



AI & Partners

Amsterdam - London - Singapore

EU AI Act

Small and medium-sized enterprises (SMEs)

Practical Guide

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AI & Partners



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AI & Partners defends and extends the digital rights of users at risk around the world. By combining direct technical support, comprehensive policy engagement, global advocacy, grassroots professional services, regulatory interventions, and participating in industry groups such as AI Commons, we fight for fundamental rights in the artificial intelligence age.

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Introduction

The EU AI Act is one of the most significant regulatory developments in recent years, reshaping compliance requirements for businesses of all sizes. For small and medium-sized enterprises (SMEs), this presents both challenges and opportunities. While AI is increasingly becoming a core driver of innovation and competitiveness, SMEs must now ensure their AI systems meet risk classification, transparency, and governance requirements under the Act.

Recognizing that SMEs face unique resource constraints, the AI Act includes tailored provisions to lower compliance costs, simplify documentation, and provide regulatory sandboxes for real-world AI testing. However, successful adoption will require businesses to proactively engage with national implementation plans, sector-specific initiatives, and evolving regulatory best practices.

This guide provides practical insights into how SMEs can navigate the AI Act, highlighting key provisions designed to support small businesses, compliance trends, and strategies for ensuring responsible AI deployment. Drawing on AI & Partners' global expertise, we offer actionable recommendations to help SMEs leverage AI responsibly while maintaining regulatory alignment.

Whether you are an AI startup, SME technology provider, or business deploying AI, this guide aims to be a valuable resource in preparing for the Act's full implementation. At AI & Partners, we remain committed to helping SMEs build AI solutions that are ethical, accountable, and compliant with EU regulatory standards.


Best regards,

Sean Musch

Founder/CEO

AI & Partners



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Key questions being asked about EU AI Act application to SMEs



1. What is the EU AI Act, and why is it important for SMEs?

The EU AI Act is the first comprehensive regulatory framework designed to ensure the safe and ethical development, deployment, and use of artificial intelligence across the EU. It categorizes AI systems by risk level, imposing stricter requirements on high-risk applications. SMEs play a crucial role in AI innovation, but they often lack the resources to navigate complex regulations. To address this, the AI Act includes provisions specifically tailored to SMEs, reducing compliance costs, providing access to regulatory sandboxes, and ensuring proportional obligations. These measures help SMEs remain competitive while ensuring their AI technologies align with EU safety and transparency standards.

2. How does the EU AI Act define SMEs?

Under EU law, SMEs are classified into three categories based on employee count and financial metrics. A **medium-sized enterprise** has fewer than 250 employees and either an annual turnover below €50 million or a balance sheet total under €43 million. A **small enterprise** has fewer than 50 employees and turnover or balance sheet total under €10 million. A **microenterprise** has fewer than 10 employees and turnover or balance sheet total under €2 million. The AI Act explicitly mentions start-ups as part of SMEs, even though EU law does not currently have a single definition for start-ups.

3. What are regulatory sandboxes, and how do they benefit SMEs?

Regulatory sandboxes provide SMEs with a controlled environment to test AI technologies under regulatory supervision without immediate compliance burdens. These sandboxes allow companies to develop, train, validate, and test AI systems according to an agreed plan with regulators. SMEs receive **priority access** to these sandboxes free of charge, reducing barriers to entry. Testing in real-world conditions is also supported. Successful participation in a sandbox can help SMEs demonstrate compliance with the AI Act, increasing legal certainty. Additionally, sandbox participants who act in good faith are protected from administrative fines, though they remain liable for damages to third parties.

4. How does the AI Act reduce compliance costs for SMEs?

The AI Act includes specific provisions to help SMEs manage compliance costs. Assessment fees for conformity evaluations must be **proportional to company size**, ensuring smaller businesses are not unfairly burdened. The European Commission is also responsible for evaluating compliance costs and working with Member States to lower them where possible. One key area is reducing translation expenses for mandatory documentation by encouraging Member States to accept widely spoken languages. Moreover, financial penalties for non-compliance are capped at **whichever is lower**—a fixed amount or a percentage of turnover—ensuring that SMEs face lower fines compared to larger corporations.

5. What role do SMEs play in AI standard-setting and governance?

The AI Act recognizes the importance of SMEs in shaping AI regulations by ensuring their participation in **standard-setting processes**. Since EU product safety laws rely heavily on technical standards, SMEs must have a voice in their development. The Act requires the European Commission and Member States to facilitate SME involvement in AI standardization efforts. SMEs must also be represented in the **AI Act's advisory forum**, which provides expert input to the European AI Board and the Commission. This guarantees that SME perspectives, challenges, and innovative capabilities are considered in shaping future AI governance and regulatory frameworks.



6. Are there simplified compliance requirements for SMEs?

Yes, the AI Act simplifies documentation and compliance requirements for SMEs, particularly those working with high-risk AI systems. The European Commission will provide **simplified technical documentation forms**, ensuring that smaller businesses can meet regulatory obligations without excessive administrative burdens. Additionally, microenterprises are allowed to comply with certain **quality management requirements** in a more streamlined manner. To support compliance, Member States must offer **training and awareness programs** tailored to SMEs. These programs will help small businesses understand the AI Act's provisions, risk classifications, and reporting obligations, ensuring they can comply efficiently without diverting excessive resources from innovation and growth.

7. How can SMEs access support for AI Act compliance?

The EU AI Act mandates that **dedicated communication channels** be established to assist SMEs with compliance. These channels provide guidance, answer questions, and ensure SMEs have the resources to understand and implement AI regulations. Some Member States, such as Austria, have already introduced AI service desks, offering direct support to businesses navigating the Act. These resources are designed to reduce uncertainty, improve regulatory alignment, and provide SMEs with up-to-date information on compliance requirements. By leveraging these services, SMEs can better integrate AI safely and legally without facing unnecessary regulatory hurdles or information gaps.

8. What are the obligations for SMEs providing general-purpose AI models?

SMEs that develop **general-purpose AI models (GPAI)** must comply with transparency obligations, such as documenting training data, disclosing limitations, and ensuring their models meet EU standards. However, obligations are **proportional** to company size, meaning SMEs face fewer regulatory burdens than large AI providers. Additional requirements apply only to **GPAI models with systemic risk**, which are advanced AI systems requiring vast computational resources and posing significant societal risks. SMEs typically do not develop these large-scale models, but if they do, they must adhere to stricter requirements, such as impact assessments, cybersecurity measures, and risk mitigation strategies.

9. How does the AI Act impact SMEs deploying AI systems?

SMEs that deploy AI systems are regulated based on **risk level classifications** rather than company size. The AI Act categorizes AI applications as **prohibited, high-risk, or requiring transparency obligations**. Most SMEs will fall under the latter, meaning they must disclose when AI is being used, particularly in consumer-facing applications. However, SMEs using **high-risk AI systems** (e.g., in hiring, healthcare, or finance) must meet stricter requirements, including risk management, data governance, and human oversight. By providing regulatory clarity, the AI Act ensures SMEs understand their responsibilities without overburdening them with unnecessary compliance measures.

10. What factors will determine the AI Act's impact on SMEs?

The real impact of the AI Act on SMEs depends heavily on **implementation at the national level**. While the Act includes SME-friendly provisions, such as cost reductions and regulatory sandboxes, their effectiveness depends on how Member States execute these policies. Key factors include the availability of **guidance documents, compliance tools, and funding support** for SMEs. SMEs should stay informed and engage with regulators to ensure fair implementation.

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Main provisions fitted to SMEs



Regulatory Sandboxes

Article 57 (AI regulatory sandboxes)

Regulatory sandboxes are a key provision of the EU AI Act designed to support small and medium-sized enterprises (SMEs) by allowing them to test AI systems in a controlled environment under regulatory supervision. These sandboxes provide a safe space for innovation, where AI developers can experiment with new technologies, fine-tune their models, and ensure compliance with EU regulations before bringing their products to market. SMEs, which often lack the financial and legal resources of larger companies, benefit significantly from these structured testing environments, as they reduce regulatory uncertainty and facilitate compliance.

Under the AI Act, all EU Member States must establish at least one national regulatory sandbox. These sandboxes allow AI providers to develop, train, validate, and test AI systems based on an agreed plan with the relevant supervisory authority. Importantly, SMEs receive priority access to these sandboxes free of charge, ensuring that they can participate without incurring excessive costs. The application, selection, and participation processes for these sandboxes must be clear, simple, and easily accessible, reducing administrative burdens on smaller businesses.

One of the key advantages of regulatory sandboxes is the opportunity to test AI systems in real-world conditions. This allows SMEs to gain practical insights into how their AI solutions will function in actual deployment scenarios while ensuring they comply with legal and ethical standards. The sandbox framework provides structured feedback and guidance from regulators, helping SMEs adjust their AI models to meet compliance requirements without facing immediate penalties.

Another significant benefit for SMEs is that, if they act in good faith and follow the sandbox plan, they are exempt from administrative fines for any unintentional regulatory infringements committed during testing. However, this does not exempt them from liability for any damages their AI systems might cause to third parties during the experimentation phase.

Several EU countries have already implemented AI regulatory sandboxes, including Luxembourg, Spain, and Lithuania. These early initiatives suggest that successful participation in a sandbox can enhance an SME's market credibility, facilitate investment, and speed up regulatory approval. For example, regulatory sandboxes in the fintech sector have been shown to significantly accelerate market authorization and improve investment prospects.

By offering SMEs a risk-mitigated environment to innovate, the AI Act's regulatory sandbox provision ensures that smaller AI providers can compete fairly while developing safe, trustworthy, and legally compliant AI solutions.





Lower Compliance Costs & Fees

Article 62 (Measures for providers and deployers, in particular SMEs, including start-ups)

One of the most significant challenges SMEs face in regulatory compliance is the cost burden associated with meeting legal requirements. Recognizing this, the EU AI Act includes specific provisions to reduce compliance costs and fees for SMEs, ensuring that smaller businesses can adhere to regulations without disproportionate financial strain. These measures are particularly crucial for startups, microenterprises, and small businesses that may lack the legal and financial resources of larger corporations.

A core principle of the AI Act is that assessment and compliance fees must be proportional to company size. This means that SMEs will not be expected to pay the same fees as large AI providers when undergoing conformity assessments. National authorities must ensure that assessment fees take into account the financial capacity, market size, and specific needs of SMEs, preventing smaller companies from facing excessive costs. This provision helps level the playing field, allowing SMEs to innovate and compete without being hindered by regulatory expenses.

Additionally, the European Commission is required to conduct periodic assessments of compliance costs for SMEs and work with Member States to implement measures that further reduce financial burdens. One area of particular focus is translation costs for mandatory documentation. Since AI providers in the EU often operate across multiple countries, they may be required to submit documents in different languages. The AI Act encourages Member States to accept documentation in widely spoken languages to minimize translation expenses for SMEs.

Another important cost-reducing measure applies to administrative fines. In cases of non-compliance, penalties for SMEs are calculated based on whichever is lower—a fixed amount or a percentage of annual turnover. This differs from larger corporations, which face penalties based on whichever is higher. This provision ensures that SMEs are not disproportionately punished for unintentional breaches, reducing financial risks for smaller businesses navigating complex AI regulations.

Beyond direct cost reductions, the AI Act promotes regulatory clarity and guidance, helping SMEs avoid unnecessary legal expenses. Through dedicated communication channels, SMEs can receive assistance in understanding compliance requirements, reducing expensive legal consultations.

By lowering costs associated with assessments, documentation, fines, and legal guidance, the AI Act ensures that SMEs can focus on innovation and growth while still meeting necessary regulatory standards. These cost-reducing provisions help enable SMEs to compete fairly in the AI market.





Standard Setting & Governance

Article 40 (Harmonised standards and standardisation deliverables)

The EU AI Act places significant emphasis on **standard setting and governance**, ensuring that AI technologies meet safety, transparency, and ethical standards. Since SMEs are at the forefront of AI innovation but often lack the influence of larger corporations, the AI Act includes **specific measures to facilitate their participation** in the development of technical standards and governance structures. These provisions ensure that SMEs have a **voice in shaping AI regulations**, making the framework more inclusive and reflective of their needs.

One of the key provisions in the AI Act is the requirement that **the European Commission and Member States facilitate SME participation in standardization processes**. Technical standards play a crucial role in product safety regulations, defining how AI systems should be designed, tested, and deployed. Without direct input from SMEs, these standards could be disproportionately influenced by larger corporations, potentially creating compliance barriers for smaller businesses. By ensuring SME involvement, the Act promotes **fair and balanced AI governance** that accounts for the realities faced by smaller AI providers.

To further reinforce SME participation, the AI Act mandates that SMEs must be **represented in advisory bodies**, such as the **AI Act Advisory Forum**. This forum provides technical expertise and policy recommendations to the European AI Board and the European Commission. By including SME representatives, the AI Act ensures that the unique challenges and perspectives of small businesses are considered in **future regulatory decisions and updates**. This representation helps prevent the creation of **overly complex or burdensome requirements** that could hinder SME innovation.

Additionally, the AI Act encourages **collaboration between SMEs, national authorities, and standardization bodies**. SMEs will have opportunities to engage in working groups and contribute to the drafting of **harmonized standards**, which will serve as the legal benchmarks for AI compliance. By being involved in these discussions, SMEs can help shape **practical and achievable** compliance requirements tailored to their capabilities.

By prioritizing SME involvement in standard setting and governance, the AI Act ensures that **smaller AI providers have a say in the regulatory landscape**, fostering a more competitive and inclusive AI ecosystem. These measures help SMEs stay ahead of compliance changes, reduce legal uncertainties, and contribute to the responsible development of AI technologies in Europe.





Streamlined Documentation & Training

Article 11 (Technical documentation)

The EU AI Act recognizes that complex documentation requirements and a lack of regulatory knowledge can create significant challenges for SMEs. To address this, the Act introduces simplified documentation processes and tailored training programs specifically designed to help SMEs comply with AI regulations efficiently. These measures reduce administrative burdens, ensure clarity, and provide the necessary support for smaller businesses to navigate compliance without excessive costs or resource allocation.

A key provision of the AI Act is the development of simplified technical documentation forms tailored to the needs of SMEs, particularly those working with high-risk AI systems. These forms are designed to be concise, standardized, and easy to complete, ensuring that SMEs do not have to produce extensive and highly technical reports that may require costly legal or compliance expertise. National authorities are required to accept these simplified forms for conformity assessments, reducing bureaucratic complexity and making compliance more accessible to smaller AI providers.

For microenterprises, which have fewer than 10 employees and limited financial resources, the AI Act provides further simplifications. Certain quality management system requirements—which are typically necessary for high-risk AI systems—can be met in a streamlined manner, ensuring that microenterprises are not held to the same rigorous standards as large AI companies. These adaptations allow SMEs to maintain regulatory compliance without sacrificing time and resources that could be directed toward product development and business growth.

In addition to streamlined documentation, the AI Act mandates that Member States provide training and awareness programs tailored specifically for SMEs. These training initiatives will cover key aspects of the AI Act, such as risk classification, documentation requirements, and compliance procedures, helping SMEs understand their obligations without requiring costly legal consultations. National governments are also expected to collaborate with industry associations, academic institutions, and regulatory bodies to develop educational materials, workshops, and online resources that can be easily accessed by SME operators.

By simplifying documentation and providing targeted training, the AI Act ensures that SMEs can comply with AI regulations efficiently, reducing barriers to entry and fostering innovation. These provisions prevent regulatory complexity from stifling smaller businesses, allowing SMEs to focus on building and deploying AI solutions responsibly while maintaining competitiveness in the European AI market.





Targeted Communication

Article 62 (Measures for providers and deployers, in particular SMEs, including start-ups)

Effective communication is crucial for ensuring that SMEs can understand, navigate, and comply with the EU AI Act without unnecessary confusion or delays. Recognizing that smaller businesses often lack dedicated legal or compliance teams, the AI Act includes provisions for dedicated communication channels that provide SMEs with clear, accessible, and tailored guidance on regulatory requirements. These targeted communication efforts help SMEs stay informed, receive timely assistance, and avoid costly misinterpretations of the law.

A core requirement of the AI Act is that Member States must establish dedicated communication channels specifically for SMEs. These channels serve as centralized points of contact where SMEs can ask questions, receive regulatory guidance, and clarify their compliance obligations. The goal is to ensure that small businesses have direct access to authoritative information, reducing reliance on expensive legal consultations or third-party compliance services.

Some EU Member States have already taken steps to implement such support systems. For example, Austria has launched an AI Service Desk, which provides businesses with direct access to regulatory guidance on AI-related compliance. Similar initiatives are expected to be developed across the EU, ensuring that SMEs in different countries can easily access relevant information without facing language or jurisdictional barriers.

Beyond direct communication channels, the AI Act encourages proactive outreach efforts, such as guidance documents, FAQs, webinars, and industry workshops tailored to SMEs.

These resources aim to explain key aspects of the AI Act in simple, non-technical language, making it easier for SMEs to understand their obligations without needing specialized legal knowledge. Additionally, regulators are expected to ensure consistency in guidance across different Member States to prevent fragmented or conflicting interpretations of the law.

Another key aspect of targeted communication is the promotion of synergies between SMEs, regulators, and industry groups. The AI Act encourages collaboration between business associations, AI developers, and regulatory bodies to ensure that SMEs can share best practices, receive sector-specific guidance, and participate in compliance-related discussions. This approach helps create a more cohesive and SME-friendly regulatory ecosystem, where small businesses can contribute to shaping AI governance rather than merely reacting to top-down regulations.

By ensuring accessible, clear, and SME-focused communication, the AI Act helps small businesses navigate AI compliance with confidence, reducing regulatory uncertainty and enabling them to focus on innovation





Proportionality

Article 53 (Obligations for providers of general-purpose AI models)

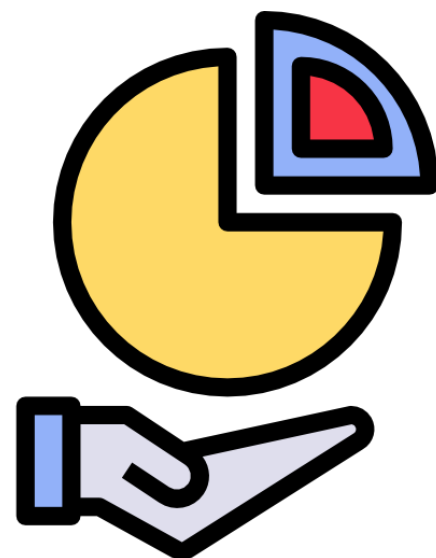
The EU AI Act is designed to regulate AI technologies based on their level of risk, but it also ensures that compliance obligations are proportionate to the size and capacity of AI providers. Recognizing that SMEs have fewer resources than large tech companies, the AI Act applies the principle of proportionality, meaning that smaller businesses are subject to lighter compliance requirements where appropriate. This approach ensures that SMEs can remain competitive while still adhering to the necessary safety, transparency, and ethical standards for AI deployment in the EU.

One of the key areas where proportionality applies is in the obligations for providers of general-purpose AI models. While all AI providers must meet certain transparency requirements, SME providers face fewer regulatory burdens than large-scale developers of advanced AI models with systemic risk. The Act acknowledges that SMEs do not have the same capacity as major AI firms to conduct extensive risk assessments, incident reporting, and mitigation efforts. Therefore, compliance obligations are scaled based on the provider's size and the potential impact of the AI model.

The AI Act also ensures proportionality in conformity assessments and technical documentation. For example, microenterprises and small businesses are allowed to comply with some high-risk AI system requirements in a simplified manner. The European Commission is tasked with developing streamlined technical documentation templates specifically for SMEs, ensuring that compliance does not require extensive legal and administrative resources. This reduces the regulatory burden on smaller AI providers, allowing them to focus on innovation rather than excessive paperwork.

In terms of penalties and enforcement, proportionality also plays a crucial role. The AI Act sets lower maximum fines for SMEs, ensuring that penalties are calculated based on whichever is lower—a fixed amount or a percentage of the company's annual turnover. This differs from large corporations, which face penalties based on whichever is higher. By capping fines at lower levels for SMEs, the AI Act prevents excessive financial penalties that could cripple small businesses for minor compliance mistakes.

By ensuring that regulatory obligations are tailored to the size and capacity of businesses, the AI Act helps SMEs comply without facing disproportionate burdens. This proportional approach promotes fairness, encourages innovation, and supports a thriving AI ecosystem where small businesses can compete alongside larger companies without unnecessary regulatory disadvantages.



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Calls to action



1. Take Advantage of AI Regulatory Sandboxes

Apply for regulatory sandboxes to test AI systems in a controlled, risk-free environment with free access for SMEs. Sandboxes help streamline compliance, provide regulatory guidance, and accelerate market entry. Check with national authorities to enrol and benefit from hands-on legal support.



2. Leverage Simplified Documentation & Compliance Tools

Use SME-friendly documentation templates to reduce compliance burdens. Explore compliance checkers and AI governance resources to assess obligations and avoid penalties. Stay updated on evolving requirements and take advantage of regulatory support programs to ensure efficient, cost-effective compliance.



3. Engage in Standard-Setting & AI Governance

Influence AI regulations by joining advisory forums and standardization committees. Collaborate with industry groups and regulators to ensure SME perspectives shape AI policies. Your input can make AI governance fairer, more practical, and supportive of small business innovation.



4. Use Dedicated AI Support Channels

Access AI support desks, helplines, and online resources for regulatory guidance. Get expert advice, training, and funding opportunities tailored to SMEs. Don't navigate compliance alone—use official channels to ensure smooth AI adoption and market readiness.



5. Monitor EU AI Act Implementation & Future Updates

Stay informed through European Commission updates, national AI authorities, and industry associations. Join training sessions, webinars, and compliance workshops to keep your business aligned with best practices. Proactive engagement ensures smooth adaptation and growth in the evolving AI landscape.





Conclusion

The EU AI Act marks a major step toward structured, ethical, and accountable AI governance. For SMEs, this regulatory shift presents both opportunities and challenges, requiring businesses to adapt while ensuring compliance with risk classification, transparency, and oversight obligations. The Act's success will depend on effective national implementation, ensuring that compliance remains accessible and proportionate for smaller enterprises.

Implementation, however, varies across Member States, creating uncertainty for SMEs. Issues such as delayed regulatory authority designations, inconsistent enforcement, and sectoral fragmentation could complicate compliance. SMEs—often lacking dedicated legal and compliance teams—face disproportionate burdens, making it crucial for regulators to balance enforcement with innovation-friendly policies.

Encouragingly, some Member States are already pioneering SME-friendly approaches. Estonia's AI-integrated e-Government model, Germany's sector-specific oversight, and Ireland's AI regulatory sandboxes show how tailored strategies can enhance compliance, promote trust, and support SME innovation. These examples highlight the importance of regulatory flexibility in accommodating national priorities while aligning with the AI Act's broader objectives.

Looking ahead, the success of the AI Act's implementation will depend on bridging regulatory gaps, improving coordination, and strengthening SME engagement. Addressing these challenges requires:

- **Tailored** support programs for SMEs
- **Simplified** compliance pathways to reduce administrative burdens
- **Investment** in AI governance capacity to ensure accessibility and fairness.

By refining national implementation plans and ensuring clear, SME-focused guidelines, the AI Act can serve as a global benchmark for responsible AI regulation. As other regions develop their own AI frameworks, the EU's approach will demonstrate how strong governance and SME support can drive both compliance and innovation—ensuring that AI remains a trusted and transformative force for businesses and society alike.





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AI & Partners – ‘AI That You Can Trust’

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.

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



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