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From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	(Digital Omnibus on AI) - MS comments on the second Presidency compromise text - deadline 26 Feb. 2026 - BG

Following the written consultation launched on 18 Feb. 2026 on the second Presidency compromise text, delegations will find below additional comments from BG received on 6.03.26

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Guidelines to be followed

Please kindly provide your contributions in the table below.

Drafting suggestions: you may use '**track changes**'* or formatting (for example **bold-underline** for additions and ~~strike-through~~ for deletions, **where necessary, in a different colour**). *Track changes can only be connected once the cursor is placed in editable areas (Drafting or Comments columns).

To make it feasible to consolidate all contributions, the structure of the table must not be changed, so **no rows can be added or deleted.**

New provisions may only be added in any of the **'existing cells'.**

Name of document: please add the **two initials** of your delegation's country followed by a space (to the MS Word document name), followed by any optional text, for example, for Austria: **AT comments on … .docx**

Thank you for your cooperation!

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General Comments		
Proposal for a		
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL		
amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)		

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(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[1], 1 OJ C , , p. .		
Having regard to the opinion of the Committee of the Regions[2], 2 OJ C , , p. .		

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Acting in accordance with the ordinary legislative procedure,		
Whereas:		
(1) Regulation (EU) 2024/1689 of the European Parliament and of the Council[3] lays down harmonised rules on artificial intelligence (AI) 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 supporting innovation. Regulation (EU) 2024/1689 entered into force on 1 August 2024. Its provisions enter into application in a staggered manner, with all rules entering into application by 2 August 2027. 3 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) The experience gathered in implementing the parts of Regulation (EU) 2024/1689 that have already entered into application can inform the		

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implementation of those parts that are yet to apply. In this context, the delayed preparation of standards, which should provide technical solutions for providers of high-risk AI systems to ensure compliance with their obligations under that regulation, and the delayed establishment of the governance and the conformity assessment frameworks at national level result in a compliance burden that is heavier than expected. In addition, consultations of stakeholders have revealed the need for additional measures that facilitate and provide clarification on the implementation and compliance, without reducing the level of protection for health, safety and fundamental rights from AI-related risks that the rules of Regulation (EU) 2024/1689 seek to achieve.		
(3) Consequently, targeted amendments to Regulation (EU) 2024/1689 are necessary to address certain implementation challenges, with a view to the effective **and simple** application of the relevant rules.		
(4) Enterprises outgrowing the micro, small and medium-sized enterprises ('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, they face challenges similar to SMEs in relation to administrative burden, leading to a need for proportionality in the implementation of		

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Regulation (EU) 2024/1689 and for targeted support. To enable the smooth transition of enterprises from SMEs into SMCs, it is important to address in a coherent manner the effect that regulation may have on their activity once those enterprises outgrow the segment of SMEs and are faced with rules that apply to large enterprises. Regulation (EU) 2024/1689 provides for several measures for small-scale providers, which should be extended to SMCs. In order to clarify the treatment of SMEs and SMCs in Regulation (EU) 2024/1689, it is necessary to introduce definitions for SMEs and SMCs, which should correspond to the definition set out in the Annex to Commission Recommendation 2003/361/EC[4] and Annex to Commission Recommendation 2025/3500/EC[5]. 4 Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, pp. 36–41, ELI: http://data.europa.eu/eli/reco/2003/361/oj). 5 Commission Recommendation (EU) 2025/1099 of 21 May 2025 on the definition of small mid-cap enterprises (OJ L, 2025/1099, 28.5.2025, ELI: http://data.europa.eu/eli/reco/2025/1099/oj).		
(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff. AI literacy development starting from		

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education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of providers and deployers in relation to the promotion of AI literacy, rendering such a horizontal obligation ineffective in achieving the objective pursued by this provision. Moreover, data indicate that imposing such an obligation creates an additional compliance burden, particularly for smaller enterprises, whereas AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. In light of that, Article 4 of Regulation (EU) 2024/1689 should be amended to require the Member States and the Commission, without prejudice to their respective competences, 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, and allowing exchange of good practices and other non-legally binding initiatives. **European competence frameworks, for example the Digital Competence Framework for Citizens (DigComp), Digital Competence Framework**		

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for Educators (DigCompEdu) and the Digital Competence Framework for Organisations (DigCompO), should be taken into account in the encouragement under this article. The European Artificial Intelligence Board ('Board') **should support the Commission and Member States in the promotion of AI literacy by adopting recommendations setting out common objectives to be achieved in order to meet their obligation and** 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. This amendment is without prejudice to the broader measures taken by the Commission and the Member States to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems. **Moreover, this encouragement complements ~~in no way affects~~ the obligations that providers and deployers have under other provisions to ensure adequate training and competence, both as specifically required by certain provisions (such as Article 26(2) of Regulation 2024/1689) and as may be required to fulfil other obligations, such as risk management obligations (Article 9 of the same Regulation) ~~such as Article 26(2) to ensure the necessary competence, training and authority of relevant persons~~.**		

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(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases' adverse effects, including discrimination. ~~Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which of~~ **For that reason,** Regulation (EU) 2024/1689 ~~already~~ provides a legal basis authorising the **providers of high-risk AI systems to process** ~~the processing of~~ special categories of personal data ~~under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council[6].~~**in certain exceptional cases and subject to strict safeguards. This legal basis is linked to those providers' obligation to establish practices concerning the detection, prevention and mitigation of biases likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law.** ~~Given that discrimination~~ **Nevertheless, biases likely to have those effects** might **also** result from ~~those other AI systems and models~~ **the actions of the deployers of high-risk AI systems. Furthermore, such biases could also arise in the case of other AI systems or models. In each of those further cases, a substantial public interest exists to permit, exceptionally and where strictly necessary, the processing of special category personal data for the purposes of bias detection and correction. I**~~i~~t is therefore ~~appropriate that~~ **necessary to extend the legal basis established**		

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under Regulation (EU) 2024/1689 **so that it also applies to the** ~~in providing for a legal basis for the processing of special categories of personal data also by~~ providers and deployers of other AI systems and AI models~~, as well as deployers of high-risk AI systems. The~~ **That** legal basis ~~is established in~~ **should be subject to the same limitations, conditions and safeguards as apply under the existing Article 10(5), thereby ensuring** compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council[7] and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council[8]**.** ~~provides a legal basis allowsing, where necessary for the~~ **purpose of the** ~~detection and removal of bias, the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.~~ **Whilst the same conditions apply, it is likely that the exceptional circumstances justifying reliance on this new legal basis will arise less frequently in practice, notably given that AI systems that are not high-risk pose lower risks to health, safety and fundamental rights. Furthermore, to enable providers of high-risk AI systems to lawfully undertake bias detection and mitigation activities in preparation for compliance with the**		

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high-risk requirements, including Article 10(2), points (f) and (g), of Regulation (EU) 2024/1689, the legal basis established by Article 4a should apply from entry into application of this Regulation. 6 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj). 7 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj). 8 Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: http://data.europa.eu/eli/dir/2016/680/oj).		

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(7) In order to ensure consistency, avoid duplication and minimise administrative burdens in relation to the procedure for designating notified bodies under Regulation (EU) 2024/1689, while maintaining the same level of scrutiny, a single application and a single assessment procedure should be available for new conformity assessment bodies and notified bodies which are designated under the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689, such as under Regulations (EU) 2017/745[9] and (EU) 2017/746[10] of the European Parliament and of the Council, where such a procedure is established under that Union harmonisation legislation. The single application and assessment procedure aims at facilitating, supporting and expediting the designation procedure under Regulation (EU) 2024/1689, while ensuring compliance with the requirements applicable to notified bodies under that Regulation and the Union harmonisation legislation listed in Section A of Annex I thereto. **Moreover, it should be clarified that a conformity assessment body that is designated under more than one Union harmonisation legislation listed in Section A of Annex I should have to apply only once to be designated under this Regulation.** 9 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on		

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medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj). 10 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj).		
(8) With a view to ensuring the smooth application and consistency of Regulation (EU) 2024/1689, amendments should be made to it. A technical correction to Article 43(3), first subparagraph, of Regulation (EU) 2024/1689 should be added to align the conformity assessment requirements with the requirements of providers of high-risk AI systems in Article 16 of that Regulation. Moreover, it should be clarified that where a provider of a high-risk AI system is subject to the conformity assessment procedure under Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689, and the conformity assessment extends to compliance of the quality management system of that Regulation and of such Union harmonisation legislation, the provider should be able to include aspects related to quality management systems under that Regulation as part of the quality management systems under such Union harmonisation		

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legislation, in line with Article 17(3) of Regulation (EU) 2024/1689. Article 43(3), second subparagraph, should be amended to clarify that notified bodies which have been notified under the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 and which aim to assess high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I to that Regulation, should apply for the designation as a notified body under that Regulation within 18 months from [the entry into application of this Regulation]. This amendment is without prejudice to Article 28 of Regulation (EU) 2024/1689. Moreover, Regulation (EU) 2024/1689 should be amended to clarify that where a high-risk AI system is both covered by the Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 and falls within one of the use-cases listed in Annex III to that Regulation, the provider should follow the relevant conformity assessment procedure as required under that relevant harmonisation legislation.		
(9) To streamline compliance and reduce the associated costs, **the registration of** ~~providers of AI systems should not be required to register~~ AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 in the EU database pursuant to Article 49(2) of that Regulation **should be simplified by streamlining the required content in Section B of Annex VIII to that Regulation**.		

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While it remains crucial for effective market surveillance and public accountability that such AI systems are registered in the EU database, ~~Given that such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons, imposing~~ **the** registration requirements ~~would constitute a disproportionate compliance burden~~**should be simplified and made more proportionate. This simplification will strike a better balance without undermining the protection laid down by Regulation 2024/1689. Such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons.** ~~Nevertheless,~~ **Furthermore, a** provider **applying** ~~who considers that an AI system falls under~~ Article 6(3) remains obligated 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.		
(10) Articles 57, 58 and 60 of Regulation (EU) 2024/1689 should be amended to strengthen further cooperation at Union level of AI regulatory sandboxes, foster clarity and consistency in the governance of AI regulatory sandboxes, and to extend the scope of real-world testing outside AI regulatory sandboxes to high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation. In particular,		

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to allow procedural simplification, where applicable, in the projects supervised in the AI regulatory sandboxes that include also real-world testing, the real-world testing plan should be integrated in the sandbox plan agreed by the providers or prospective providers and the competent authority in a single document. In addition, it is appropriate to provide for the possibility of the AI Office to establish an AI regulatory sandbox at Union level for AI systems that are covered by Article 75(1) of Regulation (EU) 2024/1689. **To ensure coherence, legal certainty and an efficient allocation of supervisory responsibilities between Union and national levels, the scope of the Union-level AI regulatory sandbox should be clearly defined in order to avoid any overlapping with national AI regulatory sandboxes established pursuant to that Regulation.** By leveraging these infrastructures and facilitating cross-border collaboration, coordination would be better streamlined and resources optimally utilised.		
(11) To foster innovation, it is also appropriate to extend the scope of real-world testing outside AI regulatory sandboxes in Article 60 of Regulation (EU) 2024/1689, currently applicable to high-risk AI systems listed in Annex III to that Regulation, and allow providers and prospective providers of high-risk AI systems covered by the Union harmonisation legislation listed in Annex I to that Regulation to also test such systems in real-world		

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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 that Union harmonisation legislation. ~~To address the specific situation of high-risk AI systems covered the Union harmonisation legislation listed in Section B of Annex I to that Regulation, it is necessary to allow the conclusion of voluntary agreements between the Commission and Member States to enable testing of such high-risk AI systems in real-world conditions.~~		
(11a) It is also appropriate to ensure that real-world testing of high-risk AI systems covered by the Union harmonisation legislation listed in Section B of Annex I to that Regulation is possible. The situation of those systems is specific, in that they are subject to the requirements and procedures of the relevant sectoral legislation and are, for most purposes, not directly subject to Regulation (EU) 2024/1689. Those sectoral acts will, in due course, incorporate requirements corresponding to the requirements laid down by Articles 8-15 of that Regulation. It is therefore not possible to lay down in that Regulation an exhaustive regime regulating real-world testing, as regards those specific requirements, under each of those acts. However, it is appropriate to ensure that Member States can allow such testing. To that end, the essential elements of		

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those testing regimes should be laid down, and Member States who choose to allow such testing should lay down the detailed rules regarding those regimes. First, those regimes should comply with the sectoral legislation, including any provisions regarding testing. However, in the event that this sectoral legislation does not (yet) enable testing as regards the high-risk AI system component, such testing should be made possible. This conflict rule is strictly limited to the extent necessary to enable testing of the requirements that correspond to Articles 8-15 of Regulation 2024/1689. If those corresponding rules have yet to be adopted, that testing should take Articles 8-15 of Regulation 2024/1689 itself as the benchmark. Second, and particularly given the risks that could be posed by real-world testing of high-risk AI systems that are safety components of or constitute products subject to that sectoral legislation, those regimes should comply with certain essential elements. Third, the detailed implementation and procedures should be laid down by the Member States, acting alone or jointly, and be subject to review by the Commission.		
(12) 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 facilitating compliance for more		

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innovators, that possibility should be extended to all SMEs, including start-ups.		
(13) Article 69 of Regulation (EU) 2024/1689 should be amended to simplify the fee structure of the scientific panel. If Member States call upon the panel's expertise, the fees they may be required to pay the experts should be equivalent to the remuneration the Commission is obliged to pay in similar circumstances. ~~Furthermore, to reduce the procedural complexity, Member States should be able to consult the experts of the scientific panel directly, without involvement of the Commission.~~		
(14) In order to strengthen the governance system for AI systems based on general-purpose AI models, it is necessary to clarify 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 the Union harmonisation legislation listed in Annex I to that Regulation **and excluding AI systems referred to in point (2) of Annex III to that Regulation**. While sectoral authorities continue to remain responsible for the supervision of AI systems related to products covered by that Union harmonisation legislation, Article 75(1) Regulation (EU) 2024/1689 should be modified 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. This does not		

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include AI systems placed on the market, put into service or used by Union institutions, bodies, offices or agencies, which are under the supervision of the European Data Protection Supervisor pursuant to Article 74(9) of Regulation (EU) 2024/1689. To ensure effective supervision for those AI 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 of the European Parliament and of the Council[11]. Article 14 of Regulation (EU) 2019/1020 should apply mutatis mutandis. Furthermore, to ensure effective enforcement, ~~the~~ **rules should be laid down regarding the cooperation with** authorities involved in the application of Regulation (EU) 2024/1689 ~~should cooperate actively~~**and assistance of those authorities to the AI Office** in the exercise of those powers, **as well as the assistance of the police or equivalent enforcement authority** ~~in particular where enforcement actions need to be taken in the territory of a Member State~~. 11 Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L		

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169, 25.6.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/1020/oj).		
(15) Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council[12], it is appropriate to grant the Commission the powers of a competent market surveillance authority under Regulation (EU) 2024/1689 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 where it is embedded in such a platform or search engine. This should contribute to ensuring that the exercise of the Commission's supervision and enforcement powers under Regulation (EU) 2024/1689 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	(15) Considering the existing supervisory and enforcement system under Regulation (EU) 2022/2065 of the European Parliament and of the Council[12], it is appropriate to grant the Commission the powers of a competent market surveillance authority under Regulation (EU) 2024/1689 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 where it is embedded in such a platform or search engine. This should contribute to ensuring that the exercise of the Commission's supervision and enforcement powers under Regulation (EU) 2024/1689 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	BG suggests the addition of this text in order to provide legal clarity.

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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 competent national authorities under (EU) 2024/1689 should coordinate their enforcement efforts with the authorities competent for the supervision and 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, those authorities should exchange views regularly and take into account, in their respective areas of competence, any fines and penalties imposed on the same provider for the same conduct 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. 12 Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/2065/oj).	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 competent national authorities under (EU) 2024/1689 should coordinate their enforcement efforts with the authorities competent for the supervision and 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, those authorities should exchange views regularly and take into account, in their respective areas of competence, any fines and penalties imposed on the same provider for the same conduct 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. **The coordination between the AI Office, the Commission services responsible for the enforcement of Regulation (EU) 2022/2065 and national competent authorities shall fully respect the principles of proportionality, legal certainty and *non bis in idem*, ensuring that**	

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	enforcement actions remain coherent and non-duplicative.	
(16) To further operationalise the AI Office's supervision and enforcement set out in Article 75(1) of Regulation (EU) 2024/1689, it is necessary to further define the ~~which of the~~**enforcement** powers ~~listed in Article 14 of Regulation (EU) 2019/1020 should be~~ conferred upon the AI Office. ~~The Commission should~~**It is** therefore ~~be empowered~~**appropriate** to ~~adopt implementing acts to specify those~~ **set out provisions regarding the exercise of the AI Office's** powers **of investigation and enforcement as well in respect of AI systems supervised by the AI Office**, including **as regards judicial authorisation and fundamental rights as well as** the ability to impose penalties, such as fines or other administrative sanctions, in accordance with the conditions and ceilings referred to in Article 99, and applicable procedures. **Moreover, the Commission should be empowered to adopt implementing acts to further specify those powers. The implementing acts should also lay down the modalities of collaboration and consultation with the authorities involved in the application of that Regulation, including on the exchange of information~~.~~, especially where national authorities require information from the AI Office to effectively fulfil their tasks under that Regulation and vice versa.** This should ensure		BG expresses its support in principle for the refined text of the recital.

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that the AI Office has the necessary tools to effectively monitor and supervise compliance with Regulation (EU) 2024/1689.		
(17) Additionally, it is essential to ensure that effective procedural safeguards apply to providers of AI systems subject to monitoring and supervision by the AI Office. To that end, the procedural rights provided for in 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.		
(18) To enable access to Union market for AI systems which are under the supervision by the AI Office pursuant to Article 75 of Regulation (EU) 2024/1689 and subject to third party conformity assessment, the Commission should be enabled to carry out pre-market conformity assessments of those systems.		
(19) Article 77 and related provisions of Regulation (EU) 2024/1689 constitute an important governance mechanism, as they aim to enable authorities or bodies responsible for enforcing or supervising Union law 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		

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such cooperation, as well as to clarify which public authorities or bodies benefit from it. With a view to reinforcing the cooperation, it should be clarified that requests to access information and documentation should be made to the competent market surveillance authority, which should respond to such requests, and that the involved authorities or bodies should have a mutual obligation to cooperate. **It should be clarified that these provisions are without prejudice to the competences, tasks, powers and independence of the relevant national public authorities or bodies under their mandates. In particular, these provisions do not limit any powers that those authorities and bodies have to request information pursuant to other Union or national law. Accordingly, those authorities and bodies retain any power they have to directly request information from operators pursuant to their mandate or other law.**		
(20) To allow sufficient time for providers of generative AI systems subject to the marking obligations laid down 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 transitional period of 6 months for providers who have already placed their systems on the market before the 2 August 2026.		

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(21) To provide sufficient time for providers of high-risk AI systems and to clarify applicable rules to the AI systems already placed on the market or put into service before the entry into application of relevant provisions of the Regulation (EU) 2024/1689, it is appropriate to clarify the application of a grace period provided in Article 111(2) of that Regulation. The grace period, for the purpose of Article 111(2), should apply to a type and model of AI systems already placed in the market. 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(2), other individual units of the same type and model of high-risk AI system are subject to the grace period provided in Article 111(2) and thus may continue to be placed on the market, made available or put into service on the Union market without any additional obligations, requirements or the need for additional certification, as long as the design of that high-risk AI system remains unchanged. For the purposes of application of the grace period provided in Article 111(2), 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(2) should trigger the obligation of the provider to comply fully with all relevant provisions of this Regulation		

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applicable to high-risk AI systems, including the conformity assessment requirements.		
(22) Article 113 of Regulation (EU) 2024/1689 establishes the dates of entry into force and application of that Regulation, notably that the general date of application is 2 August 2026. For the obligations related to high-risk AI systems laid down in Sections 1, 2 and 3 of Chapter III of Regulation (EU) 2024/1689, the delayed availability of standards, common specifications, and alternative guidance and the delayed establishment of national competent authorities lead to challenges that jeopardise those obligation's effective entry into application and that risk to significantly increase implementation costs in a way that does not justify maintaining their initial date of application, namely 2 August 2026. ~~Building on experience~~ **Against this background**, it is appropriate to **align the implementation timeline and set the date for the application of Sections 1, 2 and 3 of Chapter III to 2 December 2027 for AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and to 2 August 2028 for AI systems classified as high-risk pursuant to Article 6(1) and Annex I** ~~put in place a mechanism that links the entry into application to the availability of measures in support of compliance with Chapter III, which may include harmonised standards, common specifications, and Commission guidelines. This should be confirmed by the~~		

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~~Commission by decision, following which the rules obligations for high-risk AI systems should apply after 6 months as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and after 12 months as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to Regulation (EU) 2024/1689. However, this flexibility should only be extended until 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and until 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I to that Regulation, by which dates those rules should enter into application in any case~~. The distinction between the entry into application of the rules as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III and Article 6(1) and Annex I to that Regulation is consistent with the difference between the initial dates of application envisaged in Regulation (EU) 2024/1689 and aims to provide the necessary time for adaptation and implementation of the corresponding obligations. **The timely availability of support instruments, including guidance, relevant standards, common specifications and codes of practice is important in order to facilitate compliance and reduce the risk of divergent interpretation and uneven application of the rules across Member States.**		

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(23) 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 certain empowerments bestowed on the Commission to adopt such harmonised conditions by means of implementing acts in cases where those conditions are not met. Regulation (EU) 2024/1689 should therefore be amended to remove the empowerments conferred on the Commission in Article 50(7), Article 56(6), and Article 72(3) thereof to adopt implementing acts. The removal of the empowerment to adopt a harmonised template for a post-market monitoring plan in Article 72(3) of Regulation (EU) 2024/1689 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, recognising the need to offer clarity how providers of high-risk AI systems are required to comply, the Commission should be required to publish guidance.		
(24) Conformity assessment of high-risk AI systems under Regulation (EU) 2024/1689 may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated under that Regulation may carry out conformity assessments and only for the		

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activities related to the categories and types of AI systems concerned. To enable the specification of the scope of the designation of conformity assessment bodies notified under Article 30 of Regulation (EU) 2024/1689, it is necessary to draw up a list of codes, categories, and corresponding types of AI systems. The list of codes should take into account whether the AI system is a component of a product or itself a product covered by the Union harmonisation legislation listed in Annex I (referred to as 'AIP codes', for AI systems covered by product legislation) or a system referred in Annex III of Regulation (EU) 2024/1689, which currently concerns only biometric AI systems referred to in point (1) of Annex III (referred to as 'AIB codes', for biometric AI systems). Both AIP codes and AIB codes are vertical codes. The AIP codes are reference codes to provide a link to the Union harmonisation legislation listed in Section A of Annex I of Regulation (EU) 2024/1689. The AIB codes are new codes specific to Regulation (EU) 2024/1689 to identify biometric AI systems referred in paragraph 1 of Annex III of that Regulation. The list of codes should also take into account specific types and underlying technologies of AI systems (referred to as 'AIH codes', for horizontal AI system codes). The AIH codes are new AI technology-specific codes and can be applied in conjunction with AIP or AIB vertical codes. The AIH codes cover AI systems' underlying types and technologies. The list of codes, including three categories, should provide		

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for a multi-dimensional typology of AI systems which ensures that conformity assessment bodies designated as notified bodies are fully competent for the AI systems they are required to assess.		
(25) Regulation (EU) 2018/1139 of the European Parliament and the Council[13] lays down common rules in the field of civil aviation. Article 108 of Regulation (EU) 2024/1689 sets out amendments to Regulation (EU) 2018/1139 to ensure that the Commission takes into account, on the basis of the technical and regulatory specificities of the civil aviation sector, and without interfering with existing governance, conformity assessment and enforcement mechanisms and authorities established therein, the mandatory requirements for high-risk AI systems laid down in Regulation (EU) 2024/1689 when adopting any relevant delegated or implementing acts on the basis of that act. A technical correction extending specific articles of Regulation (EU) 2018/1139 is necessary to ensure that those 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. 13 Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No		

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2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91(OJ L 212, 22.8.2018, pp. 1–122, ELI: http://data.europa.eu/eli/reg/2018/1139/oj).		
(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**.**		
(27) The European Data Protection Supervisor and the European Data Protection Board were consulted in accordance with Article 42(1) and (2) of Regulation (EU) 2018/1725 and delivered their joint opinion on 20 January 2026,		
HAVE ADOPTED THIS REGULATION:		
Article 1		
Amendments to Regulation (EU) 2024/1689		
Regulation (EU) 2024/1689 is amended as follows:		

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(1) in Article 1(2), point (g) is replaced by the following:		
’(g) measures to support innovation, with a particular focus on small mid-cap enterprises (SMCs) and small and medium-sized enterprises (SMEs), including start-ups.’;		
(2) 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 60a, Articles 102 to ~~109 and Articles 111 and~~ 112 shall apply. Article**s** 57 **to 59** shall apply only in so far as the requirements for high-risk AI systems under this Regulation have been integrated in that Union harmonisation legislation.;		
(3) in Article 3, the following points (14a) and (14b) are inserted:		
‘(14a) micro, small and medium-sized enterprise (‘SME’) means a micro, small or medium-sized enterprise as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC;		

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(14b) small mid-cap enterprise ('SMC') means a small mid-cap enterprise as defined in point (2) of the Annex to Commission Recommendation (EU) 2025/1099';		
(4) Article 4 is replaced by the following:		
'*Article 4*		BG supports the creation of paragraph 1a and the changes to paragraph 2.
AI literacy		
'**1.** The Commission and Member States shall encourage providers and deployers of AI systems to take measures **within their respective roles and responsibilities** 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, level of 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. ~~**European competence frameworks shall be taken into account in the encouragement under this article.**~~		
1a. In addition to paragraph 1, providers and deployers of high-risk AI systems are subject to specific obligations regarding training and competence under Articles 17(1) point (m) and 26(2).		

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2. The Board shall adopt recommendations, taking into account European competence frameworks, to support the Commission and Member States in the promotion of AI literacy required by paragraph 1, including by setting out non-binding common objectives.';		
(5) the following Article 4a is inserted in Chapter I:		
'*Article 4a*		
Processing of special categories of personal data for bias detection and mitigation		
1. To the extent **strictly** necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers 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~~ **provisions** set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall 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;		

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(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 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.		

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2. ~~Paragraph 1 may apply to p~~**P**roviders and deployers of other AI systems and models and deployers of high-risk AI systems ~~where necessary and proportionate if the processing occurs for the purposes set out therein and provided that the conditions set out under the safeguards set out in this paragraph.;~~ **may exceptionally process special categories of personal data to the extent that:**		
(a) processing is strictly necessary to ensure bias detection and correction in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations; and		
(b) all of the conditions and safeguards set out in paragraph 1 are applied.		
This paragraph does not create any obligation to conduct such bias detection and correction.		
(6) ~~in Article 6(4), paragraph 4 is replaced by the following:~~		
~~'4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is~~		

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~~placed on the market or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.';~~		
(7) Article 10 is amended as follows:		
(a) paragraph 1 is replaced 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, 3 and 4 of this Article and in Article 4a(1) whenever such data sets are used.';		
(b) paragraph 5 is deleted;		
(c) paragraph 6 is replaced by the following:		
'6. For the development of high-risk AI systems not using techniques involving the training of AI models, paragraphs 2, 3 and 4 of this Article and Article 4a(1) shall apply only to the testing data sets.';		
(8) 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		

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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 SMCs and SMEs, including start-ups. 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.’;		
(9) 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 provider is an SMC or an SME, including a start-up. 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.’;		

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(10) ~~in~~ Article 28 the following paragraph~~s 8~~ **are**~~is~~ added:		
‘8. Notifying authorities designated under this Regulation responsible for AI systems covered by the Union harmonisation legislation listed in Section A of Annex I shall ~~be established, organised and operated in such a way that~~ ensure~~s~~ that the conformity assessment body that applies for designation both under this Regulation and the Union harmonisation 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 harmonisation legislation listed in Section A of Annex I, where the relevant Union harmonisation legislation provides for such single application and single assessment procedure. **To that end, notifying authorities designated under this Regulation and under any other Union harmonisation legislation listed in Section A of Annex I shall cooperate in their assessments.**		
The single application and single assessment procedure referred to in this paragraph shall also be made available to notified bodies already designated under the Union harmonisation legislation listed in Section A of Annex I, when those notified bodies apply for designation under this Regulation, provided that the relevant Union		

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harmonisation legislation provides for such a procedure.		
A conformity assessment body that is designated under more than one Union harmonisation legislation listed in Section A of Annex I shall have to apply only once to be designated under this Regulation. A designation under this Regulation shall be applicable for all Union harmonisation legislation listed in Section A of Annex I for which the conformity assessment body is designated.		
The single application and single assessment procedure shall avoid any unnecessary duplications, build on the existing procedures for designation under the 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 the relevant Union harmonisation legislation.’;		
‘9. A notifying authority that has been designated under the Union harmonisation legislation listed in Section A of Annex I is also the notifying authority for the application of the single application and single assessment procedure referred to in paragraph 8, unless the Member State designates another notifying authority for this Regulation.’;		

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(11) 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 any of the Union harmonisation legislation listed in Section A of Annex I and which apply for the single assessment referred to in Article 28(8), shall submit the single application for assessment to the notifying authority designated in accordance with that Union harmonisation legislation.		
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.';		
(12) in Article 30, paragraph 2 is replaced by the following:		
'2. Notifying authorities shall notify the Commission and the other Member States, based on the list of codes, categories, and corresponding types of AI systems referred to in Annex XIV, and		

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using the electronic notification tool developed and managed by the Commission, of each conformity assessment body referred to in paragraph 1.		
The Commission is empowered to adopt delegated acts in accordance with Article 97 to amend Annex XIV, in the light of technical progress, advances in knowledge or new scientific evidence by adding to the list of codes, categories, and corresponding types of AI systems a new code, a category or a type of AI system, withdrawing an existing code, category or a type of AI system from that list or moving a code or type of AI system from one category to another.'; PUBLIC		
(13) in Article 43, paragraph 3 is replaced by the following:		
'For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider of the system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation. 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. Assessment of the quality management system set out in Article 17 and Annex VII shall also apply.		
For the purposes of that conformity assessment, notified bodies which have been notified under the Union harmonisation legislation listed in Section A		

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of Annex I shall have the power to assess the conformity of high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with the requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under the relevant Union harmonisation legislation **and as is evidenced through the assessment as part of the existing notification**. Without prejudice to Article 28, such notified bodies which have been notified under the Union harmonisation legislation in Section A of Annex I, shall apply for designation in accordance with Section 4 at the latest [18 months from the entry into application of this Regulation].		
Where Union harmonisation legislation listed in Section A of Annex I provides the product manufacturer with an option 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 harmonisation legislation listed in Section A of Annex I and it falls within one of the categories listed in Annex III, the provider of the		

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system shall follow the relevant conformity assessment procedure as required under the relevant Union harmonisation legislation listed in Section A of Annex I.’;		
(14) ~~in Article 49, paragraph 2 is deleted;~~		
(15) 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 detection, marking and labelling of artificially generated or manipulated content. The Commission **and the Board** may assess whether adherence to those codes of practice is adequate to ensure compliance with the obligation laid down in paragraph 2 **of this Article**, in accordance with the procedure laid down in Article 56(6), ~~first subparagraph~~. 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).’;		
(16) in Article 56~~(6)~~, **paragraph 6**~~the first subparagraph~~ is replaced by the following:		
‘6. The Commission and the Board shall regularly monitor and evaluate the achievement of the		

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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.'; PUBLIC		
(17) Article 57 is amended as follows:		
	1. Member States shall ensure that their competent authorities establish at least one AI regulatory sandbox at national level, which shall be operational by **2 August 2027**. That sandbox may also be established jointly with the competent authorities of other Member States. The Commission may provide technical support, advice and tools for the establishment and operation of AI regulatory sandboxes.	BG suggests to shift the deadline regarding national regulatory sandboxes to be in line with the applicable timelines for high-risk AI systems under Article 113, ensuring legal certainty, institutional readiness and effective implementation.
(-a) paragraph 3 is replaced by:		
'3. The European Data Protection Supervisor may also establish an AI regulatory sandbox for Union institutions, bodies, offices and agencies. For this purpose references to national competent authorities in this Chapter shall be construed as references to the European Data Protection Supervisor .'		
(a) the following paragraph ~~3a~~ is inserted:		

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'**3a.** The AI Office may also establish an AI regulatory sandbox at Union level for AI systems covered by Article 75(1)**. For this purpose references to national competent authorities in this Chapter shall be construed as references to the AI Office~~, and may exercise the roles and tasks of national competent authorities in accordance with this Chapter~~**. Such an AI regulatory sandbox shall be implemented in close cooperation with relevant competent authorities, in particular when **compliance with** Union legislation other than this Regulation is supervised in the AI regulatory sandbox, and shall provide priority access to **SMCs and** SMEs**, including start-ups**.~~2~~		
3b. The establishment of a Union level AI regulatory sandbox by the AI Office shall be without prejudice to the competences of Member States to establish and supervise AI regulatory sandboxes for AI systems under their supervision.';	**3b. The establishment of a Union level AI regulatory sandbox by the AI Office shall be without prejudice to the competences of Member States to establish and supervise AI regulatory sandboxes for AI systems under their supervision and shall ensure clear delineation of supervisory responsibilities, avoiding duplication or overlapping procedures.';**	The text should explicitly ensure that the establishment of a Union-level regulatory lab does not prejudice the competences of national authorities, nor lead to parallel or overlapping procedures that could lead to legal uncertainty, procedural inefficiency or fragmented application of the regulatory framework.
(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		

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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, ensuring that appropriate safeguards are in place. Such sandboxes may include testing in real world conditions supervised therein. When applicable, the sandbox plan shall incorporate in a single document the real-world testing plan.’;		
(c) paragraph 9, point (e) is replaced by the following:		
‘(e) facilitating and accelerating access to the Union market for AI systems, in particular when provided by SMCs and SMEs, including start-ups.’;		
(d) ~~paragraph 13 is replaced by the following:~~		
~~’13. The AI regulatory sandboxes shall be designed and implemented in such a way that they facilitate cross-border cooperation between national competent authorities.’;~~		
(e) paragraph 14 is replaced by the following:		
’14. National competent authorities**, the EDPS and the AI Office** shall coordinate their activities and cooperate within the framework of the Board.		

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They ~~shall~~ **may** support the joint establishment and operation of AI regulatory sandboxes, including in different sectors.’;		
(18) Article 58, paragraph 1, is replaced by the following:		
‘1. In order to avoid fragmentation across the Union, the Commission shall adopt implementing acts specifying the detailed arrangements for the establishment, development, implementation, operation, governance, and supervision of the AI regulatory sandboxes. The implementing acts shall include common principles on the following issues:		
(a) eligibility and selection criteria for participation in the AI regulatory sandbox;		
(b) procedures for the application, participation, monitoring, exiting from and termination of the AI regulatory sandbox, including the sandbox plan and the exit report;		
(c) the terms and conditions applicable to the participants;		
(d) the detailed rules applicable to the governance of AI regulatory sandboxes covered under Article 57, including as regards ~~the exercise of the tasks of the competent authorities and~~ the coordination and cooperation at national and **Union**~~EU~~ level.’;		

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(19) Article 60 is amended as follows:		
	"Real-world testing of high-risk AI systems covered by Union harmonisation legislation shall be conducted in full compliance with the applicable sectoral legislation and under a coordinated approach among Member States, ensuring consistent safeguards, effective supervision and legal certainty."	BG believes that given that the relevant sectoral acts are subject to gradual adaptation to the requirements of Regulation (EU) 2024/1689, it is necessary to avoid the creation of parallel or fragmented testing regimes at national level. In this context, a coordinated approach between Member States and clear compliance with sectoral legislation should be ensured, including with regard to safety, the protection of fundamental rights and legal certainty.
(a) in paragraph 1, the first subparagraph is replaced by the following:		
'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 or covered by Union harmonisation legislation listed 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 or covered by Union harmonisation legislation listed in Section A of Annex I in real world conditions at any time before the placing on the		

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market or the putting into service of the AI system on their own or in partnership with one or more deployers or prospective deployers.’;		
(20) the following Article 60a is inserted:		
‘*Article 60a*		
Testing of high-risk AI systems covered by Union harmonisation legislation listed in 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 by Union harmonisation legislation listed in Section B of Annex I, **with a view to ensuring those systems' conformity with the sectoral provisions that correspond to Articles 9 to 15 of this Regulation,** in accordance with this Article and ~~a voluntary real-world testing agreement, without prejudice to the prohibitions under~~ **with the national frameworks implementing this** Article ~~5.~~**.**		
~~2. The voluntary real-world testing agreement referred to in paragraph 1 shall be concluded in writing between interested Member States and the Commission. It shall set the requirements for the~~		

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~~testing of those AI enabled products covered by Union harmonisation legislation listed in Section B of Annex I in real-world conditions.~~		
2a. ~~Member States~~ **~~that are party to the voluntary real-world testing agreement~~**~~, the Commission,~~ **Member States which choose to permit testing as referred to in paragraph 1 shall, individually or jointly, implement this Article by laying down frameworks for real-world testing. These frameworks shall lay down the detailed conditions under which that testing may take place, as well as the requirements, governance and accountability arrangements necessary for that implementation.**		
Member States shall notify the Commission of any draft framework measures in good time before their adoption. The Commission may decide, by means of implementing acts, whether the draft framework measures are appropriate in light of the applicable Union law. In the absence of a Commission decision within two months of their notification, the draft framework shall be considered approved.		
3. Member States that have adopted framework measures shall ensure that the relevant market surveillance authorities and public authorities responsible for the management and operation of infrastructure and products covered by Union harmonisation legislation listed in Section B		

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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 voluntary real-world testing agreement~~ **those framework measures** and test AI-enabled products covered by Union harmonisation legislation listed in Section B of Annex I.		
4. ~~The signatories of the voluntary real-world testing agreement, shall specify conditions of the testing in real world conditions and establish governance and accountability arrangements and detailed~~ **Testing as referred to in the first paragraph, as well as the national measures implementing this Article, shall respect the following essential** elements ~~of the~~**:**		
(a) Articles 60(2), (3), (4)(d)-(j) and (5)-(9) apply, save that any reference to market surveillance authorities shall be read as a reference to the national competent authority or appropriate authority;		
(b) A real-world testing plan ~~for AI systems covered by~~ **shall be agreed between the provider or prospective provider and the national competent authority or appropriate authority;**		
(c) Both the design of the framework and the individual real-world testing plans shall ensure		

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that any risk of harm to health, safety or fundamental rights of natural persons is minimised.		
4a. Applicable Union and national law, including the Union harmonisation legislation listed in Section B of Annex I**, shall apply in full to the testing referred to in paragraph 1. In particular, that testing shall comply with any applicable provisions of that legislation regarding the performance of tests. However, in case of a conflict between that Union harmonisation legislation and the requirements laid down in this Article, this Article shall prevail to the extent necessary to enable the testing referred to in paragraph 1.**		
~~5. Article 60(2), (5) and (9) shall apply.';~~		
(21) Article 63(1) is replaced by the following:		
'1. SMEs, including start-ups, may comply with certain elements of the quality management system required by Article 17 in a simplified manner**, provided that they do not have partner enterprises or linked enterprises within the meaning of Recommendation 2003/361/EC**. 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		

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the need for compliance with the requirements in respect of high-risk AI systems.’;		
(22) 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 pursuant to the implementing act referred to in Article 68(1).’;		
(b) ~~paragraph 3 is deleted.~~		
(23) in Article 70, paragraph 8 is replaced by the following:		
‘8. National competent authorities may provide guidance and advice on the implementation of this Regulation, in particular to SMCs and SMEs, including start-ups, taking into account the guidance and advice of the Board and the Commission, as appropriate. Whenever national competent authorities intend to provide guidance and advice with regard to an AI system in areas covered by other Union law, the national competent authorities under that Union law shall be consulted, as appropriate.’;		
(24) in Article 72, paragraph 3 is replaced by the following:		

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'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 December 2027**.';		
(25) Article 75 is amended as follows:		
(a) the heading of Article 75 is replaced by the following:		
'**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 AI systems referred to in Annex III, point 2**, and that model and that system are developed by the same provider **or by providers that are part of the same undertaking**, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations **for providers laid down in** ~~of~~ this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent	'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 AI systems referred to in Annex III, point 2**, and that model and that system are developed by the same provider **or by providers that are part of the same undertaking**, the AI Office shall be exclusively competent for the supervision and enforcement of that system with the obligations **for providers laid down in** ~~of~~ this Regulation in accordance with the tasks and responsibilities assigned by it to market surveillance authorities. The AI Office shall also be exclusively competent	BG believes that the text should explicitly ensure that the exercise of these powers complies with the principles of subsidiarity, legal certainty and effective institutional cooperation, while respecting the primary role of national authorities in supervision and enforcement at Member State level. In the absence of a sufficiently clear distinction, there is a risk of overlapping competences, parallel procedures, contradictory decisions and legal uncertainty for both competent authorities and economic operators.

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for the supervision and enforcement of the obligations under this Regulation in relation to AI systems that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065.	for the supervision and enforcement of the obligations under this Regulation in relation to AI systems that constitute or that are integrated into a designated very large online platform or very large online search engine within the meaning of Regulation (EU) 2022/2065. **The exercise of supervisory and enforcement powers by the AI Office shall ensure clear allocation of competences between Union and national authorities, respect the principle of subsidiarity, and avoid duplication of procedures or conflicting decisions.**	
~~When exercising its tasks of supervision and enforcement under the first subparagraph, the AI Office shall have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020. The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.~~		
(c) the following paragraphs ~~1a to 1e~~ are inserted:		
1aa. When a deployer is part of the same undertaking as a general-purpose AI model provider and an AI system provider under the scope of paragraph 1, the AI Office shall be exclusively competent for the supervision and		

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enforcement of the obligations for deployers laid down in this Regulation.		
1ab. By way of derogation from Article 73(1), providers of high-risk AI systems referred to in paragraph 1 shall report any serious incidents to the AI Office.		
1a. The authorities involved in the application of this Regulation shall cooperate actively **and afford the AI Office the necessary assistance for**~~in~~ the exercise of t~~hose~~**its** powers**, including, where necessary, in connection with inspections or other enforcement measures carried out in the territory of a Member State. To this end, the competent authorities shall enjoy the powers provided for under this Regulation and Regulation (EU) 2019/1020, and where relevant and limited to what is necessary to fulfil their tasks under this paragraph, in accordance with the applicable national procedures. Where the AI Office finds that a natural or legal person opposes or obstructs an inspection ordered pursuant to Article 75a, the national competent authority of the Member State concerned shall afford them the necessary assistance, requesting, where appropriate, the assistance of the police or an equivalent enforcement authority, to enable them to conduct their on-site inspection**~~in particular where enforcement actions need to be taken in the territory of a Member State~~**.;**		

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1b. When making a simple request or decision as referred to in Article 75b(1) ,the Commission shall, without delay, send a copy of the request or decision referred to in the first subparagraph to the relevant national competent authority of the Member State in whose territory the operator or its legal representative is situated.		
1c. Before taking a decision that would have the effect of prohibiting or restricting the AI system's being made available on a national market or put into service, to withdraw the AI system from that market or to recall it, the AI Office shall without undue delay notify the relevant national market surveillance authority. The AI Office may consult the authorities involved in the application of this Regulation, where appropriate, on any matter relating to the application and enforcement of this Regulation.		
~~(c) the following paragraphs 1a to 1c are inserted:~~		
~~'1a. 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~~		

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~~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.~~		
‘1b. Article 18 of Regulation (EU) 2019/1020 shall apply mutatis mutandis to providers of AI systems referred to in paragraph 1, without prejudice to more specific procedural rights provided for in this Regulation.’		
‘1c. The Commission shall organise and carry out pre-market conformity assessments and tests of AI systems referred to in paragraph 1 that are classified as high-risk and subject to third-party conformity assessment under Article 43 before such AI systems are placed on the market or put into service. 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 this Regulation, in which case the notified body shall act on behalf of the Commission. Article 34(1) and (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		

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who has 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.’;		
The following ~~Article 75a~~articles ~~is~~ are inserted after Article 75:		
‘Article 75a		
~~Investigation and~~ Eenforcement of obligations and starting an investigation in respect of AI systems supervised by the AI Office		
1. When exercising its tasks of supervision and enforcement outlined in Article 75(1), the AI Office shall have the powers set out in this Regulation. It shall additionally have all the powers of a market surveillance authority provided for in this Section and in Regulation (EU) 2019/1020, save where the relevant type of power is specified and framed in this Article or Articles 75b-75e . The AI Office shall be empowered to take appropriate measures and decisions to adequately exercise its supervisory and enforcement powers. ~~Article 14 of Regulation (EU) 2019/1020 shall apply mutatis mutandis.~~ The AI Office shall also be authorised to fully reclaim from the relevant operator the totality of the costs of its activities with respect		

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to instances of non-compliance, including costs for human and technical resources, in accordance with Article 15 of Regulation (EU) 2019/1020.		
2. Where the AI Office has reasonable grounds to suspect non-compliance with this Regulation of an AI system referred to in Article 75 (~~paragraph~~1), it ~~shall~~ may adopt a decision ~~for opening a proceeding~~ to start an investigation. The AI Office may exercise that power on its own initaitive or following a complaint received under Article 85. Upon the ~~initiating such proceedings~~ starting of such an investigation, the AI Office shall notify the operator of the AI system concerned.		
~~**For the purposes of investigating compliance of operators of the systems falling under the scope of Article 75, paragraph 1, with the obligations laid down in this Regulation, The**~~ **The AI Office may exercise its investigatory powers on ~~at~~ its own initiative or following a complaint received under Article 85 of this Regulation, even before ~~opening proceedings~~ starting an investigation pursuant to this paragraph.**		
3. The exercise of the AI Office's task of supervision and enforcement outlined in paragraph 1 may include the appointment of independent external experts and auditors, as		

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well as experts, investigative teams and auditors from Member State's competent authorities with the agreement of the authority concerned, to assist the AI Office in monitoring the effective implementation and compliance with the relevant provisions of this Regulation and to provide specific expertise or knowledge to the AI Office.		
Article 75b		
Requests for information and power to conduct inspections		
1~~3~~. In order to carry out the tasks assigned to it under this Section, the AI Office may, by simple request or by decision, require ~~the~~ an operator subject to its competence under Article 75(1) to provide information that is necessary for the purpose of assessing compliance of the operator with this Regulation.		
When sending such requests for information to the operator concerned, the AI Office shall state the legal basis and the purpose of the request, specify what information is required and set the period within which the information is to be provided. When the request is a simple request, it shall additionally indicate that there		

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is no obligation to provide information but that, in case of a voluntary reply, the information must be correct and not misleading, and indicate the potential fines provided for in Article 99 for supplying incorrect or misleading information. ~~, and the fines provided for in Article 99 for supplying incorrect, incomplete or misleading information.~~ When requesting information by decision, it shall ~~further~~ additionally indicate the fines provided for in Article 99 for supplying incomplete, incorrect or misleading information, and indicate the right to have the decision reviewed by the Court of Justice of the European Union.		
2. The operators referred to in paragraph 1 or their legal representatives shall supply the information required by a decision under paragraph 1.		
34. In order to carry out the tasks assigned to it under this Section, the AI Office may order the operators to provide access to, and explanations relating to, their AI systems. Such actions may include, imposing an obligation on the operator to retain all data and documents deemed to be necessary to assess the implementation of and compliance with the obligations under this Regulation.		

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4. In order to carry out the tasks assigned to it under this Section, t~~T~~he AI Office may conduct all necessary remote or on-site inspections, announced or unannounced. The officials of the AI Office authorised to conduct an inspection ~~may~~shall be empowered to:		
(a) enter any of the business premises, land or property located in the Union of the operator concerned;		
(b) examine the books, data and other material relevant to the execution of their tasks, irrespective of the medium on which they are stored;		
(c) take or obtain in any form copies of or extracts from such books, data and other records;		
(d) ask any of the persons subject to the inspection, or their representatives, or staff, for oral or written explanations on factors or documents relating to the subject matter and purpose of the inspection, and to record the answers.		
The operator concerned shall submit to on-site inspections ordered by decision of the Commission. The decision shall specify the subject matter and purpose of the investigation,		

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the relevant penalties referred to in paragraph 9, and the right to have the decision reviewed by the Court of Justice of the European Union.		
5. If an on-site inspection provided for in Article 75a(4) requires authorisation by a judicial authority in accordance with national law, the AI Office shall apply for such an authorisation. The AI Office may also apply for such authorisation as a precautionary measure.		
~~6~~2. Where an authorisation as referred to in paragraph 1 is applied for, the national judicial authority shall promptly verify that the coercive measures envisaged are neither arbitrary nor excessive having regard to the subject matter of the investigation or inspection and the documents provided by the AI Office with the decision. In its verification of the proportionality of coercive measures, the national judicial authority may ask the AI Office for detailed explanations, in particular relating to the grounds the AI Office has for suspecting that an infringement of this Regulation has taken place and the seriousness of the suspected infringement and, where relevant, the nature of the involvement of the person subject to the coercive measures. However, the national judicial authority shall not review the necessity of the investigation or inspection nor demand information from the case file of the Commission. In accordance with		

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the Treaties, the legality of the Commission's decision is subject to review only by the Court of Justice of the European Union.		
74~~b~~. At the request of the AI Office, the competent authority of a Member State may in its own territory carry out any investigation, inspection or other fact-finding measure on behalf and for the account of the AI Office in order to establish whether there has been an infringement of this Regulation. The officials of the competent authorities of the Member States who are responsible for conducting these investigations, inspections, or fact-finding measures as well as those authorised or appointed by them shall exercise their powers in accordance with their national law.		
Article 75c Commitments		
If, during proceedings under ~~this~~ Article 75a(2), the operator concerned offers commitments to ensure compliance with the relevant provisions of this Regulation, the AI Office may by decision make those commitments binding on the operator concerned and declare that there are no further grounds for action. The AI Office may, upon request or on its own initiative, reopen the proceedings:	**If, during proceedings under ~~this~~ Article 75a(2), the operator concerned offers commitments to ensure compliance with the relevant provisions of this Regulation, the AI Office may by decision make those commitments binding on the operator concerned and declare that there are no further grounds for action, thereby closing the proceedings with regard to the specific facts assessed, without prejudice to the powers of other competent authorities and without preventing the reopening of the case in**	In order to ensure legal certainty and a clear demarcation of competences between the Union level and the national authorities, BG considers it necessary to explicitly specify the legal effect of such a decision.

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	the event of material changes in the relevant facts or failure to comply with any commitments undertaken. The AI Office may, upon request or on its own initiative, reopen the proceedings:	
a) where there has been a material change in any of the facts on which the decision was based;		
b) where the operator acts contrary to its commitments; or		
c) where the decision was based on incomplete, incorrect or misleading information provided by the operator concerned.		
Where the AI Office considers that the commitments offered by the operator concerned are unable to ensure effective compliance with the relevant provisions of this Regulation, it shall reject those commitments in a reasoned decision when concluding the proceedings.		
Article 75d		
Non-compliance, fines and periodic penalties		
1~~6~~. The AI Office shall adopt a non-compliance decision where it finds that the operator does		

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not comply with the relevant provisions of this Regulation or with commitments made binding pursuant to Article 75c., ordering, where relevant, the operator concerned to take the necessary measures to ensure compliance with the decision.		
2. Before adopting a decision of non-compliance, the AI Office shall communicate its preliminary findings to the operator concerned. In the preliminary findings, the Commission shall explain the measures that it considers taking, or that it considers that the operator concerned should take, in order to effectively address the preliminary findings.		
3. In the decision pursuant to the first sentence paragraph 1, the AI Office shall, where relevant, order the operator concerned to take the necessary measures to ensure compliance with the decision within a reasonable period specified therein and to provide information on the measures that that operator intends to take to comply with the decision. The operator concerned shall provide the AI Office with a description of the measures it has taken to ensure compliance with the decision upon their implementation. Prior to requesting any measure, the AI Office may engage in a structured dialogue with the operator of the AI system in question.		

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During this dialogue, the operator may propose commitments in accordance with paragraph Article 75c~~5~~.		
~~4~~7. A decision of non-compliance may be accompanied by the imposition of penalties pursuant to Article 99, which shall apply mutatis mutandis to the AI Office in the execution of its supervision and enforcement tasks outlined in Article 75(~~, paragraph 1~~), of this Regulation.		
5. ~~9.~~ The AI Office may ~~impose~~ adopt a decision imposing periodic penalty payments to compel the persons referred to in ~~paragraph 4~~ subject to its competence pursuant to Article 75(1) to submit to an investigation, to comply with an information request ordered by a decision adopted under paragraph Article 75b(1)~~3~~, to submit to an on-site inspection ordered by a decision pursuant to ~~paragraph 4~~ Article 75b(4), ~~or~~ to provide correct or complete answers or explanations in response to such an investigation, request or inspection, to comply with commitments made legally binding by a decision pursuant to Article 75c, or to comply with a decision pursuant to the first paragraph of this Article. Those penalty payments shall by effective and proportionate, and where applicable shall not exceed 5% of the average daily income or worldwide annual turnover in the preceeding financial year per day,		

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calculated from the date appionted by the decision.		
6. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions of the Commission fixing a fine or periodic penalty payment under this article. It may cancel, reduce or increase the fine or periodic penalty payment imposed.		
7. Funds collected by imposition of fines or periodic penalty payments under this Article shall contribute to the general budget of the Union.		
8. Where the AI Office determines that there are no grounds to adopt a decision of non-compliance, it shall close the proceeding by a decision. The decision shall apply with immediate effect.		
Article 75e		
Safeguards and further specification		
13. The powers conferred on the AI Office under Articles ~~75 and~~ 75b~~a~~ shall not be used to require the disclosure of information or documents that are subject to legal professional privilege or journalistic material privilege, or whose disclosure would otherwise violate the Charter of Fundamental Rights.'		

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2. Article 18 of Regulation (EU) 2019/1020 shall apply *mutatis mutandis* to the persons subject to the AI Office's competence pursuant to Article 75(1), without prejudice to more specific procedural rights provided for in this Regulation.		
3~~10~~. The Commission shall adopt an implementing act to further define the investigatory and enforcement powers and the procedures for the exercise of the monitoring and supervision tasks of the AI Office under this Section, including its ability to impose penalties, such as fines or other administrative sanctions ~~as well as concerning the procedural rights outlined in Article 18 of Regulation (EU) 2019/1020~~. The implementing act shall also lay down the modalities of collaboration and consultation with the authorities involved in the application of this Regulation, including on the exchange of information where necessary for the effective supervision or enforcement of this Regulation.'		
~~**The following Article 75b is inserted:**~~		
~~**'Article 75b**~~		
~~**Judicial authorisation and fundamental rights**~~		

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~~**1. If an on-site inspection provided for in Article 75a(4) requires authorisation by a judicial authority in accordance with national law, the AI Office shall apply for such an authorisation. The AI Office may also apply for such authorisation as a precautionary measure.**~~		
~~**2. Where an authorisation as referred to in paragraph 1 is applied for, the national judicial authority shall promptly verify that the coercive measures envisaged are neither arbitrary nor excessive having regard to the subject matter of the investigation or inspection and the documents provided by the AI Office with the decision. In its verification of the proportionality of coercive measures, the national judicial authority may ask the AI Office for detailed explanations, in particular relating to the grounds the AI Office has for suspecting that an infringement of this Regulation has taken place and the seriousness of the suspected infringement and, where relevant, the nature of the involvement of the person subject to the coercive measures. However, the national judicial authority shall not review the necessity of the investigation or inspection nor demand information from the case file of the Commission. In accordance with the Treaties, the legality of the Commission's decision is subject to review only by the Court of Justice of the European Union.**~~		

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~~3. The powers conferred on the AI Office under Articles 75 and 75a shall not be used to require the disclosure of information or documents that are subject to legal professional privilege or journalistic material privilege, or whose disclosure would otherwise violate the Charter of Fundamental Rights.'~~		
(26) Article 77 is amended as follows:		
(a) the heading 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 request and access any information or documentation created or maintained from the relevant market surveillance authority under this Regulation in accessible language and format where access to that information or documentation is necessary for effectively fulfilling their mandates within the limits of their jurisdiction. **This article is without prejudice to the competences, tasks, powers and**		

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independence of the relevant national public authorities or bodies under their mandates.’;		
(c) the following paragraph 1a and 1b are inserted:		
‘1a. Subject to the conditions specified in this Article, 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.’		
‘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 ensuring coherent application of this Regulation and Union law protecting fundamental rights and streamlining 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 95, paragraph 4 is replaced by the following:		
‘4. The AI Office and the Member States shall take into account the specific interests and needs of		

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SMCs and SMEs, including start-ups, when encouraging and facilitating the drawing up of codes of conduct.’;		
(28) in Article 96(1), the second subparagraph is replaced by the following:		
‘When issuing such guidelines, the Commission shall **involve the AI Board and** pay particular attention to the needs of SMCs and SMEs including start-ups, of local public authorities and of the sectors most likely to be affected by this Regulation.’;		
(29) 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 **any** infringement~~s~~ 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. The Member States shall take into account the interests		

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of SMCs and SMEs, including start-ups, and their economic viability when imposing penalties.’;		
(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.’;		
(30) 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), third paragraph, 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 laid down in this Regulation by 2 August 2030.’;		
(b) the following paragraph 4 is added:		

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'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 February 2027.';		
(31) Article 113 is amended as follows:		
(a) in the third paragraph, point (**cd**) is ~~added~~**replaced by the following**:		
'(d) Chapter III, Sections 1, 2, and 3, shall apply ~~following the adoption of a decision of the Commission confirming that adequate measures in support of compliance with Chapter III are available, from the following dates:~~		
~~(i) 6 months after the adoption of that decision as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and~~		
~~(ii) 12 months after the adoption of the decision as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.~~		
~~In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply:~~		

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(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and		
(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.**;**		
(b) in the third paragraph, point (e) is added:		
'~~3.~~**(e)** Articles 102 to 110 shall apply from [the date of entry into ~~application~~**force** of this **amending** Regulation].';		
(32) in Annex VIII, section B**, points 7 and 9 are** ~~is~~ deleted;		
(33) the following Annex XIV is added:		
'Annex XIV		
The list of codes, categories and corresponding types of AI systems for the purpose of the notification procedure referred to in Article 30 specifying the scope of the designation as notified bodies		
1. Introduction		
Conformity assessment of high-risk AI systems under this Regulation may require involvement of conformity assessment bodies. Only conformity		

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assessment bodies that have been designated in accordance with this Regulation may carry out conformity assessments and only for the activities related to the types of AI systems concerned. The list of codes, categories, and corresponding types of AI systems sets the scope of the designation of conformity assessment bodies notified under Article 30 of this Regulation.		
2. List of Codes, categories, and corresponding AI systems		
1. AI systems subject to Annex I of the AI Act		
[…]		
2. AI systems subject to Annex III.1 of the AI Act		
[…]		
3. AI technology-specific codes		
a) Symbolic AI, expert systems and mathematical optimization		
[…]		
b) Machine learning, excluding GPAI and single modality generative AI		
[…]		

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c) AI systems based on GPAI or single modality generative AI		
[…]		
d) Agentic AI		
[…]		
3. Application for designation		
Conformity assessment bodies shall use the lists of codes, categories and corresponding types of AI systems set out in this Annex when specifying the types of AI systems in the application for designation referred to in Article 29 of this Regulation.'.		
Article 2		
Amendments to Regulation (EU) 2018/1139		
Regulation (EU) 2018/1139 is amended as follows:		
(1) in Article 27, the following paragraph is added:		

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'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[14], the requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.'; 14 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 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.';		

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(3) 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.';		
(4) 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.';		
(5) 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		

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requirements set out in Chapter III, Section 2, of that Regulation shall be taken into account.’;		
(6) 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.’;		
(7) 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.’.		
Article 3		
Entry into force and application		

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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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