EUROPEAN COMMISSION

Roberto FICO
President of the Camera dei Deputati
Piazza Montecitorio
IT – 00100 ROMA

Dear President,

The Commission would like to thank the Camera dei Deputati for its Opinion on the 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 {COM(2021) 206 final}.

The Commission welcomes the support of the Camera dei Deputati to the strategic orientations and the human-centric vision in the field of artificial intelligence as reflected in the proposed Artificial Intelligence ('AI') Act. The AI Act aims at laying down rules to ensure that AI systems used in the EU are safe and do not compromise fundamental rights. In particular, specific requirements are set for high-risk AI systems. The proposal is complementary and applies in conjunction with all existing EU acquis on data protection and fundamental rights.

The AI Act is part of a broader package adopted on 21 April 2021, which also includes the review of the Coordinated Plan on AI[1]. The reviewed plan defines concrete actions and funding possibilities and aims at ensuring complementarity and synergies between national and EU level actions on AI. Key objectives of the Plan are a wider uptake of AI across the EU. The EU should become the place where excellence thrives from the laboratory to the market, with 20 billion euro of private and public investments annually in the coming decade.

The Commission considers that both the AI Act and the Coordinated Plan on AI are essential to draw all the benefits of AI for our society and economy, including by stimulating innovation.

The Commission carefully analysed the Opinion of the Camera dei Deputati and noted the concerns expressed therein, including on the definition of AI, the involvement of Member States in the review of its scope, the need to ensure stronger harmonisation in the areas of biometrics and regulatory sandboxes as well as the need to ensure legal

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[1] https://digital-strategy.ec.europa.eu/en/library/coordinated-plan-artificial-intelligence-2021-review

certainty in respect to the application of certain requirements and the obligations of operators in the value chain. In this respect, the Commission would like to provide the following clarifications.

On the AI definition, the Commission's intention was to build on an internationally recognised and future-proof definition, and for that reason it wanted to ensure substantial alignment with the AI definition adopted by the OECD. Involvement of Member States and reliance on Member States' expertise will be ensured whenever the scope of the definition, including annex 1, will be subject to review. In line with the 2016 Interinstitutional Agreement on Better Law-making[2], the Commission will consult experts designated by each Member State in the preparation of the draft delegated acts. This is expected to be done primarily through the European Artificial Intelligence Board. See the annex to this reply for more details on Member States involvement.

On possible future European guidelines related to the authorisation of certain biometric identification systems, the Commission will consider, when necessary, providing guidance and clarifications to Member States for the authorisation of biometric identification systems in publicly accessible spaces.

The Commission fully shares the view that requirements and obligations contained in the AI Act should be proportionate, practicable and adequate, taking into account the role of the operators in the value chain. In preparing the impact assessment accompanying the proposal[3], the Commission devoted specific attention to an in-depth analysis of the AI value chain, the applicability and proportionality of the regulatory solutions proposed as well as a smooth interplay with all the relevant existing legislation.

The AI Act should smoothly interact with other legislation, either other product safety rules or in relation to the General Data Protection Regulation, finance and platform workers. The Commission was particularly keen to ensure that the relevant requirements and obligations to be fulfilled under the proposed AI Act would be fully integrated into the existing enforcement and supervision system envisaged for credit institutions. In particular, the Commission has proposed that the financial supervisory authorities should be designated as market surveillance authorities responsible for the enforcement of the AI Act vis-à-vis regulated financial institutions. The conformity assessment procedures for AI systems will also be integrated as part of the existing financial supervisory review process applicable to credit institutions under Directive 2013/36/EU. Such integration should also minimise the impact on Member States resources and ensure consistency with existing sectoral rules.

As regards the relationship with the data protection legislation, the proposed AI Act is without prejudice to applicable Union data protection law. The ex-ante requirements for high-risk AI systems must be fulfilled by providers before they place those systems on the market, so that users obtain the system in a way that enables them to comply with their existing obligations under the Union law on the protection of personal data and of other

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[2] EUR-Lex - 32016Q0512(01) - EN - EUR-Lex (europa.eu)

[3] https://digital-strategy.ec.europa.eu/en/library/impact-assessment-regulation-artificial-intelligence

fundamental rights (e.g. avoid discrimination, exercise human intervention, if needed). The proposal for a Platform work directive[4] is complementary to the horizontal approach of the AI Act and aims to introduce specific provisions applicable to the use of automated systems in the workplace from the perspective of the specificities of the employment relations.

That said, the Commission remains fully open to facilitate the ongoing negotiations, which may further support and strengthen the objectives of proportionality, legal certainty and avoidance of legal fragmentation.

On the code of conduct and the option of starting already the elaboration of a code of ethics for providers of high-risk AI systems, the Commission would like to stress that the proposed AI Act assigns a key role to harmonised standards for the operationalisation of the requirements of high-risk systems. In this context, the European standardisation organisations are already taking the necessary steps to start the preparatory work related to the preparation of those standards. On low-risk AI, the AI Act lays down that the Commission and the Member States shall encourage and facilitate the drawing up of codes of conduct intended to foster the voluntary application to low-risk systems of the requirements for high-risk AI systems, including on transparency. Finally, it should be noted that the High-Level Expert Group on Artificial Intelligence established by the European Commission in 2018 has elaborated Ethics Guidelines for Trustworthy AI together with a practical tool that translates the Ethics Guidelines into an accessible and dynamic self-assessment checklist. Such documents have significantly informed the drafting of the rules of the AI Act and continue to represent an invaluable point of reference in relation to ethical considerations for design and development of AI systems.

On the strengthened EU-wide coordination of regulatory sandboxes, the Commission agrees with the need to ensure the appropriate coordination among these structures. To this purpose, the proposed AI Act clarifies that the modalities related to the functioning of these structures will be set by the Commission in future implementing legislation. Moreover, the relevant national competent authorities are expected to coordinate their activities related to sandboxes within the framework of the future European Artificial Intelligence Board.

As to enforcement, the proposed AI Act assigns a key role to Member States for the enforcement of the future framework. Hence, the Commission shares the views of the Camera dei Deputati related to the need that Member States start their preparatory activities and equip their future authorities with the necessary resources. As AI is a new, complex and cross-cutting technology, the AI proposal sets a clear obligation for Member States to ensure the provision of adequate resources and to report on this issue to the Commission on a regular basis. The Commission will also do its utmost to ensure the necessary coordination and exchange among the national authorities and to promote necessary training activities.

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[4] COM(2021) 762 final.

The Commission shares the view that transparency and accessibility of information related to AI systems is key to enhance public trust in AI and to facilitate better enforcement. In this context, the introduction of a European database containing extensive information on high-risk AI systems constitutes one of the key marking novelties contained in the AI Act.

Finally, the Commission agrees on the need for policies aimed to improve digital literacy, as well as AI skills and hybrid skills to face future challenges linked to AI. Such skills will also constitute an essential condition for a smooth implantation of the future AI Act and the realisation of its objectives. As highlighted in the Coordinated Plan for AI reviewed in 2021, the Commission will support the creation of appropriate skills in the field by means of targeted actions under the Digital Education Action Plan 2021-2027, the Digital Europe Programme and Horizon Europe. Moreover, the Recovery and Resilience Facility Instrument is an additional unprecedented opportunity for Member States to advance their efforts in this area. The Commission is also working on various initiatives for the development of digital skills (e.g. structured dialogue on digital education and skills, implementation of the digital education action plan, Digital Decade, etc.).

Further observations on certain technical questions in the Opinion are contained in the attached annex.

Discussions between the Commission and the co-legislators, the European Parliament and the Council, concerning the proposal are now underway and the Commission remains hopeful that an agreement will be reached in the near future. The Commission will take the opinion of the Camera dei Deputati in due account in the context of those discussions.

The Commission hopes that the clarifications provided in this reply address the issues raised by the Camera dei Deputati and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Maroš Šefčovič   *Thierry Breton*
Vice-President   *Member of the Commission*

I. *Definition of AI and its future amendments*

The definition of AI has been conceived to be as technology neutral as possible, so it can be applied over time to innovation and market developments.

The regulatory proposal builds on the internationally recognised definition of OECD and describes AI as 'a software that can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with'.

To provide legal certainty, the Commission annexed a list of AI techniques and approaches to the definition. The techniques and approaches covered in that Annex reflect those that have traditionally been used in the context of the AI, based on relevant experience and literature.

The proposal gives the Commission with the possibility to amend the Annex via a delegated act, in order to update the list to market and technological developments on the basis of characteristics that are similar to the techniques and approaches listed therein. The procedure for the adoption of a delegated act ensures a high-level of involvement of Member States. Based on the interinstitutional agreement of 2016 on better law-making[5], the Commission shall consult experts designated by each Member State in the preparation of draft delegated acts. Moreover, the Council and the European Parliament may object to any delegated act following its adoption by the Commission.

II. *Applicability of requirements and role of standards*

The proposed Artificial Intelligence Act is structured as a New Legislative Framework (NLF) type legislation. NLF is a well-experimented regulatory scheme that has been successful in ensuring the development of a successful internal market for safe and compliant products.

Such scheme provides high-level provisions and essential requirements in the main legal act, while economic operators could achieve compliance with these requirements through the use of harmonised standards.

Harmonised standards are European standards produced by the European standardisation organisations (notably CEN/CENELEC and ETSI) in response to a Commission's standardisation request to provide the technical specifications that can be used to prove compliance with the 'essential requirements' of a harmonisation legislation.

Harmonised standards are hence expected to ensure that the high-level requirements set in the legal act can be operationalised into implementable technical solutions reflecting

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[5] EUR-Lex - 32016Q0512(01) - EN - EUR-Lex (europa.eu)

among other things the technical state-of-art and the context of use of the high-risk system in question.

III.   *Change to an AI system throughout its lifecycle and reassessment*

A reassessment of the AI system would be needed when the system is subject to a substantial modification. A substantial modification is to be intended as a modification of the product that may alter the compliance of the product with the relevant requirements of the applicable Union legislation or change the intended purpose of the same product. A substantially modified AI system is thus considered as a new AI system and the person operating the substantial change would be considered as the provider of the system in question and would assume all the relevant obligations.

The application of these concepts to certain AI systems, notably those systems that continue to learn after (or during) use could however generate a situation where a substantial modification would occur on a regular basis and thus the provider would be constantly required to undergo a new conformity assessment.

The AI Act aims to address this complex issue by introducing the notion of 'pre-determined change'. In practice, at the moment of the initial conformity assessment, the provider can document certain pre-determined changes of the AI system and validate the technical solutions adopted to ensure that, when those changes occur, the AI system remains compliant with the applicable requirements.

Those pre-determined changes documented and validated at the time of the initial conformity assessment would not constitute a substantial modification and would thus not trigger a new conformity assessment.

This approach ensures that the person responsible for effecting changes to AI systems assume a level of responsibility which is proportionate to the nature of the AI system and the risk associated with the changes effected.