NKF Client News / CLDS News

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The EU AI Act Enters into Force: Implications for Swiss Companies

1.   Overview and Roadmap

On 12 July 2024, the final step was taken to bring the **AI Act** into force,[1] the world's first framework regulation of artificial intelligence (AI). The publication of the AI Act in the Official Journal of the European Union triggered the following **transitional periods:**

2 August 2024	**Entry into force of the AI Act**
2 February 2025	Prohibition of AI practices with unacceptable risks (Chapter II AI Act) and entry into force of the obligation for providers and deployer of AI systems to take measures to ensure AI literacy (Chapter I AI Act)
2 May 2025	Code of Conduct must be available (otherwise rules can be issued by the EU AI Office)
2 August 2025	Applicability of governance rules and obligations for general-purpose AI (GPAI) models
2 August 2026	**General entry into force of the AI Act**, regulation of AI systems (including high-risk AI systems pursuant to Annex III AI Act), transparency provisions and national sandboxes
2 August 2027	Application of the entire AI Act to all high-risk AI systems (including embedded high-risk systems pursuant to art. 6 para. 1 AI Act)

The AI Act **aims** to create **harmonised rules** in the internal market and a **high level of protection** in terms of health, safety and the fundamental rights as enshrined in the EU Charter of Fundamental Rights, while fostering **innovation**. The EU aims to play a leading role in promoting trustworthy AI internationally.

The AI Act is a **technology regulation** in the form of a **framework regulation** that applies to the **term** "**AI system**", which is defined in art. 3 no. 1 AI Act as a "*machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments*". In addition, the AI Act contains a separate definition of a so-called "general-purpose AI system ", which is based on a general-purpose AI model trained with large amount of data using

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[1]   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) (link).

self-supervision at scale and is capable of competently performing a wide range of distinct tasks, intended for direct use or integration into various downstream systems or applications.

The AI Act follows a **risk-based approach** with four levels of risk:

Risk level	Examples	Regulatory approach
Unacceptable risk (Art. 5 AI Act)	AI systems with social scoring for public or private purposes that exploit people's vulnerabilities or use subliminal techniques	Prohibition with narrow exceptions
High risk (Art. 6 et seq., Annex II and III AI Act)	AI systems with application in critical infrastructure, education or training, human resource management or embedded AI systems used as safety components of products that is covered by EU product safety legislation	Requirement of a conformity assessment and compliance with restrictive requirements (including risk management system, monitoring, data and data governance requirements, technical documentation, record-keeping obligations, transparency, human oversight)
Limited risk (Art. 50 AI Act)	Chatbots or AI systems that generate synthetic audio, image, video or text content	Transparency and disclosure requirements, Code of Conduct
Minimal risk	All other AI systems, subject to AI systems that nevertheless present a risk (art. 82 AI Act)	No additional legal obligations under the AI Act, Code of Conduct for the voluntary application of certain requirements

In addition, art. 51 et seq. AI Act contain **specific rules** (including risk classification) **for "general-purpose AI models" (GPAI models)**, with which the EU aims in particular to regulate widely used large language models (LLMs). GPAI models are obliged to be transparent. Stricter requirements apply to GPAI models with systemic risk.

Probably the biggest challenge under the AI Act is **risk categorisation.** Of particular importance is **the distinction between high-risk AI systems** (for which the AI Act contains the majority of its regulations) **and those with limited risk.** The EU Commission will provide guidance on the classification rules for high risk AI systems (including a comprehensive list of practical use cases) by 2 February 2026 at the latest, i.e. six months before the regulations on high-risk AI systems come into force. This lead time is extremely tight and providers and deployer will have little choice but to categorise AI systems and start to implementing the requirements before then.

AI systems must be **categorised by providers.** Art. 80 AI Act provides for an **evaluation procedure by the market surveillance authority** if it has sufficient reason to consider that an AI system classified by the provider as non-high-risk is in fact high-risk. If the market surveillance authority finds that the AI system in question is high-risk, it will require the relevant provider to take all necessary actions to bring the AI system into compliance with the requirements and obligations of the AI Act and to take appropriate corrective action. If the provider does not comply with this

request within a certain period of time, fines will be imposed in accordance with art. 99 AI Act (see below).

Violations of the AI Act are subject to the penalties of art. 99 AI Act, which provides for **fines of up to EUR 35 million or 7% of the total worldwide annual turnover** of the preceding financial year.

2. Application of the AI Act to Swiss Companies

The main addressees of the AI Act are **providers**[2] and **deployer**[3] of AI systems.[4] **Providers** are **subject to the obligations of the AI Act if they place AI systems on the market or put them into service or place on the market general-purpose AI models (GPAI models) in the EU**, irrespective of whether these providers are established or located in the EU or in a third country (art. 2 para. 1 lit. a AI Act). In the case of "placing on the market", the question arises as to whether distribution to recipients takes place within the EU. The question of "putting into service" is more difficult. In particular, the question arises as to whether the AI Act already applies if data is processed by users or devices located within the EU.

In addition, AI systems may fall within the scope of the AI Act even if they are not placed on the market, put into service or used in the EU. For example, the AI Act applies to **providers and deployer** of AI systems that have their place of establishment or are located in a third country (e.g. Switzerland), **where the output produced by the AI system is used in the Union.** (art. 2 para. 1 lit. c AI Act). Recital 22 of the AI Act states:

> "This is the case, for example, where an operator established in the Union contracts certain services to an operator established in a third country in relation to an activity to be performed by an AI system that would qualify as high-risk. In those circumstances, the AI system used in a third country by the operator could process data lawfully collected in and transferred from the Union and provide to the contracting operator in the Union the output of that AI system resulting from that processing, without that AI system being placed on the market, put into service or used in the Union. To prevent the circumvention of this Regulation and to ensure an effective protection of natural persons located in the Union, this Regulation should also apply to providers and deployers of AI systems that are established in a third country, to the extent the output produced by those system is intended to be used in the Union."

In view of the broad wording, it is **possible that the AI Act will apply to AI systems in third countries (such as Switzerland), regardless of whether the data was collected in the EU.** Given the broad wording, it can be assumed that the only **decisive factor is whether the results of an AI system are used or utilised in the EU.**

Accordingly, it must be expected **that a significant proportion of Swiss providers and deployers of AI systems will fall under the new regulation of the AI Act,** for example because the results of an AI system are used for services to clients established or resident in the EU. This could have a significant

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[2] Art. 3 no. 3 AI Act defines a **provider** as a "*a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed an places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge*".

[3] Art. 3 no. 4 AI Act defines a **deployer** as "*a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity*".

[4] In addition, the AI Act contains rules for other addressees, in particular product manufacturers, authorised representatives, importers and distributors. It should also be mentioned that, according to art. 2 no. 8 AI Act, the regulation does not apply to any research, testing or development activities regarding AI systems or AI models prior to their being placed on the market or put into service. Such activities shall be conducted in accordance with applicable Union law. Testing in real world conditions shall not be covered by that exclusion.

impact on **providers of Swiss high-risk AI systems** in particular, who would be obliged under art. 22 AI Act to appoint an authorised representative established in the EU. Swiss **deployers of AI systems** whose results are used in the EU will also be subject to a number of obligations. In particular, they will have to implement the requirements for AI literacy, transparency obligations and a code of conduct.

3. Significance for Data Science Projects

AI systems are increasingly being used in data science projects, e.g. to classify and interpret data. The question therefore arises as to the extent to which the AI Act could affect data science projects. Insofar as the AI Act applies, reference can be made to the above in terms of applicability, risk categorisation and regulatory approach.

Art. 2 para. 6 AI Act contains an exception for AI systems or AI models, including their output, that are specifically developed and put into service for the sole purpose of scientific research and development. This exception was added at the suggestion of the Czech Republic's Presidency of the EU Council in order to avoid restrictions on the freedom of science. Recital 25 of the AI Act states:

> "This Regulation should support innovation, should respect freedom of science, and should not undermine research and development activity. It is therefore necessary to exclude from its scope AI systems and models specifically developed and put into service for the sole purpose of scientific research and development. Moreover, it is necessary to ensure that this Regulation does not otherwise affect scientific research and development activity on AI systems or models prior to being placed on the market or put into service. [...] That exclusion is without prejudice to the obligation to comply with this Regulation where an AI system falling into the scope of this Regulation is placed on the market or put into service as a result of such research and development activity and to the application of provisions on AI regulatory sandboxes and testing in real world conditions. Furthermore, without prejudice to the exclusion of AI systems specifically developed and put into service for the sole purpose of scientific research and development, any other AI system that may be used for the conduct of any research and development activity should remain subject to the provisions of this Regulation. In any event, any research and development activity should be carried out in accordance with recognised ethical and professional standards for scientific research and should be conducted in accordance with applicable Union law."

The exception is therefore limited to AI systems and models that are developed and put into service for the sole purpose of scientific research and development. If, on the other hand, another AI system is used for research and development purposes, the AI Act will apply. Given the enormous development costs of AI systems, this will be the case in the vast majority of cases. From the perspective of AI regulation, it is therefore also crucial whether the AI system used is itself for purely scientific or for other purposes. Given the importance of AI systems that have not been developed and put into service for the sole purpose of scientific research and development, it is to be expected that the AI Act will apply to the majority of data science projects that use AI.

4. Adoption of the AI Act in Switzerland?

Switzerland is currently evaluating approaches to regulating AI systems. To this end, the Federal Council commissioned the Federal Department of the Environment, Transport, Energy and

Communications (DETEC) to prepare an overview of possible regulatory approaches in November 2023, which should be available by the end of 2024. In view of the developments in the EU, we believe it is likely that Switzerland will enact a framework law similar to the AI Act through the ordinary legislative process, although the timeframe is not yet foreseeable.

Due to the far-reaching extraterritorial regulation of the AI Act, the question arises as to whether a coordination of the regulations is possible. Art. 39 AI Act provides for the possibility that conformity assessment bodies established under the law of a third country may be authorised to carry out the activities of notified bodies under the AI Act. However, this would require a bilateral agreement between Switzerland and the EU, which, for political reasons and based on experience in other areas, currently seems unlikely. It is therefore likely that the AI Act and a Swiss regulation on AI systems (yet to be enacted) will be applied in parallel.

Authors /Contacts

Prof Dr Tilmann Altwicker
Chair CLDS
tilmann.altwicker@ius.uzh.ch

Juerg Bloch
Partner, Compliance & Investigations
Member Advisory Board CLDS
juerg.bloch@nkf.ch

Simon Bühler
Partner, Regulatory
simon.buehler@nkf.ch

Clara-Ann Gordon
Partner, Data Protection
clara-ann.gordon@nkf.ch

Janine Reudt-Demont
Partner, Data Protection
janine.reudt-demont@nkf.ch

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