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Small Businesses' Guide to the AI Act

19 Feb, 2025

Everything you need to know about the AI Act, for small and medium-sized enterprises (SMEs) in the EU and beyond.

The AI Act has a **particular focus** on small and medium-sized enterprises (SMEs). This group of stakeholders is mentioned 38 times in the Act compared to 7 mentions of ‘industry’ and 11 mentions of ‘civil society’. More importantly, the EU AI Act has a range of measures that are specifically designed to support and simplify SME compliance with the product safety rules of the AI Act.

Quick summary of provisions tailored to SMEs

- **Regulatory sandboxes:** frameworks for testing AI products and services outside normal regulatory structures, with exemptions from administrative fees. Testing may also be

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assessments and provide **training activities** tailored to SMEs to support compliance.

- **Dedicated communication:** guidance and response to queries through dedicated channels to support SMEs in complying with the AI Act.
- **Proportionality:** obligations for providers of general-purpose AI models should be commensurate and proportionate to the type of model provider. For example, there will be separate Key Performance Indicators for SMEs under the Code of Practice.

We expand upon each of these provisions in the sections below.

The category of 'SMEs' under EU law

Under **EU law**, SMEs are an overarching category of enterprises consisting of three **subcategories**. Medium-sized enterprises have less than 250 employees and an annual turnover of less than €50 million and/or not more than €43 million on their annual balance sheet. Small enterprises employ less than 50 persons and have an annual turnover and/or balance of less than €10 million. Microenterprises employ less than 10 persons and have an annual turnover and/or balance of less

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and health, in many different jurisdictions including the UK, Japan and Singapore. With regard to the AI Act, a regulatory **sandbox** is a framework that lets providers of AI systems lawfully develop, train, validate and test novel AI systems by following a sandbox plan agreed between the provider and the supervising authority. These sandboxes could be physical, digital, or hybrid. Testing in **real world** conditions may also be facilitated through the framework of AI regulatory sandboxes. The sandboxes are **designed** to support innovation by enabling a controlled experimentation environment to demonstrate compliance, increasing legal certainty for both innovators and authorities, and removing barriers to access markets for SMEs.

The documentation from participating in a sandbox can be used to demonstrate **compliance** with the AI Act. Further, if the prospective providers observe the sandbox plan and terms and conditions and follow in good faith the guidance of the national competent authority, they will not face administrative fines for infringements of the Act. Note that providers in the AI regulatory sandboxes are not exempt from **liability** for damages to third parties caused by experimentation with AI systems in a sandbox.

SMEs will have **priority** access to sandboxes. Moreover, these sandboxes shall be **free** of charge for SMEs and the procedures for application, selection, participation, and exiting the sandboxes shall be **simple**, easy to understand and communicated in a clear way.

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proportional to the size, market size and other relevant factors. The European Commission will also carry out **assessments** of compliance costs for SMEs and collaborate with Member States to lower these costs. For example, with regard to translation costs related to mandatory documentation, Member States should try to ensure that they accept documentation and communication in languages broadly understood by the largest possible number of cross-border deployers.

In relation to fines, the Act sets the upper bound of **fines** based on whichever is higher – a fixed amount or a fixed percentage of total worldwide turnover. However, in the case of SMEs, the upper bound is set by whichever is lower.

Participation in standard setting and governance

Standards are an important part of any product safety legislation in the EU, and the AI Act is no exception. To ensure that the **perspectives** of **SMEs** are duly weighed in the standard setting process, the Commission and Member States must **facilitate** the participation of SMEs in the standardisation development process.

The AI Act also ensures representation of SMEs in the AI Act **implementation**. For example, SMEs must be represented in the **advisory forum**, a body which advises and provides technical expertise to the European AI Board and the Commission.

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Dedicated SME communication

Member States shall ensure **dedicated** communications channels for SMEs and other relevant actors, like local public authorities, to support SMEs throughout their development path. This support includes providing guidance and responding to queries about the implementation of the AI Act, ensuring synergies and homogeneity in the guidance to SMEs. Several Member States have already established relevant information channels, for example the Austrian **Service Desk** for AI.

Proportional obligations for SME providers of general-purpose AI models

Another aspect of the AI Act designed to support SMEs is the principle of proportionality. For providers of general-purpose AI models, the **obligations** should be “commensurate and proportionate to the type of model provider”. General-purpose AI models show significant generality, are capable of competently performing a range of different tasks, and can be integrated into a range of downstream systems or applications (**Art. 3(63) AIA**). The way these are released on the market (open weights, proprietary, etc) does not affect the categorisation.

A small subset of the most advanced general-purpose AI models are the so-called ‘general-purpose AI models with systemic risk’. That is,

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Providers of general-purpose AI models have certain transparency obligations. Providers of general-purpose AI models with systemic risk have additional obligations to evaluate and test models, assess and mitigate possible systemic risk, carry out incident reporting and ensure adequate levels of cybersecurity. The Code is currently being drafted in an extensive multi-stakeholder process, so the final shape is yet to be determined. Because of the principle of proportionality, the Code should take due account of the size of the general-purpose AI model provider. This is recognised, for example, in the current second draft as one of the seven high-level principles, and is reflected in separate Key Performance Indicators for SMEs compared to larger companies.

Important note: For the purpose of compliance by downstream providers and deployers who are building applications or otherwise integrating general-purpose AI models into AI systems, the distinction between general-purpose AI models and general-purpose AI models with systemic risk does not matter. Here, the only thing that matters is the intended use of their AI system and whether this use falls under the scope of any of the risk categories in the AI Act: prohibited systems, high-risk systems, or systems with special transparency obligations. This will be the case for the vast majority of SMEs in the EU.

It all depends on implementation

Ultimately, the effects and ease of compliance for SMEs depend as

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05 Nov, 2025

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11 Aug, 2025

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