lack dedicated AI governance roles). These limitations particularly affect early-stage startups balancing product development with compliance.
- **Regulatory Challenges** centered on legal ambiguity, particularly regarding risk classification and compliance requirements, with participants expressing significant concerns about unclear definitions and scope, leading to uncertainty in investment decisions and implementation planning.
- **Stakeholder Challenges** revealed how external pressure, especially from larger business customers, drives compliance efforts regardless of company size, creating cascade effects through AI value chains that effectively neutralize SME exemptions intended by the regulation. Nine interviewees described how B2B relationships force smaller companies to meet the full requirements of larger customers, similar to patterns observed with information security certification requirements.

- **Strategic Responses** showed approaches to navigating compliance. The predominant strategy involves relying on external consultancy coupled with certification through standards. Adaptation strategies include modifying products to reduce regulatory burden, avoiding high-risk classifications, or deliberately postponing compliance efforts due to resource constraints.
- **Market Impact** indicated the emergence of a compliance services industry similar to developments around the introduction of the GDPR, while raising concerns about European competitiveness. Twelve out of 21 survey respondents expected the AI Act to slow down their business operations, with resource allocation between compliance activities and core innovation emerging as a central challenge.
- **Recommendations** emphasized the need for practical implementation guidance, with 15 out of 21 survey respondents specifically requesting best practice methods and templates. Guidance on harmonizing AI Act requirements with existing regulatory frameworks was particularly important for companies in already regulated sectors like healthcare. Interviewees also highlighted the need for clear communication channels tailored to how SMEs typically gather information (such as through LinkedIn and industry associations) rather than formal regulatory channels.
- **Endorsement and Criticism** revealed a nuanced perspective rather than simple opposition to regulation. Ten of thirteen interviewees expressed strong support for the AI Act's fundamental goals of ensuring ethical AI development, while simultaneously criticizing its implementation approach, particularly regarding complexity and timeline.

4 Conclusion

By analyzing the survey responses and the interviews, we uncovered a large heterogeneity in the AI sector in terms of awareness and fit of internal procedures to the requirements of the AI Act. Key factors influencing the expected implementation capabilities are company size and previous compliance experience. Uncertainty in the implementation of legislation, due to unclear definitions, ambiguous scope, and lack of harmonized standards, adds to the lack of financial, time, and human resources faced by SMEs. Companies were hesitant to invest in AI development without clear guidance, concerned about wasted efforts if their interpretation of the requirements turned out to be wrong. **Our results highlight uncertainty as the primary barrier to effective implementation.**

It is important to note that our survey reveals a differentiated view: Participants largely supported the goals of the AI Act to ensure trustworthy AI, but at the same time criticized its unclear implementation. We recommend the following based on our findings: (1) Establishment of an official risk classification service by the European Commission's AI Office, which provides binding feedback and, hence, offers more legal certainty and reduces consultancy costs; (2) Acceleration of the development of harmonized European standards aligned with existing frameworks and ensuring sufficient certification capacity to avoid market delays; and (3) Enhancement of communication about existing SME support mechanisms through standardized information portals and utilization of communication channels that SMEs already use, such as social networks for professionals and industry associations, to address the noticeable discrepancy we observed between available support and awareness.

Although the AI Act constitutes a crucial milestone towards trustworthy AI development, its effectiveness will substantially depend on overcoming these implementation obstacles, especially for SMEs who represent the backbone of the European innovation ecosystems.

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