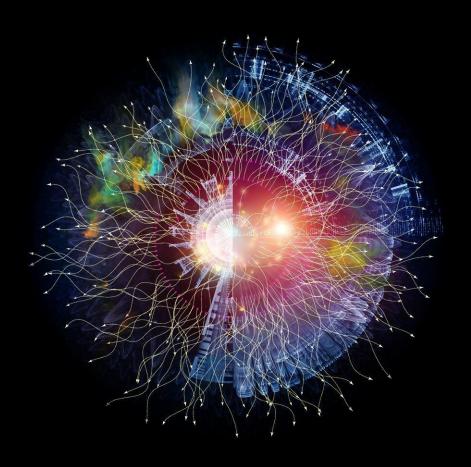
Deloitte.



Artificial Intelligence Act

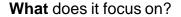
2023 Risk Advisory – Deloitte Czech Republic

The Artificial Intelligence Act in a Nutshell

The Proposal for a regulation is laying down harmonized rules on artificial intelligence.

Where do you see the AI Act impacting you?





- Human centered
- Risk-based approach
- Classification of Al systems



Who does it apply to?

 Providers, Users, Importers and Distributers of AI systems inside of the EU



When will it apply?

 According to a member of the European commission the implementation and ratification process could take 2-3 years



Why should I care?

- Clients might already have Al systems in place
- Non-compliance can lead to fees up to 30.000.000€or 6% of turnover



What can I do?

- Inform clients about the topic
- Deloitte with Trustworthy AI has the necessary competence

2



On April 21, 2021, the European Commission proposed the first legal framework on AI ever, which addresses the risks of AI and positions the European Union to play a leading role globally. The proposal is extensive, so this document provides an overview for you.

A Proposal 2 Years in the Making

In total, 1215 institutions or individuals contributed to this proposal, the overall agreement is a need for action.

How does the AI Act surprise vs prior papers?



EU focus on leading international regulation and driving innovation





-Q1



Artificial Intelligence

Affairs)

-Q2 (

13th July 2020

and Civil Liability (Legal



-Q3 (



Regulation on a European Approach for Artificial Intelligence

21st April 2021



2023-2025

Deloitte 2023

-2019

The Goal of the AI Act

The proposal lays out a legislative framework for dealing with AI in the future - with the goal of driving innovation and mitigating risks.

How do you take ethical implications of AI use cases into account?

Al Act is about...



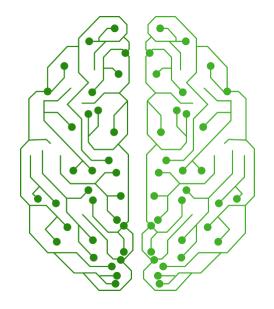
Emphasizing the **ethical application of AI**, instilling European values while improving transparency.



Establishing a process and roles to **enforce quality** at launch and throughout the life cycle.



Fostering collaboration and a **level playing field** between EU member states and protecting fundamental rights of EU citizens in the age of AI.



Penalties



Infringements can lead up to €30M or 6% of global annual turnover when violating Art. 5 or Art. 10.



Other non-compliance with requirements or obligations may result in a fine of €20M or 4% of global annual turnover.

How it intends to achieve that...

Incorporating a single standard across the EU to prevent fragmentation, enforced through Conformity Declarations and the obligation for a CE marking.



Ensuring **legal certainty** that encourages innovation and investment into AI by creating AI Regulatory Sandboxes.



Enabling National competent authorities as control instances. These instances will update a **EU database** for high-risk AI practices and systems.



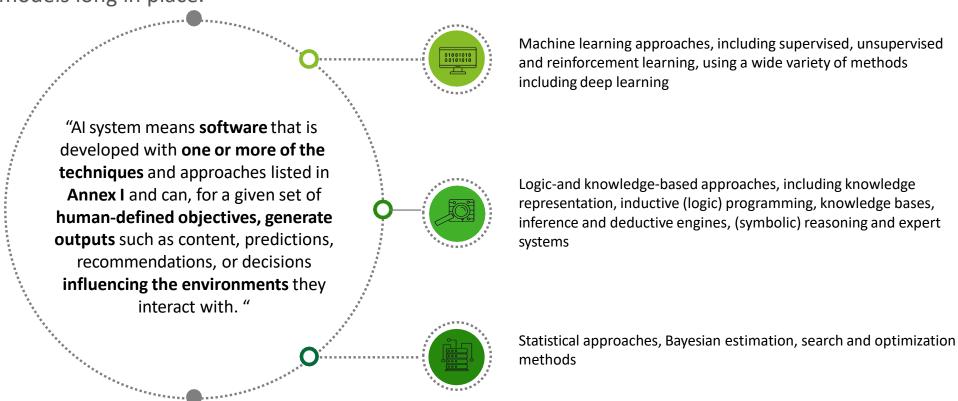


Incorrect, misleading information submitted to notified bodies or NCAs: €10M or 2% global annual turnover.

A Broad Definition of Al

What models do you have that the Al Act would consider as Al?

The Artificial Intelligence Act considers not only machine learning, but expert systems and statistical models long in place.





Comprehensive

cover all current and future AI including machine learning, deep learning as well as hybrid systems



Future proof

by focusing more on the use cases than on AI technology itself + complementary to existing legislation, especially GDPR



Legally secure

neutral as possible in regards to technical details in order to cover techniques which are not yet known or developed

5

The Scope of the Artificial Intelligence Act

The proposal focuses on high-risk AI systems being provided to/used in the European Union.

How are you affected? As a provider? An importer? A distributor? A User?

Requirements and Obligations of the AI Act

Applies to Entities

- Bodies inside and outside the EU if their AI system is running or affecting people in the EU
- Providers/Importers/Distributors provisioning AI within the EU
- Users of AI systems within the EU
- Providers and users located in a third country but where the output produced by the AI system is used in the Union

Entities Out of Scope

- Public authorities in a third country nor international organizations using AI systems in the framework of international agreements for law enforcement and judicial cooperation with the Union or with one or more Member States
- Military institutions
- Purely private, non-commercial use

Have you taken stock of your current AI systems and their degree of risk?

The proposal uses a risk-based approach to differentiate between four types of AI systems based on their potential for hazards and risk.



Unacceptable Risk Artificial Intelligence Systems (Art. 5)

Prohibited

- Manipulation of human behavior, opinions and decisions
- Classification of people based on their social behavior
- Real-time remote biometric identification, except for certain exceptions with special express authorization

Example: Social scoring



High-Risk Artificial Intelligence Systems (HRAIS, Art. 6)

Permitted subject to compliance with AI requirements ex-ante conformity assessment*

- Main focus of the regulation (Annex III)
- Common schemes with those already subject to a harmonized EU standard
- Additional list to be reviewed every year by the EAIB (Art. 84)

Example: Recruitment



Al with specific transparency obligations (Art. 52)

Permitted but subject to information/transparency obligations

- Interaction with humans
- Use to detect emotions or determine categories based on biometric data
- Generation of manipulate content

Example: Impersonation (bots)



Minimal or no Risk Artificial Intelligence Systems

Permitted without restrictions

Example: Predictive maintenance

Unacceptable Risk Artificial Intelligence Systems (Art. 5)

Applications of AI that pose an unacceptable risk are prohibited.

Do you provide AI systems that would be considered unacceptable risks?

1

Subliminal manipulation resulting in physical/psychological harm

Example: To push truck drivers to drive longer than healthy and safe, an inaudible sound is played in their cabin. At is used to find the frequency maximizing this effect on drivers.

2

Exploitation of children, mentally disabled or vulnerable persons resulting in physical/psychological harm

Example: A toy with an integrated voice assistant leads children to engage in dangerous behavior in the guise of a learning game.

3

General purpose social scoring

Example: An AI system calculates the credit range for people based on insignificant or irrelevant social "misbehavior".

4

Real-time remote biometric identification for law enforcement purposes in publicly accessible spaces*

Example: To find a low-level criminal, all public available cameras scan each face which appears in the view of the camera and checks it against a database in real time.

Deloitte 2023 * with exceptions

High-Risk Artificial Intelligence Systems (HRAIS, Art. 6)

High-risk AI is defined both by general characteristics and specifically targeted applications.

Which AI systems do you provide/use, which may be considered high-risk?

High-risk AI systems (Article 6)

- Al systems used as safety component of a product or standalone product
- Product or AI system covered by the Union harmonization legislation listed in Annex II(e.g. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending)
- If putting into service or placing on the market requires a third-party conformity assessment

Specific fields of AI deemed high-risk (Annex III)

- List includes the following:
 - 1. Biometric identification and categorization of natural persons
 - 2. Management and operation of critical infrastructure
 - 3. Education and vocational training
 - 4. Employment, workers management and access to selfemployment
 - 5. Access to and enjoyment of essential private services and public services and benefits
 - 6. Law enforcement
 - 7. Migration, asylum and border control management
 - 8. Administration of justice and democratic processes
- Not every AI system in these fields is high-risk
- List is updated regularly (12 months, Article 84)

High-Risk Artificial Intelligence Systems (HRAIS, Art. 6)

High-risk AI systems must both conform to stringent quality standards and comply with disclosure, control, and monitoring requirements.

What governance infrastructure do you have in place for your AI systems?

Risk Management System

- · Iterative and continuous process including suitable testing
- Estimation, evaluation and preparation for known foreseeable risks and more

Record Keeping

- Designed with automatic record keeping of events ('logs'):
 - · Period of each use of the system
 - Natural persons involved in the verification of the results

Robustness, Accuracy and Cybersecurity

- Designed to achieve an appropriate level of accuracy, robustness and cybersecurity throughout the lifecycle
- Appropriate levels are declared in the documentation of the AI system

Data and Data Governance

- Appropriate data governance & data management techniques must be applied
- High quality data sets & data governance:
 - Train validate test data sets
 - Relevant, representative, complete & free of errors
 - Prior assessment for availability, quantity, suitability, bias of the data

Transparency & Information

- Provision of information to users
- System should be accompanied by instructions for use
- concise, complete, correct and clear information that is relevant, accessible and comprehensible to users:
 - Characteristics and limitations of the AI system

Technical Documentation

- · Continuous updating
- · Before placement on market

Human Oversight

- Human interface tools have to be integrated
- Possibility to find signs of anomalies, dysfunctions and unexpected performance
- Ability not to use the AI system; to override, stop or reverse output

Are your users made aware they are interacting with an AI system?

While focused on high-risk, the regulation prescribes transparency and voluntary conduct for lower-risk applications.

New transparency obligations for certain AI systems (Art. 52)

- Notify people that they are interacting with an AI system, unless this is obvious
- Notify people if emotional biometric or recognition categorization systems are applied
- Apply labels to deep fakes (with certain exceptions) or other manipulated content

Possible voluntary code of conduct for AI with specific transparency requirements (Art. 69)

- No mandatory obligations
- Commission and Board will define codes of conduct intended to foster the voluntary application of requirements to low-risk Al systems
- Might include environmental sustainability or accessibility to persons with a disability
- Codes of Conduct can also be defined individually

Governance Structure

The AI Act follows a clear chain of responsibility across national and supranational entities.

With which regulators do you interact already now concerning AI?

The European Commission

 Develop new guidelines on the recommendations of the European Union Artificial Intelligence Board and an expert group

Member State

- Key role in the application and enforcement of the regulation
- Designates national competent authorities

National Competent Authorities (NCA) ensure the application of the regulation and serve as single source of truth

Artificial Intelligence Board

- High-level representatives of national competent authorities, the European Data Protection Supervisor, and the Commission
- Provides advice and assistance to the Commission
- Further assists in coordination and cooperation activities

Notifying Authority (NA)

Provides and executes processes for the assessment, designation and notification of conformity assessment bodies and their monitoring

National Supervisory Authority

- Coordinates activities, acts as contact point for the Commission, represents the Member State at Al Board
- Acts as NA and MSA unless a member state designates more than one authority

Market Surveillance Authority (MSA)

- Monitors market activities
- Informs national authorities if breach of obligations
- Performs activities and takes measures pursuant to Regulation (EU) 2019/1020

Conformity Assessment Bodies apply for notification and in result become a notified body

Notified Body

- Performs conformity assessment, testing, certification and inspection
- Cooperates with national competent authorities

Stakeholders, Roles and Obligations

Stakeholders are interconnected and each must fulfill specific obligations.

Which roles are relevant to you?

Source

Intermediate

End-User

Provider

Develops an AI system with the intention to place it on the market or put it into service in the EU.

- Compliance check
- Quality management system
- Technical documentation & updates

- Logging of AI system's activities
- Conformity assessment
- Continuously cooperate and collaborate with NCA
- Register AI system in EU database
- Affix CE marking and sign conformity declaration
- Post-market monitoring

Importer & Distributor

Importer places AI on the market or puts it into service (if AI from outside the EU). Distributor makes the AI available to others.

- Ensure that the conformity assessment has been carried out, a technical documentation, instructions and CE exist
- Withdraw, recall or do not place the AI system on the market if it is non-compliant or does not fulfill the requirements
- Ensure that the provisioning process of the AI does not cause compliance issues

Authorized Representative Representative with a mandate

- Perform the tasks specified in the mandate received from the provider
- Keeps records such as declaration of conformity, tech. documentation etc.

User

Entity using an AI system for professional activities.

- Use AI system according to given instructions
- Safeguard human oversight
- Verify input data is suited for given purpose

- Continuous monitoring of AI system's activity
- In case of malfunctioning or identification of serious incidents or other risks, inform the AI system's provider or distributor
- Keep logs for a specific period of time
- Comply with already existing regulatory and legal obligations

Does your governance process include declarations of quality? Monitoring?

1. Design in line with requirements

 Assure AI systems performs consistently for their designed purpose and are in compliance with the requirements of the Regulation

5. New Conformity assessment

- Substantial modification (e.g., purpose of the system) requires an update of the conformity assessment
- Assessment by providers or any third-party
- This includes adjustments outside the predefined range indicated by the provider for continuously learning AI systems



2. Conformity assessment

- Ex-ante Conformity assessment
- · Performed by the provider (Art. 43):
 - Based on internal controls (Annex VI)
 - Based on assessment of the quality management system and assessment of the technical documentation with involvement of a notified body (Annex VII)

3. Post-market monitoring

Providers have to regularly and consistently collect, document and analyze relevant data in order to ensure the reliability, performance and safety of AI systems throughout their lifetime and to evaluate continuous compliance of AI systems with the Regulation

Communicate and record serious events as well as malfunctioning leading to violation of fundamental rights

Deloitte 2023 maifunctioning leading to violation of fundamental rights

nge.

Is there a gap between the AI Act and your standards? How large is it?

The proposed regulation lays forth requirements for AI within the EU. It will usher in change. We offer a path forward.

- The proposed regulation focuses on ethical application of AI, that use cases are responsible, that practitioners are accountable for upholding stringent quality standards.
- This includes general principles of **fair & impartial** treatment of subjects (regardless of the AI application), but also explicitly forbids certain applications.
- It specifically highlights high-risk applications and prescribes extensive disclosure accompanied by rigorous controls to ensure AI systems are **robust & reliable**.
- To ensure **safe & secure** operation of AI, the regulation demands human oversight, the ability to assume control or override the AI.
- Even for applications deemed lower risk, the Artificial Intelligence Act demands
 that AI systems are sufficiently transparent, alerting subjects to processing by AI,
 and that they are explainable, enabling their designers to monitor them
 effectively.
- The proposed regulation is grounded in the fundamental rights of the citizen, guarding against exploitation of vulnerabilities, ensuring due process, defending the rights of children, among others. It **preserves privacy** by outright forbidding applications of AI for the live, remote surveillance of citizens.

Deloitte Trustworthy Al Framework Fair & Impartial Transparent & Robust & Al Governance **Explainable** Reliable Trustworthy Responsible & **Preserves** Accountable Privacy Safe & Secure

Your Steps Towards Compliance

The proposed regulation requires a declaration of conformity and CE marking prior to launch a high-risk AI system, as well as longer-term monitoring through end-of-life...

What has to change in your Al processes to integrate the Al Act?



1. Identification

Conduct a close examination of your existing assets and find out which ones use AI or qualify as AI under the new regulation.



3. Compliance

Ensure design, development and quality management system are in compliance with the Al regulation.



5. Declaration (ϵ)

Write a Declaration of conformity (Annex V) for each (high-risk) Al system and affix the CE marking.*



7. Monitoring

After launching the high-risk Al system, it needs to be monitored because the system learns.



2. Classification

Determine which assets entail which potential risks (e.g. unacceptable, high or low risks).



4. Conformity assessment

High-risk AI systems must undergo a specified conformity assessment (Art. 19 and 43) and must repeat this step if they are substantially modified.



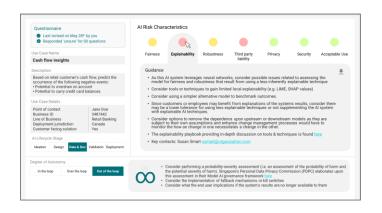
6. Market launch

Placing the high-risk AI system on the market or into service.



A **Deloitte** tool designed to help organizations efficiently **govern and manage the risks associated with the use of Artificial Intelligence systems** throughout the lifecycle.

The workflow guides users through labyrinth of detailed questions to accurately assess risk. Straightforward and clear results are rendered on dashboards.



Contacts

Trustworthy AI



Jakub HöllDirector
Risk Advisory

Kontakt: jholl@deloittece.com +420 734 353 815



Vilém Krejcar Consultant Risk Advisory

Contact: vkrejcar@deloittece.com +420 778 438 998

Deloitte.

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited, a UK private company limited by guarantee ("DTTL"), its network of member firms, and their related entities. DTTL and each of its member firms are legally separate and independent entities. DTTL (also referred to as "Deloitte Global") does not provide services to clients. Please see www.deloitte.com/cz/about to learn more about our global network of member firms.

Deloitte provides audit, consulting, legal, financial advisory, risk advisory, tax and related services to public and private clients spanning multiple industries. Deloitte serves four out of five Fortune Global 500® companies through a globally connected network of member firms in more than 150 countries and territories bringing world-class capabilities, insights, and high-quality service to address clients' most complex business challenges. To learn more about how Deloitte's approximately 245,000 professionals make an impact that matters, please connect with us on Facebook, LinkedIn, or Twitter.

Deloitte Central Europe is a regional organization of entities organized under the umbrella of Deloitte Central Europe Holdings Limited, the member firm in Central Europe of Deloitte Touche Tohmatsu Limited. Services are provided by the subsidiaries and affiliates of Deloitte Central Europe Holdings Limited, which are separate and independent legal entities. The subsidiaries and affiliates of Deloitte Central Europe Holdings Limited are among the region's leading professional services firms, providing services through more than 6,000 people in 44 offices in 18 countries.

© 2023. For more information, contact Deloitte Czech Republic.