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. 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 they guarantee the safety and fundamental rights of people and businesses, while strengthening AI uptake, investment and innovation 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 be used to solve many societal challenges, certain AI systems create risks that need to be addressed 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 reached a certain outcome. 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**

![Risk-based pyramid](image)

**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, workers management 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.

In particular, all remote biometric identification systems are considered high risk and subject to strict requirements. Their live use in publicly accessible spaces for law enforcement purposes is prohibited in principle. Narrow exceptions are strictly defined and regulated (such as where strictly 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**, i.e. 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 risk**: The proposal allows the free use of 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, where they represent minimal or no risk.

**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 the AI system is on the market, authorities are in charge of the 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 is based on 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 in the second half of 2022 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.

Proposal for a Regulation on artificial intelligence
Study supporting the impact assessment
FAQs: New rules for Artificial Intelligence
Press release: New rules and actions for excellence and trust in AI
Follow the latest progress and learn more about getting involved.
The European Commission has completed the delivery of 305 disinfection robots as part of an action taken early in the COVID-19 pandemic to ease the burden on hospitals across the EU.
PRESS RELEASE | 10 December 2021
Annual report lays out the challenges of protecting fundamental rights in the digital age

The European Commission has released its annual report on the application of the Charter of Fundamental Rights in the EU.

PRESS RELEASE | 17 November 2021
First calls for proposals under the Digital Europe Programme are launched in digital tech and European Digital Innovation Hubs

The Commission announced this week the first set of calls for proposals under the Digital Europe Programme. This follows the adoption of the work programmes allocating nearly €2 billion for investments aimed to advance on the digital transition.

PRESS RELEASE | 10 November 2021
Commission to invest nearly €2 billion in delivering digital advances to business, citizens, and public administrations

The Commission has adopted three work programmes for the Digital Europe Programme, outlining the objectives and specific topic areas that will receive a total of €1.98 billion in funding. This first set of work programmes includes strategic investments that will be instrumental in realising the Commission's goals in making this Europe's Digital Decade.

Browse Artificial intelligence
Related Content

Big Picture

A European approach to artificial intelligence

The EU’s approach to artificial intelligence centres on excellence and trust, aiming to boost research and industrial capacity and ensure fundamental rights.

See Also

International outreach for human-centric artificial intelligence initiative
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 2021 Review**

The key aims of the Coordinated Plan on Artificial Intelligence 2021 Review are to accelerate investment in AI, act on AI strategies and programmes and align AI policy to avoid fragmentation.

**High-level expert group on artificial intelligence**

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

**The European AI Alliance**

The European AI Alliance is a forum engaged in a broad and open discussion of all aspects of Artificial Intelligence development and its impact.