

Navigating Compliance: The Role of Harmonized Standards in AI Regulation

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Introduction

In the evolving landscape of artificial intelligence (“AI”) regulation within the European Union (“EU”), the introduction of harmonized standards under the EU AI Act (the “EU AI Act”) marks a pivotal development for AI providers. These standards serve as a cornerstone for ensuring that high-risk AI systems align with the stringent requirements set forth by the Act, thereby facilitating a smoother path to regulatory compliance. By adhering to these harmonized standards, AI providers can avail themselves of the “presumption of conformity”, a crucial provision that significantly eases the compliance burden. This presumption implies that AI systems conforming to these standards are automatically considered to meet the regulatory requirements, streamlining the process of demonstrating compliance.



Moreover, the role of harmonized standards extends beyond mere regulatory adherence. They are instrumental in fostering innovation within the AI sector, providing a clear framework within which AI developers can innovate safely and responsibly. The standards are expected to reflect the state of the art in AI and AI-related technologies, thereby promoting not only compliance but also competitiveness and growth in the single market. This dual function of harmonized standards—ensuring compliance while encouraging innovation—sets the stage for a detailed exploration of their impact on the AI sector within the EU's regulatory framework.

Understanding the EU AI Act

The EU AI Act represents a pioneering legislative effort to regulate artificial intelligence technologies across its member states. At its core, the Act aims to foster an environment where AI can thrive, ensuring that advancements in this field are human-centric, trustworthy, and aligned with fundamental rights and safety standards. The EU AI Act sets out to improve the functioning of the internal market while promoting the uptake of AI, ensuring a high level of protection against the harmful effects of AI systems, and supporting innovation.

High-risk AI systems are subject to stringent compliance requirements due to their potential impact on critical areas such as employment, law enforcement, and essential private and public services. The Act mandates a comprehensive risk management approach for these systems, ensuring they are safe, transparent, and traceable. For general-purpose AI models, the Act requires providers to maintain detailed documentation and demonstrate compliance with specific obligations, promoting transparency and accountability.

Central to the Act's enforcement mechanism is the role of harmonized standards. These standards provide a presumption of conformity for AI systems that adhere to them, simplifying the compliance process for providers and fostering innovation within a secure and regulated framework. By aligning AI technologies with these harmonized standards, the EU AI Act aims to mitigate risks, protect citizens, and support the sustainable development of AI technologies across the Union.

Harmonized Standards Explained

Within the framework of the EU AI Act, harmonized standards play a pivotal role in guiding AI providers towards compliance with regulatory requirements. These standards are developed through a collaborative process involving the European Commission, standardization bodies, and stakeholders, ensuring that they reflect the state of the art and address the specific needs of AI technologies. Harmonized standards under the EU AI Act are designed to offer technical solutions that facilitate compliance with the Act's provisions, particularly for high-risk AI systems and general-purpose AI models.

The development of these standards follows a request from the Commission to European standardization organizations, aiming to cover all requirements set out in the Act. This includes not only the technical aspects of AI systems but also their impact on energy consumption and resource efficiency during their lifecycle. By adhering to these harmonized standards, AI providers can benefit from the "presumption of conformity," which significantly simplifies the demonstration of compliance with the Act's requirements. This presumption implies that AI systems conforming to the harmonized standards are automatically deemed to meet the regulatory obligations, thereby streamlining the path to market access and fostering an environment of trust and safety in AI technologies.



The Presumption of Conformity

The presumption of conformity is a fundamental concept within the EU AI Act, particularly articulated in Articles 40 and 42. This principle facilitates AI providers' compliance journey by offering a streamlined path to demonstrate adherence to the Act's stringent requirements. When AI providers align their high-risk AI systems or general-purpose AI models with harmonized standards—or parts thereof—published in the Official Journal of the European Union, they are granted a presumption of conformity.

This presumption implies that their AI systems are considered to meet the Act's safety, transparency, and accountability standards to the extent that these harmonized standards cover the Act's stipulated requirements or obligations.

Harmonized standards are developed through a collaborative process involving the European Commission, standardization bodies, and stakeholders, ensuring they reflect the latest technological advancements and ethical considerations in AI. By adhering to these standards, AI providers not only simplify their compliance process but also signal their commitment to upholding high levels of safety and ethical responsibility in AI development and deployment. Article 42 further elaborates on this presumption of conformity, specifying that high-risk AI systems, when trained and tested on data reflective of their intended operational context, are deemed compliant with relevant requirements laid down in the Act. This includes adherence to cybersecurity requirements, assuming the AI systems have been certified or issued a statement of conformity under a recognized cybersecurity scheme.

This framework of presumption of conformity through compliance with harmonized standards significantly eases the regulatory burden on AI providers. It not only facilitates a smoother certification and market entry process for AI systems but also ensures that these systems meet the EU's high standards for safety, transparency, and accountability. By leveraging these harmonized standards, AI providers can navigate the regulatory landscape more efficiently, focusing on innovation while maintaining compliance with the EU AI Act's provisions.

Codes of Practice and Alternative Compliance

Within the EU AI Act, codes of practice emerge as a fundamental mechanism for ensuring compliance, particularly for providers of general-purpose AI models. Recital 117 underscores the significance of these codes as a primary tool for adhering to the obligations stipulated under the regulation. Providers can lean on these codes of practice to demonstrate their compliance with the Act's requirements. This approach offers a structured pathway for providers to align their AI models with the regulatory expectations, ensuring that their technologies are developed and deployed within the legal framework established by the EU.

Moreover, the Act acknowledges the potential absence or inadequacy of harmonized standards at the time of its application. In such scenarios, providers are not left without recourse. They have the flexibility to demonstrate conformity through alternative adequate means, ensuring that the absence of harmonized standards does not hinder their compliance efforts. This provision reflects the Act's adaptability and its aim to foster innovation while maintaining a high standard of safety and accountability in AI development and usage. The Commission's role in approving codes of practice and providing common rules for implementation further exemplifies the structured yet flexible approach to AI regulation within the EU.



Challenges and Opportunities

AI providers face a dual challenge in navigating the regulatory landscape set forth by the EU AI Act. On one hand, they must ensure their high-risk AI systems and general-purpose AI models comply with the Act's stringent requirements, which demand adherence to safety, transparency, and accountability standards. On the other hand, they must maintain the agility and innovation that drive progress in the AI field. This balancing act between innovation and regulation is at the heart of the challenges AI providers encounter.

Harmonized standards, as outlined in the EU AI Act, offer a solution to this conundrum. By providing a clear, consistent framework for compliance, these standards help demystify the regulatory requirements for AI providers. Compliance with these standards grants a presumption of conformity with the Act's mandates, simplifying the path to market access for AI technologies. This not only aids in ensuring that AI systems are safe and trustworthy but also supports the competitiveness and growth of the Union market by promoting investment and innovation in AI.

Thus, while the journey to meet these standards may present challenges, it also opens up significant opportunities. Adherence to harmonized standards can enhance an AI provider's reputation, foster trust among users, and ultimately, support the broader objective of harmonizing innovation with regulation. This synergy between compliance and innovation ensures that the development of AI technologies remains both dynamic and responsible.

Conclusion

Harmonized standards under the EU AI Act play a pivotal role in shaping the regulatory landscape for artificial intelligence within the European Union. These standards, developed through a collaborative process involving European standardization organizations, provide technical solutions that help AI providers meet the Act's stringent requirements, particularly for high-risk AI systems and general-purpose AI models. By adhering to these standards, AI providers can benefit from a presumption of conformity, which significantly eases the burden of demonstrating compliance with the Act's mandates.

This framework not only simplifies the compliance process for AI providers but also ensures that AI technologies developed or deployed within the EU are safe, transparent, and accountable. Furthermore, harmonized standards support the EU's objectives of fostering innovation and competitiveness in the AI sector. They encourage investment in AI technologies while ensuring that such advancements align with Union values, fundamental rights, and interests. In essence, harmonized standards are instrumental in creating a balanced ecosystem where innovation thrives within a framework of safety and regulatory certainty, positioning the EU as a leader in the responsible development and deployment of AI technologies.



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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