

Navigating the Registration Process for High-Risk AI Systems Under the EU AI Act

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

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Introduction

The EU AI Act marks a pivotal step in AI regulation, particularly with its focus on the registration process for high-risk AI systems. This process is paramount in ensuring the safety, transparency, and accountability of AI deployment within the European Union. By requiring registration, the Act aims to mitigate potential risks associated with advanced AI technologies while fostering innovation in a responsible manner. The Act's emphasis on registration underscores the need for thorough assessment and scrutiny of high-risk AI systems before they are deployed in various sectors. This approach not only enhances consumer trust but also provides regulatory clarity for businesses operating in the AI landscape.



Understanding the intricacies of the registration process is essential for AI developers, manufacturers, and service providers looking to navigate the regulatory landscape effectively. Compliance with registration requirements demonstrates a commitment to upholding the highest standards of safety and transparency in AI development and deployment.

In this article, we will explore the key aspects of the registration process under the EU AI Act, offering insights and guidance to help stakeholders navigate this regulatory framework seamlessly. Through clear and concise explanations, we aim to provide a comprehensive understanding of the registration requirements for high-risk AI systems and their implications for businesses operating within the EU.

Understanding High-Risk AI Systems

High-risk AI systems, as defined by the EU AI Act, are those that pose significant risks to the health, safety, or fundamental rights of individuals. These systems are categorized based on their intended purpose and potential to cause harm, as outlined in Annexes I and III of the legislation.

The EU AI Act identifies several categories of high-risk AI systems, including those used in critical infrastructure sectors such as healthcare, transportation, and energy. Additionally, AI systems designed for law enforcement or immigration control purposes are considered high-risk due to their potential impact on individual rights and freedoms.

Providers of high-risk AI systems are subject to specific obligations under the EU AI Act to ensure compliance and mitigate risks. These obligations include conducting thorough risk assessments, implementing appropriate safety measures, and providing transparent documentation to regulatory authorities.

Understanding the criteria for high-risk AI systems is essential for providers seeking to navigate the registration process under the EU AI Act. By identifying whether their AI systems fall into these high-risk categories, providers can determine the scope of their regulatory obligations and take necessary steps to ensure compliance with the legislation.

Step-by-Step Registration Process

Navigating the registration process for high-risk AI systems under the EU AI Act involves several key steps to ensure compliance and safety.

1. **Pre-Registration Requirements:** Before placing a high-risk AI system on the market or putting it into service, providers must fulfil pre-registration obligations. This includes ensuring compliance with the Act's requirements, such as conducting risk assessments and establishing a robust quality management system to oversee the AI system's development and deployment.
2. **Registration in the EU Database:** Providers must register their high-risk AI systems in the EU database, following a detailed process outlined in Article 49 and Annex VIII of the Act. This involves submitting comprehensive information about the AI system, including its intended purpose, technical specifications, and risk mitigation measures. The database has both public and secure non-public sections, with certain high-risk AI systems listed in the latter for additional security measures.



3. **Conformity Assessment and CE Marking:** High-risk AI systems undergo a conformity assessment procedure to ensure they meet the requirements set forth by the EU AI Act. This process includes verifying compliance with safety and performance standards and drawing up an EU declaration of conformity. Once approved, the AI system receives the CE marking, indicating its conformity with EU regulations. Notified bodies play a crucial role in overseeing this assessment process to verify compliance and uphold safety standards.

Following these steps means providers can navigate the registration process effectively and ensure their high-risk AI systems meet the necessary regulatory standards for market access within the EU.

Post-Registration Obligations

After successfully registering their high-risk AI systems, providers must adhere to several ongoing obligations to maintain compliance with the EU AI Act.

- **Accurate Information Maintenance:** Providers are required to ensure the accuracy and completeness of the information provided during the registration process. This includes promptly updating any changes or modifications to the AI system that may affect its performance or safety.
- **EU Declaration of Conformity:** Providers must retain the EU declaration of conformity for their high-risk AI systems. This document serves as a formal statement declaring that the AI system complies with the relevant regulatory requirements and standards set forth by the EU AI Act.
- **Post-Market Monitoring:** Providers are responsible for conducting post-market monitoring of their high-risk AI systems to assess their ongoing performance and safety. This involves monitoring feedback, collecting data on incidents or malfunctions, and implementing corrective measures if necessary to mitigate risks and ensure continuous compliance.

As a result of fulfilling these post-registration obligations diligently, providers can demonstrate their commitment to upholding safety and regulatory standards in the deployment and use of high-risk AI systems within the EU. This not only ensures compliance with the EU AI Act but also contributes to building trust among users and stakeholders in the AI ecosystem.

Challenges and Best Practices

Navigating the registration process for high-risk AI systems under the EU AI Act can present challenges for providers, but adopting best practices can streamline compliance efforts.

One significant challenge is understanding the intricate requirements outlined in the Act and ensuring full compliance. To overcome this, providers should engage with notified bodies early in the process. These bodies can offer guidance on regulatory requirements, assess conformity, and facilitate smoother registration procedures.

Another challenge is aligning with diverse regulatory standards across different EU member states. Providers can mitigate this challenge by leveraging harmonized standards whenever possible. Harmonized standards offer a common framework recognized across the EU, simplifying the registration process and ensuring compliance consistency.

Best practices also include thorough documentation and record-keeping throughout the registration journey. Providers should maintain detailed records of their AI systems, assessments, and conformity documentation to demonstrate compliance and facilitate post-registration obligations.



Furthermore, continuous communication and collaboration with relevant stakeholders, including regulatory authorities and industry peers, are essential. Sharing best practices and lessons learned can help navigate complex registration requirements more effectively.

By adopting these best practices, providers can overcome registration challenges, streamline compliance efforts, and ensure the timely and successful registration of their high-risk AI systems under the EU AI Act.

Conclusion

In conclusion, the registration process outlined in the EU AI Act stands as a pivotal component in regulating high-risk AI systems within the EU market. Compliance with this process is not only a legal requirement but also a fundamental step towards ensuring the safety, transparency, and accountability of AI systems.

By adhering to the registration requirements, providers demonstrate their commitment to meeting stringent standards and upholding ethical principles in AI development and deployment. This process fosters trust among stakeholders, including consumers, regulatory authorities, and industry peers, thereby enhancing the credibility of AI systems in the market.

In navigating the registration process, providers must approach it with diligence, understanding, and strategic planning. By overcoming challenges and embracing best practices, providers can successfully navigate the registration journey, paving the way for the responsible integration of high-risk AI systems into the EU market.

Ultimately, compliance with the registration process not only facilitates market access but also contributes to the broader objectives of the EU AI Act, promoting innovation, protecting fundamental rights, and safeguarding public interests in the rapidly evolving AI landscape.



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

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