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TELECOM 156
JAI 429
COPEN 191
CYBER 108
DATAPROTECT 103
EJUSTICE 41
COSI 69
IXIM 74
ENFOPOL 148
FREMP 103
RELEX 347
MI 271
COMPET 275
IA 60
CODEC 573

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	22 April 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SEC(2021) 167 final
Subject:	*REGULATORY SCRUTINY BOARD OPINION* Proposal for a Regulation of the European Parliament and of the Council aying down harmonized rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts

Delegations will find attached document SEC(2021) 167 final.

Encl.: SEC(2021) 167 final

EUROPEAN COMMISSION

SEC(2021) 167

22.03.2021

REGULATORY SCRUTINY BOARD OPINION

Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts

{COM(2021) 206}
{SWD(2021) 84}
{SWD(2021) 85}

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Proposal for a Regulation laying down requirements for artificial intelligence

Overall 2nd opinion: POSITIVE

(A) Policy context

Artificial intelligence (AI) can contribute to make the EU ready for the digital age. The EU approach to AI aims to promote innovation capacity in AI, while supporting the development and uptake of ethical and trustworthy AI across the economy. The strategy proposed in the White Paper on AI aims to build ecosystems of excellence and trust for AI. The ecosystem of excellence consists of measures to support research, foster collaboration between Member States and increase investment in AI development and deployment. The ecosystem of trust foresees robust safety requirements for AI-based products and services that respect fundamental EU values and rights. It would give citizens the confidence to embrace AI-based solutions, while encouraging businesses to develop them.

(B) Summary of findings

The Board notes the substantial changes and significant improvements made to the report and the clarifications provided on key issues, such as the interaction with other initiatives and the content of options.

The Board gives a positive opinion. The Board also considers that the report should further improve with respect to the following aspect:

(1) The report does not clearly justify the presented cost levels and does not present their sources. The remaining uncertainty on the costs of the initiative make it difficult to judge to what extent the (fixed) costs could create prohibitive barriers for SMEs or new market entrants.

This opinion concerns a draft impact assessment which may differ from the final version.

(C) What to improve

(1) The report should explain the methodology and sources for its cost calculations in the relevant annex. It should include a detailed discussion of where and why the presented costs deviate from the supporting study. The report should better discuss the combined effect of the foreseen support measures for SMEs (lower fees for conformity assessments, advice, priority access to regulatory sandboxes) and the (fixed) costs, including for new market entrants.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

(D) Conclusion

The DG may proceed with the initiative.

The DG must take these recommendations into account before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Proposal for a Regulation of the European Parliament and the Council laying down requirements for artificial intelligence
Reference number	PLAN/2020/7453
Submitted to RSB on	23 February 2021
Date of RSB meeting	Written procedure

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

Overview of Benefits (total for all provisions) – Preferred Option

DESCRIPTION	AMOUNT	COMMENTS
	Direct benefits	
Fewer risks to safety and fundamental rights	Not quantifiable	Citizens
Higher trust and legal certainty in AI	Not directly quantifiable	Businesses
	Indirect benefits	
Higher uptake	Not directly quantifiable	Businesses
More beneficial applications	Not quantifiable	Citizens

Not quantifiable: impossible to calculate (e.g. economic value of avoiding fundamental rights infringements)

Not directly quantifiable: could in theory be calculated if many more data were available (or making large numbers of assumptions)

Overview of costs – Preferred option

		CITIZENS/ CONSUMERS		BUSINESSES		ADMINISTRATIONS	
		One-off	**Recurrent**	**One-off**	**Recurrent**	**One-off**	**Recurrent**
Comply with substantial require-ments	**Direct costs**			€ 6000 – 7000 per application	€ 5000 – 8 000 per application		
	Indirect costs						
Verify compliance	**Direct costs**			€ 3000 – 7500 per application			
	Indirect costs			Audit QMS €1000 – 2000 per day, depending on complexity	Renew audit, €300 per hour, depending on complexity		
Establish competent authorities	**Direct costs**						1-25 FTE per MS; 5 FTE at EU
	Indirect costs						

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Proposal for a Regulation laying down requirements for Artificial Intelligence

Overall opinion: NEGATIVE

(A) Policy context

Artificial intelligence (AI) plays a key role in the agenda of making the EU ready for the digital age. The European approach to AI aims to promote Europe's innovation capacity in AI, while supporting the development and uptake of ethical and trustworthy AI across the economy. The EU strategy proposed in the White Paper on AI aims to build ecosystems of excellence and trust for AI. The ecosystem of excellence consists of measures to support research, foster collaboration between Member States, and increase investment in AI development and deployment. The ecosystem of trust foresees robust safety requirements for AI-based products and services that respect fundamental EU values and rights. It would give citizens the confidence to embrace AI-based solutions, while encouraging businesses to develop them.

(B) Summary of findings

The Board notes the useful additional information provided in advance of the meeting and commitments to make changes to the report.

However, the Board gives a negative opinion, because the report contains the following significant shortcomings:

(1) The report is not sufficiently clear on how this initiative will interact with other AI initiatives, in particular with the liability initiative.

(2) The report does not discuss the precise content of the options. The options are not sufficiently linked to the identified problems. The report does not present a complete set of options and does not explain why it discards some.

(3) The report does not show clearly how big the relative costs are for those AI categories that will be regulated by this initiative. Even with the foreseen mitigating measures, it is not sufficiently clear if these (fixed) costs could create prohibitive barriers for SMEs to be active in this market.

(C) What to improve

(1) The content of the report needs to be completed and reworked. The narrative should be improved and streamlined, by focusing on the most relevant key information and analysis.

(2) The report should clearly explain the interaction between this horizontal regulatory initiative, the liability initiative and the revision of sectoral legislation. It should present which part of the problems will be addressed by other initiatives, and why. In particular, it should clarify and justify the policy choices on the relatives roles of the regulatory and liability initiatives.

(3) In the presentation of the options, the report focusses mainly on the legal form, but it does not sufficiently elaborate on the content. The report should present a more complete set of options, including options that were considered but discarded. Regarding the preferred option, the report should give a firm justification on what basis it selects the four prohibited practices. There should be a clear definition and substantiation of the definition and list of high-risk systems. The same applies to the list of obligations. The report should indicate how high risks can be reliably identified, given the problem drivers of complexity, continuous adaptation and unpredictability. It should consider possible alternative options for the prohibited practices, high-risk systems, and obligations. These are choices that policy makers need to be informed about as a basis for their decisions.

(4) The report should be clearer on the scale of the (fixed) costs for regulated applications. It should better analyse the effects of high costs on market development and composition. The report should expand on the costs for public authorities, tasked to establish evolving lists of risk rated AI products. It should explain how a changing list of high-risk products is compatible with the objective of legal certainty. The analysis should consider whether the level of costs affects the optimal balance with the liability framework. It should reflect on whether costs could be prohibitive for SMEs to enter certain markets. Regarding competiveness, the report should assess the risk that certain high-risk AI applications will be developed outside of Europe. The report should take into account experiences and lessons learnt from third countries (US, China, South Korea), for instance with regard to legal certainty, trust, higher uptake, data availability and liability aspects.

(5) The report should explain the concept of reliable testing of innovative solutions and outline the limits of experimenting in the case of AI. It should clarify how regulatory sandboxes can alleviate burden on SMEs, given the autonomous dynamics of AI.

(6) The report should better use the results of the stakeholder consultation. It should better reflect the views of different stakeholder groups, including SMEs and relevant minority views, and discuss them in a more balanced way throughout the report.

(7) The report should make clear what success would look like. The report should elaborate on monitoring arrangements and specify indicators for monitoring and evaluation.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.

Full title	Proposal for a Regulation of the European Parliament and the Council laying down requirements for Artificial Intelligence

Reference number	PLAN/2020/7453
Submitted to RSB on	18 November 2020
Date of RSB meeting	16 December 2020

Electronically signed on 22/03/2021 14:31 (UTC+01) in accordance with article 11 of Commission Decision C(2020) 4482