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Delegations will find attached document SEC(2022) 344 final.

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**REGULATORY SCRUTINY BOARD OPINION**

Liability rules for Artificial Intelligence

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EUROPEAN COMMISSION  
Regulatory Scrutiny Board

Brussels,  
RSB/

## **Opinion**

**Title: Impact assessment / Liability rules for Artificial Intelligence**

**Overall opinion: POSITIVE WITH RESERVATIONS**

### **(A) Policy context**

The 2020 White Paper on Artificial Intelligence (AI) aimed to promote the uptake of AI and to address the risks associated with certain uses. The proposed AI Act would introduce rules to reduce risks for safety and fundamental rights.

When persons suffer harm caused by AI systems, they should enjoy the same level of protection as those having suffered harm caused by other technologies. Currently, victims rely on national liability rules and, in certain cases, on the Product Liability Directive (PLD), which is being revised in parallel. However, such liability rules are not adapted to handle compensation claims for harm caused by AI-enabled products or services. Victims need to prove a wrongful action or omission of a person that caused the damage, but the specific characteristics of AI make it difficult or prohibitively expensive to identify the liable person and, therefore, to prove the requirements for a successful liability claim. This impact assessment assesses possible ways to address these problems.

### **(B) Summary of findings**

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

**However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the lead DG to rectify the following aspects:**

- (1) The set of options is incomplete and does not discuss certain options that were put forward by the European Parliament. The addition of a future targeted review in option 3 does not distinguish it from option 1, which includes the same measures.**
- (2) The report is not clear on how credible and relevant the quantitative impact estimates of the options are. The conclusion that the preferred option will deliver benefits for businesses resulting from increased legal certainty and reduced legal fragmentation that outweigh the costs is not sufficiently argued and substantiated.**

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

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**(3) The choice of the preferred option is not properly analysed and substantiated, also taking into account the effectiveness to reach the objectives.**

**(C) What to improve**

(1) The report should explain clearly, why the initiative cites fragmentation of national rules as the main justification for the proposed single market legal base, yet limits the scope of the initiative to AI alone, given the highly fragmented state of tort law covering other products and services between different Member States. It should better justify how, in the specific case of AI, the variety of national rules on burden of proof differs from other types of products or services. The subsidiarity assessment should be strengthened, given the initiative's aim to create harmonised AI liability rules in deeply embedded and diverse national liability systems. The initiative should also present evidence on the perception and level of support from businesses, Member States and the European Parliament.

(2) The likely evolution of the problem and the baseline should better incorporate the likely positive effects of the proposed EU legislation on AI, as it should reduce the risks for damage from AI and the need for liability compensation. Given their timing, it is not clear whether or to what extent the supporting studies and consultations incorporate the expected positive effects of the proposed AI legislation.

(3) The report should analyse a more complete set of options. The report needs to discuss the reasons why it does not consider as an option the European Parliament's Article 225 Resolution for a complete reversal of the burden of proof. If it considers that this option is not realistic or feasible, it should demonstrate this clearly in the discarded options section. In addition, the report should be more specific on the exact content of some of the measures, such as the 'targeted alleviation of the burden of proof' or the 'harmonised strict liability regime'. It should consider whether there are possibly alternative solutions and should analyse these as sub-options if policy choices need to be made. Again, if some of them are not feasible or realistic, the report should discuss this in the discarded options section.

(4) The structure of the policy options should be presented in a coherent manner. The report should present genuine and credible alternatives that can tackle the identified problems. The report should bring out much more clearly the differences between options 1 and 3, which, in terms of substance and of expected impacts, appear to be identical given that both options can be reviewed once a more robust evidence base (that could justify more ambitious action) is in place. Given that the two options, on substance, seem identical, the report should consider the continued practical relevance of option 3, and, if retained, it should be adjusted to make it substantively different from option 1 both in terms of measures included and expected impacts. Such differences would need to be substantiated by credible and robust evidence.

(5) At the minimum, the report should ensure that options 1 and 3 score equally in terms of effectiveness, efficiency and coherence since any other scoring lacks credibility given their inherent similarity. The assessment of impacts for option 2 needs to be revisited and clarified, in a manner that justifies why it is not the preferred option, considering the objectives to be reached, assuming it is maintained as a realistic and feasible option at this point in time. The sub-option on insurance should be explicitly analysed.

(6) The report should be more transparent about the credibility and relevance of the quantitative impact estimates. As the economic support study did not model the impacts of

the options as described in the report, it should clearly explain the limitations of its results. It should better justify the conclusion that the (non-quantified) benefits for businesses resulting from increased legal certainty and reduced legal fragmentation outweigh their (quantified) costs, not least given this appears to contradict businesses' views.

(7) The report should add a separate subsection on the application of the 'one in, one out' approach. It should explain why it has been concluded that the preferred option will not entail significant administrative costs. As indirect administrative costs are in scope of the 'one in, one out' approach, they should also be discussed.

(8) The report should explain the reasons behind divergent stakeholder views on the policy options and, if possible, differentiate the views of various businesses segments (e.g. producers, service providers, distributors versus users etc). It should explore and discuss the reasons cited by stakeholders opposed to EU-level action. The report needs to explain particularly why business stakeholders are less positive about the initiative than other stakeholders are. It should also explain whether and how such less positive views have been taken into consideration in the impact analysis and the comparison of the options. The report should be upfront about the absence of Member States views and the reasons for their decision not to engage in the tailored consultations.

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

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

**(D) Conclusion**

**The lead DG must revise the report in accordance with the Board's findings 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 lead DG may need to further adjust the attached quantification tables to reflect this.**

Full title	Adapting liability rules to the digital age and Artificial Intelligence
Reference number	PLAN/2020/9848
Submitted to RSB on	04 March 2022
Date of RSB meeting	06 April 2022

## **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.*

The costs and benefits of the preferred policy option are summarised in the following tables.

<b>I. Overview of Benefits (total for all provisions) – Preferred Option</b>		
<i>Description</i>	<i>Amount</i>	<i>Comments</i>
<i>Direct benefits</i>		
Increased AI market value in the EU, due to reduced costs and increased revenues achieved through increased legal certainty, reduced legal fragmentation and increased consumer uptake	From ca. EUR 500 mln (low estimated value) to ca. EUR 1.1 bln (high estimated value) <sup>1</sup>	Businesses active in AI
Reduced AI induced compensation gap	No quantified estimates available. <sup>2</sup> The targeted alleviations of the burden of	Citizens and businesses as potential victims

<sup>1</sup> These values are obtained by multiplying the estimated shares of the AI market affected by legal uncertainty and fragmentation regarding civil liability in 2025 under the baseline scenario (low and high scenarios assumed by the economic study supporting this IA) with the estimated impact of the preferred option (+5%). This percentage was determined conservatively, taking into account the estimated impact generated by a combination of measures to ease the burden of proof with a harmonisation of strict liability limited to certain AI applications (cf. Economic Study, pp. 195 et seq.). In the supporting study, policy options including these elements were estimated to increase the production value of the affected cross-border trade by 5-7 %, for the six use-cases analysed specifically by that study (AI-enabled autonomous vehicles, autonomous drones/delivery robots, AI-enabled road traffic management systems, AI-enabled warehouse robot, AI-enabled medical-diagnosis services, AI-enabled automated lawnmowers/vacuum cleaners). In order to quantify the overall economic benefits generated by the preferred option (not limited to the six use-cases), a conservative extrapolation of this estimate was applied to the relevant market shares of all sectors affected by legal uncertainty and fragmentation, taking into account that the preferred PO does not include the strict liability element assumed for the supporting study with respect to a small number of specific AI application.

The Joint Research Centre (JRC) has provided complementary micro-economic quantification of the impacts of the preferred policy option, based on the use-case example of robotic vacuum cleaners. This analysis reaches the conclusion that the envisaged measures to ease the victim's burden of proof would generate an increase in consumer welfare of EUR 11.5-19.12mln and in total welfare of EUR 30.11-53.74mln for this product category in the EU-27. See Annex 11 for the JRC report with detailed explanations and results.

<sup>2</sup> Due to the future-oriented nature of this initiative, aimed at creating the right conditions for the rollout of AI-enabled products and services, the technologies to which this initiative would apply are in most cases not yet on the market. There is hence no statistical data available on damage caused by such products and services, nor on the success rate of liability claims brought on the basis of current liability rules. The qualitative assessment of the expected compensation gaps (under the current liability rules = baseline scenario) and the extent to which the policy options would address those gaps are based on expert analysis, stakeholder feedback and desk research on the tools used in national and EU law to overcome information asymmetries and difficulties of proof.

	proof are expected to effectively ensure that victims of damage caused with the involvement of AI enjoy the same level of protection as persons having suffered harm caused by other technologies.	
Reduced costs	<p>For citizens and businesses as potential victims, the alleviations of the burden of proof are expected to reduce litigation and enforcement costs linked to meeting the burden of proof under current liability rules by ca. EUR 2 000 per case in which those alleviations apply.<sup>3</sup> This estimate should not be misconstrued as a quantification of the AI-specific difficulty of meeting the burden of proof, because it does not take into account the cases in which liability claims would not be pursued in the first place based on current liability rules, because the victim either cannot identify the liable party or considers the prospect of a successful claim insufficient to justify legal action. The preferred policy option will help victims also in the latter cases, by overcoming the compensation gaps induced by the specific characteristics of AI. This benefit is reflected in the previous row ('reduced AI induced compensation gaps').</p> <p>The burden of proof will be distributed more efficiently overall, as potentially liable parties must by definition be capable of influencing, to some extent, the operation of AI-systems. They are therefore typically in a position to discharge more easily the burden of proof, with respect to how or why such systems arrived at a certain harmful output. This has a cost-cutting effect on overall litigation costs.</p>	Citizens and businesses as potential victims

<sup>3</sup> This quantification is based on estimated costs of technical expertise to be advanced by victims to claim compensation under current liability rules. In the framework of the supporting economic study (Deloitte), these costs were estimated, on the one hand, for cases where AI systems are involved in causing damage, and on the other hand, for cases not involving AI. The difference between these estimates was used to approximate the cost of meeting the burden of proof due to the specific characteristics of certain AI systems. On that basis, assumptions were made regarding the effect each policy options would have on this cost factor. For detailed explanations regarding the methodology and assumptions made, see Annex 10, A.2.1.3.(d) and B.1.1.(b).



<i>Indirect benefits</i>		
Safer AI systems		Citizens and businesses as potential victims
<i>Administrative cost savings related to the 'one in, one out' approach*</i>		
(direct/indirect)	n/a	

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Targeted and harmonised alleviation of the burden of proof	Direct adjustment costs		EUR 5.35mln (based on the lower estimate of the AI market size) to EUR 16.1mln (based on the higher estimate of the AI market size) <sup>4</sup> This estimate represents the estimated increase, due to the preferred policy option, of the overall amount of general liability insurance premiums paid annually in the EU. <sup>5</sup> It would be distributed over all potentially liable parties (citizens / consumers and		EUR 5.35mln (based on the lower estimate of the AI market size) to EUR 16.1mln (based on the higher estimate of the AI market size) <sup>6</sup> This estimate represents the possible increase, due to the preferred policy option, of the overall amount of general liability insurance premiums paid annually in the EU. It would be distributed over all potentially liable parties (citizens / consumers and		

<sup>4</sup> For the purposes of this estimate, it is assumed that the preferred policy option would entail an increase by 15% of the share of general liability insurance premiums attributable to AI liability risks. For detailed explanations regarding the considerations underpinning this assumption and the methodology for calculating the added insurance costs, see Annex 10, A.2.1.3.(f) and B.2.1.(a).

<sup>5</sup> This impact derives from the fact the preferred policy option prevents liability gaps induced by the specific characteristics of certain AI systems (e.g. opacity/lack of transparency, highly autonomous behaviour, complexity, limited predictability). It materialises where these characteristics would not have allowed the victim to prove the necessary facts under the baseline scenario. Only in these cases, the intervention would shift the cost of compensating the relevant damage from the victim to the liable person, increasing the latter's liability exposure, which is expected to lead to a moderate incremental increase in the insurance premiums linked to AI liability risks. This effect is in line with one of the fundamental justice-related purposes of liability law, i.e. to ensure that a person who harms another person in an illegal way will compensate the harm caused to the victim. It is also inherent in the Commission's policy objective to ensure that victims of damage caused with the involvement of AI systems have the same level of protection as victims of damage caused by other technologies. It leads to a more efficient cost-allocation to the person who has actually caused the damage/is best placed to prevent damage from occurring. Moreover, the potentially liable party is much more likely to have the necessary knowledge of the relevant AI systems in-house, and thus to discharge the burden of proof more efficiently without the need to procure external technical expertise. This effect approximated through the impacts on insurance premiums is, therefore, not regarded as an undesirable impacts or undue burden.

<sup>6</sup> See footnotes 25 and 26.

		businesses). While it is not possible to estimate the precise distribution, this cost factor is likely to be mostly relevant for businesses as potentially liable parties than for natural persons. This is because the AI-specific liability gaps addressed by the preferred policy option are more likely to affect the liability exposure of actors with an active influence on the functioning of the relevant AI systems.		businesses). While it is not possible to estimate the precise distribution, this cost factor is likely to be more relevant for businesses as potentially liable parties than for natural persons. This is because the AI-specific liability gaps addressed by the preferred policy option are more likely to affect the liability exposure of actors with an active influence on the functioning of the relevant AI systems.		
Direct administrative costs	The preferred policy option does not involve administrative obligations that would entail direct administrative costs.					
Direct enforcement costs		n/a In particular, the preferred policy option is not expected to entail additional litigation costs for private persons (as potentially liable parties). <sup>7</sup> These stakeholders are likely to defend themselves against liability claims using the same type of		Between ca. EUR 200 and ca. EUR 1600 to be advanced by businesses as potentially liable party, per case in which the measures to alleviate the burden of proof apply. <sup>8</sup>		

<sup>7</sup> As explained in the main part of the IA, only the targeted alleviation of the burden of proof regarding the ‘inner workings’ of an AI system could apply vis-à-vis citizens as potentially liable parties. The other measures forming part of the preferred policy option (presumption of causality in the case of non-compliance with relevant requirements of the AI Act / harmonised rules on the disclosure of information on AI systems to be documented/logged pursuant to the AI Act) are designed to apply only to addressees of obligations under the AI Act, that is to say businesses.

<sup>8</sup> This quantified estimate is based on reasoned assumptions regarding the extent to which the liable parties might have to advance the costs of technical expertise that would otherwise be borne by victims under the baseline scenario. This extent would vary widely in practice, as it depends on the liable party’s knowledge and information on the AI system. Moreover, it is important to underline that this cost increase would apply only in cases where national courts consider it necessary to establish how or why an AI system arrived at a certain output. As it is not possible to estimate in how many instances this might be the case, the costs are estimated only per individual case in which the targeted alleviation of the burden of proof would apply. The estimate also takes into account that for businesses falling under the AI Act, the preferred PO can trigger, aside from the targeted alleviation of the burden of proof, the disclosure (subject to appropriate confidentiality safeguards) of information on the relevant AI system as well as a presumption of causality in the case of non-compliance with the AI Act. For details regarding the methodology and assumptions underpinning these estimates, see Annex 10, A.2.1.3.(d) and B.2.1.(g).

			arguments and evidence as under the existing burden of proof rules. For example, they might seek to avoid liability by demonstrating that they acted diligently and in accordance with the instructions of use accompanying an AI-enabled product. Contrary to potentially liable businesses, which may have special knowledge and be subject to certain requirements regarding the functioning and 'inner workings' of an AI system (in particular under the AI Act), private persons would not have to base their defence on an analysis of the functioning of such a system. The envisaged alleviation of victims' burden of proof regarding the 'inner workings' of AI systems is therefore not expected to prompt potentially liable private persons to commission technical expertise.				
	Indirect costs		The preferred policy option would not entail costs incurred in related markets or experienced by stakeholders that are not directly targeted by the initiative. In particular, as the initiative is expected to generate net cost savings for businesses active in AI (see benefits), it is not expected to lead to increased consumer prices.				
<b>Costs related to the 'one in, one out' approach</b>							
<b>Total</b>	Direct adjustment costs	n/a	n/a	n/a	EUR 5.35m to EUR 16.1m per year		
	Indirect adjustment costs	n/a	n/a	n/a	n/a		
	Admini	n/a	n/a	n/a	n/a		

	strative costs (for off setting)								
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