

Overcoming Hurdles: A Guide to Registering High-Risk AI Systems in the EU

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Introduction

The European Union's AI Act marks a pivotal advancement in the regulation of artificial intelligence, setting a global benchmark for the safety and reliability of AI systems. At the heart of this legislative framework is a comprehensive registration process for high-risk AI systems, a critical step for providers aiming to secure market access and ensure regulatory compliance. This process, detailed in Article 49 of the Act, mandates that providers or their authorized representatives register their high-risk AI systems in an EU database before market introduction.



The registration requires submitting extensive information, including the provider's details, the AI System's intended purpose, and a description of its components and functions, as outlined in Annex VIII of the Act. Additionally, providers must demonstrate compliance with the Act's stringent requirements, such as risk management and technical documentation, to ensure their AI systems meet the highest safety and transparency standards. Navigating this registration process presents several challenges, including understanding the specific requirements for high-risk AI systems and ensuring all necessary documentation is accurately prepared and submitted. However, by closely adhering to the Act's guidelines and leveraging available resources, providers can overcome these hurdles, paving the way for a safer and more accountable AI-driven future.

Understanding High-Risk AI Systems

High-risk AI systems are defined by the EU AI Act as those that pose significant implications for health, safety and fundamental rights. To determine whether an AI system qualifies as high-risk, providers are required to assess their AI system in accordance with Article 6. For an AI system to be high-risk one of the two primary criteria must be met:

(1) It falls within the category of Annex I, namely that, the AI system must either be intended as a safety component of a product or itself be a product that is covered by Union harmonisation legislation listed in Annex I. The product, which includes the AI system as a safety component or the AI system itself, must be required to undergo a third-party conformity assessment for market placement or service provision according to the Union harmonisation legislation; such conformity assessment may well already be in place for non-AI products.

Or

(2) It falls within the category of Annex III, namely that the EU AI Act specifies that AI systems referred to in Annex III are also considered high-risk. This broad classification encompasses a range of AI applications, from critical infrastructure and education and vocational training, to law enforcement and border migration, seeking to ensure a comprehensive approach to risk management. Only if it can be proven that an Annex III system shall not pose a significant risk to the health, safety or fundamental rights of natural persons (and the AI System is such that it only carries out a narrow procedural task, improves the result of a previously completed human activity, is intended to detect decision making patterns, or is intended to be used to perform a preparatory task) might such an Annex III system benefit from the derogation in Article 6(3) for being subject to the high-risk rules, but this does not alleviate any registration requirement.

Understanding these criteria is crucial for providers navigating the registration process for high-risk AI systems in the EU. By identifying whether their AI system falls under the high-risk category, providers can take the necessary steps towards compliance, including thorough risk management and technical documentation, as mandated by the Act. This foundational understanding not only facilitates market access but also aligns with the EU's commitment to ensuring the safety and reliability of AI systems within its jurisdiction.



The Registration Process: Key Steps and Requirements

The registration process for high-risk AI systems under Annex III of the EU AI Act is a meticulous procedure designed to ensure that these systems meet the EU's stringent safety and compliance standards before they are introduced to the market or put into service, particularly by public sector deployers. At the core of this process is the submission of detailed documentation to the EU database, as mandated by Article 49 of the Act. Annex I high-risk AI systems are not required to be registered in the EU database in this way because this demonstrates the EU's commitment to complement and not duplicate existing regulations for those products which already have safety and conformity requirements in place.

Providers are required to furnish a range of information, including the name, address, and contact details of the provider, the AI system's trade name, a description of its intended purpose, components, functions, and the type of data it uses. Additionally, the status of the AI system (whether it is on the market, in service, or has been recalled) must be declared. If applicable, providers must also submit the type, number, and expiry date of the certificate issued by the notified body, along with a scanned copy of the certificate itself.

The technical documentation, which must be drawn up before the AI system is placed on the market or put into service, plays a crucial role in demonstrating compliance with the Act's requirements. This documentation should provide clear and comprehensive information to assess the AI system's compliance, including details on the design, development, and quality assurance processes .

Challenges in the Registration Process

The registration process for high-risk AI systems in the EU, as mandated by the EU AI Act, presents several challenges for providers. One significant hurdle is navigating the complex requirements set forth by the legislation. Providers must ensure their AI systems comply with the stringent standards for safety, transparency, and accountability. This involves a deep understanding of the Act's provisions, including the specific obligations related to high-risk AI systems and the roles of notified bodies in the conformity assessment procedures.

Another challenge lies in the preparation and submission of comprehensive technical documentation. This documentation must clearly demonstrate the AI system's compliance with the Act's requirements, including details on design, development, and risk management processes. The documentation must be kept up-to-date and presented in a clear and comprehensive form to facilitate the assessment of the AI system's compliance .

Obtaining the necessary certificates from notified bodies is also a critical step that can pose difficulties. Providers must choose a notified body to assess their AI system's conformity with the required standards . This process involves submitting detailed information about the AI system for evaluation, which can be daunting, especially for micro- and small enterprises concerned about administrative burdens and compliance costs.

To address these challenges, providers can adopt several strategies. Firstly, engaging with the regulatory process early and seeking guidance from notified bodies or regulatory experts can clarify the requirements and streamline the compliance process. Secondly, leveraging existing documentation and procedures, where possible, can reduce duplication and minimize additional burdens. Lastly, maintaining open communication with notified bodies throughout the conformity assessment process can help identify and rectify potential issues early, facilitating a smoother registration process.



The Role of Notified Bodies

Notified bodies play a pivotal role in the EU's regulatory framework for high-risk AI systems, acting as independent assessors that verify the conformity of these systems with the requirements set out in the AI Act. Their responsibilities include evaluating AI systems, ensuring they meet stringent safety, transparency, and accountability standards, and issuing conformity certificates. This certification is a crucial step in the registration process, serving as proof that an AI system complies with the Act's mandates.

For providers looking to navigate the registration process successfully, understanding how to engage with notified bodies is essential. Providers must prepare comprehensive documentation that details the AI system's design, development, and intended use. This documentation, along with evidence of compliance with the AI Act's requirements, will be scrutinized by the notified body during the assessment process.

Effective engagement with notified bodies involves clear communication, transparency, and readiness to provide all necessary information and documentation. Providers should also be prepared to address any concerns or requests for additional information from the notified body to ensure a smooth assessment process. By closely collaborating with notified bodies, providers can facilitate the registration of their high-risk AI systems, paving the way for their introduction to the EU market.

Ensuring Compliance: Beyond Registration

For providers of high-risk AI systems, securing registration under the EU AI Act is merely the initial step towards ensuring long-term compliance. The dynamic nature of AI technology and regulatory landscapes necessitates continuous monitoring and updating of both the AI system and its accompanying documentation. This ongoing process is crucial for maintaining alignment with evolving legislation and standards.

Achieving continuous compliance involves several key actions. Providers must systematically review and update their AI systems to reflect advancements in technology and changes in regulatory requirements. This includes updating technical documentation to ensure it accurately represents the AI system's current state, including its design, development, and operational logic. Furthermore, providers are required to keep this documentation up to date, ensuring it remains comprehensive and clear throughout the AI system's lifecycle.

Additionally, the implementation of a quality management system is essential. Such a system should encompass strategies for regulatory compliance, including procedures for managing modifications to the AI system and ensuring ongoing conformity with the EU AI Act's requirements, and having continuous regard to the impact an AI system's impact might have on health, safety and fundamental rights.

By prioritizing continuous compliance, providers can not only navigate the complexities of the EU's regulatory framework but also contribute to the development of trustworthy and safe AI technologies. This proactive approach ensures that high-risk AI systems remain compliant, secure, and effective in their intended applications, thereby safeguarding public safety and rights.



Conclusion

Successfully navigating the registration of high-risk AI systems under the EU AI Act is a critical yet complex process for providers aiming to enter or continue operating within the EU market. The Act sets forth stringent requirements for these systems, emphasizing the need for compliance with safety, transparency, and accountability standards. Engaging effectively with notified bodies is an essential step in this process, as these entities verify the conformity of AI systems with the Act's mandates. Providers must prepare comprehensive documentation, demonstrating their AI system's compliance with the requirements laid out in the Act, including a detailed description of the system's intended purpose, components, functions, and data usage.

Moreover, the journey doesn't end with registration. Providers must commit to ongoing compliance, continuously monitoring and updating their AI systems and documentation to align with any changes in legislation and standards. This includes maintaining a quality management system that encompasses strategies for regulatory compliance and the management of modifications to and changes in the impact of the AI system.

This guide aims to simplify the complexities of the EU AI Act's registration process, offering providers a clear pathway to compliance. By understanding the requirements, engaging with notified bodies, and ensuring continuous compliance, providers can overcome the hurdles to successfully operate in the EU market.



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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