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Digital Package on Simplification

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)

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The Commission announced its commitment to an ambitious programme in the Communication on a Simpler and Faster Europe[1] to promote forward-looking, innovative policies that strengthen the Union's competitiveness and radically lighten the regulatory load for people, businesses and administrations, while maintaining the highest standard in promoting the Union's values.

Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence ('AI Act'), which entered into force on 1 August 2024, establishes a single market for trustworthy and human-centric artificial intelligence across the European Union. Its purpose is to promote innovation and the uptake of AI while ensuring a high level of protection for health, safety, and fundamental rights, including democracy and the rule of law.

The AI Act applies progressively until 2 August 2027, allowing experience gained in the early stages to inform later implementation. The most comprehensive provisions — those governing high-risk AI systems — will apply from 2 August 2026 and 2 August 2027. These include detailed requirements for data governance, transparency, documentation, human oversight, and robustness, ensuring that AI systems placed on the EU market are safe, transparent, and reliable.

The Commission has committed to a clear, simple, and innovation-friendly implementation of the AI Act, as set out in the **AI Continent Action Plan**[2] and the **Apply AI Strategy**[3]. The prohibitions of practices with unacceptable risks and the obligations related to general-purpose AI models are already applicable. Initiatives such as the General-Purpose AI Code of Practice, Commission guidelines and template, the AI Pact and the launch of the AI Act Service Desk deliver clarity regarding the applicable rules and support for their application. These efforts will continue, with further guidance and digital tools under preparation.

Building on early lessons from the roll-out, the Commission has run a series of consultation exercises, including a public consultation to identify implementation challenges with the AI Act, a Call for Evidence in preparation of the Digital Omnibus, a Reality Check allowing stakeholders to directly share their experiences from the implementation and an SME panel to identify their particular needs in the implementation.

These consultations revealed **implementation challenges** that could jeopardize the effective entry into application of key provisions. These include the slow designation of national competent authorities and conformity assessment bodies, as well as a lack of harmonised standards for the AI Act's high-risk requirements, guidance, and compliance tools. Such delays risk increasing costs for businesses and slowing innovation.

To address these challenges, the Commission is proposing **targeted simplification measures** aimed at ensuring timely, smooth, and proportionate implementation. These include:

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1 COM(2025) 47 final.
2 COM(2025)165 final.
3 COM(2025) 723 final.

- [Placeholder for measure still under consideration: **Aligning the implementation timelines** to address the uncertainty and challenges caused by the delay in availability of standards];
- Introducing a transitional grace period for the "watermarking" obligation for AI systems which have been placed on the market before the watermarking obligations became applicable;
- **Extending regulatory privileges granted to small and medium-sized enterprises (SMEs) to small mid-caps,** including simplified technical documentation requirements and special consideration in the application of penalties;
- Requiring the Commission and Member States to foster AI literacy instead enforcing unspecified obligation on operators;
- **Offering more flexibility in the post-market monitoring** by removing a prescription of a harmonised post-market monitoring plan;
- Reducing the registration burden for AI systems which are used in high-risk areas but for which the provider has concluded that they are not high-risk as they are only used for narrow or procedural tasks;
- **Facilitating compliance with data protection laws** by allowing providers and deployers of all AI systems and models to process special categories of personal data for ensuring bias detection and correction, subject to appropriate safeguards;
- **A broader use of AI regulatory sandboxes** and real-world testing, that will benefit Europe's strong industries such as automotive, and facilitating an EU-level AI regulatory sandbox.
- Clarifying the interplay between the AI Act and other EU legislation;
- **Centralising oversight** over AI embedded in very large online platforms and search engines with the AI Office.

Beyond the legislative measures, the Commission is taking **further measures to facilitate compliance and address the concerns raised** by stakeholders. Further guidance is under preparation, with a focus on offering clear and practical pathways to apply the AI Act in parallel with other Union legislation.

These simplification efforts will help ensure that the implementation of the AI Act is smooth, predictable, and innovation-friendly, enabling Europe to strengthen its position as the AI Continent and to pursue an AI-First approach safely.

- **Consistency with existing policy provisions in the policy area**

This proposal is part of a broader Digital Package on Simplification composed of measures aiming to reduce the administrative costs for compliance for businesses, administrations and citizens in the EU in application of several regulations of the EU's digital acquis without compromising the objectives of the underlying rules. It builds on the AI Act and is aligned with existing policies to make the EU a global leader in AI, to make the EU an AI continent and to promote the uptake of human-centric and trustworthy an AI.

- **Consistency with other Union policies**

This proposal is part of a series of simplification packages.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

This proposal has as its legal basis Article 114 of the Treaty on the Functioning of the European Union in line with the original legal basis for the adoption of the legal act which this proposal aims to amend.

• Subsidiarity (for non-exclusive competence)

Regulation (EU) 2024/1689 was adopted at EU level. Accordingly, amendments to this regulation need to be made at EU level.

• Proportionality

The initiative does not go beyond what is necessary to achieve the objectives of simplification and burden reduction without lowering the protection of health, safety and fundamental rights.

• Choice of the instrument

This proposal amends Regulation (EU) 2024/1689 adopted by ordinary legislative procedure and therefore the amendments of that Regulation need to be adopted by a regulation in accordance with the ordinary legislative procedure.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

• Ex-post evaluations/fitness checks of existing legislation

This proposal is accompanied by a Commission staff working document that includes a detailed overview of the impact of provisions of Regulation (EU) 2024/1689 that are proposed to be amended. It also provides an analysis of the positive impacts of the proposed measures, based on existing data, information gathered through consultations and during a Reality Check and through written inputs received from stakeholders through a Call for Evidence.

• Stakeholder consultations

Numerous consultation streams were carried out in the context of the proposal. Each were conceived as complementary to one another, addressing either different topical aspects or stakeholder groups concerned by the initiative.

In the initial scoping phase of the Digital Omnibus, three public consultations and calls for evidence were published on the key pillars of the proposal in the spring of 2025. A consultation ran on the Apply AI Strategy from 9 April to 4 June[4], another on the revision of the Cybersecurity Act from 11 April to 20 June[5], and finally another on the European Data Union Strategy from 23 May to 20 July[6]. Each questionnaire had a dedicated section (or at times multiple) on implementation and simplification concerns, directly related to the reflexions on the Digital Omnibus. Taken together, 718 unique responses were obtained as part of this first consultation stream.

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4 European Commission (2025) *Call for evidence on the Apply AI Strategy*. Available at: Apply AI Strategy – strengthening the AI continent

5 European Commission (2025) *Call for evidence on the revision of the Cybersecurity Act.* Available at: The EU Cybersecurity Act

6 European Commission (2025) *Call for evidence on the European Data Union Strategy*. Available at: European Data Union Strategy

A Call for Evidence on the Digital Omnibus was further published from 16 September to 14 October 2025[7]. Its aim was to cover the entirety of the initiative, and give the opportunity to stakeholders to comment on a more targeted set of proposals in a consolidated stream. 513 responses were received, by diverse stakeholder categories.

With a view of raising awareness on the Digital Omnibus among small and medium-sized enterprises (SMEs), and collect their feedback, a dedicated SME Panel was run via the Enterprise Europe Network (EEN) between 4 September to 16 October 2025. The EEN is the world's largest support network for small and medium-sized enterprises, and is implemented by the European Commission's European Innovation Council and SMEs Executive Agency (EISMEA). SME Panels are a consultation stream falling under this framework, whereby small and medium-sized enterprises have the opportunity to contribute their views to an upcoming policy initiative. In addition to the online written consultation (where 106 SME responses were gathered), the Commission also presented the Digital Omnibus proposal to SME associations part of the network, in a dedicated meeting on 1 October.

Finally, a large number of bilateral meetings were organized by Commission services with stakeholders throughout the year of 2025, to address specific concerns. Discussions were also held with Member States. In addition to bilateral exchanges, dedicated agenda points on the Digital Simplification Package were discussed at Council Working Parties in June and September 2025, where the Commission presented the state of play and asked for Member States' views.

Overall, stakeholder feedback converged as to the need for a simplified application of some of the digital rules. Better coherence, and a focus on optimisation of compliance costs, is largely welcome by stakeholders of all nature. Some divergence exists as to some of the more tailored measures. While discrepancies between stakeholder categories were noted across the Digital Omnibus span of targeted amendments, they are to be viewed through the prism of the specific legal change considered. A more detailed overview of these stakeholder consultations, and how they were reflected upon in the proposal, can be found in the Staff Working Document attached to the Digital Omnibus.

- **Collection and use of expertise**

In addition to the consultation streams outlined above, the Commission mainly relied on internal analysis for the purpose of this proposal.

- **Impact assessment**

The amendments put forward in the Digital Omnibus are technical in their nature. They are solely designed to ensure a more efficient implementation of rules that were already agreed at political level. They are not prone to multiple policy options that could meaningfully be tested and compared in an impact assessment report.

The attached Staff Working Document goes in depth into the rationale for such amendments, the stakeholder views on the different measures, and presents costs savings and other types of impacts the proposals may entail. In many cases, it builds on the respective Impact Assessments that were originally done for the different acts.

The Staff Working Document thereby serves as a referral point to inform the co-legislators' debate on the proposal, as well as the general public, in a clear and engaged way.

[7] European Commission (2025) *Call for evidence on the digital package and omnibus*. Available at: Simplification – digital package and omnibus

- **Regulatory fitness and simplification**

The Digital Omnibus entails very strong burden reduction for businesses, as well as for public administrations and citizens. Initial estimates foresee possible savings of at least [placeholder, to be added in line with figures of staff working document]. Non-quantifiable benefits are also largely expected, notably from a streamlined set of rules which will facilitate their engagement and compliance thereof.

SMEs already benefit from regulatory privileges under a certain number of provisions in the Regulation (EU) 2024/1689. Some regulatory privileges already provided to SMEs are extended to small mid-caps (SMCs). Since SME and SMC are disproportionality more impacted by compliance burden, it is expected that they will particularly benefit from the proposed simplification measures.

The proposal is also fully consistent with the Commission's 'Digital Check', aimed at ensuring the adequate alignment of policy proposals with digital environments. More details on this can be found in the attached Legislative and Financial Digital Statement's Chapter 4.

- **Fundamental rights**

The AI Act is expected to enhance and promote the protection of multiple rights set out in the Charter,[8] as well as positively affect the rights of a number of special groups.[9] At the same time, the AI Act imposes some restrictions on certain rights[10], which are proportionate and limited to the minimum necessary. In light of the targeted nature of envisaged amendments, which do not touch on the scope of the regulated AI systems or on the substantive requirements applicable to these systems, they are not expected to modify such impact.

4. BUDGETARY IMPLICATIONS

The proposal foresees a modification to the supervision and enforcement system of Regulation (EU) 2024/1689, whereby the oversight over certain AI systems will be reallocated to the Commission's AI Office. In addition, to facilitate compliance for operators, the AI Office should set up an EU-level AI regulatory sandbox. In order to face these new tasks, it is necessary to appropriately resource the Commission's services, which is estimated to require [55] FTE. These implications have to be weighed against reduced budgetary implications for Member States, who no longer have to ensure the oversight for those certain AI systems. A detailed overview of the costs involved is provided in the 'financial statement' of this proposal.

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8 In detail: the right to human dignity (Article 1), respect for private life and protection of personal data (Articles 7 and 8), non-discrimination (Article 21) and equality between women and men (Article 23), freedom of expression (Article 11) and freedom of assembly (Article 12), right to an effective remedy and to a fair trial, the rights of defence, and the presumption of innocence (Articles 47 and 48), right to a high level of environmental protection and the improvement of the quality of the environment (Article 37).

9 In detail: workers' rights to fair and just working conditions (Article 31), a high level of consumer protection (Article 28), the rights of the child (Article 24) and the integration of persons with disabilities (Article 26).

10 In detail: the freedom to conduct business (Article 16) and the freedom of art and science (Article 13).

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission will monitor the implementation and application of new provisions and compliance with them. Furthermore, the Regulation to be amended by this proposal is subject to regular evaluation of its efficiency, effectiveness in reaching their objectives, relevance, coherence and value added in accordance with better regulation principles. This proposal does not require an implementation plan.

- **Explanatory documents (for directives)**

Not applicable.

- **Detailed explanation of the specific provisions of the proposal**

Article 1 introduces changes to Regulation (EU) 2024/1689 ('AI Act'). In particular,

- Paragraph 1 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.
- Paragraph 2 adds legal definitions of SME and SMC.
- Paragraph 3 transforms the obligation for providers and deployers of AI systems with regards to AI literacy to an obligation for the Commission and Member States.
- Paragraph 4 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.
- Paragraphs 5, 16 and 30 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.
- Paragraphs 6, 7 and 8 contain editorial follow-up changes to changes made under paragraph 4.
- Paragraphs 9 and 10 extend existing regulatory privileges for SME to SMC on technical documentation and putting in place a quality management system.
- Paragraph 11 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.
- Paragraph 12 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.
- Paragraph 13 empowers the Commission to adopt implementing acts to specify the scope of the notification of notified bodies.

- Paragraph 14 adds a provision on the interplay with Regulation (EU) 2024/2847 (the 'Cyber Resilience Act') clarifying compliance if a high-risk AI system is subject to the Cyber Resilience Act and Regulation (EU) 2024/1689 **(**'AI Act').
- Paragraph 15 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.
- Paragraphs 17 and 18 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.
- Paragraph 19 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 supervision and require Member States to strengthen cross-border cooperation of their sandboxes.
- Paragraph 20 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.
- Paragraph 21 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.
- Paragraph 22 extends the derogation to comply with certain elements of the quality management system required by Article 17 of Regulation (EU) 2024/1689 **(**'AI Act') in a simplified manner from microenterprises to SMEs.
- Paragraph 23 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.
- Paragraph 24 replaces the empowerment of the Commission to adopt an implementing act with regard to the post-market monitoring plan.
- Paragraph 25 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 supervision 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.

    - Point (d) empowers the Commission to carry out conformity assessments of AI systems within the scope of Article 75.
- Paragraph 26 makes amendments to powers of authorities or bodies protecting fundamental rights and cooperation with market surveillance authorities.
- Paragraph 27 extends existing regulatory privileges on penalties for SMEs to SMCs.
- Paragraph 28 makes amendments with regards to Regulation (EU) 2018/1139.
- 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.
- Paragraph 30 introduces changes to the applicability of parts of the Regulation (EU) 2024/1689 **(**'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.

Article 2 provides the rule of entry into force and the binding nature of this regulation.

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)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[11], [where necessary]

Having regard to the opinion of the Committee of the Regions[12], [where necessary]

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The Commission announced its commitment to an ambitious programme in the Communication on a Simpler and Faster Europe[13] to promote forward-looking, innovative policies that strengthen the Union's competitiveness and radically lighten the regulatory load for people, businesses and administrations, while maintaining the highest standard in promoting the Union's values.

(2) Regulation (EU) 2024/1689 establishes harmonised rules on artificial intelligence and aims to improve the functioning of the internal market, to promote the uptake of human-centric and trustworthy artificial intelligence, while ensuring a high level of protection of health, safety and fundamental rights, and to support innovation. Regulation (EU) 2024/1689 applies progressively until 2 August 2027. The progressive entry into application allows that the experience gathered in implementing the first parts of the rules can feed into the preparations for the parts that are yet to apply. In this context, the delayed preparation of standards, which should provide technical solutions for providers to ensure compliance of high-risk AI systems, and the delayed establishment of the governance and the conformity assessment system on national level result in a compliance burden that is heavier than expected. In addition, consultation of stakeholders has revealed the need for additional measures that facilitate the implementation and compliance, without reducing the level of protection for health, safety and fundamental rights from risks that AI can pose that the rules of Regulation (EU) 2024/1689 seek to achieve.

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11 OJ C […], […], p. […].
12 OJ C […], […], p. […].
13 COM(2025) 47 final.

(3) Consequently, this Regulation sets out targeted amendments to Regulation (EU) 2024/1689. It is necessary to address certain implementation challenges through amendments, with a view that the rules can effectively fully enter into application.

(4) *[SMC changes]* Enterprises outgrowing the SME definition – the 'small mid-cap enterprises' ('SMCs') – play a vital role in the Union's economy. Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, where administrative burden is concerned, they face similar challenges as SMEs, leading to a need for proportionality in legislation and for targeted support. To enable the smooth transition of SMEs into SMCs, it is important to address in a coherent manner the cliff-effect that may arise once they outgrow the segment of SMEs and are faced with rules that apply to large enterprises. To make business easier for SMCs and reduce their administrative burden, the Commission has adopted a Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2016/679, (EU) 2016/1036, (EU) 2016/1037, (EU) 2017/1129, (EU) 2023/1542 and (EU) 2024/573 as regards the extension of certain mitigating measures available for small and medium sized enterprises to small mid-cap enterprises and further simplification measures[14]. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs, in taking forward these objectives. In order to clarify the treatment of SME and SMCs in Regulation (EU) 2024/1689, 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. 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. Article 99 sets out a privileged treatment of SME in the calculation of fines, which should be extended to SMC.

(5) *[AI literacy]* Article 4 sets out an obligation for all providers and deployers of AI systems to ensure AI literacy of their staff. AI literacy is crucial to equip providers, deployers and affected persons with the necessary notions to make informed decisions regarding AI systems. However, 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 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. The European Artificial Intelligence Board ('Board') will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community.

(6) *[Personal data processing]* Bias detection and correction constitute a substantial public interest because it protects natural persons from the biases' adverse effects,

[14] COM(2025) 501 final.

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 Regulation (EU) 2016/679. Given that discrimination might result also from other AI systems and models, it is appropriate that Regulation (EU) 2024/1689 provides for the legal basis of personal data processing, in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 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 Regulation (EU) 2016/679,Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.

(7) *[Notification of notified bodies/changes in Articles 28, 29]* 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 Regulation (EU) 2024/1689 and the Union harmonization legislation listed in Section A of Annex I.

(8) *[Article 30 and 43]* With a view to ensure the optimal application of Regulation (EU) 2024/1689, 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 Regulation (EU) 2024/1689, which is necessary for a smooth application of Regulation (EU) 2024/1689. 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 Regulation (EU) 2024/1689. 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 Regulation (EU) 2024/1689 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.'

(9) *[Article 42]* Regulation (EU) 2024/1689 and Regulation (EU) 2024/2847 are complementary laws that ensure the safety and cybersecurity of products with digital elements. It is necessary to ensure alignment of Regulation (EU) 2024/1689 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 Regulation (EU) 2024/1689 in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued under this Regulation.

(10) [*Articles 49(2), 6(4) and Annex VIII section B*] 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.

(11) *[Article 57]* Articles 57 and 60 of Regulation (EU) 2024/1689 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 Regulation (EU) 2024/1689 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.

(12) *[Article 60 and 60a]* To foster innovation, it is also appropriate to extend the scope of real-world testing outside the AI regulatory sandboxes in Article 60 of Regulation (EU) 2024/1689, currently applicable to high-risk AI systems listed in Annex III of Regulation (EU) 2024/1689, and allow providers and prospective providers of high-risk AI systems listed in Annex I of that Regulation to also test such systems in real-world 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 Regulation (EU) 2024/1689. 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.

(13) *[Article 63]* Article 63 of Regulation (EU) 2024/1689 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.

(14) *[Article 69]* Article 69 of Regulation (EU) 2024/1689 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 remuneration 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.

(15) *[Article 75]* 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 Regulation (EU) 2024/1689, 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 Regulation (EU) 2024/1689. To ensure effective supervision for such systems in accordance with the tasks and responsibilities assigned to market surveillance authorities under Regulation (EU) 2024/1689, 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 Regulation (EU) 2024/1689 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* non-compliance 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 Regulation (EU) 2024/1689, 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 Regulation (EU) 2024/1689.

(19) To enable access to EU market for AI systems which are in the scope of Article 75 of Regulation (EU) 2014/1689 and subject to third party conformity assessment, the Commission should be enabled to carry out pre-market conformity assessments of those systems.

(20) *[Article 77]* Article 77 and the related provisions throughout Regulation (EU) 2014/1689 constitute an important mechanism within the governance of that Regulation, as they aim to enable authorities or bodies that are responsible to enforce 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.

(21) *[Article 108]* 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 Regulation (EU) 2024/1689 are fully covered when adopting relevant delegated or implementing acts on the basis of Regulation (EU) 2018/1139.

(22) *[Article 111]* To provide sufficient time for providers of generative AI systems subject to marking obligations in Article 50(2) of Regulation (EU) 2024/1689 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, 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'[15], 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

[15] OJ C 247, 29.6.2022, p. 1.

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 high-risk 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.

(24) *[Article 113]* 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.

(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 Regulation (EU) 2024/1689. 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 post-market 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.

(26) In order to ensure legal certainty as soon as possible, with a view to the imminent general application of Regulation (EU) 2024/1689, this Regulation should enter into force as a matter of urgency,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2024/1689

Regulation (EU) 2024/1689 is amended as follows:

(1) in Article 2, paragraph 2 is replaced by the following:

‘2. For AI systems classified as high-risk AI systems in accordance with Article 6(1) related to products covered by the Union harmonisation legislation listed in Section B of Annex I, only Article 6(1), Article 60(10), Articles 102 to 109 and Article 111 apply. Article 57 applies only in so far as the requirements for high-risk AI systems under this Regulation have been integrated in that Union harmonisation legislation.;

(2) in Article 3, the following definitions are added:

'(14a) 'SME' means a small or medium-sized enterprise within the meaning of the Annex to Commission Recommendation 2003/361/EC;

(14b) 'SMC' means a small mid-cap enterprise within the meaning of the Annex to Commission Recommendation 2025/3500/EC;';

(3) Article 4 is replaced by the following:

''The Commission and Member States shall encourage providers and deployers of AI systems to take measures to ensure a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.';

(4) the following Article 4a is inserted:

'To the extent that it is necessary for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with Article 10 paragraph (2), points (f) and (g) of this Regulation, the providers and deployers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions must be met in order for such processing to occur:

(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;

(b) the special categories of personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;

(c) the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;

(d) the special categories of personal data are not to be transmitted, transferred or otherwise accessed by other parties;

(e) the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;

(f) the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was necessary to detect and correct biases, and why that objective could not be achieved by processing other data.

2. Providers and deployers of other AI systems and models may respectively rely on paragraph 1 of this Article where necessary for the purpose and under the safeguards set out in this paragraph.;

(5) in Article 6(4), the second sentence is deleted.

(6) in Article 10, paragraph 1 is amended by the following:

'1. High-risk AI systems which make use of techniques involving the training of AI models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 4 of this Article and Article 4a paragraph 1 of this Regulation whenever such data sets are used.';

(7) in Article 10, paragraph 5 is deleted.

(8) in Article 10, paragraph 6 is replaced by the following:

'For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2 to 4 of this Article and Article 4a paragraph 1 of this Regulation apply only to the testing data sets.';

(9) in Article 11(1), the second subparagraph is replaced by the following:

'That technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in this Section and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV. SMCs and SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner. To that end, the Commission shall establish a simplified technical documentation form targeted at the needs of small and microenterprises. Where an SMC or SME, including a start-up, opts to provide the information required in Annex IV in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purposes of the conformity assessment.';

(10) In Article 17, paragraph 2 is replaced by the following:

'2. The implementation of the aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation, in particular, if the companies are SMCs or SMEs, including start-ups. Providers shall, in any event, respect the degree of rigour and the level of protection required to ensure the compliance of their high-risk AI systems with this Regulation.';

(11) in Article 28, the following paragraph 8 is inserted:

'Notifying authorities designated under this Regulation responsible for AI systems covered by Union harmonisation legislation listed in Section A of Annex I shall be established, organized and operated in such a way as to ensure that the 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 under this Regulation and Union harmonization legislation listed in Section A of Annex I, where that Union harmonisation legislation provides for such single application and single assessment procedure.

The single application and single assessment procedure referred to in this Article shall also be made available to notified bodies already designated under the harmonization legislation listed in Section A of Annex I, when those notified bodies apply for designation under this Regulation, provided that the relevant Union harmonization legislation foresees such a procedure.

This single application and single assessment shall avoid any unnecessary duplications, build on the existing procedures for designation under Union harmonisation legislation listed in Section A of Annex I and ensure compliance with the requirements both relating to notified bodies under this Regulation and Union harmonisation legislation listed in Section A of Annex I.;

(12) In Article 29, paragraph 4 is replaced by the following:

'4. For notified bodies which are designated under any other Union harmonisation legislation, all documents and certificates linked to those designations may be used to support and expedite their designation procedure under this Regulation, as appropriate.

Notified bodies, which are designated under Union harmonisation legislation listed in Section A of Annex I, that apply for the single assessment within the meaning of Article 28(8), shall submit the single application for assessment to the notifying authority designated in accordance with Union harmonisation legislation listed in Section A of Annex I.

The notified body shall update the documentation referred to in paragraphs 2 and 3 of this Article whenever relevant changes occur, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements laid down in Article 31.';

(13) in Article 30, the following paragraph 5a is inserted:

'The Commission, by means of implementing acts, may draw up a list of codes for the purpose of specifying the scope of the notification of notified bodies set out in this Article, measures setting out the detailed arrangements specifying the procedure for application for notification and the assessment of the application set out in this Section. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).';

(14) In Article 42, the following paragraph 3 is added:

'3. Where an AI system is subject to the requirements of Regulation (EU) 2024/2847 as well as requirements set out in Article 15, and where those high-risk AI systems fulfil the essential cybersecurity requirements set out in the Regulation (EU) 2024/2847, they shall be deemed to comply with the cybersecurity requirements set out in Article 15 in so far as those

requirements are covered by the EU declaration of conformity or parts thereof issued under Regulation (EU) 2024/2847.';

(15) Article 43(3) is amended as follows:

'For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider shall follow the relevant conformity assessment procedure as required under those legal acts. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.

For the purposes of that assessment, notified bodies which have been notified under those legal acts [Section A of Annex I], shall be entitled to control the conformity of high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under those legal acts. Notified bodies, referred to in the sentence above, which have been notified under those legal acts, shall apply for designation in accordance with Section 4 within 12 months after publication of [the implementing act setting out a list of codes specifying the scope of the notification of notified bodies set out in Article 30].

Where a legal act listed in Section A of Annex I enables the product manufacturer to opt out from a third-party conformity assessment, provided that that manufacturer has applied harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.

Where a high-risk AI system is both covered by the Union harmonization legislation listed in Section A of Annex I and falls within one of the categories listed in Annex III, the provider shall follow the relevant conformity assessment procedure as required under the relevant harmonisation legislation listed in Section A of Annex I.;

(16) in Article 49, paragraph 2 is deleted.

(17) in Article 50, paragraph 7 is replaced by the following:

'7. The AI Office shall encourage and facilitate the drawing up of codes of practice at Union level to facilitate the effective implementation of the obligations regarding the marking, detection and labelling of artificially generated or manipulated content. The Commission may approve those codes of practice in accordance with the procedure laid down in Article 56(6). If it deems the code is not adequate, the Commission may adopt an implementing act specifying common rules for the implementation of those obligations in accordance with the examination procedure laid down in Article 98(2).';

(18) in Article 56, paragraph 6 is replaced by the following:

‘6. The Commission and the Board shall regularly monitor and evaluate the achievement of the objectives of the codes of practice by the participants and their contribution to the proper application of this Regulation. The Commission, taking utmost account of the opinion of the Board, shall assess whether the codes of practice cover the obligations provided for in Articles 53 and 55, and shall regularly monitor and evaluate the achievement of their objectives. The Commission shall publish its assessment of the adequacy of the codes of practice.’;

(19) Article 57 is amended as follows:

(a) the following paragraph 3a is inserted:

‘The AI Office may also establish an AI regulatory sandbox at EU level for AI systems that are covered by Article 75(1) of this Regulation. Such a sandbox is to be implemented in close involvement of relevant competent authorities, in particular when other Union legislation is supervised in the sandbox and shall provide priority access to SMEs in accordance with Article 62(1)(a) of this Regulation.’;

(b) paragraph 5 is replaced by the following:

‘5. AI regulatory sandboxes established under this Article shall provide for a controlled environment that fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority. Such sandboxes may include testing in real world conditions supervised therein.’;

(c) paragraph 13 is replaced by the following:

‘The AI regulatory sandboxes shall be designed and implemented in such a way that they facilitate cross-border cooperation between national competent authorities.’;

(d) paragraph 14 is replaced by the following:

‘National competent authorities shall coordinate their activities and cooperate within the framework of the Board. Such authorities shall support the establishment and operation of joint sandboxes, including in different sectors.’;

(20) Article 60 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

‘1. Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of high-risk AI systems listed in Annex III and in Section A of Annex I, in accordance with this Article and the real-world testing plan referred to in this Article, without prejudice to the prohibitions under Article 5.;

(b) paragraph 2 is replaced by the following:

‘2. Providers or prospective providers may conduct testing of high-risk AI systems referred to in Annex III and in Section A of Annex I in real

world conditions at any time before the placing on the market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.';

(21) The following Article 60a is added:

'Testing of high-risk AI systems covered by Section B of Annex I in real-world conditions outside AI regulatory sandboxes

1. Testing of high-risk AI systems in real world conditions outside AI regulatory sandboxes may be conducted by providers or prospective providers of AI enabled products covered in Section B of Annex I. This testing shall be based on the voluntary real-world testing agreement and shall be without prejudice to the prohibitions under Article 5.

2. The voluntary real-world testing agreement referred to in the previous paragraph shall set the conditions including on procedures, conformity assessment, supervision and enforcement mechanisms for testing those AI enabled products covered in Section B of Annex I in real-world conditions. The real-world testing agreement shall expedite and foster the uptake of those AI systems in the Union market. This voluntary real-world testing agreement shall be concluded in writing between interested Member States and the Commission.

3. Member States, the Commission, market surveillance authorities and public authorities responsible for management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B of Annex I shall cooperate closely with each other and in good faith, and shall remove any practical obstacles, including on procedural rules providing access to physical public infrastructure, where this is necessary, to successfully implement the real-world testing agreement and test AI enabled products referred in paragraph 1.

4. The signatories of the real-world testing agreement, shall specify conditions of the testing in real world conditions and establish detailed elements of the real-world testing plan for AI systems covered by Union harmonization legislation listed in Section B of Annex I.

5. Article 60 paragraphs 2, 5 and 9 apply.';

(22) Article 63(3) is replaced by the following:

'1. SMEs, including start-ups, may comply with certain elements of the quality management system required by Article 17 of this Regulation in a simplified manner. For that purpose, the Commission shall develop guidelines on the elements of the quality management system which may be complied with in a simplified manner considering the needs of SMEs, without affecting the level of protection or the need for compliance with the requirements in respect of high-risk AI systems.';

(23) Article 69 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. The Member States may be required to pay fees for the advice and support provided by the experts at a rate equivalent to the remuneration fees

applicable to the Commission set out in the implementing act referred to in Article 68(1).';

(b) paragraph 3 is deleted.

(24) in Article 72, paragraph 3 is replaced by the following:

'3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in Annex IV. The Commission shall adopt guidance on the post-market monitoring plan by 2 February 2027.';

(25) Article 75 is amended as follows:

(a) the heading of Article 75 is replaced by the following:

'Article 75

Market surveillance and control of AI systems and mutual assistance';

(b) paragraph 1 is replaced by the following:

'1. Where an AI system is based on a general-purpose AI model, with the exclusion of AI systems related to products covered by the Union harmonisation legislation listed in Annex I, and the model and the system are developed by the same provider, the AI Office shall have powers to monitor and supervise compliance of that AI system with obligations under this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall have all the powers of a market surveillance authority provided for in this Section and Regulation (EU) 2019/1020 and be empowered to take the appropriate measures and decisions to adequately exercise its powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis. The authorities involved in the application of this Regulation shall cooperate actively in the exercise of these powers, in particular where enforcement actions need to be taken in the territory of a Member State.';

(c) the following paragraph 1a is inserted:

'1a. Paragraph 1 shall also apply where an AI system constitutes or is integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.';

(d) the following paragraph 1b is inserted:

'1b. The Commission shall adopt an implementing act to define the enforcement powers and the procedures for the exercise of those powers of the AI Office, including its ability to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings identified in Article 99, in relation to AI systems referenced to in paragraphs 1 and 1a of this Article that are found to be non-compliant with this Regulation, in the context of its monitoring and supervision tasks under this Article.';

(e) the following paragraph 1c is inserted:

‘1c. Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to the providers of AI systems referred to in this Article, without prejudice to more specific procedural rights provided for in this Regulation.’;

(f) the following paragraph 1d is inserted:

‘The Commission shall organise and carry out pre-market conformity assessments and tests of AI systems referred to in this Article that are classified as high-risk and subject to third-party conformity assessment under Article 43. These tests and assessments shall verify that the systems comply with the relevant requirements of this Regulation and may be placed on the market or put into service in the Union in accordance with this Regulation. The Commission may entrust the performance of these tests or assessments to notified bodies designated under the AI Act, in which case the notified body shall act on behalf of the Commission. Article 34(1) and Article 34(2) shall apply *mutatis mutandis* to the Commission when exercising its powers under this paragraph.

The fees for testing and assessment activities shall be levied on the provider of a high-risk AI system who have applied for third-party conformity assessment to the Commission. The costs related to the services entrusted by the Commission to the notified bodies in accordance with this Article shall be directly paid by the provider to the notified body.’;

(26) Article 77 is amended as follows:

(a) the heading of Article 77 is replaced by the following:

‘Powers of authorities protecting fundamental rights and cooperation with market surveillance authorities’

(b) paragraph 1 is replaced by the following:

‘1. National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights, including the right to non-discrimination, shall have the power to make a reasoned request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language and format when access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction.’;

(c) the following paragraph 1a is inserted:

‘1a. Subject to the conditions specified in this provision, the market surveillance authority shall grant the relevant public authority or body referred to in paragraph 1 access to such information or documentation, including by requesting such information or documentation from the provider or the deployer, where necessary.’;

(d) the following paragraph 1b is inserted:

‘1b. Market surveillance authorities and public authorities or bodies referred to in paragraph 1 shall cooperate closely and provide each other with mutual assistance necessary for fulfilling their respective mandates, with a view to ensure coherent application of this Regulation and Union law

protecting fundamental rights and streamline procedures. This shall include, in particular, exchange of information where necessary for the effective supervision or enforcement of this Regulation and the respective other Union legislation.';

(27) Article 99 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. In accordance with the terms and conditions laid down in this Regulation, Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented, thereby taking into account the guidelines issued by the Commission pursuant to Article 96. The penalties provided for shall be effective, proportionate and dissuasive. They shall take into account the interests of SMCs and SMEs, including start-ups, and their economic viability.';

(b) paragraph 6 is replaced by the following:

'6. In the case of SMCs and SMEs, including start-ups, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 3, 4 and 5, whichever thereof is lower.';

(28) Article 108 is replaced by the following:

'Regulation (EU) 2018/1139 is amended as follows:

in Article 17, the following paragraph is added:

'3. Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.

(*) 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) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).';"

(2) in Article 19, the following paragraph is added:

'4. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(3) in Article 43, the following paragraph is added:

'4. When adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the

meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(4) in Article 47, the following paragraph is added:

'3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(5) in Article 57, the following subparagraph is added:

'When adopting those implementing acts concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(6) in Article 58, the following paragraph is added:

'3. When adopting delegated acts pursuant to paragraphs 1 and 2 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'.

(7) in Article 27, the following paragraph is added:

'3.Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(8) in Article 31, the following paragraph is added:

'3.Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(9) in Article 32, the following paragraph is added:

'3. When adopting delegated acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council (*), the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(10) in Article 36, the following paragraph is added:

'3.Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(11) in Article 39 the following paragraph is added:

'3.When adopting delegated acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of

Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(12) in Article 36, the following paragraph is added:

'3.Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(13) in Article 50, the following paragraph is added:

'3.Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'

(14) in Article 53, the following paragraph is added:

'3.Without prejudice to paragraph 2, when adopting implementing acts pursuant to paragraph 1 concerning Artificial Intelligence systems which are safety components within the meaning of Regulation (EU) 2024/1689 of the European Parliament and of the Council, the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.';

(29) Article 111 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. Without prejudice to the application of Article 5 as referred to in Article 113(3), point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations of this Regulation by 2 August 2030.';

(b) the following paragraph 4 is added:

'4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 August 2027.';

(30) Article 113 is amended as follows:

(a) subparagraph 3, point (c) is replaced by the following:

'(c) Articles 99 and 100 with respect to infringements of Article 50(2) shall apply from 2 August 2027.';

(b) [placeholder for measure still under consideration];

(c) the following paragraph 3 is added:

‘ 3. Articles 102 to 110 shall apply from [the date of entry into application of this Regulation]. The Commission shall initiate the legislative proposals for the delegated or implementing acts referred to in Articles 102 to 110 by [within 12 months after entry into application of this Regulation].;

(2) in Annex VIII, section B is deleted.

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

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1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Regulation of the European Parliament and of the Council on a European Approach for (to) Artificial Intelligence – Digital Package on Simplification's impact

1.2. Policy area(s) concerned

Communications Networks, Content and Technology;

Internal Market, Industry, Entrepreneurship and SMEs

The budgetary impact concerns the new tasks entrusted with the AI Office.

1.3. Objective(s)

1.3.1. General objective(s)

1. To strengthen the monitoring and supervision of certain categories of AI systems by the AI Office.

2. To facilitate the development and testing at EU level of innovative AI systems under strict regulatory oversight before these systems are placed on the market or otherwise put into service.

1.3.2. Specific objective(s)

Specific objective No 1

To enhance governance and effective enforcement of the AI Act rules related to AI systems by reinforcing the powers and procedures applicable as well as by providing for new resources for the AI Office in charge of the enforcement.

Specific objective No 2

To provide for the establishment of a sandbox at EU level, enabling cross border activities and testing.

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

AI providers should benefit from a centralised level of governance and the access to a EU-level sandbox for certain categories of AI systems, avoiding duplication of procedures and costs.

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

Indicator 1

Number of AI systems falling under the scope of the monitoring and supervision tasks to be carried out by the AI Office.

Indicator 2

Number of providers and prospective providers requesting access to the sandbox at EU level.

1.4. The proposal/initiative relates to:

☐ a new action

☐ a new action following a pilot project / preparatory action[16]

☒ the extension of an existing action

☐ a merger or redirection of one or more actions towards another/a new action

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

The additional elements relevant for the enhancement of the governance structure of the AI Office should be in place before the entry into force of the provisions applicable to AI systems.

The first EU sandbox is expected to be operational within one year of the entry into force of the provisions applicable to AI systems, although some key setting details should be established beforehand.

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

The AI Office will have the power to monitor and supervise the compliance of all AI systems based on general-purpose AI (GPAI) models, where the model and the system are developed by the same provider, as well as all AI systems embedded in very large online platforms or search engines, even if the system and GPAI model provider are different. The tasks that the AI Office would need to carry out for this vast range of AI systems include requesting full access to documentation, training/validation/testing datasets, and, when necessary, the source code of high-risk AI systems, supervising real-world testing, identifying and evaluating risks, dealing with serious incidents, taking preventive and corrective measures while ensuring cooperation with national MSAs, dealing with AI systems classified as not high-risk by the provider, dealing with complaints of non-compliance, and imposing penalties. Moreover, to allow market access for AI systems in the scope of this provision which are also subject to pre-market third-party conformity assessment under the AI Act, the AI Office will be the responsible body to carry out conformity assessments. All these actions require resources and a set of enforcement procedures to be developed and implemented, as well as the appropriate technical support to assess and evaluate systems.

The AI Office's role in ensuring compliance would also involve ensuring synergies with the evaluation of the GPAI models, which would strengthen the overall evaluations of models and systems provided by the same provider. This would enable a more comprehensive understanding of the AI systems and their associated risks, allowing for more effective monitoring and enforcement. The AI Office will also need to consider the unique challenges posed by agentic AI, which can operate

[16] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

autonomously and make decisions that may have significant consequences, and develop strategies to address these risks.

The enhancement of the AI Office's governance would bring numerous benefits to the regulation of AI systems in the EU. One of the primary advantages is the consistency and coherence it would ensure in the application of the AI Act across the EU. By having a single authority overseeing the implementation of the AI Act in relation to certain categories of AI systems, the risk of conflicting interpretations and decisions would be significantly reduced, providing clarity and certainty for companies operating in the EU.

Furthermore, this would simplify the regulatory landscape for companies, as they would only need to deal with one regulator, rather than multiple national authorities. This would reduce the complexity and administrative burden associated with navigating different regulatory frameworks, allowing companies to focus on innovation and growth. The centralized approach would also enable the development within the Commission of specialized expertise in AI systems and GPAI models, enabling more effective monitoring and enforcement of the AI Act.

1.5.3. Lessons learned from similar experiences in the past

The European Commission's experience in enforcing the Digital Services Act (DSA) provides valuable lessons that can be applied to the enforcement of the AI Act. In particular, the establishment of a robust and transparent enforcement framework, which sets out clear procedures for investigating and addressing breaches of the DSA and the close cooperation with national authorities, to ensure that enforcement actions are coordinated and effective, represent relevant elements in this context.

The Commission's experience with DSA enforcement has shown that this approach can be effective in promoting compliance and protecting users' rights. For example, the Commission has already taken action against several online platforms for breaches of the DSA, and has worked with national authorities to develop guidance and best practices for compliance.

By building on the lessons learned from DSA enforcement, the Commission can develop an effective enforcement framework for the AI Act that promotes compliance, and supports the development of a trustworthy and innovative AI ecosystem in the EU. This will involve enhancing the AI Office enforcement role to duly monitor and supervision certain categories of AI systems, and working closely with national authorities to ensure that the AI Act is enforced in a consistent and effective manner.

The possibility to provide for an EU-level sandbox should be seen as complementing the sandboxes established at national level and should be implemented in a way to facilitate cross-border cooperation between national competent authorities.

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

The amendments proposed to the AI Act as part of the Digital Omnibus initiative would result in a significant increase in the number of AI systems subject to the monitoring and supervision of the AI Office, with a corresponding rise in the number of systems potentially eligible to participate in an EU-level sandbox. To effectively manage this expansion, it is essential to strengthen the European regulatory and coordination function, as proposed in this initiative. This reinforcement would enable

the AI Office to efficiently oversee the growing number of AI systems, ensure compliance with the regulatory framework, and provide a supportive environment for innovation and testing through the EU-level sandbox.

1.5.5. Assessment of the different available financing options, including scope for redeployment

Additional staff will be funded under DEP support, given that the objectives of the proposed amendments contribute directly to one key objective of Digital Europe – accelerating AI development and deployment in Europe.

1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☒ **unlimited duration**

– Implementation with a start-up period from 2026 to 2027,

– followed by full-scale operation.

1.7. Method(s) of budget implementation planned

☒ **Direct management** by the Commission

– ☐ by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated

– ☐ international organisations and their agencies (to be specified)

– ☐ the European Investment Bank and the European Investment Fund

– ☐ bodies referred to in Articles 70 and 71 of the Financial Regulation

– ☐ public law bodies

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees

– ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

– ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

The strengthened dispositions will be reviewed and evaluated with the entire AI Act in August 2029. The Commission will report on the findings of the evaluation to the European Parliament, the Council and the European Economic and Social Committee.

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

The regulation reinforces the European policy with regard to harmonised rules for the provision of artificial intelligence systems in the internal market while ensuring the respect of safety and fundamental rights. The simplified single supervision ensures consistency for the cross-border application of the obligations under this Regulation. In order to face these new tasks, it is necessary to appropriately resource the Commission's services. The enforcement of the new regulation is estimated to require [55] FTE.

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

The risks correspond to the standard risks of Commission operations and are adequately covered by existing standard risk minimising procedures.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

For the meeting expenditure, given the low value per transaction (e.g. refunding travel costs for a delegate for a meeting), standard control procedures seem sufficient.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the anti-fraud strategy.

The existing fraud prevention measures applicable to the Commission will cover the additional appropriations necessary for this Regulation.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[17]	from EFTA countries [18]	from candidate countries and potential candidates [19]	From other third countries	other assigned revenue
7	20 02 06 Administrative expenditure	Nondiff	No			
1	02 04 03 DEP Artificial Intelligence	Diff.	YES	NO	yes	NO
1	02 01 30 01 Support expenditure for the Digital Europe programme	Nondiff	yes		yes	

17 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
18 EFTA: European Free Trade Association.
19 Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below

3.2.1.1. Appropriations from voted budget

[

EUR million (to three decimal places)

Heading of multiannual financial framework	1	

DG: CNECT			Year **2024**	Year **2025**	Year **2026**	Year **2027**	After 2027 **After 2027**	**TOTAL MFF 2021-2027**
Budget line 02 04 03	Commitments	(1a)			0,500[20]	0,500[21]		**1,000**
	Payments	(2a)				0,500	0,500	**1,000**
Appropriations of an administrative nature financed from the envelope of specific programmes								
Budget line 02 01 30 01		(3)			**2,642[22]**	**6,283 [23]**	**7,485**	**8,925**

[20] This budget is already eamarked in the DEP WP 26-27 for the AI office

[21] This budget is already eamarked in the DEP WP 26-27 for the AI office

[22] This budget corresponds to [48] additional FTEs for 6 months [(43 CAs and 5 SNEs)], **the baseline being the staffing level agreed in the context of the 2026 budgetary procedure.** The budget will be redeployed in the DEP admin envelope to cover the additional costs.

[23] The amount will be redeployed from 02.0403 (SO2 artificial intelligence) in 2027, the request will be introduced in the 2027 budgetary procedure.

TOTAL appropriations for DG CNECT	Commitments	=1a+1b+3			**3,142**	**6,783**	**7,485**	**9,925**
	Payments	=2a+2b+3			**2,642**	**6,783**	**7,985**	**9,925**

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Mandatory table

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TOTAL			Year **2024**	Year **2025**	Year **2026**	Year **2027**	After 2027 **After 2027**	**TOTAL MFF 2021-2027**
Budget line 02 04 03	Commitments	(1a)			0,500[24]	0,500[25]		**1,000**
	Payments	(2a)				0,500	0,500	**1,000**
Appropriations of an administrative nature financed from the envelope of specific programmes								
Budget line 02 01 30 01		(3)			**2,642**[26]	**6,283** [27]	**7,485**	**8,925**

[24] This budget is already eamarked in the DEP WP 26-27 for the AI office

[25] This budget is already eamarked in the DEP WP 26-27 for the AI office

[26] This budget corresponds to 48 additional FTEs for 6 months (43 CAs and 5 SNEs), **the baseline being the staffing level agreed in the context of the 2026 budgetary procedure.** The budget will be redeployed in the DEP admin envelope to cover the additional costs.

[27] The amount will be redeployed from 02.0403 (SO2 artificial intelligence) in 2027, the request will be introduced in the 2027 budgetary procedure.

TOTAL appropriations for DG CNECT	Commitments	=1a+1b+3			**3,142**	**6,783**	**7,485**	**9,925**
	Payments	=2a+2b+3			**2,642**	**6,783**	**7,985**	**9,925**

]

[

Heading of multiannual financial framework	**7**	'Administrative expenditure'

DG: CNECT		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021-2027**
Ÿ Human resources				0,940	0,940	**1,880**
Ÿ Other administrative expenditure				0,025	0,025	**0,050**
TOTAL DG CNECT	Appropriations			**0,965**	**0,965**	**1,930**
TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)			**0,965**	**0,965**	**1,930**

EUR million (to three decimal places)

		Year **2024**	Year **2025**	Year **2026**	Year **2027**	After 2027	**TOTAL MFF 2021-2027**
TOTAL appropriations under HEADINGS 1 to 7	Commitments			**4,107**	**7,748**	**8,450**	**11,855**
of the multiannual financial framework	Payments			**3,607**	**7,784**	**8,950**	**11,891**

]

3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **2024**		Year **2025**		Year **2026**		Year **2027**		Enter as many years as necessary to show the duration of the impact (see Section1.6)						**TOTAL**	
	OUTPUTS																	
	Type[28]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[29]…																		
- Output																		
- Output																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 ...																		
- Output																		
Subtotal for specific objective No 2																		
TOTALS																		

[28] Outputs are products and services to be supplied (e.g. number of student exchanges financed, number of km of roads built, etc.).

[29] As described in Section 1.3.2. 'Specific objective(s)'

3.2.3. Summary of estimated impact on administrative appropriations

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below

3.2.3.1. Appropriations from voted budget

[

VOTED APPROPRIATIONS	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL 2021 - 2027
HEADING 7					
Human resources			0,940	0,940	**1,880**
Other administrative expenditure			0,025	0,025	**0,050**
Subtotal HEADING 7			**0,965**	**0,965**	**1,930**
Outside HEADING 7					
Human resources			2,429	4,858	**7,287**
Other expenditure of an administrative nature			0,213	1,425	**1,638**
Subtotal outside HEADING 7			**2,642**	**6,283**	**8,925**

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]

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together, if necessary, with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

3.2.4. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– ☒ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. Financed from voted budget

Estimate to be expressed in full-time equivalent units (FTEs)

[

VOTED APPROPRIATIONS		Year 2024	Year 2025	Year 2026	Year 2027
Ÿ Establishment plan posts (officials and temporary staff)					
20 01 02 01 (Headquarters and Commission's Representation Offices)		0	0	5	5
20 01 02 03 (EU Delegations)		0	0	0	0
01 01 01 01 (Indirect research)		0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
• External staff (inFTEs)					
20 02 01 (AC, END from the 'global envelope')		0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. Support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (02 01 30 01) - Outside Heading 7		0	0	48	48
TOTAL		**0**	**0**	**53**	**53**

]

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The staff required to implement the proposal (in FTEs):

	To be covered by current staff available in the Commission services	Exceptional additional staff*		
		To be financed under Heading 7 or Research	To be financed from BA line	To be financed from fees
Establishment plan posts		[5]	N/A	
External staff (CA, SNEs, INT)			[48]	

Description of tasks to be carried out by:

Officials and temporary staff	The strengthening of the central supeivison by the AI Office will lead to a significant increase in the number of AI systems. These task cannot be carried out by the current staff levels, which are only sufficient for the current number of AI systems un der supervision.
External staff	

3.2.5. Overview of estimated impact on digital technology-related investments

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 7 should be presented in the designated line.

The appropriations under Headings 1-6 should be reflected as “Policy IT expenditure on operational programmes”. This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 “Digital dimensions”.

TOTAL Digital and IT appropriations	Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021 - 2027
HEADING 7					
IT expenditure (corporate)	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Policy IT expenditure on operational programmes	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.6. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ☒ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF)

The amounts will be redeployed from 02.013001 support expenditure for the Digital Europe Programme for 2026 and from 02.0403 (SO2 artificial intelligence) for 2027.

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation

Explain what is required, specifying the headings and budget lines concerned, the corresponding amounts, and the instruments proposed to be used.

– ☐ requires a revision of the MFF

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.7. Third-party contributions

The proposal/initiative:

– ☒ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **2024**	Year **2025**	Year **2026**	Year **2027**	Total
Specify the co-financing body					
TOTAL appropriations co-financed					

3.3. Estimated impact on revenue

– ☒ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

  – ☐ on own resources

  – ☐ on other revenue

  – ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[30]			
		Year **2024**	Year **2025**	Year **2026**	Year **2027**

[30] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

Article …….					

For assigned revenue, specify the budget expenditure line(s) affected.

[…]

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

[…]

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

Reference to the requirement	Requirement description	Actors affected or concerned by the requirement	High-level Processes	Categories
Article 1(4)	**Inserting Article 4a**: Allowing providers and deployers of AI systems and AI models to exceptionally process special categories of personal data to the extent necessary for the purpose of ensuring bias detection and correction, subject to certain conditions.	Providers and deployers of AI systems and AI models Concerned data subjects	Data processing	Data
Article 1(9)	**Amending Article 11(1), second subparagraph**: Relating to the technical documentation of high-risk AI systems that needs to be drawn up before that system is placed on the market or put into service. SMEs and SMCs are given certain regulatory privileges as concerns this provision of information.	Providers of high-risk AI systems (including SMCs and SMEs) National competent authorities Notified bodies European Commission	Technical documentation	Data

Article 1(11)	**Amending Article 28, inserting paragraph (1a)**: Conformity assessment bodies that apply for a designation may be offered the possibility to submit a single application and undergo a single assessment procedure.	Conformity assessment bodies Notifying authorities	Application submission	Data
Article 1(12)	**Amending Article 29(4)**: Notified bodies which apply for a single assessment shall submit the single application to the notifying authority. The notified body shall update the documentation if relevant changes occur.	Notified bodies Notifying authority	Application submission	Data
Article 1(13)	**Inserting paragraph (5a) into Article 30**: The Commission may draw up a list of codes for the purpose of specifying the scope of the notification (*via implementing acts*).	European Commission Notified bodies Notifying authority	Scope of notification	Data
Article 1(18)	**Amending Article 56(6)**: The Commission shall publish its assessments on the adequacy of the codes of practice.	European Commission	Assessment publication	Data
Article 1(26)	**Amending Article 77**: • **Paragraph 1**: National public authorities/bodies which supervise/enforce EU law obligations protecting fundamental rights may make a reasoned request and access any information/documentation from the relevant market surveillance authority • **Paragraph 1a**: market surveillance	National public authorities/bodies which supervise/enforce EU law obligations protecting fundamental rights Market surveillance authorities Providers/deployers of AI systems	Information exchange	Data

	authority shall grant access and, where needed, request the information from the provider/deployer • **Paragraph 1b**: where necessary, the aforementioned market surveillance authorities and public authorities/bodies shall exchange information.			

4.2. Data

High-level description of the data in scope

Type of data	**Reference to the requirement(s)**	**Standard and/or specification (if applicable)**
Special categories of personal data (where the processing is needed for bias detection/correction)	Article 1(4)	//
Technical documentation for high-risk AI systems	Article 1(9)	Technical documentation shall contain, at a minimum, the elements set out in Annex IV of the AI Act. The Commission shall establish a simplified technical documentation form targeted at SMCs and SMEs.
Applications of conformity assessment bodies for designation	Article 1(11)	//
Applications of a conformity assessment bodies for	Article 1(12)	The notified body shall update the relevant

notification		documentation whenever relevant changes occur.
Notifications for AI systems	Article 1(13)	List of codes to specify the scope of the notification (implementing act may be adopted to this effect).
Commission assessment of the adequacy of the codes of practice	Article 1(18)	//
Reasoned request for access to information on AI systems	Article 1(26)(b)	//
Information or documentation requested by national public authorities/bodies which supervise/enforce obligations relating to fundamental rights	Article 1(26)(b)	To be provided in accessible language and format.
Information or documentation requested by market surveillance authorities	Article 1(26)(c)	//
Information exchanges as part of the cooperation of market surveillance authorities and public authorities/bodies which supervise/enforce obligations relating to fundamental rights	Article 1(26)(d)	

Alignment with the European Data Strategy

Explanation of how the requirement(s) are aligned with the European Data Strategy

Article 1(4) establishes that the processing of special categories of personal data shall be subject to appropriate safeguards for fundamental rights and freedoms of natural persons. This is in alignment with Regulations (EU) 2016/679 (GDPR) and (EU) 2018/1725 (EUDPR).

Alignment with the once-only principle

Explanation of how the once-only principle has been considered and how the possibility to reuse existing data has been explored

Article 1(10) states that conformity assessment bodies may be provided the possibility to submit a single application and undergo a single assessment procedure.

Explanation of how newly created data is findable, accessible, interoperable and reusable, and meets high-quality standards

Data flows

High-level description of the data flows

Type of data	**Reference(s) to the requirement(s)**	**Actors who provide the data**	**Actors who receive the data**	**Trigger for the data exchange**	**Frequency (if applicable)**
Applications of a conformity assessment bodies for notification	Article 1(12)	Notified bodies which are designated under Union harmonisation legislation listed in Section A of Annex I	Notifying authority designated in accordance with Union harmonisation legislation listed in Section A of Annex I	Application being made for single assessment	//
Commission assessment of the adequacy of the codes of practice	Article 1(18)	European Commission	General Public	Performance of an assessment as regards the codes of practice	Regularly

Reasoned request for access to information on AI systems	Article 1(26)(b)	National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights	Market surveillance authority	National public authorities/bodies require the information in order to fulfil their mandates	//
Information or documentation requested by national public authorities/bodies which supervise/enforce obligations relating to fundamental rights	Article 1(26)(b)	Market surveillance authority	National public authorities or bodies which supervise or enforce the respect of obligations under Union law protecting fundamental rights	Submission of a reasoned request to access information	//
Information or documentation requested by market surveillance authorities	Article 1(26)(c)	Market surveillance authorities	Providers/ deployers of AI systems	Market surveillance authority is in need of the information so as to answer to a request from national public authorities/bodies which	//

				supervise/enforce obligations relating to fundamental rights)	
Information exchanges as part of the cooperation of market surveillance authorities and public authorities/bodies which supervise/enforce obligations relating to fundamental rights	Article 1(26)(d)	Market surveillance authorities / Public authorities/bodies	Market surveillance authorities / Public authorities/bodies	Information exchange need identified in the course of cooperation and mutual assistance	//

4.3. Digital solutions

High-level description of digital solutions

Digital solution	Reference(s) to the requirement(s)	Main mandated functionalities	Responsible body	How is accessibility catered for?	How is reusability considered?	Use of AI technologies (if applicable)
N.A. (the proposed amendments to the AI Act do not foresee the adoption of new digital solutions)						

For each digital solution, explanation of how the digital solution complies with applicable digital policies and legislative enactments

Digital Solution #1

Digital and/or sectorial policy (when these are applicable)	Explanation on how it aligns
AI Act	
EU Cybersecurity framework	
eIDAS	
Single Digital Gateway and IMI	
Others	

4.4. Interoperability assessment

High-level description of the digital public service(s) affected by the requirements

Digital public service or category of digital public services	Description	Reference(s) to the requirement(s)	Interoperable Europe Solution(s) (NOT APPLICABLE)	Other interoperability solution(s)
N.A. (the proposed amendments to the AI Act do not affect digital public services)				

Impact of the requirement(s) as per digital public service on cross-border interoperability

Digital Public Service #1

Assessment	Measure(s)	Potential remaining barriers (if applicable)
Alignment with existing digital and sectorial policies **Please list the applicable digital and sectorial policies identified**		
Organisational measures for a smooth cross-border digital public services delivery **Please list the governance measures foreseen**		
Measures taken to ensure a shared understanding of the data **Please list such measures**		
Use of commonly agreed open technical specifications and standards **Please list such measures**		

4.5. Measures to support digital implementation

High-level description of measures supporting digital implementation

Description of the measure	**Reference(s) to the requirement(s)**	**Commission role** (if applicable)	**Actors to be involved** (if applicable)	**Expected timeline** (if applicable)
N.A.				