



Unfolding the EU AI Act for U.S. Businesses



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The Global Impact of AI Regulation

The EU AI Act represents the world's first comprehensive legal framework specifically designed to regulate artificial intelligence and foster the development of trustworthy, human-centric AI.

With its extraterritorial scope, the Regulation extends far beyond European borders, creating a complex new compliance landscape that U.S. businesses must navigate with care.

As of August 2, 2025, obligations for general-purpose AI models came into force, bringing this landmark legislation to bear on an unprecedented number of companies worldwide.

Even organizations relying on off-the-shelf AI tools may be subject to transparency, monitoring, and due diligence requirements—meaning nearly any U.S. business leveraging AI could be affected.

For American companies operating in today's AI-driven marketplace, understanding these core principles is no longer optional—it is essential.



Is Your Business Concerned? AI Systems: A Broad Definition

The AI Act refers to an "AI system" as a machine-based system designed to operate with varying levels of autonomy, capable of generating outputs like predictions, recommendations, or decisions for explicit or implicit objectives. These systems utilize algorithms and data to perform tasks that typically require human intelligence, processing information, recognizing patterns, and adapting over time.

Examples include:

- Resume Screening Tools
- Customer Support Chatbots
- Predictive Analytics for Sales
- Medical Diagnosis Systems
- Financial Fraud Detection
- Autonomous Driving Systems



Is Your Business Concerned? Territorial Scope

The EU AI Act applies to U.S.-based companies when:

- As a Provider, you are placing on the market or putting into service AI systems or placing on the market general-purpose AI models in the EU.
- As a Provider or a Deployer, the output produced by the AI system is used in the EU.

Example: A U.S.-based SaaS company offering AI-driven credit scoring services to EU banks falls directly under AI Act jurisdiction.



How Can You Comply? Determining Your Role in the AI Value Chain

The AI Act creates governance and compliance obligations across the entire AI ecosystem.
Your specific obligations depend on your role in this value chain.

Provider

You develop or place an AI system on the market, taking primary responsibility for compliance and system safety.

Deployer

You use an AI system in your business operations, requiring adherence to deployment and monitoring obligations.

Importer

You place on the market an AI system bearing the name of a company established in a third country.

Distributor

You make an AI system available on the Union market without being a Provider or Importer.



How Can You Comply? A Risk-Based Approach to AI Systems

The AI Act classifies AI systems according to the level of risk they pose to fundamental rights and safety.



How Can You Comply? High-Risk AI Systems: Critical Applications

Safety Components – examples include:

- Medical devices with AI components
- Automotive safety systems
- Aviation navigation tools
- Industrial machinery controls

High-risk AI systems are considered to pose a significant risk of harm to the health, safety or fundamental rights of natural persons.

They mainly concern safety components of products covered by EU legislation, or other AI systems in specific areas listed in Annex III.

Annex III Applications – examples include:

- Remote biometric identification systems
- HR management and recruitment tools
- Educational assessment systems
- Credit scoring and loan approval



How Can You Comply? General-Purpose AI Models: A Two-Tier System

The AI Act introduces specialized rules for General-Purpose AI (GPAI) models, recognizing their unique capabilities and widespread applications.

These models are defined by their versatility across multiple tasks and typically encompass large language models (LLMs) that have become increasingly prevalent in business applications.

All GPAI Models – Must meet transparency duties including technical documentation, copyright statements, and training data summaries.

Systemic Risk Models – High computational power models face stricter obligations: in-depth evaluation, risk mitigation measures, incident reporting, and cybersecurity protection.



Why Should You Care? Avoiding Pitfalls

Complying with the EU AI Act not only helps your business avoid heavy penalties, but also protects it from reputational damage – especially if you operate in a B2C environment.

35 mil. €

or 7%

of the total worldwide annual turnover for the preceding financial year

15 mil. €

or 3%

of the total worldwide annual turnover for the preceding financial year

7.5 mil. €

or 1%

of the total worldwide annual turnover for the preceding financial year

NON-COMPLIANCE WITH THE PROHIBITION OF AI PRACTICES

NON-COMPLIANCE WITH ALL OTHER OBLIGATIONS RELATED TO OPERATORS OR NOTIFIED BODIES

SUPPLY OF INCORRECT, INCOMPLETE OR MISLEADING INFORMATION TO NOTIFIED BODIES AND NATIONAL COMPETENT AUTHORITIES



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Turning Compliance Into Competitive Advantage

Although it poses a major challenge to entering the European Union market with confidence, the AI Act can also be seen as an opportunity.

As a U.S.-based business, you can leverage its documentation and organizational requirements to gain clearer visibility over your risk management.

Technology evolves faster than regulation. Building strong governance now can give you a lasting competitive edge.

As you work toward compliance, consider:

- **Vendor assessment** – Which vendor represents a hidden vulnerability? Can you reduce or eliminate this risk?
- **ROI optimization** – Are you investing in dependencies, or in innovation you can control? Is your projected ROI still valid?
- **Security enhancement** – Can you streamline data security costs or improve your infrastructure?
- **Strategic alignment** – Does your AI strategy support your long-term business goals?



Conclusion

For U.S. businesses, the EU AI Act is more than just another European Union regulation – it marks a global shift in compliance.

Those who address it swiftly and thoroughly will not only secure access to the EU market with reduced penalty risks in the short term, but also build a lasting competitive edge through stronger risk management and digital governance.

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