EU COMMISSION

PROPOSAL FOR A

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the simplification of the implementation artificial intelligence rules, amending Regulation (EU) 2024/1689 (Digital Omnibus on AI)

Article I. Amendments to AI Act

(arts. 2, 3, 4, 4a (nuevo), 6, 10, 11, 17, 28, 29, 30, 42, 43, 49, 50, 56, 57, 60, 60a (nuevo), 63, 69, 72, 75, 77, 99, 108, 111, 113 y Anexo VIII)

Prg	Artículo modificado	
1	**2** *(Ámbito de aplicación)* Nueva redacción del apartado 2	
	Considerando[1]	-
	Descripción[2]	Is a technical change that is necessary to enable extending the real-world testing to high-risk AI systems embedded in products covered under Section B of Annex I
2	**3** *(Definiciones)* Nuevas definiciones 14a. SME 14b. SMC	
	Considerando	4. … In order to clarify the treatment of SME and SMCs in AI Act, it is necessary to introduce in its Article 3 definitions for SME and SMC, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC and Annex to Commission Recommendation 2025/3500/EC.
	Descripción	Adds legal definitions of SME and SMC
3	**4** *(Alfabetización en materia de IA)* Nueva redacción	
	Considerando	5. [AI literacy] …The experience shared by organisations reveals that a one-size-fits-all solution is not suitable for all types of providers and deployers, rendering a horizontal obligation ineffective in achieving this objective. Moreover, data indicates that imposing such an obligation may create an additional compliance burden, particularly

[1] Se refiere al Considerando del Reglamento modificador, tal como aparece en el borrador.
[2] Recoge la Descripción que aparece en el apartado "Detailed explanation of the specific provisions of the proposal", del número 5 (Other elements) de la propuesta.
Se recomienda consultar también el apartado 4 (Digital dimensions) de la sección "Legislative financial and digital Statement de la propuesta

		for small companies, whereas AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. In light of this, Article 4 should be amended to require the Commission and Member States to individually, collectively and in cooperation with relevant stakeholders encourage providers and deployers to provide a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, including through offering training opportunities, providing informational resources, allowing exchange of good practices and other non-legally binding initiatives.
	Descripción	Transforms the obligation for providers and deployers of AI systems with regards to AI literacy to an obligation for the Commission and Member States
4	**Nuevo artículo 4a** (sin título)	
	Considerando	6. [Personal data processing] Bias detection and correction constitute a substantial public interest because it protects natural persons from the biases' adverse effects, including discrimination. Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which the AI Act already provides for a legal basis authorising the processing of special categories of personal data under Article 9(2), point (g) of GDPR. Given that discrimination might result also from other AI systems and models, it is appropriate that AI Act provides for the legal basis of personal data processing, in compliance with Article 9(2), point (g) of GDPR and Article 10(2), point (g) of Regulation (EU) 2018/1725 [and Article 10, point (a) of Directive (EU) 2016/680] to allow, where necessary, processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards as specified in that Regulation that complement GDPR, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.
	Descripción	Introduces a new Article 4a, replacing Article 10(5) and providing a legal basis for providers and deployers of AI systems and AI models to exceptionally process special categories of personal data for the purpose of ensuring bias detection and correction under certain conditions.
5	**6** (*Reglas de clasificación de los sistemas de IA de alto riesgo)* Se suprime la última frase del apartado 4	
	Considerando	10. To streamline compliance and reduce the associated costs, providers of AI systems should not be required to register AI systems referred to in Article 6(3). Given that such systems are exempted from classifying as high-risk because they do not pose significant risk of harm to the health, safety or

		fundamental rights of persons, imposing registration requirements would constitute a disproportionate compliance burden. Nevertheless, a provider who considers that an AI system falls under the exemption in Article 6(3) maintains an obligation to document its assessment before that system is placed on the market or put into service. This assessment may be requested by national competent authorities.
	Descripción	Refer to the deletion of the obligation for providers to register AI systems in the EU database for high-risk systems under Annex III, where they have been exempted from classifying as high-risk under Article 6(3), because they are for instance only used for preparatory tasks.
6 7 8	**10** *(Datos y gobernanza de datos)* Nueva redacción del apartado 1 Se suprime el apartado 5 Nueva redacción del apartado 6	
	Considerando	6 (See art. 4a)
	Descripción	Introduces a new Article 4a, replacing Article 10(5) and providing a legal basis for providers and deployers of AI systems and AI models to exceptionally process special categories of personal data for the purpose of ensuring bias detection and correction under certain conditions.
9	**11** *(Documentación técnica)* Nueva redacción del segundo párrafo del apartado 1	
	Considerando	4. … In order to clarify the treatment of SME and SMCs in AI Act … Articles 11 and 17 include provisions to take facilitate compliance where SME are providers of high-risk AI systems, which should be extended to SMC.
	Descripción	Extend existing regulatory privileges for SME to SMC on technical documentation and putting in place a quality management system.
10	**17** (*Sistema de gestión de la calidad)* Nueva redacción del apartado 2	
	Considerando	4. … In order to clarify the treatment of SME and SMCs in AI Act … Articles 11 and 17 include provisions to take facilitate compliance where SME are providers of high-risk AI systems, which should be extended to SMC.
	Descripción	Extend existing regulatory privileges for SME to SMC on technical documentation and putting in place a quality management system
11	**28** *(Autoridades notificantes)* Nuevo apartado 8	
	Considerando	7. In order to ensure consistency, avoid duplication and minimize administrative burden for the

		designation procedure under this Regulation while maintaining the same level of scrutiny, a single application and single assessment procedure should be available for new conformity assessment bodies and notified bodies which are designated under Union harmonization legislation in Section A of Annex I, such as under Regulations (EU) 2017/745 and (EU) 2017/746, where such procedure is established under Union harmonization legislation. The single application and assessment procedure should facilitate, support and expedite the designation procedure under Regulation (EU) 2024/1689, while ensuring compliance with the requirements applicable to notified bodies under both AI Act and the Union harmonization legislation listed in Section A of Annex I.
	Descripción	Introduces a new provision on notifying authorities that require Member States to ensure that a conformity assessment body that applies for designation both under this Regulation and Union harmonization legislation listed in Section A of Annex I shall be provided with the possibility to submit a single application and undergo a single assessment procedure to be designated.
12	**29** *(Solicitud de notificación por parte de un organismo de evaluación de la conformidad)* Nueva redacción del apartado 4	
	Considerando	7 (Same as art. 28)
	Descripción	Contains a follow up change to the change under paragraph 11 and requires conformity assessment bodies to submit a single application in the cases referred to.
13	**30** *(Procedimiento de notificación)* Nuevo apartado 5a	
	Considerando	8. With a view to ensure the optimal application of AI Act, amendments should be made to ensure its overall consistency. Article 30 should be amended to allow the Commission to draw up a list of codes for the purpose of specifying the scope of the notification of notified bodies under AI Act, which is necessary for a smooth application of AI Act.
	Descripción	Empowers the Commission to adopt implementing acts to specify the scope of the notification of notified bodies.
14	**42** *(Presunción de conformidad con determinados requisitos)* Nuevo apartado 3	
	Considerando	9. AI Act and Regulation (EU) 2024/2847 [Cyber Resilience Act) are complementary laws that ensure the safety and cybersecurity of products with digital

		elements. It is necessary to ensure alignment of AI Act and Regulation (EU) 2024/2847, to allow for their smooth interplay. Where those high-risk AI systems fulfil the essential cybersecurity requirements set out in this Regulation, they should be deemed to comply with the cybersecurity requirements set out in Article 15 of AI Act in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued under this Regulation.
	Descripción	Adds a provision on the interplay with the Cyber Resilience Act clarifying compliance if a high-risk AI system is subject to the Cyber Resilience Act and AI Act.
15	**43** *(Evaluación de la conformidad)* Nueva redacción del apartado 3	
	Considerando	8. … The second sub-paragraph of paragraph 3 of Article 43 is amended to clarify that notified bodies which have been notified under Union harmonisation legislation listed in Section A of Annex I and which aim to assess high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, should apply for the designation as a notified body under this Regulation within 12 months after the adoption of the implementing act setting out list of codes for the purpose of specifying the scope of the notification of notified bodies under AI Act. Moreover, it should be clarified in that Article that where a high-risk AI system is both covered by the Union harmonization legislation listed in Section A of Annex I of AI Act and falls within one of the use-cases listed in Annex III of that Regulation, the provider shall follow the relevant conformity assessment procedure as required under the relevant harmonisation legislation listed in Section A of Annex I.
	Descripción	Clarifies the conformity assessment procedure in case a high-risk AI system is covered by Union harmonisation legislation under Section A of Annex I and in case a high-risk AI system is classified under both Annex I and Annex III.
16	**49** *(Registro)* Se suprime el apartado 2	
	Considerando	10. To streamline compliance and reduce the associated costs, providers of AI systems should not be required to register AI systems referred to in Article 6(3). Given that such systems are exempted from classifying as high-risk because they do not pose significant risk of harm to the health, safety or fundamental rights of persons, imposing registration requirements would constitute a disproportionate compliance burden. Nevertheless, a provider who

		considers that an AI system falls under the exemption in Article 6(3) maintains an obligation to document its assessment before that system is placed on the market or put into service. This assessment may be requested by national competent authorities.
	Descripción	Refer to the deletion of the obligation for providers to register AI systems in the EU database for high-risk systems under Annex III, where they have been exempted from classifying as high-risk under Article 6(3), because they are for instance only used for preparatory tasks.
17	**50** *(Obligaciones de transparencia de los proveedores y responsables del despliegue de determinados sistemas de IA)* Nueva redacción del apartado 7	
	Considerando	25. [Removal of implementing acts] In light of the objective to reduce implementation challenges for citizens, businesses and public administrations, it is essential that harmonised conditions for the implementation of certain rules are adopted only where strictly necessary. For that purpose, it is appropriate to remove empowerments of the Commission to adopt such harmonised conditions by means of implementing acts in cases where these conditions are not met, and thus to remove the empowerments of Article 50(7), Article 56(6), and Article 72(3) in AI Act.
	Descripción	Remove the Commission empowerments to adopt implementing acts to approve a code of practice for general purpose AI models and transparency obligations for certain AI systems.
18	**56** *(Códigos de buenas prácticas)* Nueva redacción del apartado 6	
	Considerando	25. [Same as arts. 50(7) and 72(3)]
	Descripción	Remove the Commission empowerments to adopt implementing acts to approve a code of practice for general purpose AI models and transparency obligations for certain AI systems
19	**57** *(Espacios controlados de pruebas para la IA)* Se añade un nuevo apartado 3a Nueva redacción del apartado 5 Nueva redacción del apartado 13 Nueva redacción del apartado 14	
	Considerando	11. Articles 57 and 60 of AI Act should be amended to strengthen further cooperation at EU level of AI regulatory sandboxes and at extending the scope of real-world testing outside AI regulatory sandboxes to high-risk AI systems listed in Annex I. In addition, it

		is appropriate that the AI Office should be able to also establish an AI regulatory sandbox at EU-level for AI systems that are covered by Article 75(1) of AI Act that should provide priority access to SMEs as required by Article 62(1)(a). By leveraging these infrastructures and facilitating cross-border collaboration, there is better streamlining of coordination and optimising of resources.
	Descripción	Introduces amendments to the rules on AI regulatory sandboxes, inter alia by providing the legal basis for the AI Office to introduce a regulatory sandbox on EU level for certain AI systems within its exclusive competence of supervisión and require Member States to strengthen cross-border cooperation of their sandboxes.
20	**60** *(Pruebas de sistemas de IA de alto riesgo en condiciones reales fuera de los espacios controlados de pruebas para la IA)* Nueva redacción del primer párrafo del apartado 1 Nueva redacción del apartado 2	
	Considerando	12. To foster innovation, it is also appropriate to extend the scope of real-world testing outside the AI regulatory sandboxes in Article 60 of AI Act, currently applicable to high-risk AI systems listed in Annex III of AI Act, and allow providers and prospective providers of high-risk AI systems listed in Annex I of that Regulation to also test such systems in realworld conditions. This is without prejudice to other Union or national law on the testing in real-world conditions of high-risk AI systems related to products covered by Union harmonisation legislation listed in Annex I of AI Act.
	Descripción	Introduces changes to the testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes, inter alia extending this opportunity to high-risk AI systems covered by Section A of Annex I.
21	**Nuevo artículo 60a.** *Testing of high-risk AI systems covered by Section B of Annex I in real-world conditions outside AI regulatory sandboxes*	
	Considerando	12. … To address the specific situation of high-risk AI systems covered by Section B of Annex I of that Regulation, a new Article 60a is added, allowing conclusions of voluntary agreements between the Commission and Member States to enable testing of such high-risk AI systems in real-world conditions.
	Descripción	Creates an additional legal basis for interested Member States and the Commission, on voluntary basis, to enter into written agreement to test high-risk AI systems referred to in Section B of Annex I in real world-conditions.

22	**63** (Excepciones para operadores específicos) Nueva redacción del apartado 3 (¿?)	
	Considerando	13. Article 63 of AI Act offers microenterprises who are providers of high-risk AI systems the possibility to benefit from a simplified way to comply with the obligation to establish a quality management system. With a view to facilitate compliance for more innovators, this privilege should be extended to all SMEs, including start-ups.
	Descripción	Extends the derogation to comply with certain elements of the quality management system required by Article 17 of AI Act in a simplified manner from microenterprises to SMEs
23	**69** *(Acceso a expertos por parte de los Estados miembros)* Nueva redacción del apartado 2 Se suprime el apartado 3	
	Considerando	14. Article 69 of AI Act should be amended to simplify the fee structure of the scientific panel. If Member States call upon its expertise, the fees they may be required to pay the experts should be equivalent to the remunerationn applicable to the Commission. Furthermore, to reduce the procedural complexity, the Member States should be able to consult the experts directly, without involvement of the Commission.
	Descripción	Removes an empowerment of the Commission for an implementing act relating to the reimbursement of experts of the scientific panel when called upon by Member States, to simplify the procedure.
24	**72** *(Vigilancia poscomercialización por parte de los proveedores y plan de vigilancia poscomercialización para sistemas de IA de alto riesgo)* Nueva redacción del apartado 3	
	Considerando	25. [Same as arts. 50(7) and 56(6) plus:] The removal of the empowerment to adopt a harmonised template for a post-market monitoring plan in Article 72(3) has as an additional benefit that it will offer more flexibility for providers of high-risk AI systems to put in place a system for postmarket monitoring that is tailored to their organisation. At the same time, recognizing the need to offer clarity how providers of high-risk AI systems are required to comply, the Commission should be required to publish guidance.
	Descripción	Replaces the empowerment of the Commission to adopt an implementing act with regard to the post-market monitoring plan.

25	**75** *(Asistencia mutua, vigilancia del mercado y control de sistemas de IA de uso general)* **Nuevo título:** Market surveillance and control of AI systems and mutual assistance Nueva redacción de su apartado 1 Nuevo apartado 1a Nuevo apartado 1b Nuevo apartado 1c Nuevo apartado 1d	
	Considerando	15. It is necessary to strengthen the governance system for AI systems based on general-purpose AI models by clarifying the role of the AI Office in monitoring and supervising compliance of such AI systems with AI Act, while excluding AI systems related to products covered by Union harmonisation legislation listed in Annex I of that Regulation. This change is intended to bring all AI systems based on general-purpose AI models developed by the same provider within the scope of the AI Office's supervision, and to ensure that sectoral authorities continue to supervise AI systems related to products covered by Union harmonisation legislation listed in Annex I of AI Act. To ensure effective supervision for such systems in accordance with the tasks and responsibilities assigned to market surveillance authorities under AI Act, the AI Office should be empowered to take the appropriate measures and decisions to adequately exercise its powers provided for in that Section and Regulation (EU) 2019/1020. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, the authorities involved in the application of AI Act should cooperate actively in the exercise of these powers, in particular where enforcement actions need to be taken in the territory of a Member State. 16. [DSA related change:] Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065, it is appropriate to grant the Commission the powers as the competent market surveillance authority under this Regulation where an AI system qualifies as a very large online platform or a very large online search engine within the meaning of Regulation (EU) 2022/2065, or is embedded in one. This should contribute to ensuring that the exercise of the Commission's supervision and enforcement powers under this Regulation and Regulation (EU) 2022/2065, as well as those applicable to general-purpose AI models integrated into such platforms or search engines, are carried out in a coherent manner. In the case of AI systems

		embedded in or qualifying as a very large online platform or search engine, the first point of entry for the assessment of the AI systems are the risk assessment, mitigating measures and audit obligations prescribed by Articles 34, 35 and 37 of Regulation (EU) 2022/2065, without prejudice to the AI Office's powers to investigate and enforce ex post noncompliance with the rules of this Regulation. In the context of the analysis of this risk assessment, mitigating measures and audits, the Commission services responsible for the enforcement of Regulation (EU) 2022/2065 may seek the opinion of the AI Office on the outcome of a potential earlier or parallel risk assessment carried out under this Regulation and the applicability of prohibitions under this Regulation. In addition, the AI Office and the relevant national authorities should coordinate their enforcement efforts with the authorities responsible for the enforcement of Regulation (EU) 2022/2065, including the Commission, in order to ensure that the principles of loyal cooperation, proportionality and non bis in idem are respected, while information obtained under the respective other Regulation would be used for the purposes of supervision and enforcement of the other only provided the undertaking agrees. In particular, the AI Office and the Commission services responsible for the enforcement of Regulation (EU) 2022/2065 should exchange views regularly and take into account, in their respective areas of competence, any fines and penalties imposed on the same legal person for the same facts through a final decision in proceedings relating to an infringement of other Union or national rules, so as to ensure that the overall fines and penalties imposed are proportionate and correspond to the seriousness of the infringements committed. 17. To operationalise the governance system of AI Act, it is necessary to define the enforcement powers and procedures for the exercise of those powers by the AI Office. The Commission should therefore adopt an implementing act to specify the enforcement powers of the AI Office, including the ability to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings identified in Article 99, and applicable procedures. This will ensure that the AI Office has the necessary tools to effectively monitor and supervise compliance with this Regulation, and to take enforcement actions against providers of AI systems that are found to be non-compliant. 18. Additionally, it is essential to ensure that effective procedural safeguards apply to providers of AI systems subject to the supervision of the AI

		Office. To this end, the provisions of Article 18 of Regulation (EU) 2019/1020 should apply mutatis mutandis to providers of AI systems, without prejudice to more specific procedural rights provided for in AI Act. 19. To enable access to EU market for AI systems which are in the scope of Article 75 of AI Act and subject to third party conformity assessment, the Commission should be enabled to carry out pre-market conformity assessments of those systems.
	Descripción	Makes amendments to the market surveillance and control of certain AI systems: • Point (a) changes the heading. • Point (b) reinforces the empowerment of the AI Office for the supervision of certain AI systems, that are based on a general-purpose AI model, and where the model and the system are provided by the same provider. At the same time, the provision excludes AI systems related to products covered under Annex I from that supervision. • Point (c) clarifies that AI systems embedded in designated very large online platforms or very large online search engines should be under the supervisión of the AI Office. • Point (d) empowers the Commission to adopt an implementing act to define the enforcement powers and the procedures for the exercise of those powers of the AI Office. • Point (e) introduces a reference to Regulation (EU) 2019/1020 ensuring certain procedural safeguards apply to providers covered.EN 8 EN • Point (d) empowers the Commission to carry out conformity assessments of AI systems within the scope of Article 75.
26	**77** *(Poderes de las autoridades encargadas de proteger los derechos fundamentales)* **Nuevo título:** Powers of authorities protecting fundamental rights and cooperation with market surveillance authorities Nueva redacción del apartado 1 Nuevo apartado 1a Nuevo apartado 1b	
	Considerando	20. Article 77 and the related provisions throughout Regulation (EU) 2014/1689 [sic] constitute an important mechanism within the governance of that Regulation, as they aim to enable authorities or bodies that are responsible to enforcé or supervise Union laws intended to protect fundamental rights to fulfil their mandate under specific conditions and to foster cooperation with market surveillance

		authorities responsible for the supervision and enforcement of that Regulation. It is necessary to clarify the scope of the cooperation rights and duties, as well as the scope of public authorities or bodies benefitting from them. With a view to reinforce the cooperation, it should be clarified in Article 77 that request to access information and documentation should be made to the competent market surveillance authority, which should be required to respond to reasoned requests, and that there should be a mutual obligation to cooperate between the involved authorities or bodies.
	Descripción	Makes amendments to powers of authorities or bodies protecting fundamental rights and cooperation with market surveillance authorities.
27	**99** *(Sanciones)* Nueva redacción del apartado 1 Nueva redacción del apartado 6	
	Considerando	4. … In order to clarify the treatment of SME and SMCs in AI Act … Article 99 sets out a privileged treatment of SME in the calculation of fines, which should be extended to SMC.
	Descripción	Extends existing regulatory privileges on penalties for SMEs to SMCs.
28	**108** *(Modificación del Reglamento (UE) 2018/1139)* Nueva redacción [Modifica el art. 17; añade un núm. 4 al art. 19; añade un núm. 3 al art. 27; añade un núm. 3 al art. 31; añade un núm. 3 al art. 32; añade un núm. 3 al art. 36; añade un núm. 3 al art. 39; añade un núm. 4 al art. 43; añade un núm. 3 al art. 47; añade un núm. 3 al art. 50; añade un núm. 3 al art. 53; añade un nuevo párrafo al art. 57; añade un núm. 3 al art. 58; da nueva redacción al apartado 2 y añade un núm. 4 al art. 111; del Regl. (UE) 201/1139]	
	Considerando	21. Article 108 sets out empowerments for the adoption of implementing legislation to amend Regulation (EU) 2018/1139. A technical correction extending specific articles of Regulation (EU) 2018/1139 is necessary to ensure that mandatory requirements for high-risk AI systems laid down in AI Act are fully covered when adopting relevant delegated or implementing acts on the basis of Regulation (EU) 2018/1139.
	Descripción	Makes amendments with regards to Regulation (EU) 2018/1139.
29	**111** *(Sistemas de IA ya introducidos en el mercado o puestos en servicio y modelos de IA de uso general ya introducidos en el mercado)* Nueva redacción del apartado 2 Nuevo apartado 4	

	Considerando	22. To provide sufficient time for providers of generative AI systems subject to marking obligations in Article 50(2) of AI Act to adapt their practices within a reasonable time without disrupting the market, it is appropriate to introduce a grace period of one year for providers who have already placed their systems on the market before the date of application of the rules on 2 August 2026. 23. To provide clarity on the entry into application of Regulation (EU) 2014/1689 [sic], the concept of placing on the market in context of Article 111(2) needs to be clarified. By derogation from the definition of placing on the market provided in Commission notice 'The "Blue Guide" on the implementation of EU product rules 2022', **for the purpose of Article 111(2), the concept of placing on the market should mean a broader category that covers a type and model of a high-risk AI system, and not each individual unit of that high-risk AI system. This means that if at least one individual unit of the high-risk AI system has been lawfully placed on the market or put into service before the date specified in Article 111, other individual units of the same type and model of high-risk AI system may continue to be placed on the market, made available or put into service on the Union market without any additional obligations, requirements or the need for additional certification, as long as the design of that highrisk AI system remains unchanged.** For the purposes of Article 111, the decisive factor is the date on which the first unit of that type and model of high-risk AI system was placed on the market or put into service on the Union market for the first time. Any significant change to the design of that AI system after the date specified in Article 111 should trigger the obligation of the provider to comply fully with all relevant provisions of this Regulation applicable to high-risk AI systems, including the conformity assessment requirements.
	Descripción	Paragraph 29 contains follow up changes to changes made under paragraph 30 and introduces a grace period of one year for providers who need to retroactively include technical solutions in their generative AI systems, to make them machine readable and detectable as artificially generated or manipulated.
30	**113** *(Entrada en vigor y aplicación)* Nueva redacción del 3er párrafo de la letra c) Nuevo apartado 3	

	Considerando	24. Article 113 establishes the entry into force and application of that Regulation, notably that the general entry into application is 2 August 2026. To provide sufficient time for adaptation of providers and deployers of AI systems to implement the transparency obligation in Article 50(2) as detailed in the Code of Practice under development, it is appropriate to envisage that while the rules remain applicable and market surveillance authorities can enforce them from 2 August 2026, rules on administrative fines under 99 and 100 with respect to infringements should apply from 2 August 2027.
	Descripción	Refer to the deletion of the obligation for providers to register AI systems in the EU database for high-risk systems under Annex III, where they have been exempted from classifying as high-risk under Article 6(3), because they are for instance only used for preparatory tasks. Introduces changes to the applicability of parts of the AI Act: • For the obligation under Article 50(2) AI Act a "grace period" is foreseen under which market surveillance authorities can impose penalties only from 2 August 2027. • It is clarified that the amendments necessary to integrate the high-risk requirements into sectoral law listed in Section B of Annex I apply with the Digital Omnibus' entry into force. Moreover, the Commission should present proposals for delegated or implementing acts to integrate these requirements into the existing law within 1 year.
-	**Anexo VIII** *(Información que debe presentarse para la inscripción en el registro de sistemas de IA de alto riesgo de conformidad con el artículo 49)* Se elimina la sección B *(Información que deben presentar los proveedores de sistemas de IA de alto riesgo de conformidad con el artículo 49, apartado 2)*	
	Considerando	10. To streamline compliance and reduce the associated costs, providers of AI systems should not be required to register AI systems referred to in Article 6(3). Given that such systems are exempted from classifying as high-risk because they do not pose significant risk of harm to the health, safety or fundamental rights of persons, imposing registration requirements would constitute a disproportionate compliance burden. Nevertheless, a provider who considers that an AI system falls under the exemption in Article 6(3) maintains an obligation to document its assessment before that system is placed on the market or put into service. This assessment may be requested by national competent authorities.

	Descripción	-