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# **Regulation (EU) 2024/1689 of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) SME Test**

February 2025

## Introduction

The EU AI Act<sup>1</sup> entered into force in August 2024 and applies, in a phased manner, over the period to August 2027.

This risk-based regulation puts in place guardrails for the development and deployment of trustworthy, human-centered AI in the European Union, balancing protection of fundamental rights with promotion of innovation. The Act provides regulatory clarity and certainty for businesses that are planning to develop AI or to invest in AI solutions.

By increasing legal certainty and harmonising rules across all EU member states, AI providers will benefit from seamless access to the EU's single market—a bloc of over 450 million consumers and businesses, where goods, services, capital, and people move freely. This harmonisation reduces fragmentation caused by differing national regulations, enabling AI providers to scale their innovations more efficiently across the region.

The AI Act is primarily focused on high risk uses that have the potential to significantly impact individuals' rights or safety – examples include the use of AI for recruitment or to control access to essential services such as credit or health insurance. The Act prohibits use of AI in cases of unacceptable risk (for example criminal profiling and social scoring), and it sets out clear requirements that must be met for use in cases of high and medium risk.

Typical low risk business applications include voice to text transcription, content recommendation, marketing tools, and back-office administration tools, such as inventory management, accounting and scheduling.

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<sup>1</sup> [Regulation \(EU\) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations \(EC\) No 300/2008, \(EU\) No 167/2013, \(EU\) No 168/2013, \(EU\) 2018/858, \(EU\) 2018/1139 and \(EU\) 2019/2144 and Directives 2014/90/EU, \(EU\) 2016/797 and \(EU\) 2020/1828 \(Artificial Intelligence Act\)Text with EEA relevance.](#)

## Potential Effect on SMEs

In 2021 the European Commission conducted an in-depth Impact Assessment Report<sup>2</sup> of the proposal for the AI Act, a key element of its better regulation agenda<sup>3</sup>, which included an SME Test. This SME Test concluded that most SMEs would not be affected by the Act, since obligations would be introduced only for high-risk applications. The AI Act Regulation adopts a risk-based approach, so that its measures are targeted and proportionate. SMEs falling outside the scope of the Act would benefit from legal certainty on their use of AI, free of concerns of compliance costs or administrative burdens.

Ireland's national AI Strategy<sup>4</sup> also highlights the fact that EU AI Act will place few, or no, obligations on most businesses who use AI to improve their productivity and to provide better customer experiences. Most AI systems pose minimal or no risk and will have no obligations under the Act.

In parallel with the rules to mitigate the risks of harm from AI systems, the AI Act contains measures in support of innovation with a particular focus on the needs and constraints of SMEs, including startups. The Act provides simplified ways of compliance for SMEs, and the interests of SMEs must be represented in the development of standards under the Act. It requires the European Commission to regularly assess the certification and compliance costs for SMEs and to work with Member States to lower such costs. Member States must provide priority access to the AI regulatory sandboxes for SMEs. Member States must establish dedicated channels for communication to support SMEs throughout their development journey by providing guidance and responding to queries about the implementation of this Regulation.

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<sup>2</sup> [Impact Assessment of the Regulation on Artificial intelligence](#)

<sup>3</sup> [Better regulation - European Commission](#)

<sup>4</sup> [National AI Strategy Refresh 2024](#)

Finally, the Act stipulates that penalties for infringements of the Act must take into account the interests of SMEs and their economic viability.

## National approach

The AI Act is a harmonised EU Regulation with direct legal effect in all Member States.

Consequently, the obligations it places on regulated entities, including SMEs, are settled EU law, which is directly applicable in Ireland, and require no further implementation in national law. There is no scope for Member States to amend these obligations.

The Act requires Member States to provide for the supervision and enforcement of the Act at national level. For example, Member States must designate or establish at least one Notifying Authority, and one or more Market Surveillance Authorities, as National Competent Authorities for the Act by 2 August 2025.

Therefore, national implementing legislation will be technical, necessary to give full effect to the supervision and enforcement provisions of the Regulation. National legislation will neither add to, nor alter, the obligations placed on the regulated entities by the Regulation.

## SME Test

### Screening question

Is the new policy, primary or secondary legislation, or regulatory compliance requirement relevant for SMEs?

- Are SMEs within the scope of the measure? Yes ☒ No ☐
- Does the measure specifically target SMEs? Yes ☒ No ☐
- Will or could SMEs be impacted directly or indirectly by the measure? Yes ☒ No ☐
- Are SME impacts likely to be more substantial than on other companies, for example, in terms of adverse effects? Yes ☐ No ☒

## Step 1 – Consultation

1. What consultation will/has taken place to capture input from the SME community, particularly those most impacted by this measure?

- Public consultation ☒
- Online consultation ☒
- Consultation with SME representative bodies ☒
- Notifications of consultation to database of interested stakeholders ☒
- Interviews and panels with experts ☒
- Webinars ☐
- Roundtables ☒
- Public meetings ☒
- Other ☒

*If Other, please provide details:*

### European Commission Consultations

In 2020 the European Commission conducted an extensive public consultation on the White Paper on Artificial Intelligence. The consultation included a section that outlined a series of options for a regulatory framework for AI. A wide variety of stakeholders participated in the public consultation with 29% of submissions received from business and industry including 83 submissions from SMEs.

Following this public consultation the Commission conducted an Impact Assessment Report which noted that businesses, public authorities, academics and non-governmental organisations all agreed that legislative gaps exist or that new legislation is needed.

Article 96 of the AI Act requires the European Commission to develop guidelines on the practical implementation of the AI Act. These guidelines are required to pay particular attention to the needs of SMEs. In November 2024 the Commission launched a targeted

stakeholder consultation on AI Act prohibitions and AI system definition to assist with the first set of guidelines to be published in February 2025.

## **National Consultations**

### **June 2021**

In June 2021, the Department conducted a public consultation<sup>5</sup> calling for stakeholder views on the European Commission's draft proposal for a regulation laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act). A total of 21 submissions were received from a broad range of stakeholders. Several of these included views that should be considered for SMEs, including –

- Highlighting that SME's may have less capacity to absorb the regulatory burden.
- Clarifying risk classification use cases to aid SMEs.
- The need to be cognisant of other EU regulations entering force around the same time, including the Digital Services Act and Digital Markets Act, which may result in companies may be faced with a number of new regulatory obligations within a short period of time.
- Welcoming the establishment of a European Artificial Intelligence Board to facilitate cooperation and also the additional measures to support innovation, SMEs and start-ups.
- Support for the establishment of a sandbox to help enable innovation and support SMEs.

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<sup>5</sup> [Call for views in response to the European Commission Proposal for a Regulatory Framework on Artificial Intelligence - DETE](#)

## **Act Negotiations**

During the negotiations of the Act, the Department assessed the draft text for its impact on SMEs and engaged bilaterally with relevant stakeholders throughout the process to incorporate their views where appropriate.

## **June 2024**

In advance of the Act entering force in June 2024, the Department conducted another consultation to inform Ireland's approach to implementing the Act and, specifically in relation to the configuration of national competent authorities required for implementation. It received feedback from SME industry bodies such as IBEC, Scale Ireland and Chambers Ireland. Further details on this can be found on the Department's website - [here](#). This feedback will prove valuable throughout the national implementation phase of the Act.

## **Other communications**

In addition to this, the Department has communicated and consulted with SMEs and their representative bodies through -

- Speaking at industry events – Enterprise Digital Advisory Forum, Enterprise Forum, AI Forum, Company Law Review Group, Health Safety Authority Workplace Safety seminars, IBEC.
- Bilateral engagements.
- The Enterprise Newsletter.
- Publishing information on the Department website and social media channels.<sup>6 7</sup>

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<sup>6</sup> [Artificial Intelligence - DETE](#)

<sup>7</sup> [EU AI Act - DETE](#)

## Step 2 - Identification of Affected Businesses

2a: Please identify the type of SMEs that will be directly or indirectly (i.e. SMEs not in scope, but potentially affected indirectly, for instance through impacts on supply chain) affected by proposed policy change -

- Micro (1-9 employees) ☐
- Small (10-49 employees) ☐
- Medium (50-249) employees ☐
- All of the above ☒

2b: Has an estimate been carried out of the numbers of micro, small and medium companies affected directly or indirectly by the measure? Yes ☒ No ☐

2c: Will the proposed policy change have a greater impact on SMEs in any particular economic sector?

Yes ☒ No ☐

If Yes, please specify. *See below.*

2d: Will the proposed policy change have a greater impact on SMEs in any particular region?

Yes ☐ No ☒



## **Risk Based Approach**

The AI Act applies equally to uses of AI in the public service as to the private sector. However, it provides exemptions for certain applications of AI relating to national defence; national security; scientific R&D; R&D for AI systems, models; open-sourced models; and personal use.

Irish businesses are increasingly using AI and advanced digital tools to achieve success in international markets. Irish entrepreneurs are developing AI solutions in sectors including healthcare, cybersecurity, education, sustainability, finance, content creation, supply chain and customer service, for a global market.

The Act is not a blanket regulation applying to all AI systems. Rather, it adopts a risk-based approach to regulation, based on four risk categories in order to ensure that its measures are targeted and proportionate. The Act also makes allowance for the unique circumstances of SMEs.

## **Effect on SMEs**

Due to the risk-based approach of the Act, many SMEs will not be affected, since obligations apply only for high-risk applications. Many businesses who use AI to improve their productivity or enhance their customers' experiences, use AI systems that pose minimal or no risk and will have no obligations under the Act.

The AI act's four risk levels and their corresponding rules are:

### Minimal or no risks

Most AI systems do not pose risks. AI-powered games or spam filters can be used freely. They are not regulated or affected by the EU's AI act

### Limited risks

AI systems that present only limited risks, such as chatbots or AI systems that generate content, are subject to transparency obligations, such as informing users that their content was generated by AI so that they can make informed decisions concerning further use.

### High risks

High-risk AI systems, such as those used in disease diagnoses, autonomous driving and the biometric identification of individuals involved in criminal activities or investigations, must meet strict requirements and obligations to gain access to the EU market. These include rigorous testing, transparency and human supervision.

### Unacceptable risks

AI systems that pose a threat to people's safety, rights or livelihoods are banned from use in the EU. These include cognitive behavioural manipulation, predictive policing, emotion recognition in the workplace and educational institutions, and social scoring. The use of real-time remote biometric identification systems such as facial recognition by law enforcement authorities in public spaces is also prohibited, with some limited exceptions.

### **Scope of Application**

The AI Act applies to:

- Providers placing on the market or putting into service AI systems or placing on the market general-purpose AI models in the Union, irrespective of whether those providers are established or located within the Union or in a third country.
- Deployers of AI systems that have their place of establishment or are located within the Union.
- Providers and deployers of AI systems that have their place of establishment or are located in a third country, where the output produced by the AI system is used in the Union.
- Importers and distributors of AI systems.
- Product manufacturers placing on the market or putting into service an AI system together with their product and under their own name or trademark;
- Authorised representatives of providers, which are not established in the Union.
- Affected persons that are located in the Union.

**Innovation – access to AI Regulatory Sandbox for SMEs.**

The AI Act requires Ireland to create an AI regulatory sandbox which will be a controlled environment where AI systems can be developed, tested, and validated before being released to the market. The goal is to foster innovation while identifying and mitigating any risks, particularly those related to fundamental rights, health, and safety. If an AI system is successfully tested in a sandbox, the provider can use this as proof of compliance with regulations. The sandbox aims to facilitate and accelerate access to the Union market for AI systems, in particular when provided by SMEs.

## Step 3 - Measurement of the Impact on SMEs

### 3a: What are the expected positive impacts of the policy change on SMEs?

- Improved regulatory framework Yes ☒ No ☐
- Improved working conditions Yes ☒ No ☐
- Cost savings Yes ☒ No ☐

If other, please provide details. *See below.*

### 3b: Will the proposed changes result in any of the following impacts for SMEs.

- Administrative costs, including the obligation to provide information on the activities or products of the company, including one-off and recurring administrative costs? Yes ☒ No ☐
- Compliance costs, including the obligation to pay fees or duties; and costs created by the obligation to adapt the nature of the product/service and/or production/service delivery process to meet economic, social or environmental standards. Yes ☐ No ☒
- Other impacts, including on business entry and exit; competition and competitiveness? Yes ☒ No ☐
- Discourage entrepreneurship or innovation? Yes ☐ No ☒
- Impacts of any proposed exemption thresholds on business growth? Yes ☐ No ☒
- Impacts on SME population composition and location? Yes ☐ No ☒
- Additional reporting requirements? Yes ☒ No ☐

The European Commission conducted an in-depth impact assessment to assess the case for action, the objectives, and the impact of different policy options for a European framework for AI. This report also contained an SME test. It concluded that the vast majority of SMEs would not be affected at all but would benefit more from a higher overall level of trust in AI than large companies who can also rely on their brand image. SMEs developing applications classified as high risk would have to bear similar costs as large companies. Indeed, due to the high scalability of digital technologies, small and medium enterprises can have an enormous reach despite their small size, potentially impacting millions of individuals.

Thus, when it comes to high-risk applications, excluding AI supplying SMEs from the application of the regulatory framework could seriously undermine the objective of increasing trust. However, the framework envisages specific measures, including regulatory sandboxes or assistance through the Digital Innovation Hubs, to support SMEs in their compliance with the new rules, taking into account their special needs.

The beneficial impacts of the AI Act include for providers of AI, it will create legal certainty and ensure that no obstacle to the cross-border provision of AI-related services and products emerge. For companies using AI, it will promote trust among their customers. For citizens, it will mitigate risks to their safety and fundamental rights.

## Step 4 - Assessment of Alternative Options and Mitigating Measures

### Mitigating Measures

The AI Act contains provisions to support SMEs and mitigate certain aspects of the regulation. Some examples of this include:

- Simplified technical reporting obligations, the Commission shall establish a simplified technical documentation form targeted at the needs of small and microenterprises. This will reduce the cost of compliance.
- The development of guidelines on the practical implementation of the AI Act. These guidelines are required to pay particular attention to the needs of SMEs.
- Reduced penalty thresholds for SMEs.
- The national notified body shall avoid unnecessary burdens for providers when performing their activities, and take due account of the size of the provider, the sector in which it operates, its structure and the degree of complexity of the high-risk AI system concerned, in particular in view of minimising administrative burdens and compliance costs for micro- and small enterprises
- Ireland's national AI regulatory sandbox, which is a requirement under the EU AI Act, will provide a supervised environment for that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems by start-ups and SMEs.
- Encouraging Member States to develop initiatives, which are targeted at SMEs, including on awareness raising and information communication.
- Member States should support SMEs throughout their development path by providing guidance and responding to queries about the implementation of the Regulation.

- The Commission has committed to regularly assess the certification and compliance costs for SMEs, including start-ups, through transparent consultations and should work with Member States to lower such costs.

### **European Supports**

The European AI Office<sup>8</sup> is the centre of AI expertise across the EU. It plays a key role in implementing the AI Act. It also prepares guidance and guidelines, provides advice on best practices and enabling ready-access to AI sandboxes, real-world testing and other European support structures for AI uptake.

The European Commission established the AI Pact<sup>9</sup> to help stakeholders prepare for the implementation of the AI Act. As part of this initiative there are workshops specifically tailored to companies.

The AI Office hosts events within the AI Pact to engage the AI community, promote knowledge sharing, and best practices to foster trustworthy AI.

### **National Supports**

A range of Government supports are available for businesses, particularly SMEs, to support them in investigating and adopting AI technology. CeADAR, Ireland's European Digital Innovation Hub for AI, offers low-cost or no-cost supports including Test Before Invest, Skills and Training, Support to Find Investments and Ecosystem Building.

The Department of Enterprise, Trade and Employment (DETE) has worked with CeADAR, Ireland's Centre for AI to develop an online AI literacy training course "AI for You: Introduction to AI and the EU AI Act", which is available free of cost to all SMEs.

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<sup>8</sup> [European AI Office | Shaping Europe's digital future](#)

<sup>9</sup> [AI Pact | Shaping Europe's digital future](#)

## Conclusion

Throughout the process of developing the AI act, consideration has been given to the circumstances of SMEs. In parallel with the rules to mitigate the risks of harm from AI systems, the AI Act contains measures in support of innovation with a particular focus on the needs and constraints of SMEs, including startups.

The Act provides for:

- Simplified ways of compliance for SMEs.
- The interests of SMEs must be represented in the development of standards under the Act.
- The European Commission must regularly assess the certification and compliance costs for SMEs and to work with Member States to lower such costs.
- Member States must provide priority access to the AI regulatory sandboxes for SMEs.
- Member States must establish dedicated channels for communication to support SMEs.

As outlined in this paper, the AI Act Regulation adopts a risk-based approach, so that its measures are targeted and proportionate. Consequently, many SMEs will experience no, or minimal, impact due to the lower risk nature of their AI systems.

The AI Act is harmonised EU legislation and there is no discretion for Member States to deviate from the agreed EU policy in their national implementation. However, the Department notes that respondents to the Department's June 2024 consultation on national implementation of the AI Act suggested that a "hybrid" approach, with a central coordinating body working together with sector-specific authorities. This was seen as a way to leverage both centralised oversight and domain expertise. This approach would also be beneficial to SMEs by providing a central body to support SMEs throughout their development journey by providing guidance and responding to queries about the implementation of this Regulation.



The Department of Enterprise, Trade and Employment will continue to consider the impact of the Regulation on SMEs as it further develops and implements the national supervisory and regulatory framework.