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Special edition on Artificial Intelligence

Artificial intelligence, or 'AI' for short, is on everyone's lips worldwide. Many legal issues are linked to this.

I. AI Regulation

(1) (Special) regulations of AI yes or no? Developments in the EU with the AI Regulation and in the USA with Executive Order 14110

If legal uncertainties can be identified with regard to AI concerning authorisations, possible uses, liability, etc., the initial question arises as to whether and to what extent these areas are specifically regulated at all. If there are no special regulations, regulations and legal principles that are not specifically tailored to AI can be used at best, but these often do not cover the specific constellations. There are opposing trends here worldwide:

After taking office in January 2025, US President Trump immediately revoked an Executive Order issued under his predecessor Biden in 2023 to regulate AI, the *Executive Order on the Safe, Secure and Trustworthy Development and Use of Artificial Intelligence, EO 14110*[1], according to which risks in the development of AI were to be limited and large AI developers were to pass on essential information to the federal authorities. Deregulation is now the new direction in order to give companies the greatest possible freedom.

In the EU, on the other hand, some first provisions of the **AI Regulation (EU) 2024/1689 of**

[1] https://www.govinfo.gov/content/pkg/FR-2023-11-01/pdf/2023-24283.pdf (all websites last visited on 21 February 2025)

13 June 2024 apply from 2 February 2025 (in short: **AI Act**).[2] This AI Act is intended to improve the functioning of the internal market and promote the uptake of human-centric and trustworthy AI, while ensuring a high level of protection of health, safety, fundamental rights, including democracy, the rule of law and environmental protection and supportuig innovation (see Art. 1 para. 1 AI Act – *the following provisions refer to the AI Act unless otherwise stated*). In particular, the AI Act also aims to limit risks and is intended to provide greater legal certainty.

The provisions of the AI Act apply successively as follows (Art. 113):

02/02/2025	The date of application for Chapters I and II was 2 February 2025. These provisions in Articles 1 to 5 concern the subject matter, the scope of application, definitions, AI literacy and, above all, prohibited AI practices.
02/08/2025	From 2 August 2025, the EU Member States will have to set up notifying authorities, the EU will create an AI body and an advisory forum as part of the governance requirements and will issue provisions on the establishment of a scientific body. A sanction mechanism to be initiated by the EU Member States is also to take effect from this point in time, as are confidentiality requirements for the institutions named therein. *In Germany, the Draft Bill ("Referentenentwurf") for an implementation law is available as of 4 December 2024, although some voices consider it to be unconstitutional and contrary to European law.*
02/08/2026	Almost all other provisions of the AI Act will then apply from 2 August 2026.
02/08/2027	The classification rules for high-risk AI systems and the corresponding obligations will only apply from 2 August 2027.

(2) "AI systen"

Based on the AI Act, the question often arises for companies as to whether they are affected by it at all and when an AI system exists. The term "*AI system*" is defined in Art. 3 No. 1 of the 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".*

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401689

And yet this definition still contains many uncertainties in terms of interpretation. In order to provide a tool for handling this, the European Commission published more specific Guidelines on the definition of AI on 6 February 2025 on the basis of Article 96 (1) (f).[3] However, even these Guidelines point out that it is impossible to provide an exhaustive list of possible AI systems. Furthermore, the Guidelines are not binding, as only the European Court of Justice (ECJ) can provide a final binding interpretation.

(3) Categorisation into risk classes according to severity

If an entrepreneur in the EU comes to the conclusion that there is an AI system, they must consider which risk class the AI system should be assigned to. The higher the risks associated with the respective AI systems, the stricter the requirements to be placed on them.

(3.1) Prohibited AI practices

Some AI practices are completely prohibited (Art. 5). These include, for example - albeit in more detail - the use of intentionally manipulative or deceptive techniques or the subliminal influencing of a person outside of their awareness, the exploitation of a person's vulnerability, social scoring, the creation of databases for facial recognition through the untargeted reading of facial images from the internet or surveillance footage and much, much more. As many questions of demarcation remain unanswered here too, the European Commission published further (non-binding) Guidelines on 4 February 2020 to clarify the prohibited AI practices.[4]

(3.2) High risk AI systems

The requirements are particularly high for so-called high-risk AI systems (Art. 6). Roughly speaking, these include in particular the use as a safety component (if the product is subject to the harmonisation provisions listed in Annex I) or the inclusion in Annex III of the AI Act if no exception applies. Art. 8 et seqq. set out special requirements for them, such as the need for a risk management system, data governance procedures, technical documentation obligations, transparency and supervisory obligations, obligations of importers and distributors, obligations of providers (e.g. for conformity assessment – for AI systems with special risks in accordance with Art. 43 by independent notified bodies) and deployers, such as a fundamental rights impact assessment and much more.

[3] https://digital-strategy.ec.europa.eu/en/library/commission-publishes-guidelines-ai-system-definition-facilitate-first-ai-acts-rules-application

[4] https://digital-strategy.ec.europa.eu/en/library/commission-publishes-guidelines-prohibited-artificial-intelligence-ai-practices-defined-ai-act

(3.3) Certain AI systems with transparency requirements

For providers and deployers of certain AI systems, Art. 50 sets out special transparency and disclosure obligations, for example for providers of AI systems that are intended for direct interaction with natural persons (keyword: chatbots) or if image, sound and video content is generated or manipulated that is a deepfake.

(3.4) AI systems with little or no risk

For AI systems with no or only low risk, voluntary application of the AI requirements is possible (Art. 95)

(3.5) AI models with a general purpose

Beyond these items Art. 51 et seqq. regulate AI models with a general purpose (General Purpose Artificial Intelligence). The EU Commission published a First Draft of the General-Purpose AI Code of Practice on 14 November 2024[5] and a Second Draft on 19 December 2024.[6] This sets out general obligations for providers of general-purpose AI models and, in a second part, specific obligations for providers of general-purpose AI models with inherent systemic risks. A Third Draft is to follow for the time commencing 17 February 2025, with the Final Version to be available in May 2025.

(4) Differentiation between provider and deployer

Difficulties in the application of the AI Regulation can already arise for an entrepreneur when deciding whether he is only a deployer or already a provider.

According to the legal definition in Art. 3 No. 3 on the one hand, a '**provider**' is 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 and 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".

According to Art. 3 No. 4 on the other hand, a '**deployer**' is 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".

The obligations of a mere deployer are less than those of a provider. However, it is not always easy to determine the exact line of demarcation. Above all, a decision will have to be made

[5] https://digital-strategy.ec.europa.eu/en/library/first-draft-general-purpose-ai-code-practice-published-written-independent-experts

[6] https://digital-strategy.ec.europa.eu/en/library/second-draft-general-purpose-ai-code-practice-published-written-independent-experts

depending on the specific case as to the extent to which changes and customisations can still be made to acquired AI systems without slipping into provider status respectively without being upgraded from operator to provider.

It is pleasing that at least 'placing on the market' has also been legally defined as "the first making available of an AI system or a general-purpose AI model on the Union market" (Art. 3 No. 9); 'making available on the market' in turn means "the supply of an AI system or a general-purpose AI model for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge" (Art. 3 No. 10). Transactions outside of a commercial activity are therefore not covered. And 'putting into service' does not cover the supply of an AI system for any use, but only for the "first use directly to the deployer or for own use in the Union for its intended purpose" (Art. 3 No. 11).

(5) Remedies

Possible legal remedies are regulated in Art. 85 - 87. The right of anyone to submit complaints to the relevant market surveillance authority is enshrined in Art. 85. And Art. 86, which grants affected persons a right to explanations, is worth noting, too. Irrespective of this, the Whistle-blower Directive applies – in accordance with Art. 87 – to breaches of the AI Act.

(6) Penalties

Art. 99 - 101 provide for sanctions in the event of violations of the provisions of the AI Act. The range of penalties is remarkably high when it comes to infringements by companies, notified bodies or even EU Member State authorities. For example, penalties of up to €35 million can be imposed for an infringement of prohibited AI practices (Art. 5) or, in the case of companies, 7% of the total worldwide annual turnover for the preceding financial year, whichever is higher (Art. 99 (3)).

Infringements of other obligations, such as obligations of providers of high-risk AI systems (Art. 16), obligations of authorised representatives (Art. 22), importers (Art. 23), distributors (Art. 24), deployers (Art. 26) and transparency obligations (Art. 50) can be sanctioned with penalties of up to €15 million or 3% of annual global turnover. The range of penalties for providers of general-purpose AI models in accordance with Art. 101 is also within this range.

Even if false, incomplete or misleading information is provided in response to requests for information from notified bodies or competent national authorities, the penalties can still amount to up to EUR 7.5 million or up to 1% of annual worldwide turnover for companies.

Nevertheless, for small and medium-sized enterprises, including start-ups, the lower amount from the percentages or sums is taken as a basis (Art. 99 para. 6).

A lot of criteria are defined for determining the amount of the penalty, which must be taken into account, starting with the type, gravity and duration of the infringement (Art. 99 para. 7).

Surprisingly, the AI Regulation does not include a definition of its own of which entity is actually to be regarded as an 'undertaking'. According to recital (150) sentence 3 of the European General Data Protection Regulation (GDPR), the concept of undertaking under antitrust law within the meaning of Art. 101 and 102 TFEU is decisive for legal stipulations imposing penalties (see ECJ, Deutsche Wohnen, Case C-807/121, para. 55), which is, however, broader than the concept of undertaking defined in Art. 4 No. 18 GDPR for the GDPR. According to the ECJ's understanding of the term under antitrust law, '*any entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed*' is an undertaking (ECJ, Höfner and Elser, Case C-41/90 para. 21). In this sense, companies can also consist of several legal or natural persons. Presumably, a decision by the ECJ must also bring final clarity to the AI Act.

If EU institutions commit infringements, a much lower penalty applies – the impression is that the European legislator wanted to do itself a favour here (Art. 100). Even for violations of the prohibited AI practices listed in Art. 5, fines for EU institutions only amount to up to EUR 1.5 million (Art. 100 (2)), whereas they can be up to EUR 35 million for other actors, as mentioned above.

II. Data protection law

Irrespective of the AI Regulation, the General Data Protection Regulation must continue to be observed.

III. Withdrawal of the European AI Liability Directive

Concerning the European Commission's idea to issue also an AI Liability Directive there is another development of events: In contrast to the AI Act, this is not about an ex-ante situation in order to avoid damage as far as possible, but about an ex-post reaction if damage has actually occurred as a result of AI use. In February 2025, the Commission withdrew[7] its Draft from 2022[8]. If the use of AI leads to damage, an injured party will have to see for the time being whether they can claim compensation at all in the maze of heterogeneous national regulations of the EU Member States. The Commission will reconsider the planned approach.

[7] https://commission.europa.eu/document/download/7617998c-86e6-4a74-b33c-249e8a7938cd_en?filename=COM_2025_45_1_annexes_EN.pdf, page 26 No. 32.

[8] https://commission.europa.eu/business-economy-euro/doing-business-eu/contract-rules/digital-contracts/liability-rules-artificial-intelligence_en

IV. However, a new EU Product Liability Directive and a new Product Safety Regulation

However, a **new General Product Liability Directive (EU) 2024/2853** for defective products[9] was issued and came into force on 8 December 2024 with regard to no-fault (ex-post) liability, which must be transposed into national law by the EU Member States **by 9 December 2026**. It will then replace the 40-year-old Product Liability Directive 85/374/EEC. While it was disputed under the old Product Liability Directive whether the term 'product' also included software, this will be expressly affirmed in future. Easier proof is provided for injured parties, including the disclosure of evidence and presumption rules regarding the burden of proof. The destruction or the corruption of data may also give the right to compensation under certain circumstances. Maximum liability limits have been abolished.

Compared to the new **General Product Safety Regulation (EU) 2023/988 of 10 May 2023 (GPSR)**[10] for ex ante safety measures, which applies from 13 December 2024 and is directly applicable in the EU Member States, the AI Act in turn contains considerably more specific provisions, so that provisions of the General Product Safety Regulation can only be applied complementary to AI products, if at all, for single aspects (see Art. 2 of the General Product Safety Regulation).

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Conclusion:

AI is an area that is developing at an incredible speed. At the same time, many legal issues will arise or are already acute, for some of which the new AI Act should be consulted with the gradual entry into force of its provisions, supplemented by (non-binding) Guidelines from the Commission for further interpretation and clarification.

However, where no special provisions exist, it must always be examined to what extent more general standards, for example from product safety law and product liability law, apply.

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9 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202402853

10 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0988

Contact (Legal notice on the website: https://www.haver-mailaender.de/en/impressum)

Rechtsanwalt
Dr. Thomas M. Grupp
Maître en droit (Aix-Marseille III)
Tel.: +49 (0) 711/22744-66
tg@haver-mailaender.de