Brussels, 05.02.2022
C(2022) 780 final

Dear Chair,

The Commission would like to thank the Eerste Kamer for its Opinion on the Communication 'Fostering a European approach to artificial intelligence' {COM(2021) 205 final} and 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}.

Artificial intelligence concerns fast evolving technologies that can bring a wide array of economic and societal benefits across the entire spectrum of industries and social activities. The Commission's approach is to facilitate the development of an ecosystem of artificial intelligence excellence and an ecosystem of trust in artificial intelligence. With this legislative proposal, the Commission aims to give people the confidence to embrace artificial intelligence-based solutions, while encouraging businesses to develop them.

Artificial intelligence should be a tool for people with the ultimate aim of increasing human well-being. Rules for artificial intelligence available 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.

Notably, the Artificial Intelligence Act proposal sets harmonised rules for the development, placement on the market and use of artificial intelligence systems in the Union, with the specific objectives to:

- ensure that artificial intelligence systems placed on the Union market and used are safe and respect fundamental rights and Union values;

- facilitate the development of a single market for lawful, safe and trustworthy artificial intelligence applications;

- ensure legal certainty to facilitate investment and innovation; and

- enhance governance and effective enforcement of existing law on fundamental rights and safety requirements applicable to artificial intelligence systems.

In proposing these measures, the Commission follows up on the commitment to put forward legislation for a coordinated European approach on the human and ethical

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implications of artificial intelligence, announced in President von der Leyen's political guidelines for the 2019-2024 Commission.

The Commission takes seriously concerns expressed by the Eerste Kamer as regards some of the aspects and regulatory choices of the proposed Artificial Intelligence Act, such as the scope of the envisaged prohibited artificial intelligence practices, the risk-based approach and the governance system. The Commission has thoroughly analysed them and is pleased to provide its clarifications in the Annex to this reply. The points made in the annex are based on the initial proposal presented by the Commission on 21 April 2021, which is currently in the legislative process involving both the European Parliament and the Council.

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

Yours faithfully,

Maroš Šefčovič
Vice-President

Thierry Breton
Member of the Commission

Annex

The Commission welcomes the examination that the Eerste Kamer has carried out on the important subject of artificial intelligence. The Eerste Kamer's questions constitute an important contribution to the debate on the Artificial Intelligence Act proposal that is now underway. The Commission would like to offer the following answers in relation to the questions posed, grouped by topics.

Concerning the prohibited artificial intelligence practices laid out in Article 5 of the Artificial Intelligence Act proposal, and in particular, the use of subliminal techniques which may lead to physical or psychological harm, the Commission notes that such practices are particularly harmful and contradict Union values and fundamental rights. While other harms may indeed occur as a result of such practices, beyond the physical and psychological harms mentioned in Article 5(1)(a), the Commission has decided that it is important to ensure legal certainty for operators and address only those risks specific to artificial intelligence which are not covered by other legislation. Other risks that may occur beyond physical or psychological harm are being addressed by the existing legislation on the protection of fundamental rights and safety and the regulation of specific activities such as those of online intermediaries. For instance, the proposed Digital Services Act will significantly improve the mechanisms for the removal of illegal content and for the effective protection of users' fundamental rights online and will create a stronger public oversight of large online platforms. Among other things, it lays down transparency requirements for certain online platforms on a variety of issues, including on the algorithms used for recommendations so that recipients are appropriately informed and can influence the information presented to them. Moreover, the Unfair Commercial Practices Directive regulates unfair business practices, such as misleading actions and aggressive marketing techniques to influence consumers' choices. As regards the burden of proof, the Commission intends to put forward a proposal on the revision of the product liability rules, also in respect of artificial intelligence. Moreover, prohibited practices will be penalised with the most severe sanctions laid down in the Artificial Intelligence Act proposal (Article 71, para. 3), which will likely entail the necessary deterrent effect.

Concerning the prohibition of the placing on the market, putting into service or use of social scoring systems by public authorities, the Commission considers that this is necessary due to the specific power imbalances and the large-scale effects of such scoring systems affecting often the entire population. Nevertheless, the extension of the prohibition on the use of social scoring to private actors may be considered by the co-legislators in the framework of the ordinary legislative procedure.

With regard to artificial intelligence systems used for biometric identification, the Commission considers that the use of 'real-time' remote biometric identification intrudes on the rights and freedoms of the persons concerned. It may affect the private life of a large part of the population, evoke a feeling of constant surveillance and indirectly dissuade the exercise of the freedom of assembly and other fundamental rights. In addition, the immediacy of the impact and the limited opportunities for further checks or corrections in relation to the use of such systems operating in 'real-time' carry heightened risks for the rights and freedoms of the persons concerned. According to the Artificial Intelligence Act proposal, 'real-time' implies that the capturing of the biometric data, the comparison and the identification occur all instantaneously, near-instantaneously or in any event without a significant delay. This comprises not only instant identification, but also limited short delays in order to avoid circumvention, as explained in Article 3, point 37 of the proposal.

Notably, the Commission carefully balanced the risks and the benefits of artificial intelligence systems used for biometric identification in drafting the proposal, as well as analysed the already existing rules. The General Data Protection Regulation[1] in principle already prohibits the processing of biometric data for identification purposes, for purposes other than law enforcement, unless in specific situations. This includes 'post' and 'near' identification in publicly and privately accessible spaces. There are a number of decisions by the national data protection authorities prohibiting such uses. When it comes to the processing of biometric data for law enforcement purposes, the Law Enforcement Directive[2] makes such use subject to an authorisation by Union or Member State law. Under Article 10 of that Directive, a number of Member States already provided a legal basis for post-processing of biometric data, while for real-time processing they have not adopted specific legislation. The Artificial Intelligence Act proposal builds upon the data protection acquis and complements it by explicitly prohibiting the use of real-time remote biometric identification systems in publicly accessible places for law enforcement purposes, unless three limited exceptions apply and subject to strong safeguards (including independent judicial authorisation and restrictions on the geographical and temporal scope of use and the data to be included in the reference database). This creates a level playing field when it comes to the use of artificial intelligence systems for remote biometric identification.

The Commission also notes that Article 5 of the proposed Artificial Intelligence Act does not provide the legal basis for personal data processing in the context of using artificial intelligence systems for real-time remote biometric identification for law enforcement purposes, but requires additional national legislation should the Member States intend to deploy such systems. The final decision in this respect is therefore in the hands of the national legislator.

Furthermore, while the use of artificial intelligence systems for biometric identification may certainly pose significant risks, such systems can also entail important benefits, for example, when it comes to public security, e.g. fighting terrorism. Artificial intelligence systems for emotional recognition can also be beneficial, for example to help the blind or people with an autistic disposition or for the detection of drowsiness of drivers to issue warnings and prevent car crashes. The same holds true for biometric categorisation systems, which can be used for the detection and verification of the age of video gamers and hence protect children from harmful content, as well as for the classification of child sexual abuse images where biometric categorisation is used to ascertain the criminal relevance of the images or to localise victims. For these reasons, the Artificial Intelligence Act proposal attempts to balance the risks and benefits and does not lay down outright prohibitions.

The Artificial Intelligence Act proposal does, however, classify as high-risk all artificial intelligence systems used for remote biometric identification (including real-time and post-processing), subjecting them to a third-party conformity assessment before being placed on the market or put into service. This aims to ensure that those systems, which do

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[1] 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)

[2] 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

not fall under the scope of the prohibition of Article 5 (1)(d) are tested, documented and used in a way that is compliant with fundamental rights. In addition, the use of artificial intelligence systems for emotional recognition and biometric categorisation will be subject to transparency obligations, so that people are aware when exposed to such systems. Consequently, the Commission considers that the existing obligations and restrictions under the data protection legislation combined with the new obligations under the Artificial Intelligence Act proposal are appropriate for the protection of fundamental rights with regard to biometric systems.

The Commission takes seriously the concerns expressed in relation to the risk-based approach of the proposed Artificial Intelligence Act. The proposal classifies as high-risk a limited number of artificial intelligence systems identified by the Commission at the time of drafting the proposal, whose risks to safety and fundamental rights had already materialised or were likely to materialise in the near future. While the possibility exists that future technological developments potentially lead to artificial intelligence systems posing risks in sectors beyond our current awareness and expectations, in order to ensure legal certainty and that the proposed Artificial Intelligence Act is future-proof, the Commission has identified several critical areas where risks are known to exist at present. Within these areas, the proposal provides the possibility to add new high-risk artificial intelligence systems in a swift fashion by way of delegated acts, in the light of the dynamic market and technological developments and in accordance with a solid set of criteria and risk assessment methodology. Should future developments nevertheless lead to the use of high-risk artificial intelligence systems in other areas, the Commission may submit proposals for appropriate amendments to the EU co-legislators.

As regards the Eerste Kamer's enquiries about the obligations of providers and users of artificial intelligence systems, the proposed Artificial Intelligence Act indeed places the bulk of the envisaged obligations on providers, in line with EU product safety legislation, while users' obligations are strictly limited to what is necessary to ensure that the artificial intelligence system operates safely throughout its lifetime. Such users' obligations include the requirement to use the artificial intelligence system in line with the instructions of use. Moreover, all other legal obligations continue to apply, for example to do a data protection impact assessment. The Commission also would like to emphasise that misuse of a system would be a violation of the rules.

Concerning the perspective of people affected by artificial intelligence systems, the proposal carefully considers the role played by existing instruments to ensure the relevant protections. The purpose of the Artificial Intelligence Act proposal is thus to facilitate the implementation of existing legislation, e.g. on non-discrimination, consumer protection, or data protection, and the respective authorities can get access to all the information necessary to pursue a case. In cases of infringements of fundamental rights, effective redress will be made possible by ensuring transparency and traceability of the artificial intelligence system coupled with strong ex post controls.

With respect to the Eerste Kamer's concerns about the practical implementation and political translation of legal requirements applicable to artificial intelligence systems, the Commission would like to emphasise that the requirements laid down in the proposed Artificial Intelligence Act will be subject to detailed harmonized standards that will have been developed by the time the proposal enters into force. This will significantly facilitate the development of artificial intelligence systems in compliance with requirements.

The Commission agrees that transparency in the use of artificial intelligence systems is of significant importance to foster innovation, which is indeed the primary purpose of the Union's artificial intelligence policy. Concerning the Eerste Kamer's questions related to governance and conformity assessment, the Commission notes that the proposed Artificial Intelligence Act provides for a two-layer governance structure with a key role for national supervisory authorities, which will be charged with implementing the legislation.

Under the proposed rules, providers of high-risk artificial intelligence systems will have to undergo a conformity assessment procedure, which, if successful, will allow the provider to place the artificial intelligence system on the Union market or put it into service. In the case of artificial intelligence systems embedded into products, the conformity assessment procedures under the existing legislation regulating the placing on the market of the respective product will apply, and the conformity assessment will thus in general be performed by a designated conformity assessment body. This will also be the case with respect to remote biometric identification systems used for purposes other than law enforcement. For other stand-alone high-risk artificial intelligence systems, the Commission has opted for self-assessment at this stage. It should be borne in mind that the proposal intervenes at the early stages of the deployment of the artificial intelligence system, while existing EU and national regulations also apply. Market surveillance authorities are designated to enforce compliance with the requirements laid down in the Artificial Intelligence Act proposal. The Artificial Intelligence Board would ensure a coherent implementation throughout the Union. Consequently, the Commission believes that a comprehensive ex-ante self-assessment, combined with a strong ex-post enforcement by authorities, including substantial penalties in case of violations, will ensure an effective, proportionate and realistic solution for stand-alone artificial intelligence systems (which are today unregulated before being placed on the market). Moreover, the proposed Artificial Intelligence Act provides that the Commission should also maintain an EU database where all stand-alone high-risk artificial intelligence systems should be registered. This will facilitate market surveillance at EU and national level and increase transparency towards the wider public. Finally, this approach is complemented by the possibility for the Commission to introduce a third-party conformity assessment (via delegated act) for high-risk artificial intelligence systems based on experience and information gathered. This will allow fast adaptation to any emerging risk or relevant regulatory finding.

Finally, the Commission will encourage the creation of codes of conduct by providers of all categories of artificial intelligence systems, so as to devise and implement concrete requirements related, among others, to environmental sustainability, but also, to the diversity of development teams, stakeholder participation in the design and development of the artificial intelligence systems, and accessibility for persons with a disability. Moreover, the Commission pursues an active policy to bring artificial intelligence into play for climate and environment and foresees a number of concrete action steps, outlined in the Coordinated Plan on Artificial Intelligence 2021 review[3].

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