[Regulatory framework proposal on artificial intelligence (https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai)](https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai)

The Commission is proposing the first-ever legal framework on AI, which addresses the risks of AI and positions Europe to play a leading role globally.

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The regulatory proposal aims to provide AI developers, deployers and users with clear requirements and obligations regarding specific uses of AI. At the same time, the proposal seeks to reduce administrative and financial burdens for business, in particular small and medium-sized enterprises (SMEs).

The proposal is part of a wider AI package, which also includes the updated Coordinated Plan on AI. Together, the Regulatory framework and Coordinated Plan will guarantee the safety and fundamental rights of people and businesses when it comes to AI. And, they will strengthen uptake, investment and innovation in AI across the EU.

Why do we need rules on AI?

The proposed AI regulation ensures that Europeans can trust what AI has to offer. While most AI systems pose limited to no risk and can contribute to solving many societal challenges, certain AI systems create risks that we must address to avoid undesirable outcomes.

For example, it is often not possible to find out why an AI system has made a decision or prediction and taken a particular action. So, it may become difficult to assess whether someone has been unfairly disadvantaged, such as in a hiring decision or in an application for a public benefit scheme.

Although existing legislation provides some protection, it is insufficient to address the specific challenges AI systems may bring.

The proposed rules will:

- address risks specifically created by AI applications;
- propose a list of high-risk applications;
- set clear requirements for AI systems for high risk applications;
- define specific obligations for AI users and providers of high risk applications;
- propose a conformity assessment before the AI system is put into service or placed on the market;
- propose enforcement after such an AI system is placed in the market;
- propose a governance structure at European and national level.

A risk-based approach
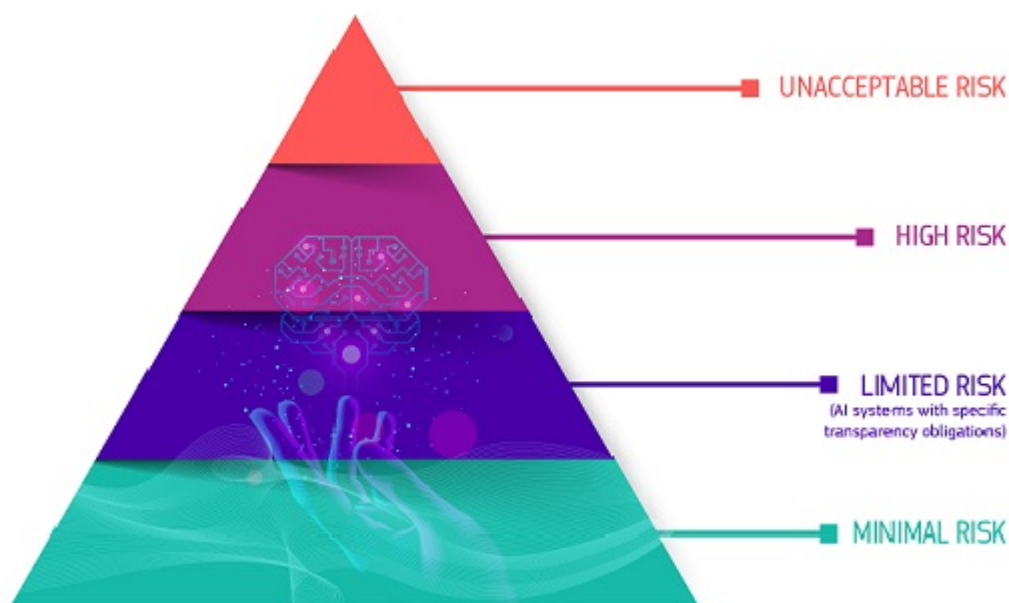
The Regulatory Framework defines 4 levels of risk in AI:

- Unacceptable risk
- High risk
- Limited risk
- Minimal or no risk

Unacceptable risk

All AI systems considered a clear threat to the safety, livelihoods and rights of people will be banned, from social scoring by governments to toys using voice assistance that encourages dangerous behaviour.

High risk

AI systems identified as high-risk include AI technology used in:

- critical infrastructures (e.g. transport), that could put the life and health of citizens at risk;

- educational or vocational training, that may determine the access to education and professional course of someone's life (e.g. scoring of exams);
- safety components of products (e.g. AI application in robot-assisted surgery);
- employment, management of workers and access to self-employment (e.g. CV-sorting software for recruitment procedures);
- essential private and public services (e.g. credit scoring denying citizens opportunity to obtain a loan);
- law enforcement that may interfere with people's fundamental rights (e.g. evaluation of the reliability of evidence);
- migration, asylum and border control management (e.g. verification of authenticity of travel documents);
- administration of justice and democratic processes (e.g. applying the law to a concrete set of facts).

High-risk AI systems will be subject to strict obligations before they can be put on the market:

- adequate risk assessment and mitigation systems;
- high quality of the datasets feeding the system to minimise risks and discriminatory outcomes;
- logging of activity to ensure traceability of results;
- detailed documentation providing all information necessary on the system and its purpose for authorities to assess its compliance;
- clear and adequate information to the user;
- appropriate human oversight measures to minimise risk;
- high level of robustness, security and accuracy.

All remote biometric identification systems are considered high risk and subject to strict requirements. The use of remote biometric identification in publicly accessible spaces for law enforcement purposes is, in principle, prohibited.

Narrow exceptions are strictly defined and regulated, such assuch as when necessary to search for a missing child, to prevent a specific and imminent terrorist threat or to detect, locate, identify or prosecute a perpetrator or suspect of a serious criminal offence.

Such use is subject to authorisation by a judicial or other independent body and to appropriate limits in time, geographic reach and the data bases searched.

Limited risk

Limited risk refers to AI systems with specific transparency obligations. When using AI systems such as chatbots, users should be aware that they are interacting with a machine so they can take an informed decision to continue or step back.

Minimal or no risk

The proposal allows the free use of minimal-risk AI. This includes applications such as AI-enabled video games or spam filters. The vast majority of AI systems currently used in the EU fall into this category.

STEP1 — A high-risk AI system is developed.

STEP2 — It needs to undergo the conformity assessment and comply with AI requirements.*

*For some systems a notified body is involved too.

STEP3 — Registration of stand-alone AI systems in an EU database.

STEP4 — A declaration of conformity needs to be signed and the AI system should bear the CE marking. **The system can be placed on the market.**

If substantial changes happen in the AI system's lifecycle

GO BACK TO STEP 2

How does it all work in practice for providers of high risk AI systems?

Once an AI system is on the market, authorities are in charge of market surveillance, users ensure human oversight and monitoring, and providers have a post-market monitoring system in place. Providers and users will also report serious incidents and malfunctioning.

Future-proof legislation

As AI is a fast evolving technology, the proposal has a future-proof approach, allowing rules to adapt to technological change. AI applications should remain trustworthy even after they have been placed on the market. This requires ongoing quality and risk management by providers.

Next steps

Following the Commission's proposal in April 2021, the regulation could enter into force late 2022/early 2023 in a transitional period. In this period, standards would be mandated and developed, and the governance structures set up would be operational. The second half of 2024 is the earliest time the regulation could become applicable to operators with the standards ready and the first conformity assessments carried out.

As an additional regulatory delivery of the White Paper on AI, a proposed AI liability Directive (https://ec.europa.eu/info/business-economy-euro/doing-business-eu/contract-rules/digital-contracts/liability-rules-artificial-intelligence_en) was adopted on 28 September 2022.

Quick links

The AI pact

[(https://digital-strategy.ec.europa.eu/en/policies/ai-pact)](https://digital-strategy.ec.europa.eu/en/policies/ai-pact)
[Proposal for a Regulation on artificial intelligence](https://digital-strategy.ec.europa.eu/en/policies/ai-pact)

[(https://digital-strategy.ec.europa.eu/en/library/proposal-regulation-laying-down-harmonised-rules-artificial-intelligence)](https://digital-strategy.ec.europa.eu/en/library/proposal-regulation-laying-down-harmonised-rules-artificial-intelligence)
[Impact assessment of the regulation](#)

[(https://digital-strategy.ec.europa.eu/en/library/impact-assessment-regulation-artificial-intelligence)](https://digital-strategy.ec.europa.eu/en/library/impact-assessment-regulation-artificial-intelligence)
[Study supporting the impact assessment](https://digital-strategy.ec.europa.eu/en/library/impact-assessment-regulation-artificial-intelligence)

[(https://digital-strategy.ec.europa.eu/en/library/study-supporting-impact-assessment-ai-regulation)](https://digital-strategy.ec.europa.eu/en/library/study-supporting-impact-assessment-ai-regulation)
[FAQs: New rules for Artificial Intelligence](#)

Follow the latest progress and learn more about getting involved.

- [Follow the Commission's work on robotics @RoboticsEU (https://twitter.com/RoboticsEU)](https://twitter.com/RoboticsEU)

Latest News

[Commission welcomes political agreement on Artificial Intelligence Act (https://digital-strategy.ec.europa.eu/en/news/commission-welcomes-political-agreement-artificial-intelligence-act)](https://digital-strategy.ec.europa.eu/en/news/commission-welcomes-political-agreement-artificial-intelligence-act)

The Commission welcomes the political agreement reached between the European Parliament and the Council on the Artificial Intelligence Act (AI Act), proposed by the Commission in April 2021.

PRESS RELEASE | 24 November 2023
[EU and Canada launch Digital Partnership to strengthen strategic cooperation (https://digital-strategy.ec.europa.eu/en/news/eu-and-canada-launch-digital-partnership-strengthen-strategic-cooperation)](https://digital-strategy.ec.europa.eu/en/news/eu-and-canada-launch-digital-partnership-strengthen-strategic-cooperation)

Today, the EU and Canada strengthened their relationship as strategic and like-minded partners in the digital field.

PRESS RELEASE | 16 November 2023
[Commission opens access to EU supercomputers to speed up artificial intelligence development (https://digital-strategy.ec.europa.eu/en/news/commission-opens-access-eu-supercomputers-speed-artificial-intelligence-development)](https://digital-strategy.ec.europa.eu/en/news/commission-opens-access-eu-supercomputers-speed-artificial-intelligence-development)

The Commission and the European High-Performance Computing Joint Undertaking (EuroHPC JU) have committed to open and widen access to the EU's world-class supercomputing resources for European artificial intelligence (AI) start-ups, SMEs and the broader AI community as part of the EU AI Start-Up Initiative.

DIGIBYTE | 17 November 2023
[Fourth European AI Alliance Assembly took place in Madrid (https://digital-strategy.ec.europa.eu/en/news/fourth-european-ai-alliance-assembly-took-place-madrid)](https://digital-strategy.ec.europa.eu/en/news/fourth-european-ai-alliance-assembly-took-place-madrid)

The fourth edition of the European AI Alliance Assembly took place in Madrid on 16 and 17 November.

[Browse Artificial intelligence](#)

Report / Study

- 30-11-2023
  [Europe's Potential in Edge Computing: Supporting Industrial Innovation through Large-scale Pilots (https://digital-strategy.ec.europa.eu/en/library/europes-potential-edge-computing-supporting-industrial-innovation-through-large-scale-pilots)](https://digital-strategy.ec.europa.eu/en/library/europes-potential-edge-computing-supporting-industrial-innovation-through-large-scale-pilots)
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Factsheet / infographic

- 31-05-2023
  [EU-US Trade and Technology Council - Fourth Ministerial Meeting - Key outcomes (https://digital-strategy.ec.europa.eu/en/library/eu-us-trade-and-technology-council-fourth-ministerial-meeting-key-outcomes)](https://digital-strategy.ec.europa.eu/en/library/eu-us-trade-and-technology-council-fourth-ministerial-meeting-key-outcomes)
- 16-05-2023
  [Factsheet EU-India Trade and Technology Council (https://digital-strategy.ec.europa.eu/en/library/factsheet-eu-india-trade-and-technology-council)](https://digital-strategy.ec.europa.eu/en/library/factsheet-eu-india-trade-and-technology-council)

- 05-12-2022
  [Technology outcomes of the TTC of December 2022 (https://digital-strategy.ec.europa.eu/en/library/technology-outcomes-ttc-december-2022)](https://digital-strategy.ec.europa.eu/en/library/technology-outcomes-ttc-december-2022)

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Related Content

Big Picture

[A European approach to artificial intelligence (https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence)](https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence)

The EU's approach to artificial intelligence centers on excellence and trust, aiming to boost research

and industrial capacity while ensuring safety and fundamental rights.

Dig deeper

AI Pact (https://digital-strategy.ec.europa.eu/en/policies/ai-pact)

The AI Pact will encourage and support companies in planning ahead for the measures provided for in the AI Act.

See Also

International outreach for human-centric artificial intelligence initiative (https://digital-strategy.ec.europa.eu/en/policies/international-outreach-ai)

The international outreach for human-centric artificial intelligence initiative will help promote the EU's vision on sustainable and trustworthy AI.

Coordinated Plan on Artificial Intelligence (https://digital-strategy.ec.europa.eu/en/policies/plan-ai)

The Coordinated Plan on Artificial Intelligence aims to accelerate investment in AI, act on AI strategies and programmes and align AI policy to avoid fragmentation in Europe.

High-level expert group on artificial intelligence (https://digital-strategy.ec.europa.eu/en/policies/expert-group-ai)

The European Commission appointed a group of experts to provide advice on its artificial intelligence strategy.

The European AI Alliance (https://digital-strategy.ec.europa.eu/en/policies/european-ai-alliance)

The European AI Alliance is an initiative of the European Commission to establish an open policy dialogue on Artificial Intelligence. Since its launch in 2018, the AI Alliance has engaged around 6000 stakeholders through regular events, public consultations and online forum...

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