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Navigating the EU AI Act

Seminar AI and Standards - Building a Trusted Future for Europe 14 May 2025, Stavanger

> **Dr. Tatjana Evas** Legal and Policy Officer European Al Office

Fundamentals of the EU AI Act

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The rationale

Complexity—O Opacity Unpredictability—O Autonomy—O Data

TRUST

 O Safety
 O Fundamental rights and values

Solid framework of EU legislation already in place at EU and national level HOWEVER



Certain **specific features of Al** can make application and enforcement of the existing rules more challenging and generate **risks to safety and fundamental rights**

Artificial Intelligence Act

A tailored regulatory response needed

EU AI Act – rules for trustworthy AI in Europe

Risk-based rules for Al systems:

Al with unacceptable risk is prohibited e.g. social scoring, biometrics

Requirements for high-risk Al e.g. AI in employment, medical devices

Disclosure for AI with transparency risks e.g. chatbots who impersonate humans

No rules for AI with minimal risk e.g. AI enabled videogames, spam filters





Enhanced Product Safety legislation + Lifecycle approach



Coordinated governance system – based on well established logic



Fostering responsible innovation through AI regulatory sandboxes and real-world testing

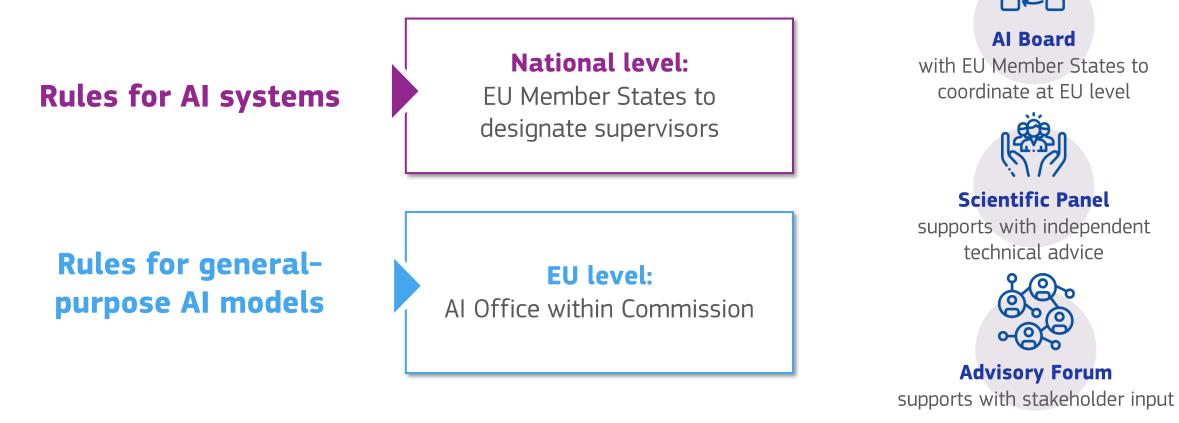


Future-proof legislation through use of standards, codes of practice and delegations



NTELLIGENCE OFFICE

A holistic governance structure





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Deep-dive into the Al Act's rules on high-risk Al systems

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When is an Al system 'high-risk' under the Al Act?

The AI Act classifies AI systems as 'high-risk' in two ways:



Al system is embedded into a regulated product or is itself a regulated product

Concerns 22 product regulations (Annex I). Examples: *Machinery Regulation, Radio Equipment Directive, Toy Safety Regulation*

Two conditions:

- Al system is intended as a **safety component** of a product or **is itself a product**
- Product in question is subject to a thirdparty conformity assessment



Al system is intended to be used in a high-risk use case

8 areas which are sensitive for health, safety and fundamental rights (Annex III) with concrete use cases listed for each area.

Al system classifies as high-risk if it is **intended to be used for one of these use cases**.



"Filter": AI systems can be excluded from the high-risk use cases in four cases, e.g. if they perform only a narrow procedural task.



Requirements

Mandatory Requirements for high-risk Al system <u>before</u> they can be used on the EU market

<u>Provider</u> is responsible for EU declaration of conformity + CE marking



(Harmonized) Standards:



→ Operational tools to support regulatory compliance with requirements

→ Ongoing work in ISO/IEC SC-42 and CEN/CENELC JTC-21. The main principle 'international first' i.e. build on IEC/ISO work as much as possible, however, as long as the international standards are aligned with the AIA Objectives and approach and cover same type of risks

Specific obligations for the public sector

Specific obligations for deployers of high-risk AI systems apply only to the public sector:



Bodies governed by public law have to carry out a **fundamental rights impact assessment**



Public authorities, agencies and other bodies have to **register the deployment** of high-risk AI in EU database



AI Act and product safety legislation

AI Act & sectoral product safety legislation

Key principle: **complementarity**

- New Legislative Framework (Annex I A) + Cyber Resilience Act → high-risk requirements apply immediately
- Old Legislative Framework (Annex I B):
 → high-risk requirements apply through the amendments into sectoral legislation



AI Act and EU Data protection law are complementary and mutually reinforcing

AI Act

Sets harmonised rules for the marketing and use of AI systems, irrespective of whether personal data is processed

- Market-based and product safety approach aiming to address risks to health, safety and fundamental rights across the whole AI lifecycle and value chain, while fostering innovation
- Risk-based with targeted rules (prohibitions, high-risk, transparency) complementing EU data protection law
- For example, Article 5(1)h) AIA lex specialis for the EU law enforcement directive
- Al Act does not create a legal basis for personal data processing, except Art. 10(5) and Art. 59

EU data protection law

Sets rules for processing of personal data

- GDPR, LED and EUDPR
- Fundamental rights and technology neutral approach
- Sets general principles and obligations for controllers/processors and rights of data subjects
- Relevant rules continue to apply when personal data is processed for training or using AI systems/AI models



Clarity needed how rules interplay and cooperation between supervisory authorities



AI as the touchpoint: how the digital rulebook applies

DSA, DMA and AI Act are designed to be complementary and mutually reinforcing.

The DSA

The DMA

AI can be used within online platforms and search engines

- Disclosure obligations for recommender, advertising and content moderation systems
- Providers of very large online platforms and search engines must analyse and mitigate systemic risks of algorithmic systems in their services

DMA covers AI if it is part of core platform services

- For example, a virtual assistant, a search engine or an operating system.
- DMA requirements may include limiting the use of data accumulated through services (e.g. for training AI), ensuring that users have access to their data and requiring fair ranking in search results.

The Al Act

AI Act applies to AI integrated into online services or if the AI is an online service

- Prohibition of harmful manipulative or exploitative AI
- Transparency obligations for generative AI, e.g. watermarking and labelling of deep fakes
- Transparency and risk management for generalpurpose AI models (synergy with DSA – reflected in AIA)

Interplay of DSA and AI Act in addressing harmful Aienabled practices of online platforms

DSA addresses societal and systemic harms of online services. AI Act adds additional protection by prohibiting unacceptable cases resulting in significant harm.



DSA allows **targeted advertising and recommender systems**, but mandates transparency and gives opt-out from profiling



AI Act prohibits **AI-enabled manipulation and social scoring** resulting in significant harm



DSA provides a high-level of privacy, safety and security to minors



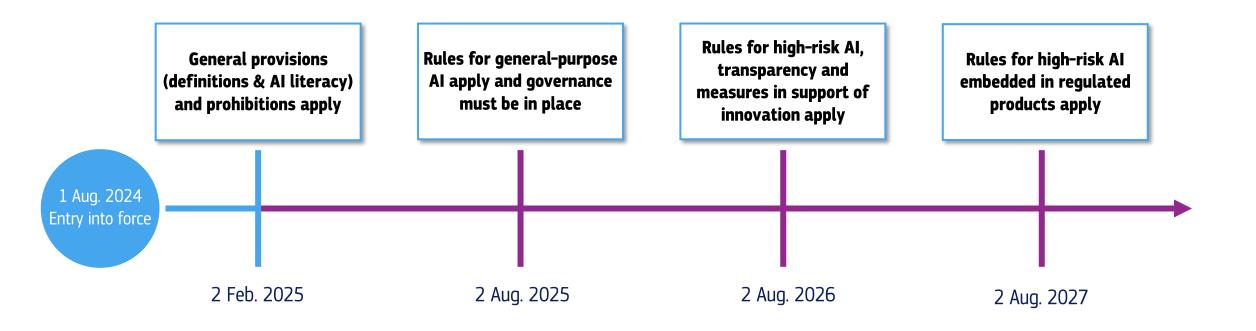
AI Act prohibits AI-enabled **exploitation of children's vulnerabilities** resulting in significant harm



Update on the AI Act's implementation

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The AI Act timeline





Implementation priorities for the AI Act

Set-up of governance structure



- Growing the **AI Office**
- Collaboration with **Member States** in the AI Board
- Establishing the Scientific Panel and Advisory Forum

Providing guidance on the practical AI Act application



- Publication of guidance documents & guidelines
- Coordinating the development of stakeholder-driven instruments like standards and the code of practice on general-purpose AI

Stakeholder outreach and support in compliance



- **AI Pact** network with more than 3000 stakeholders
- Actions under **Digital Europe Programme**
- Upcoming **AI Act Service Desk**





Publication of guidelines on the <u>AI system definition</u> and <u>prohibitions</u>.

Publication of a **repository of good practices for AI literacy.**

Ongoing iterative drafting of **<u>Code of practice on general-purpose AI</u>**.

Our <u>AI Pact webinars</u> for an in-depth look into the AI Act.

Explore all our activities online:

Recent activities





Thank you for your attention.

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