



EUROPEAN COMMISSION

Brussels, 20.12.2021  
C(2021) 9107 final

*Dear President,*

*The Commission would like to thank the Bundesrat 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}.*

*In proposing the Artificial Intelligence Act, the Commission delivered on the commitment in its 2020 Work Programme to take legislative action to turn Europe into the global hub for trustworthy Artificial Intelligence (AI). The proposed rules aim to guarantee the safety and fundamental rights of citizens, strengthen AI uptake, investment and innovation across the EU, and increase users' trust in the new technology. The proposal was drafted in full complementarity with existing rules such as on data protection or audio visual media services.*

*The Commission is pleased that the Bundesrat supports the Commission's proposal of a first-ever horizontal legal framework on AI and its risk-based approach. It agrees with the Bundesrat that the uptake of AI has a strong potential to increase societal benefits and economic growth, boost innovation and develop solutions for social challenges.*

*The proposed Regulation addresses certain specific risks posed by AI applications that are related to user safety and fundamental rights. In addressing these risks, the Commission aims to create a framework that provides legal certainty and allows investment to flow in the AI sector. It believes that it is vital to create one set of rules for AI to create a European market and build the trust of citizens that is the basis of any technological transformation.*

*As underlined in the Bundesrat's Opinion, a definition of AI that is both sufficiently precise and future-proof is a regulatory challenge. The Commission proposed a definition based on the functional characteristics of AI that can be dynamically adapted to cover techniques and approaches, which are not yet known or developed. The Commission will take the Bundesrat's concern about including statistical approaches and search and optimization methods into consideration. It will closely follow the technological development in AI and regularly update the techniques and approaches considered to be AI in Annex I.*

*Mr Bodo RAMELOW  
President of the Bundesrat  
Leipziger Straße 3 - 4  
D – 10117 BERLIN*

*The Commission welcomes the Bundesrat support for including suppliers and users of AI systems established in third countries within the scope of the Regulation, and takes note of the request to broaden or clarify the scope of the Regulation regarding providers and users in third countries analysing EU-citizens data, where the result generated by the AI system may have an impact on citizens in the Union.*

*The Commission takes note of the position of the Bundesrat not to introduce disproportionate restrictions on the use of AI by security authorities. The Bundesrat finds that if such restrictions are needed at all there should be a separate legal act and asks to assess the impact of the proposal on internal security. The Commission would like to emphasise, first, that national security is excluded from the scope of the proposed Artificial Intelligence Act. The requirements on law enforcement authorities are proportionate and limited to the strict minimum. They were subject to an impact assessment. The Commission would further like to emphasise that only a horizontal approach is able to prevent divergences that would be difficult to cope with by economic actors. If they want to develop or use AI systems, they need one coherent set of rules. A software might, in principle, be used for different purposes, by private and public bodies alike. The Commission would find it difficult to justify that different sectorial initiatives might use different definitions of AI, or different requirements in terms of risk mitigation. A horizontal approach does not, however, mean a “one size fits all” approach. On the contrary, the proposal takes into account sectorial specificities in several instances, including in the field of law enforcement.*

*The Commission takes note of the Bundesrat’s views on the prohibited practices and in particular to include economic harm in the prohibited practices under Article 5 (1) (a) and (b). The Commission would, however, like to point out that such economic harm is already subject to Directive 2005/29/EC on unfair commercial practices. The Commission also takes note of the view of the Bundesrat to extend the prohibition of the use of AI in Articles 5(1) (c) and (d) for social scoring and real-time remote biometric identification systems to emotional recognition systems and to private actors. The Commission will consider the Bundesrat’s suggestion to prohibit judicial decisions being taken or significantly influenced by AI systems.*

*The Commission shares the Bundesrat’s view that AI systems intended to be used as a safety component of motor vehicles should fall within the scope of the Regulation. It will draw the attention of the co-legislators to the editorial mistake in Annex II, Section B (6) to clarify that both Regulation (EU) 2018/858 and Regulation (EU) 2019/2144 on motor vehicles are considered relevant Union harmonisation legislation as referred to in Art. 6 (1). Motor vehicles are regulated under an approach which does not allow for a direct application of the proposed horizontal AI framework. However, the proposed targeted amendments to the respective regulations, specifically mentioned in Art. 80 and 82 of the proposal, will make sure that AI related requirements will be taken into consideration when adopting future sector-specific implementing acts.*

*The Commission does not share the Bundesrat’s view that the proposal does not contain any substantive requirements relating to the protection of fundamental rights, protection against undesirable discrimination, or compliance with legal requirements. The Commission would like to emphasise that these legal requirements have been translated into the key requirements*

*for high-risk use cases, for example, high data quality is essential to ensure that a high-risk AI system does not become the source of discrimination prohibited by Union law.*

*The Commission welcomes the Bundesrat's feedback on the risk-based approach, definition, scope, content and term 'high-risk', and agrees with the need of legal certainty. It will consider the Bundesrat's suggestion that whilst, on the one hand, the classification as high-risk AI system could be too far-reaching, and that in particular in the field of justice there is a need for clear definitions (it should be noted however that the term 'law enforcement authority' also includes criminal courts), on the other hand, for reasons of consumer protection, other AI scoring procedures, for example for health services, health insurance, housing or holiday accommodation, should be included in the list of high-risk AI systems and that the risk of significant economic damage to a large group of consumers should be included in Article 7(1)(b) and (2).*

*The Commission welcomes the Bundesrat's comments regarding the requirements for high-risk systems and will further analyse them, in particular regarding the question whether, when high-risk AI systems are used as security components in products, the further development of the systems by self-learning should be subject to certain rules that cannot be overcome by the AI system. The Commission will also analyse the question whether there is a need to have specific considerations regarding vulnerable groups when establishing the risk management system.*

*The Commission welcomes the Bundesrat's position regarding conformity assessment and market surveillance authorities and, in particular, the need for uniform and high quality and sufficient resources. The Commission takes note of the request to extend third-party conformity assessments, in particular for high-risk cases used for commercial purposes. The proposed Artificial Intelligence Act provides the possibility to move to such third-party assessments for high-risk AI systems should self-assessments prove to be insufficient. The Commission agrees with the Bundesrat's position that appropriate cooperation and coordination between national authorities will be needed. This will be a task for the proposed Artificial Intelligence Board. The Commission also agrees that effective safeguarding of trade secrets is key.*

*As to the right to seek redress requested by the Bundesrat, the General Data Protection Regulation already contains effective provisions in that respect, notably in terms of the rights of the data subject (information, human intervention and review) in case of solely automated decision-making with legal or similarly significant effects, as well as rights to compensation and damage. Other existing legislation aimed to enforce fundamental rights in the area of, among others, non-discrimination, consumer protection, product liability, product safety, law enforcement and border managements also provides for rights and remedies whose exercise will be facilitated with the new requirements and the obligations under the proposed Artificial Intelligence Act, i.e. the right of these authorities to request all pertinent information from the AI market surveillance authorities.*

*The Commission takes seriously the concerns expressed by the Bundesrat that excessive regulation might stifle innovation and have a negative impact on the competitiveness of European companies, especially small and medium sized enterprises and start-ups. The*

*Commission will continue to ensure that requirements are proportionate and limited to AI posing a risk to safety or fundamental rights. To ease the regulatory burden on small and medium sized enterprises and start-ups, the proposed Artificial Intelligence Act includes several provisions to support their compliance and reduce their costs, including regulatory sandboxes and the obligation of notified bodies to consider small and medium sized enterprises interests when setting the fees for conformity assessment. The Commission welcomes the Bundesrat's recommendations regarding regulatory sandboxes.*

*The Commission takes note of the Bundesrat's position on the use of data in AI systems and on the media sector.*

*The Commission agrees with the Bundesrat that AI systems already used for many years must not be withdrawn from the market because of subsequent requirements. The Artificial Intelligence Act proposes that the requirements will only apply to high-risk AI systems that have been placed on the market up until two years after the Regulation enters into force if those systems are subject to significant changes in their design or intended purpose (Art. 83).*

*A proposal for liability may be presented in 2022.*

*The points made above are based on the initial proposal presented by the Commission, currently in the legislative process involving both the European Parliament and the Council. The Bundesrat's opinion has been forwarded to the relevant Commission services and will feed the ongoing legislative discussions.*

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

*Yours faithfully,*

*Maroš Šefčovič  
Vice-President*

*Thierry Breton  
Member of the Commission*