



# Ensuring Safety and Compliance: The Imperative of Post-Market Monitoring for High-Risk AI Systems

Co-authored with Dr. Benedikt Kohn, **Taylor Wessing**, *Tech Attorney | AI-Regulation, IT & Data*



12 August 2024

## 3. Post-Market Monitoring: The importance of continuous oversight.

### 3.1 Monitoring System Requirements

*Establishing a post-market monitoring system.*

### 3.2 Data Collection and Analysis

*Gathering and analysing data on AI system performance.*

### 3.3 Post-Market Monitoring Plan

*Developing a comprehensive monitoring plan.*

### 3.4 Integration with Existing Legislation

*Aligning AI monitoring with other EU harmonization legislation.*

## Introduction

In the rapidly evolving landscape of Artificial Intelligence (“AI”) within the European Union (“EU”), the introduction of the EU AI Act represents a pivotal shift towards more stringent regulation of AI technologies. This landmark legislation underscores the EU's commitment to ensuring that AI systems, particularly those deemed high-risk, are utilized in a manner that prioritizes public safety and compliance with ethical standards. Central to the EU AI Act's framework is the establishment of robust post-market monitoring provisions for high-risk AI systems.





These provisions mandate that providers of high-risk AI systems implement a comprehensive system to actively and systematically collect, document, and analyse data on the performance of these systems throughout their lifecycle. This ensures ongoing evaluation of compliance with the Act's stringent requirements, including an analysis of interactions with other AI systems where relevant. By instituting such measures, the EU AI Act aims to safeguard against potential risks that may emerge from the deployment of high-risk AI systems, thereby fostering a safer and more accountable AI ecosystem across the Union.

## The EU AI Act and High-Risk AI Systems

Central to the EU AI Act is the concept of high-risk AI systems. These are defined as AI applications that pose significant risks to the health and safety of individuals or have the potential to impact fundamental rights significantly. High-risk AI systems include those used in critical infrastructure, employment, essential private and public services, law enforcement, and management of migration, asylum, and border control, among others.

The Act mandates that these systems undergo rigorous assessment and compliance procedures before deployment, including thorough testing, risk management, and adherence to strict standards of data governance and transparency.

This focus on high-risk AI systems underscores the EU's commitment to ensuring that AI technologies are leveraged in a manner that prioritizes human safety and ethical standards. By delineating clear regulations for these systems, the EU AI Act aims to mitigate risks and instil a culture of accountability and trust in the rapidly evolving AI landscape.

## Establishing a Post-Market Monitoring System

In accordance with the EU AI Act, establishing a post-market monitoring system for high-risk AI systems is a critical requirement for providers. This system is designed to ensure that these AI systems continue to operate safely and in compliance with regulatory standards throughout their lifecycle. Providers are mandated to actively and systematically collect, document, and analyse data on the performance of high-risk AI systems. This includes data provided by deployers or collected through other sources, enabling providers to assess ongoing compliance with the Act's requirements.

The Act emphasizes the proportionality of the post-market monitoring system to the nature of the AI technologies and the risks posed by the high-risk AI system. This means that the monitoring efforts must be commensurate with the level of risk and complexity of the AI system in question. The system should be capable of identifying any performance issues or risks that emerge during the operational phase, including the interaction with other AI systems, where relevant. However, it is specified that this obligation does not extend to sensitive operational data of deployers which are law enforcement authorities.

By instituting these requirements, the EU AI Act aims to ensure that high-risk AI systems remain safe and effective throughout their use, adapting to any changes or unforeseen risks that may arise post-deployment.





## Components of an Effective Post-Market Monitoring System

An effective post-market monitoring plan for high-risk AI systems, as mandated by the EU AI Act, is a cornerstone for ensuring these technologies remain safe and compliant throughout their lifecycle. This plan must encompass systematic data collection, documentation, and analysis of relevant data that reflects the AI system's performance. This includes data provided by deployers or collected from other sources, enabling a comprehensive evaluation of the system's ongoing compliance with the Act's stringent requirements.

The post-market monitoring plan plays a pivotal role in maintaining continuous compliance with the Act. It ensures that any emerging risks or non-compliance issues are identified and addressed promptly. By actively and systematically analysing the AI system's interaction with users and other AI systems, providers can detect and mitigate potential issues before they escalate. This proactive approach not only safeguards the public but also reinforces the trustworthiness of AI technologies in the market.

Moreover, the plan must be documented as part of the technical documentation and tailored to the nature of the AI technologies and the risks posed by the high-risk AI system, ensuring a proportionate and effective monitoring strategy.

## Reporting and Compliance

Under the EU AI Act, providers of high-risk AI systems bear significant responsibilities, particularly in the realm of reporting serious incidents. The Act mandates that any serious incident linked to a high-risk AI system must be reported to the market surveillance authorities of the Member States where the incident occurred. This reporting must occur immediately after the provider establishes a causal link between the AI system and the incident, or when there's a reasonable likelihood of such a link, and in any event, not later than 15 days after becoming aware of the incident. In cases involving widespread infringement or serious incidents leading to death, reports must be submitted within even shorter timeframes.

The significance of these reporting obligations cannot be overstated. Timely and accurate reporting is crucial for mitigating risks and ensuring public safety. It enables authorities to take swift action to prevent further harm, ensuring that AI systems continue to operate within the safety and compliance parameters set by the EU. This framework not only protects users and the public but also reinforces the trustworthiness of AI technologies by demonstrating a commitment to transparency and accountability. Through diligent compliance with these reporting requirements, providers play a pivotal role in maintaining a safe and responsible AI ecosystem.

## Enforcement and Penalties

Under the EU AI Act, enforcement mechanisms are rigorously outlined to address non-compliance with post-market monitoring requirements for high-risk AI systems. Market surveillance authorities play a crucial role in this process. If a provider fails to classify an AI system correctly as high-risk and does not comply with the post-market monitoring obligations, the market surveillance authority can evaluate the system and demand necessary actions to achieve compliance. Failure to adhere to these demands within a prescribed period can result in the provider facing fines.





Moreover, the Act specifies that providers must ensure all necessary actions are taken to bring the AI system into compliance with the regulation's requirements. This includes taking appropriate corrective action for all AI systems made available on the Union market. If adequate corrective action is not taken within the given timeframe, further enforcement measures, such as withdrawal of the AI system from the market or recall, can be applied. These enforcement mechanisms and potential penalties underscore the EU's commitment to ensuring that high-risk AI systems are continuously monitored and remain compliant, safeguarding public safety and maintaining trust in AI technologies.

## Conclusion

Post-market monitoring plays an indispensable role in the lifecycle of high-risk AI systems, ensuring their continuous compliance with the EU AI Act's stringent requirements. This process, as outlined in the Act, mandates providers to actively and systematically collect, document, and analyse data on the performance of these systems throughout their operational life. Such diligence aids in evaluating the systems' ongoing adherence to safety and regulatory standards, including their interaction with other AI systems where relevant.

The EU AI Act's emphasis on post-market monitoring underscores the critical importance of this activity in maintaining public trust and safety in the deployment of AI technologies. For providers of high-risk AI systems, adherence to these requirements is not just about regulatory compliance; it's about demonstrating a commitment to ethical standards and the well-being of society. By establishing and documenting a robust post-market monitoring system, providers play a pivotal role in the responsible stewardship of AI technologies, ensuring they remain beneficial and safe for all users throughout their use.

In conclusion, the EU AI Act's post-market monitoring requirements are a cornerstone of the safe and ethical deployment of high-risk AI systems, highlighting the essential role of providers in upholding these standards for the greater good.





## 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?



### Amsterdam - London - Singapore

#### AI & Partners – ‘AI That You Can Trust’

Your trusted advisor for EU AI Act Compliance. Unlock the full potential of artificial intelligence while ensuring compliance with the EU AI Act by partnering with AI & Partners, a leading professional services firm. We specialize in providing comprehensive and tailored solutions for companies subject to the EU AI Act, guiding them through the intricacies of regulatory requirements and enabling responsible and accountable AI practices. At AI & Partners, we understand the challenges and opportunities that the EU AI Act presents for organizations leveraging AI technologies. Our team of seasoned experts combines in-depth knowledge of AI systems, regulatory frameworks, and industry specific requirements to deliver strategic guidance and practical solutions that align with your business objectives.

To find out how we can help you, email [contact@ai-and-partners.com](mailto:contact@ai-and-partners.com) or visit <https://www.ai-and-partners.com>.

