WORK SAMPLE · POLICY BRIEF

The Digital Omnibus on AI: What Changes for Deployers of High-Risk AI under Annex III

Policy brief on Regulation (EU) 2026/1744

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Summary

Regulation (EU) 2026/1744 postpones the high-risk obligations for deployers of AI systems under Annex III to 2 December 2027, but leaves the wording of the human oversight provisions unchanged. It weakens the AI literacy obligation and makes it easier to link the fundamental rights impact assessment with the data protection impact assessment, but it does not amend the GDPR, so Article 22 GDPR and the CJEU's SCHUFA judgment already apply today. Deployers should use the extra time to put oversight, documentation and provider contracts in place, because the deadlines are fixed and key questions of interpretation remain open.

What has changed

Regulation (EU) 2026/1744 of 8 July 2026 amends the AI Act, Regulation (EU) 2024/1689. It has been in force since 27 July 2026 [1].

Deadlines. Chapter III, Sections 1 to 3, applies to high-risk systems under Article 6(2) and Annex III from 2 December 2027 instead of 2 August 2026, with the exception of Article 6(5). For Annex I, the date is 2 August 2028 [1, 2]. The dates are fixed and do not depend on whether technical standards are available [1]. The prohibitions (Article 5) and the transparency obligations (Article 50) are not part of the high-risk postponement [1, 2]. The new prohibitions in Article 5(1)(ba) and (bb) and Article 5(1a) and (1b) apply from 2 December 2026 (amended Article 113, third paragraph, point (a)). For the provider obligation under Article 50(2), systems placed on the market before 2 August 2026 have a transition period until 2 December 2026 (Article 111(4)) [1].

Human oversight. The wording of Articles 14 and 26 is unchanged [1]. Under Article 26(2), deployers assign human oversight to natural persons who have the necessary competence, training and authority, as well as the necessary support [2]. For Annex III, this applies from 2 December 2027.

AI literacy. Under the amended Article 4, providers and deployers must still take measures to support the development of AI literacy of their staff. They do not have to guarantee a specific individual level [1]. The previous wording ("to their best extent") did not guarantee results either [2]. The Commission's FAQs reflect the new wording only in part. According to the FAQ, no certificate is needed, but relying on the instructions for use alone is not enough for deployers of high-risk AI [12].

Fundamental rights impact assessment (FRIA). Under the amended Article 27(4), deployers may refer to or incorporate parts of a data protection impact assessment (DPIA) where those parts already meet the requirements of Article 27. The remaining points must still be assessed [1]. Since 16 November 2026, the Commission has been consulting on the draft questionnaire template [11]. For Annex III, Article 27 applies from 2 December 2027 [1].

Right to explanation. Article 86 was neither amended nor expressly postponed [1]. It covers decisions that a deployer takes on the basis of the output of a high-risk AI system listed in Annex III (except point 2) and that produce legal effects or similarly significantly affect the person in a way they consider adverse to their health, safety or fundamental rights. The affected person then has a right to clear and meaningful explanations of the role of the AI system in the decision-making procedure and the main elements of the decision taken. The right applies only to the extent that it is not otherwise provided for under Union law (Article 86(3)) [2].

Existing systems. High-risk systems placed on the market or put into service before Chapter III applies (Annex III: 2 December 2027) are subject to the high-risk rules only after a significant change in their design. Article 5 applies regardless (amended Article 111(2)). Providers and deployers of high-risk systems intended to be used by public authorities must meet the requirements by 2 August 2030 in any case [1].

Fundamental rights protection. Article 77 has been redrafted. Market surveillance authorities and fundamental rights bodies must now cooperate closely (new Article 77(1b)) [1].

What this means for public authorities and companies

Article 22 GDPR already applies. The AI Act leaves the GDPR unaffected, without prejudice to Articles 4a and 59 of the AI Act (amended Article 2(7)). The postponement therefore does not affect Article 22 GDPR [1]. Article 22 covers decisions based solely on automated processing that produce legal effects or similarly significant effects, not every use of AI [3]. Under the SCHUFA judgment of 7 December 2023 (C-634/21), the automated generation of a score can itself be such a decision if a third party draws strongly on it to establish, implement or terminate a contractual relationship. Not every score is prohibited [4].

AI Act oversight does not replace the Article 22 GDPR test. Articles 14 and 26(2) of the AI Act are useful guidance, but they are not the test for whether Article 22 GDPR applies. What matters is whether a person actually reviews the specific decision and can change it. A formal sign-off is not automatically enough [3, 8]. Human intervention under Article 22(3) GDPR is a safeguard. It does not turn the decision into a human one after the fact [3, 8].

Two levels of competence. The weaker Article 4 does not affect the requirements for oversight persons under Article 26(2). Breaches of Article 26 can be fined under Article 99(4) of the AI Act. For Article 4, neither that provision nor the German AI Market Surveillance and Innovation Promotion Act (KI-MIG) contains a specific fine [1, 2, 9].

Explanation in individual cases. The right of access under Article 15(1)(h) GDPR already applies. According to the Dun & Bradstreet Austria judgment of 27 February 2025 (C-203/22), it covers intelligible information about the procedures and principles actually applied. Where trade secrets are claimed, the information must be provided to the supervisory authority or court, which weighs the interests [5]. This is not a full substitute for Article 86. Article 15 applies to automated decisions under Article 22, Article 86 to decisions based on the output of a high-risk system listed in Annex III (except point 2). Where Article 15(1)(h) GDPR already grants the right, Article 86 does not apply (Article 86(3)) [2, 3].

German supervision. The KI-MIG is Article 1 of the German act implementing the AI Act (BGBl. 2026 I No. 223) and has been in force since 29 July 2026 [9]. Supervision is hybrid. The Federal Network Agency (BNetzA) is the central point of contact and complaints body, coordinates supervision and carries out market surveillance unless the act provides otherwise. Alongside it are, among others, BaFin where there is a direct link to regulated financial activities, state (Länder) authorities and an independent AI market surveillance chamber [9]. BNetzA lists as fundamental rights bodies the Federal Commissioner for Data Protection (BfDI), 17 state data protection authorities, the Federal Anti-Discrimination Agency and the Berlin LADG ombudsperson office [10]. Under the amended Article 77(1) and (1a), they can request information and documentation through the competent market surveillance authority. Where necessary, that authority obtains it from the provider or deployer. If the documentation is insufficient, they can ask the market surveillance authority to organise technical testing (Article 77(3)) [1, 2].

	Public authorities and bodies	Companies
FRIA	From 2 December 2027, required for bodies governed by public law, except for critical infrastructure (Annex III point 2) [1, 2]	From 2 December 2027, required for private entities providing public services (except point 2) and for creditworthiness assessment and life and health insurance (Annex III point 5(b) and (c)) [1, 2]
Fines	Excluded under Section 17(2) KI-MIG for the provisions listed there; other supervisory measures remain possible [9]	Article 99 AI Act; nationally up to EUR 50,000 for certain breaches of Article 27(1) to (3) and of Article 86 for Annex III points 1, 3, 4 and 5 (Section 15 KI-MIG) [9]
Advice	Case-by-case advice from BNetzA (Section 12, second sentence, no. 2 KI-MIG) only under an administrative agreement with the competent ministry [9]	Not available (public bodies only) [9]

Open questions

When does Article 86 take effect in practice? Formally, Article 86 has applied since 2 August 2026 [2]. It requires a "high-risk AI system listed in Annex III", but the classification rules only apply from December 2027. How this element applies until then is unresolved [1, 2]. In C-806/24 (Yettel Bulgaria), the CJEU did not rule on the merits on 3 June 2026 after the main action was withdrawn [6]. The reference in C-245/25 (DZI) does not expressly raise the new timing conflict [7]. This also affects the fine under Section 15(2) KI-MIG [9].

What happens to Article 22 GDPR? The separate data omnibus (COM(2025) 837) has not been adopted. The Council mandate of 21 October 2026 deletes from the article text the clause under which contractual necessity would apply even where a person could take the decision as well. Recital 38, however, retains the idea. The Council proposes a redraft of the whole article, and Parliament has no committee decision yet [13, 14, 15].

How far does grandfathering extend? The wording of Article 111(2) refers to the individual system. Recital 39 of Regulation 2026/1744 extends protection to further units of the same type and model as long as the design remains unchanged. The decisive date is when the first unit was lawfully placed on the market or put into service [1]. Recitals are not binding. Whether courts will follow this reading is open. When updates or retraining amount to a significant change in design is not settled either.

How will Article 4 be enforced? The amended Article 99(1) requires penalties or other enforcement measures, not necessarily a specific fine [1]. In addition, Section 15 KI-MIG refers statically to the AI Act as worded on 13 June 2024 [9]. Whether Germany will adjust the KI-MIG is open.

Recommendations for deployers

1. **Take stock.** Record AI systems with a possible Annex III link, with purpose, own role, date of placing on the market or putting into service, and later changes. The date determines grandfathering; for series products, it is the date of the first unit of the same type and model (Recital 39 of Regulation 2026/1744) [1]. A deployer that changes the intended purpose so that a system becomes high-risk becomes a provider under Article 25 [2].
2. **Check Article 22 GDPR now.** For each decision process, record whether there is a decision based solely on automated processing with significant effects, including scores used by third parties [4]. Where a person is meant to decide, document that they review the individual case and can change the outcome [8]. Otherwise, an exception under Article 22(2) with the safeguards under paragraphs 3 and 4 is needed [3].
3. **Separate oversight from general training.** Tailor Article 4 measures to the context of use and document them internally [12]. Designate the oversight persons under Article 26(2) separately. They need the necessary competence, training and authority, as well as the necessary support [2].
4. **Plan the DPIA and FRIA together.** Structure the DPIA so that the FRIA can refer to it [1]. Address the remaining points of Article 27(1) separately, such as affected groups, risks of harm and remedial measures [2]. Comment on the draft questionnaire template in the consultation [11].

5. **Secure explainability by contract.** Require providers to supply the information needed for access requests under Article 15(1)(h) GDPR and for explanations under Article 86 [2, 5]. Set up a process for such requests now.

Sources

1. Regulation (EU) 2026/1744 of 8 July 2026 (Digital Omnibus on AI), OJ L, 24 July 2026.
2. Regulation (EU) 2024/1689 (AI Act), original version.
3. Regulation (EU) 2016/679 (GDPR).
4. CJEU, judgment of 7 December 2023, C-634/21, SCHUFA Holding.
5. CJEU, judgment of 27 February 2025, C-203/22, Dun & Bradstreet Austria.
6. CJEU, order of 3 June 2026, C-806/24, Yettel Bulgaria (in French).
7. Request for a preliminary ruling, C-245/25, DZI, OJ C, C/2026/276.
8. Article 29 Working Party, Guidelines on Automated individual decision-making and Profiling, WP251 rev.01.
9. German Act implementing the AI Act, BGBl. 2026 I No. 223 (Article 1: KI-MIG), in German.
10. Bundesnetzagentur, network meeting on fundamental rights protection, 9 September 2026, in German.
11. European Commission, consultation on the draft FRIA template, 16 November 2026.
12. European Commission, AI Literacy: Questions & Answers.
13. Council of the EU, press release of 21 October 2026 on the data omnibus.
14. Council of the EU, negotiating mandate ST 14756/26.
15. European Parliament, Legislative Observatory, procedure 2025/0360(COD).