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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE
(ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION
LEGISLATIVE ACTS**

{SEC(2021) 167 final} - {SWD(2021) 84 final} - {SWD(2021) 85 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Reasons for and objectives of the proposal

This explanatory memorandum accompanies the proposal for a Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act). Artificial Intelligence (AI) is a fast evolving family of technologies that can bring a wide array of economic and societal benefits across the entire spectrum of industries and social activities. By improving prediction, optimising operations and resource allocation, and personalising service delivery, the use of artificial intelligence can support socially and environmentally beneficial outcomes and provide key competitive advantages to companies and the European economy. Such action is especially needed in high-impact sectors, including climate change, environment and health, the public sector, finance, mobility, home affairs and agriculture. However, the same elements and techniques that power the socio-economic benefits of AI can also bring about new risks or negative consequences for individuals or the society. In light of the speed of technological change and possible challenges, the EU is committed to strive for a balanced approach. It is in the Union interest to preserve the EU's technological leadership and to ensure that Europeans can benefit from new technologies developed and functioning according to Union values, fundamental rights and principles.

This proposal delivers on the political commitment by President von der Leyen, who announced in her political guidelines for the 2019-2024 Commission “A Union that strives for more”¹, that the Commission would put forward legislation for a coordinated European approach on the human and ethical implications of AI. Following on that announcement, on 19 February 2020 the Commission published the White Paper on AI - A European approach to excellence and trust². The White Paper sets out policy options on how to achieve the twin objective of promoting the uptake of AI and of addressing the risks associated with certain uses of such technology. This proposal aims to implement the second objective for the development of an ecosystem of trust by proposing a legal framework for trustworthy AI. The proposal is based on EU values and fundamental rights and aims to give people and other users the confidence to embrace AI-based solutions, while encouraging businesses to develop them. AI should be a tool for people and be a force for good in society with the ultimate aim of increasing human well-being. Rules for AI available in the Union market or otherwise affecting people in the Union should therefore be human centric, so that people can trust that the technology is used in a way that is safe and compliant with the law, including the respect of fundamental rights. Following the publication of the White Paper, the Commission launched a broad stakeholder consultation, which was met with a great interest by a large number of stakeholders who were largely supportive of regulatory intervention to address the challenges and concerns raised by the increasing use of AI.

The proposal also responds to explicit requests from the European Parliament (EP) and the European Council, which have repeatedly expressed calls for legislative action to ensure a well-functioning internal market for artificial intelligence systems (‘AI systems’) where both benefits and risks of AI are adequately addressed at Union level. It supports the objective of the Union being a global leader in the development of secure, trustworthy and ethical artificial

¹ https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf

² European Commission, White Paper on Artificial Intelligence - A European approach to excellence and trust, COM(2020) 65 final, 2020.

intelligence as stated by the European Council³ and ensures the protection of ethical principles as specifically requested by the European Parliament⁴.

In 2017, the European Council called for a ‘sense of urgency to address emerging trends’ including ‘issues such as artificial intelligence ..., while at the same time ensuring a high level of data protection, digital rights and ethical standards’⁵. In its 2019 Conclusions on the Coordinated Plan on the development and use of artificial intelligence Made in Europe⁶, the Council further highlighted the importance of ensuring that European citizens’ rights are fully respected and called for a review of the existing relevant legislation to make it fit for purpose for the new opportunities and challenges raised by AI. The European Council has also called for a clear determination of the AI applications that should be considered high-risk⁷.

The most recent Conclusions from 21 October 2020 further called for addressing the opacity, complexity, bias, a certain degree of unpredictability and partially autonomous behaviour of certain AI systems, to ensure their compatibility with fundamental rights and to facilitate the enforcement of legal rules⁸.

The European Parliament has also undertaken a considerable amount of work in the area of AI. In October 2020, it adopted a number of resolutions related to AI, including on ethics⁹, liability¹⁰ and copyright¹¹. In 2021, those were followed by resolutions on AI in criminal matters¹² and in education, culture and the audio-visual sector¹³. The EP Resolution on a Framework of Ethical Aspects of Artificial Intelligence, Robotics and Related Technologies specifically recommends to the Commission to propose legislative action to harness the opportunities and benefits of AI, but also to ensure protection of ethical principles. The resolution includes a text of the legislative proposal for a regulation on ethical principles for the development, deployment and use of AI, robotics and related technologies. In accordance with the political commitment made by President von der Leyen in her Political Guidelines as regards resolutions adopted by the European Parliament under Article 225 TFEU, this

³ European Council, [Special meeting of the European Council \(1 and 2 October 2020\) – Conclusions](#), EUCO 13/20, 2020, p. 6.

⁴ European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies, 2020/2012(INL).

⁵ European Council, [European Council meeting \(19 October 2017\) – Conclusion](#) EUCO 14/17, 2017, p. 8.

⁶ Council of the European Union, [Artificial intelligence b\) Conclusions on the coordinated plan on artificial intelligence-Adoption](#) 6177/19, 2019.

⁷ European Council, [Special meeting of the European Council \(1 and 2 October 2020\) – Conclusions](#) EUCO 13/20, 2020.

⁸ Council of the European Union, [Presidency conclusions - The Charter of Fundamental Rights in the context of Artificial Intelligence and Digital Change](#), 11481/20, 2020.

⁹ European Parliament resolution of 20 October 2020 on a framework of ethical aspects of artificial intelligence, robotics and related technologies, [2020/2012\(INL\)](#).

¹⁰ European Parliament resolution of 20 October 2020 on a civil liability regime for artificial intelligence, [2020/2014\(INL\)](#).

¹¹ European Parliament resolution of 20 October 2020 on intellectual property rights for the development of artificial intelligence technologies, [2020/2015\(INI\)](#).

¹² European Parliament Draft Report, Artificial intelligence in criminal law and its use by the police and judicial authorities in criminal matters, [2020/2016\(INI\)](#).

¹³ European Parliament Draft Report, Artificial intelligence in education, culture and the audiovisual sector, [2020/2017\(INI\)](#). In that regard, the Commission has adopted the [Digital Education Action Plan 2021-2027: Resetting education and training for the digital age, which foresees the development of ethical guidelines in AI and Data usage in education – Commission Communication COM\(2020\) 624 final](#).

proposal takes into account the aforementioned resolution of the European Parliament in full respect of proportionality, subsidiarity and better law making principles.

Against this political context, the Commission puts forward the proposed regulatory framework on Artificial Intelligence with the following **specific objectives**:

- ensure that AI systems placed on the Union market and used are safe and respect existing law on fundamental rights and Union values;
- ensure legal certainty to facilitate investment and innovation in AI;
- enhance governance and effective enforcement of existing law on fundamental rights and safety requirements applicable to AI systems;
- facilitate the development of a single market for lawful, safe and trustworthy AI applications and prevent market fragmentation.

To achieve those objectives, this proposal presents a balanced and proportionate horizontal regulatory approach to AI that is limited to the minimum necessary requirements to address the risks and problems linked to AI, without unduly constraining or hindering technological development or otherwise disproportionately increasing the cost of placing AI solutions on the market. The proposal sets a robust and flexible legal framework. On the one hand, it is comprehensive and future-proof in its fundamental regulatory choices, including the principle-based requirements that AI systems should comply with. On the other hand, it puts in place a proportionate regulatory system centred on a well-defined risk-based regulatory approach that does not create unnecessary restrictions to trade, whereby legal intervention is tailored to those concrete situations where there is a justified cause for concern or where such concern can reasonably be anticipated in the near future. At the same time, the legal framework includes flexible mechanisms that enable it to be dynamically adapted as the technology evolves and new concerning situations emerge.

The proposal sets harmonised rules for the development, placement on the market and use of AI systems in the Union following a proportionate risk-based approach. It proposes a single future-proof definition of AI. Certain particularly harmful AI practices are prohibited as contravening Union values, while specific restrictions and safeguards are proposed in relation to certain uses of remote biometric identification systems for the purpose of law enforcement. The proposal lays down a solid risk methodology to define “high-risk” AI systems that pose significant risks to the health and safety or fundamental rights of persons. Those AI systems will have to comply with a set of horizontal mandatory requirements for trustworthy AI and follow conformity assessment procedures before those systems can be placed on the Union market. Predictable, proportionate and clear obligations are also placed on providers and users of those systems to ensure safety and respect of existing legislation protecting fundamental rights throughout the whole AI systems’ lifecycle. For some specific AI systems, only minimum transparency obligations are proposed, in particular when chatbots or ‘deep fakes’ are used.

The proposed rules will be enforced through a governance system at Member States level, building on already existing structures, and a cooperation mechanism at Union level with the establishment of a European Artificial Intelligence Board. Additional measures are also proposed to support innovation, in particular through AI regulatory sandboxes and other measures to reduce the regulatory burden and to support Small and Medium-Sized Enterprises (‘SMEs’) and start-ups.

1.2. Consistency with existing policy provisions in the policy area

The horizontal nature of the proposal requires full consistency with existing Union legislation applicable to sectors where high-risk AI systems are already used or likely to be used in the near future.

Consistency is also ensured with the EU Charter of Fundamental Rights and the existing secondary Union legislation on data protection, consumer protection, non-discrimination and gender equality. The proposal is without prejudice and complements the General Data Protection Regulation (Regulation (EU) 2016/679) and the Law Enforcement Directive (Directive (EU) 2016/680) with a set of harmonised rules applicable to the design, development and use of certain high-risk AI systems and restrictions on certain uses of remote biometric identification systems. Furthermore, the proposal complements existing Union law on non-discrimination with specific requirements that aim to minimise the risk of algorithmic discrimination, in particular in relation to the design and the quality of data sets used for the development of AI systems complemented with obligations for testing, risk management, documentation and human oversight throughout the AI systems' lifecycle. The proposal is without prejudice to the application of Union competition law.

As regards high-risk AI systems which are safety components of products, this proposal will be integrated into the existing sectoral safety legislation to ensure consistency, avoid duplications and minimise additional burdens. In particular, as regards high-risk AI systems related to products covered by the New Legislative Framework (NLF) legislation (e.g. machinery, medical devices, toys), the requirements for AI systems set out in this proposal will be checked as part of the existing conformity assessment procedures under the relevant NLF legislation. With regard to the interplay of requirements, while the safety risks specific to AI systems are meant to be covered by the requirements of this proposal, NLF legislation aims at ensuring the overall safety of the final product and therefore may contain specific requirements regarding the safe integration of an AI system into the final product. The proposal for a Machinery Regulation, which is adopted on the same day as this proposal fully reflects this approach. As regards high-risk AI systems related to products covered by relevant Old Approach legislation (e.g. aviation, cars), this proposal would not directly apply. However, the ex-ante essential requirements for high-risk AI systems set out in this proposal will have to be taken into account when adopting relevant implementing or delegated legislation under those acts.

As regards AI systems provided or used by regulated credit institutions, the authorities responsible for the supervision of the Union's financial services legislation should be designated as competent authorities for supervising the requirements in this proposal to ensure a coherent enforcement of the obligations under this proposal and the Union's financial services legislation where AI systems are to some extent implicitly regulated in relation to the internal governance system of credit institutions. To further enhance consistency, the conformity assessment procedure and some of the providers' procedural obligations under this proposal are integrated into the procedures under Directive 2013/36/EU on access to the activity of credit institutions and the prudential supervision¹⁴.

¹⁴ Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC Text with EEA relevance, OJ L 176, 27.6.2013, p. 338–436.

This proposal is also consistent with the applicable Union legislation on services, including on intermediary services regulated by the e-Commerce Directive 2000/31/EC¹⁵ and the Commission's recent proposal for the Digital Services Act (DSA)¹⁶.

In relation to AI systems that are components of large-scale IT systems in the Area of Freedom, Security and Justice managed by the European Union Agency for the Operational Management of Large-Scale IT Systems (eu-LISA), the proposal will not apply to those AI systems that have been placed on the market or put into service before one year has elapsed from the date of application of this Regulation, unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.

1.3. Consistency with other Union policies

The proposal is part of a wider comprehensive package of measures that address problems posed by the development and use of AI, as examined in the White Paper on AI. Consistency and complementarity is therefore ensured with other ongoing or planned initiatives of the Commission that also aim to address those problems, including the revision of sectoral product legislation (e.g. the Machinery Directive, the General Product Safety Directive) and initiatives that address liability issues related to new technologies, including AI systems. Those initiatives will build on and complement this proposal in order to bring legal clarity and foster the development of an ecosystem of trust in AI in Europe.

The proposal is also coherent with the Commission's overall digital strategy in its contribution to promoting technology that works for people, one of the three main pillars of the policy orientation and objectives announced in the Communication 'Shaping Europe's digital future'¹⁷. It lays down a coherent, effective and proportionate framework to ensure AI is developed in ways that respect people's rights and earn their trust, making Europe fit for the digital age and turning the next ten years into the **Digital Decade**¹⁸.

Furthermore, the promotion of AI-driven innovation is closely linked to the **Data Governance Act**¹⁹, the **Open Data Directive**²⁰ and other initiatives under the **EU strategy for data**²¹, which will establish trusted mechanisms and services for the re-use, sharing and pooling of data that are essential for the development of data-driven AI models of high quality.

The proposal also strengthens significantly the Union's role to help shape global norms and standards and promote trustworthy AI that is consistent with Union values and interests. It provides the Union with a powerful basis to engage further with its external partners, including third countries, and at international fora on issues relating to AI.

¹⁵ Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce'), OJ L 178, 17.7.2000, p. 1–16.

¹⁶ See Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC COM/2020/825 final.

¹⁷ Communication from the Commission, Shaping Europe's Digital Future, COM/2020/67 final.

¹⁸ [2030 Digital Compass: the European way for the Digital Decade](#).

¹⁹ Proposal for a Regulation on European data governance (Data Governance Act) [COM/2020/767](#).

²⁰ Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information, PE/28/2019/REV/1, OJ L 172, 26.6.2019, p. 56–83.

²¹ [Commission Communication, A European strategy for data COM/2020/66 final](#).