

Compliance Blueprint: Documentation and Data Requirements for High-Risk AI System Registration

Co-authored with Matt Hervey, *Gowling WLG, Partner*



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11. AI System Registration: Requirements for high-risk systems.

11.1 Registration Process

Detailing the steps for registering high-risk AI systems.

11.2 Documentation and Data Requirements

What information providers need to submit.

11.3 Benefits of Registration

How registration facilitates market access and compliance.

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Addressing potential hurdles in the registration process.

Introduction

The EU AI Act represents a landmark regulation aimed at ensuring the safe and responsible deployment of AI technologies, particularly those classified as high-risk. At the core of this regulatory framework lies the meticulous documentation and data submission requirements imposed on providers of high-risk AI systems.



These requirements serve as the backbone of compliance, offering regulators and stakeholders critical insights into the functioning, capabilities, and potential risks associated with AI systems. Thorough documentation encompasses various aspects, including system specifications, data sources, algorithmic processes, and risk mitigation strategies.

In mandating comprehensive documentation and data submission, the EU AI Act aims to enhance transparency and accountability in AI development and deployment. It empowers regulators to conduct thorough assessments of AI systems' compliance with safety and ethical standards, thereby bolstering public trust in these technologies. Moreover, adherence to documentation and data requirements fosters a culture of responsibility among AI system providers, encouraging proactive risk management and continuous improvement. It enables providers to demonstrate their commitment to ethical AI practices and regulatory compliance, positioning them as trustworthy actors in the burgeoning AI landscape.

In this context, understanding and fulfilling documentation and data requirements are essential for providers seeking to navigate the regulatory landscape effectively and ensure the successful registration of high-risk AI systems under the EU AI Act. Compliance with these requirements not only facilitates market access but also reinforces the Act's overarching goals of promoting safety, transparency, and accountability in AI innovation and deployment.

Understanding High-Risk AI Systems

High-risk AI systems, under the EU AI Act, are defined based on specific criteria that denote their potential to impact fundamental rights, safety, or societal values significantly. These criteria encompass various factors, including the intended purpose of the AI system, its technical complexity, and the context of its use.

Firstly, high-risk AI systems are those designed for purposes that could lead to threats to health, safety, or fundamental rights. This includes AI systems used in critical infrastructure sectors like healthcare, transportation, or energy, where malfunctions or errors could have severe consequences.

Secondly, the technical complexity of the AI system is a determining factor. Systems employing novel or cutting-edge technologies, such as deep learning algorithms or autonomous decision-making processes, are more likely to be classified as high-risk due to their inherent unpredictability and potential for unintended outcomes.

Finally, the context of use plays a crucial role in categorizing AI systems as high-risk. If the AI system interacts directly with individuals or has significant societal implications, such as in the fields of law enforcement, recruitment, or credit scoring, it is likely to be deemed high-risk due to the potential for bias, discrimination, or privacy breaches.

Overall, high-risk AI systems are characterized by their potential to significantly impact individuals, society, or the environment. As such, they require rigorous documentation and data submission for registration under the EU AI Act to ensure transparency, accountability, and regulatory compliance.

Documentation Requirements

High-risk AI systems necessitate comprehensive documentation to ensure compliance with the EU AI Act's stringent requirements. This documentation serves as a crucial tool for demonstrating the system's conformity with regulatory standards and facilitating its assessment by national competent authorities and notified bodies.



Key documentation requirements include technical documentation, which must be prepared before the AI system is placed on the market or put into service. This technical documentation should provide detailed information on the AI system's design, functionality, intended use, risk assessment, and mitigation measures. Additionally, it should outline the system's compliance with relevant safety, transparency, and accountability requirements outlined in the Act.

Notably, the EU Commission has introduced a simplified technical documentation form tailored for small and medium-sized enterprises (SMEs), including startups. This streamlined form aims to alleviate the administrative burden on smaller businesses while ensuring compliance with regulatory standards. Notified bodies, responsible for assessing AI system conformity, accept this simplified documentation format, facilitating SMEs' participation in the market.

In summary, the documentation requirements for high-risk AI systems under the EU AI Act are stringent, aiming to ensure transparency, accountability, and safety. Technical documentation plays a pivotal role in demonstrating compliance with regulatory standards, while the introduction of simplified forms by the Commission caters to the needs of SMEs and startups, fostering innovation and market participation.

Data Submission Requirements

Registering high-risk AI systems in the EU database involves fulfilling detailed data submission requirements as specified in Annex VIII of the EU AI Act. Providers must submit comprehensive information to ensure their systems meet the necessary safety, transparency, and accountability standards.

Key information required includes:

1. **Provider Details:** The name, address, and contact information of the provider, ensuring traceability and accountability.
2. **AI System Details:** Specifics about the AI system, including its name, type, model, and version. This information helps in identifying the system accurately within the market.
3. **Intended Purpose:** A clear description of the AI system's intended use and application. This ensures the system is assessed within the correct context of its deployment.
4. **Components and Functions:** Detailed information on the system's components and functionalities, including software, algorithms, and hardware elements. This is crucial for assessing the system's operational aspects and potential risks.
5. **AI System Status:** The current status of the AI system, including whether it is still under development, has been placed on the market, or is already in service. This information is vital for monitoring and post-market surveillance.

Additionally, providers must submit a scanned copy of the certificate issued by a notified body, if applicable. This certificate verifies that the AI system has undergone the necessary conformity assessment procedures.

Moreover, an EU declaration of conformity must be included. This declaration is a formal statement by the provider asserting that the AI system complies with all relevant requirements of the EU AI Act.



In summary, the data submission requirements for high-risk AI systems under the EU AI Act are rigorous, aiming to ensure thorough assessment and monitoring. Providers must supply detailed information about their AI systems, including provider details, system specifics, intended use, components, and current status. Compliance with these requirements, including the submission of relevant certificates and declarations, is essential for gaining market access and ensuring the safety and transparency of AI technologies in the EU.

Post-Registration Obligations

After registering high-risk AI systems under the EU AI Act, providers must adhere to several ongoing obligations to ensure continued compliance and safety. One of the primary responsibilities is maintaining the accuracy of the registration information. Providers must promptly update any changes to the system or its usage, ensuring that the EU database remains current.

Another crucial obligation is fulfilling post-market monitoring requirements. This involves continuously assessing the AI system's performance and safety after it has been deployed. Providers need to identify and address any risks or issues that arise during the system's lifecycle. Effective post-market monitoring helps in detecting unforeseen problems and implementing necessary updates or corrections.

Technical documentation plays a vital role in this ongoing compliance process. Comprehensive and up-to-date documentation facilitates post-market monitoring by providing a detailed record of the AI system's design, development, and operational parameters. This documentation should include information about the system's performance metrics, any incidents or malfunctions, and the measures taken to resolve them.

Maintaining thorough technical documentation ensures that the AI system remains compliant with the EU AI Act's requirements. It also aids national competent authorities and notified bodies in assessing the system's safety and effectiveness over time. By adhering to these post-registration obligations, providers can help ensure that their high-risk AI systems operate safely and transparently, protecting users and maintaining trust in AI technologies.

Conclusion

In conclusion, the comprehensive documentation and data submission required for the registration of high-risk AI systems under the EU AI Act play a pivotal role in ensuring compliance and fostering trust in AI technologies. Adhering to these stringent requirements is not merely a bureaucratic necessity but a crucial step in safeguarding the public. Detailed technical documentation and accurate data submissions provide clear, transparent, and accountable records that are essential for both initial assessment and ongoing post-market monitoring.

These processes ensure that AI systems are safe, reliable, and aligned with the ethical standards set by the EU. By meeting these requirements, providers not only comply with the legal framework but also contribute to the broader goal of establishing a trustworthy AI ecosystem. This trust is fundamental in promoting the widespread adoption and acceptance of AI technologies, as it assures users that AI systems are developed and operated with the highest standards of safety and integrity. In a rapidly evolving technological landscape, such diligent adherence to regulatory standards is indispensable for the sustained growth and ethical deployment of AI innovations globally.



Glossary

Act or EU AI Act: European Union Artificial Intelligence Act

AI: Artificial Intelligence

Board: European Union Artificial Intelligence Board

EU: European Union

SME: Small and Medium-Sized Enterprise

How can we help?



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At AI & Partners, we’re here to help you navigate the complexities of the EU AI Act, so you can focus on what matters—using AI to grow your business. We specialize in guiding companies through compliance with tailored solutions that fit your needs. Why us? Because we combine deep AI expertise with practical, actionable strategies to ensure you stay compliant and responsible, without losing sight of your goals. With our support, you get AI you can trust—safe, accountable, and aligned with the law.

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