Adapting liability rules to artificial intelligence

Impact assessment (SWD(2022) 319, SWD(2022) 320 (summary)) accompanying the Commission proposal
for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules
to artificial intelligence, COM(2022) 496

This briefing provides an initial analysis of the strengths and weaknesses of the European Commission's impact assessment (IA) accompanying the above-mentioned proposal, submitted on 28 September 2022 and referred to the European Parliament's Committee on Legal Affairs (JURI). The proposal was included in the Commission's 2020 work programme and in the working document accompanying the joint declaration of the European Parliament, the Council of the European Union and the European Commission on the EU's legislative priorities for 2023 and 2024.

The existing EU liability framework consists of national liability rules and, in certain cases, of the Product Liability Directive (PLD), which has been revised in parallel to this initiative.[1] In its white paper on artificial intelligence (AI) from 2020, the Commission proposed a legislative package of measures to address problems caused by the introduction and use of AI comprising three work streams:

- a horizontal framework addressing fundamental rights and safety risks specific to AI systems (AI act);
- a revision of sectoral and horizontal product safety rules;[2]
- EU rules to address liability issues related to AI systems.

The Commission's white paper states that 'persons having suffered harm caused with the involvement of AI systems need to enjoy the same level of protection as persons having suffered harm caused by other technologies, whilst technological innovation should be allowed to continue to develop'.[3] A lack of compensation can negatively affect their trust in AI and the uptake of AI-enabled products and services. According to the Commission, the present AI liability proposal (AILD)[4] tackles AI-specific problems regarding other liability rules than those covered by the PLD. The present proposal responds to the European Parliament's legislative own-initiative resolution of 20 October 2020 on a civil liability regime for AI.[5]

Problem definition

The IA starts by outlining the political and legal context, the scope of the IA and the interaction with related policy initiatives, in particular the proposal for an AI act and the revision of the PLD. The Commission proposed rules to reduce risks for health, safety and fundamental rights, with the AI act aiming to ensure AI in the EU is safe and respects fundamental rights and democracy without hampering innovation. However, the AI act does not prohibit the placing on the market of AI systems that pose a risk to safety and fundamental rights (IA, p. 5). In 2018, the Commission concluded an evaluation of the PLD, and in September 2022, published its proposal for a directive on liability of defective products revising the existing PLD.[6] However, this proposal covers the harm that can be caused by AI systems only partially.[7] Building on the 2018 evaluation of the PLD, among other things, and in line with the IA accompanying the proposal for a directive on liability of defective products,[8] the Commission states that existing liability rules (in particular national fault-

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based rules) are not adapted to handle satisfactorily compensation claims for harm caused by (complex) AI-enabled products and services. Under these rules, victims need to prove a person's wrongful action or omission that caused the damage. The specific characteristics of AI (including autonomous behaviour, opacity or lack of transparency and explainability, complexity, continuous adaptation and limited predictability) make it difficult or expensive to identify the liable person and prove the requirements for a successful liability claim (IA, Annexes 5 and 13, including case scenarios illustrating AI-specific difficulties in claiming compensation). It is also expected that, if the EU does not act, Member States will adapt their national liability rules to the challenges of AI.

The first problem identified in the IA is **legal uncertainty (P1)**. According to the IA, it is unclear how the current liability rules apply when AI is involved. It is uncertain how existing national liability rules can be applied and how national courts will address the specificities of AI on an ad hoc basis in a way to come to a just result. Consequently, a risk exists that national courts will diverge in their approaches, which could lead to further fragmentation of liability rules for damage caused by AI-based systems and services across the EU. The second problem relates to **legal fragmentation (P2)**, which is interlinked with P1. Existing national liability rules are already very diverse, which is problematic especially in a cross-border context, where 'different liability regimes and burden of proof rules could be applied to the same kind of AI-enabled product/service deployed in several Member States which causes the same kind of damage' (IA, p. 11). In addition, several Member States are already planning to adapt their national civil liability rules for AI, which will result in further legal fragmentation. The third problem focuses on the **lack of compensation (P3)** for victims (e.g. private individuals, consumers, businesses) harmed by AI, which would lead to a lack of societal trust and hamper the uptake of AI-enabled products and services in the EU. A victim currently relies on national liability rules and, in certain cases, on the PLD to claim compensation for damage arising from AI-enabled products and services.

Overall, the problem definition is clear and well substantiated, in particular by the above-mentioned evaluation of the PLD, external supporting studies and stakeholder feedback, with the exception of Member States' views. This evidence sources partly compensate for the considerable lack of data that is openly acknowledged by the IA (IA, Annexes 4 and 10; see also section 'Supporting data and analytical methods used' below). The IA examines the nature and scale of the problems, as well as whom they would affect (businesses, victims of damage caused by AI, consumers, insurance companies) and how (IA, Annex 3). It illustrates the drivers behind the problems and the specific objectives to be addressed by the present initiative. With the aid of a problem tree, accompanied by explanatory text, the IA illustrates the drivers behind the problems and the consequences deriving from them (IA, p. 7). The IA provides a well-structured analysis of the existing situation and how likely the problem will persist without EU intervention. It includes a separate annex (IA, Annex 5), where it describes in detail the specific characteristics of AI and the challenges this brings for existing liability rules. In addition, the IA transparently explains in Annex 4 (IA, pp. 117-119) how the European Parliament's legislative own-initiative resolution was taken into account in the IA's proposed policy options. However, the interplay between the initiative and relevant EU initiatives, in particular the AI act, the revised PLD and the [Machinery Products Regulation](#), with regard to their scope of application (e.g. definition of AI and risk classification of AI systems, distinction between AI and complex software systems) and the likely evolution of the problems could have been described in a more detailed and comprehensive manner.

Subsidiarity / proportionality

The proposal is based on [Article 114](#) (approximation of laws in the single market) of the Treaty on the Functioning of the European Union (TFEU). The IA includes a section on subsidiarity (IA, pp. 19-22), where it describes the legal basis and explains the necessity and added value of EU action. According to the IA, EU action is necessary to effectively address the negative effects of legal uncertainty and fragmentation between Member States regarding 'the conditions under which business would face compensation claims for damage caused by AI' (IA, p. 20). EU-level action would enable the adoption of harmonised measures on civil liability for AI and improve the roll-out and

development of AI-based technologies in the internal market. As recommended by the Task Force on subsidiarity, proportionality and 'doing less more efficiently', a separate subsidiarity grid accompanies the IA, which also covers **proportionality**. According to the IA, the initiative is limited to what is necessary to achieve the initiative's objective and address the specific identified problems. It focuses on targeted proof-related measures to ensure that victims have the same level of protection as people having suffered harm caused by other technologies, and it 'would not touch upon the substantive conditions of liability like fault or causality (which remain in the remit of national law)'.[9] Although a regulation – as proposed by the European Parliament in its resolution – would probably achieve more far-reaching harmonisation effects, the IA notes that for reasons of subsidiarity and coherence with the existing national liability regimes, a directive would be the most suitable instrument. This appears not sufficiently convincing, taking into account the risk of diverging transposition in the Member States. The deadline for the submission of reasoned opinions on the grounds of subsidiarity was 28 November 2022. Contributions were received from the Czech Senate, the French Senat, the German Bundesrat, the Portuguese Assembleia da República and the Spanish Cortes Generales.

Objectives of the initiative

The IA identifies **two general** and **three specific objectives**. The **first general objective** is to improve the functioning of the internal market by reducing existing obstacles and preventing the emergence of new ones to the cross-border trade in AI-enabled products and services (with a positive effect for the economy and the competitiveness of the European AI sector); the **second** is to contribute to an 'ecosystem of trust' to promote the uptake of AI-enabled products and services by ensuring that victims of AI-enabled products and services are equally protected as victims of traditional technologies. The general and specific objectives are coherent with the IA's identified problems and their drivers.

Specific objectives to address the problems 1, 2 and **3** include:

> to increase legal certainty about the liability risk exposure of business activities involving AI (P1);
> to prevent the emergence of fragmented AI-specific rules across the internal market (P2);
> to prevent a lack of compensation by ensuring the same level of protection in cases involving AI (P3).

Although the IA does not set out operational objectives (defining deliverables of specific policy actions after identifying the preferred option, as envisaged by the Better Regulation Guidelines (BRG)), it provides in Annex 12 groups of indicators for the preferred option, which point to more specific deliverables of the envisaged measures; however, they remain rather general. It therefore appears that not all of the S.M.A.R.T criteria of the BRG (according to which objectives should be specific, measureable, achievable, relevant and time-bound) have been fully met, in particular measurability. The IA outlines that the initiative's objectives are consistent with other AI-related Commission proposals, such as the AI act and the revision of the PLD (IA, Annexes 6 and 7). In line with the BRG, the IA explains how the initiative helps achieve relevant United Nations Sustainable Development Goals (UN SDGs), namely SDG 3 (good health and well-being), SDG 9 (industry, innovation and infrastructure), SDG 13 (climate action) and SDG 16 (peace, justice and strong institutions).

Range of options considered

The existing liability framework consists primarily of Member States' fault-based liability and strict liability rules [10] and, in certain cases, the PLD. Under the assumption that this framework will remain unchanged, the IA presents a dynamic **baseline scenario** within a 10-year horizon, analysing the course of no further EU action by including legislative initiatives such as the AI act, the Machinery Products Regulation and the revised PLD, among others, which will complement newly adapted national liability rules. Following the problem definition, the main deficiencies in the baseline would

arise from legal fragmentation, its impacts on cross-border trade, and legal uncertainty in Member States that will fail to adapt liability measures. However, because of data limitations, the IA does not quantify the extent of these issues. In addition to the baseline scenario, the IA presents **three policy options** that are cumulative, proposing varying degrees of stringency in addressing the specific objectives. It is therefore questionable whether they fully qualify as alternative options under the BRG. For all policy options, the IA considers the possibility of implementing the policy measures through either a binding or a non-binding instrument (i.e. a recommendation). To address the difficulties of determining accountability in AI-related claims, **policy option 1 (PO1)** aims to ease the burden of proof through three complementary measures:

> The first measure involves the disclosure, for liability claims, of information that the user or provider of high-risk AI has to document or record in accordance with the AI act, including technical specifications, usage instructions, and related details. Failure to comply will result in the presumption that the withheld information could have assisted the victim in proving the party's liability;

> If the victim demonstrates that the liable party failed to adhere to the provisions of the AI act, the second measure would establish a rebuttable presumption that such non-compliance with safety requirements contributed directly to the damage incurred;

> The third measure seeks to avoid the need for the victim to explain the AI's inner workings (how or why the AI system reached a certain output) by adjusting the burden of proof. If the victim shows that it is sufficiently plausible that the liable party caused the damage, this will be presumed true unless the liable party proves otherwise.

Policy option 2 (PO2) encompasses all measures in PO1 and combines them with a harmonised strict liability framework for AI products with a special risk profile. Under this regime, entities operating highly autonomous products would assume legal accountability for any resulting harm, while the victims only need to prove that the risk materialised. The categorisation of these products would be subjected to periodic updates, potentially overseen by the Commission, to reflect evolving market dynamics. Additionally, within the scope of PO2, a subsidiary measure entails an insurance obligation for parties that are subject to strict liability.

Policy option 3 (PO3) proposes a phased approach: initially adopting all measures from PO1, followed by a targeted review of the need to implement strict liability and mandatory insurance. The rationale behind this two-stage model is the need to gather more data on potential harms stemming from AI, emerging challenges to liability rules, and the spectrum of risk profiles as more products enter the market. Concurrently, as insurance markets are expected to adjust to AI-specific risks, their actuarial data will help to determine whether mandatory insurance requirements are necessary. This policy option was chosen as the **preferred option**.

The IA provides an overview of two discarded measures (harmonisation of risk-based liability for damage caused by all AI-enabled products and services, irrespective of their risk profile, coupled with mandatory insurance; harmonisation of the types of harm giving rise to civil liability claims when caused by AI), and it is transparent about the reasons for discarding them (IA, pp. 41-42). The retained options are linked to the specific objectives and the problem drivers. Overall, the IA provides a balanced description of the options and explains the similarities and differences between them. However, as the presented options are different versions of PO1, the IA fails to present an adequate offer of alternative solutions. Moreover, despite clear descriptions, they notably lack details on the implementation process and appear to be insufficiently supported by data.

Assessment of impacts

In line with the BRG, the IA assesses each policy option in terms of its economic, social and environmental impacts against the baseline scenario. The mainly qualitative assessment is focused on the economic impacts. When assessing **social impacts** (not quantified), the IA expects an increase in societal trust in AI technologies through an efficient civil liability regime, which would be adapted to the specificities of AI, where justified claims for compensation of damage are

successful. Citizens could indirectly benefit from safety-enhanced innovation, leading to an overall higher level of protection of health and safety (all policy options). The faster roll-out of AI technologies would benefit consumers (e.g. more personalised services, innovative products). The strict liability element of PO2 would be more likely to increase societal trust in the justice system than PO1. In the assessment of **environmental impacts**, the IA expects relatively small direct impacts. As regards indirect impacts, the IA states that 'all policy options are expected to contribute – albeit to a non-quantifiable extent – to the uptake of AI applications that are beneficial for the environment' (IA, p. 59), for instance improved vehicle automation and traffic management (multi-modal transport) leading to lower energy use and emissions. (On the positive contribution of the initiative to achieving several UN SDGs, see section 'Objectives of the initiative' above.) The IA primarily elaborates on **economic impacts**, particularly regarding the EU market share affected and the opportunity costs stemming from legal uncertainty and fragmentation. The IA acknowledges that data limitations significantly hinder quantification, as stakeholders during the consultation activities were unfamiliar with AI products and unable to provide reliable estimates of related financial consequences. The main direct and indirect economic benefits are anticipated to arise from reduced fragmentation, which will lower compliance costs for companies and increase cross-border revenue, outweighing associated adjustment and redistribution costs. PO1 alone is estimated to expand the AI market size by €500 million to €1.1 billion compared with the baseline (IA, p. 49). Additionally, combining PO1 with the harmonisation of strict AI liability (PO2 and PO3) is projected to boost cross-border trade for AI-enabled products by between 5 and 7 % (IA, p. 48). By contrast, a non-binding instrument (recommendation) is not expected to have significant impact on cross-border trade. Another cost-limiting effect would come from insurance companies, which would improve victims' chances for compensation. As more companies would be incentivised to take out insurance, insurance providers would be able to diversify risks across a larger pool of insurers and gather more precise actuarial data, thus curbing upward pressures on insurance premiums. Moreover, the burden of proof alleviation under PO1 would reduce victims' litigation and compliance costs by an average of €2 000 per case (IA, p. 47). Potentially liable parties would need to allocate between €200 and €1 600 for enforcement to defend themselves against liability claims. By contrast, PO2 offers even greater savings for victims, averaging €2 500 per case in reduced litigation costs, and enforcement costs of between €100 and €1 500 for potentially liable parties (IA, p. 55). However, this added benefit over PO1 would only apply to a limited number of cases falling under strict liability. While harmonised strict liability under PO2 would in theory enhance victims' compensation prospects compared with alleviations of the burden of proof in PO1, the IA refrains from quantifying overall market and cross-border trade benefits from PO2 owing to high uncertainty surrounding future risk profiles. Lastly, PO3 is assumed to yield the same benefits as PO1, while also diminishing overall uncertainty concerning economic outcomes.

In the assessment of impacts on **fundamental rights** (separate Annex 8), the IA mentions positive impacts of the preferred option on the right to an effective remedy and a fair trial (Article 47 of the Charter of Fundamental Rights of the European Union) by ensuring that victims of damage can effectively claim compensation. However, since the scope of the initiative is limited to civil liability matters, the rules only apply once an AI-specific damage has materialised. It therefore complements existing and future preventive and supervisory rules (e.g. AI act, General Data Protection Regulation, Digital Services Act, non-discrimination/equal treatment *acquis*). The IA explains the AI-specific fundamental rights concerns and the initiative's complementarity with other EU rules aimed directly at avoiding fundamental rights breaches (IA, Annex 8, pp. 155-161).

When comparing the policy options, the IA considers their **effectiveness**, **efficiency**, **coherence** and **proportionality**. PO1 and PO3 score higher than PO2. However, the IA states that with its staged approach, PO3 is 'the most balanced, politically feasible, proportionate and yet effective option' (IA, p. 213). According to the IA, it best takes into account all elements suggested by the European Parliament's resolution and stakeholder feedback.

SMEs / Competitiveness

The IA notes that legal uncertainty and fragmentation disproportionately affect start-ups and other small and medium-sized enterprises (SMEs), which account for the large majority of companies and the major share of investments in the relevant markets, [11] because 'they cannot rely on comparable in-house legal expertise and an established cross-border network' (IA, p. 16). SMEs would therefore potentially benefit more than other stakeholders from reduced legal uncertainty and fragmentation and from being able to explore new markets across borders. However, this effect is neither quantified nor further substantiated in the IA. Moreover, the IA does not present any mitigating measures, since the preferred option expects that businesses, in particular SMEs, are more likely to face higher costs than potentially liable parties. The IA comprehensively describes the views of business associations representing SMEs and – to some extent – of individual SMEs in the course of the Commission's consultation activities. For instance, in the open public consultation, they confirmed the obstacles in the internal market to a larger extent than other business stakeholders (i.e. that the lack of adaptation and fragmented AI-specific liability rules at national level will increase costs of companies and insurance premiums, entail higher prices of AI-enabled products and services, and cause companies to refrain from using AI). However, the IA acknowledges the limited feedback from several stakeholders, especially SMEs and associations, to data gathering surveys in the external economic analysis study (IA, p. 116). Overall, the impacts of the policy options on SMEs could have been explored in more depth. The IA mentions **competitiveness** in the general objectives (in terms of improving the functioning of the internal market, IA, p. 23) and in the assessment of impacts of the policy options (IA, pp. 48 and 55), without however discussing it in detail. It expects the proposed measures to have a positive impact on the competitiveness of companies active in the AI market in the EU and globally.

Simplification and other regulatory implications

The IA explains the preferred option's coherence and consistency with other liability regimes and existing provisions and proposed initiatives at EU level in the policy area, in particular the AI act, the revision of the PLD, and the Digital Services Act. The IA finds that this initiative would fill a gap in the EU regulatory framework by harmonising certain rules for claims outside of the scope of the PLD, in cases in which damage is caused by AI systems. In light of the 'one-in, one-out' approach, the initiative is expected not to generate significant administrative costs to businesses and citizens since it 'the preferred policy option will not introduce any administrative requirements (e.g. reporting, registration, monitoring) for any of the entities within its scope, i.e. potentially liable parties or victims' (IA, p. 62). However, the IA estimates adjustment costs of between €5.35 million and €16.1 million a year under the preferred option for an increase of premiums paid for liability insurance. This will be mostly relevant for businesses as potentially liable parties (IA, p. 62).

Monitoring and evaluation

To monitor the proposal's operation, the IA presents a set of monitoring indicators linked to the specific objectives. The monitoring process is a key element of the initiative and is explained in the policy options. The preferred option follows a 'staged approach' with a targeted review mechanism by first introducing policy measures to alleviate the burden of proof on the victim and then conducting an evaluation of the measures' effectiveness, efficiency, coherence and proportionality (IA, pp. 231-232; Article 5 of the proposal provides for five years after the end of the transposition period). It would be assessed whether additional measures are be needed, such as introducing a strict liability regime and/or mandatory insurance coverage. The indicators seem relevant for achieving the specific objectives; however, some of the indicators appear to be rather vague.

Stakeholder consultation

The Commission gathered stakeholder views on multiple occasions and referred to the feedback in several parts of the IA. In line with the BRG, a comprehensive summary of the stakeholder consultations and an outline of the targeted groups (e.g. consumer associations, civil society

organisations, industry associations, businesses, including SMEs, legal firms and lawyers, academia/research bodies, insurance associations and national authorities) are provided in a separate annex (IA, Annex 2). The consultation on the inception IA ran from 30 June until 28 July 2021 and received 34 responses. As recommended by the BRG, the Commission also conducted a 12-week open public consultation (OPC) from 18 October 2021 to 10 January 2022 (233 responses), which jointly concerned AI liability issues and the revision of the PLD. It yielded 233 responses on issues concerning this IA, mostly from individual citizens (94) and business associations (63); however, participation of national authorities was rather low, with only five providing their views. Although most stakeholders expressed support for PO1 and PO2, business organisations and associations largely opposed all sub-measures of PO1 and harmonisation of strict liability (coupled with mandatory insurance), and cautioned against a complete shift of the burden of proof. The IA's preferred option, PO3, was not presented as a separate policy option in the OPC; the IA notes that the preferred option was developed and refined in light of feedback received from stakeholders throughout the IA process (IA, p. 74). Moreover, the Commission undertook a 16-week open online consultation on the white paper on AI. Furthermore, the Commission organised 12 webinars focusing on AI liability, a workshop with Member State representatives, and surveys and targeted interviews conducted for the external supporting studies.

Supporting data and analytical methods used

The IA draws primarily on stakeholder input and three supporting studies, all of which are referenced, publicly available, and detailed in Annex 4. These studies cover crucial aspects of the IA.

> The comparative law study analyses key differences in various national legal frameworks concerning AI issues, civil liability and standards of the burden of proof.
> The behavioural study explores societal trust in AI and willingness to adopt AI products in relation to the existing legal challenges of claiming compensation.
> The economic study assesses the market for AI products, costs of claiming compensation, as well as the economic implications of legal uncertainty and fragmentation.

The studies use multiple data sources, including market surveys and additional stakeholder consultations. However, the Commission highlights significant data gaps in most quantification efforts across the IA. With minimal exposure to real-world AI liability cases and only an emerging market for AI technologies at the time, stakeholders reported it was too early to give precise estimates for cost-benefit evaluations. The policy options' economic impacts are therefore extrapolated from six AI-use cases, such as robotic vacuum cleaners or autonomous vehicles. Considering the rapid advancement of AI technologies since the IA's publication, these data constraints significantly diminish its relevance for the status quo. In an effort to facilitate the assessment of the mentioned criteria by multi-criteria analysis, followed by a sensitivity analysis, the IA presents the policy options in a summary table showing how they score (IA, Annex 10).

Follow-up to the opinion of the Commission Regulatory Scrutiny Board

The Regulatory Scrutiny Board (RSB) issued a positive opinion with reservations on the draft IA on 8 April 2022. Annex 1 to the IA lists and explains how the RSB's comments were addressed in the final IA (IA, pp. 65-68). According to the RSB's concerns, the IA should rectify several shortcomings, relating to i) the set of policy options, which appeared incomplete and did not address certain options put forward by the European Parliament in its legislative own-initiative resolution on a civil liability regime for AI; ii) the credibility and relevance of the quantitative impact estimates of the policy options, and iii) the choice of the preferred option, which was not properly analysed and substantiated. It appears that the RSB's comments were taken broadly into account in the final IA.

Coherence between the Commission's legislative proposal and IA

The proposal appears to follow the preferred policy option identified by the IA.

The impact assessment (IA) defines the problems, their drivers, the objectives and the options of the initiative in a robust intervention logic. It explains the initiative's coherence with ongoing legislation. However, the interplay between the initiative and, in particular, the artificial intelligence act and the revised Product Liability Directive with regard to their scope of application and the likely evolution of the problems appear to be addressed insufficiently. The IA is based on several sources, including the European Parliament's legislative own-initiative resolution on a civil liability regime for artificial intelligence, stakeholder consultations, supporting studies and desk research. The IA presents a range of cumulative policy options; it is however questionable whether they fully qualify as alternative options under the Better Regulation Guidelines. The assessment of the options' impacts (economic, social, environmental, fundamental rights) is mainly qualitative owing to considerable data limitations, which are addressed transparently throughout the IA.

ENDNOTES

1 See IA, pp. 3-4 on the types of civil liability.

2 Proposal for a regulation on general product safety; proposal for a regulation on machinery products; Commission Delegated Regulation (EU) 2022/30 supplementing Directive 2014/53/EU with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f) of that directive.

3 White paper on Artificial Intelligence – A European approach to excellence and trust, COM(2020) 65, p. 15.

4 T. Madiega, Artificial intelligence liability directive, EPRS, European Parliament, February 2023.

5 T. Evas, Civil liability regime for artificial intelligence, EPRS, European Parliament, 2020. See also the European Parliament's resolution of 3 May 2022 on artificial intelligence in a digital age, specifying that while high-risk AI systems should fall under strict liability laws, combined with mandatory insurance cover, any other activities, devices or processes driven by AI systems that cause harm or damage should remain subject to fault-based liability (point 146).

6 S. De Luca, New Product Liability Directive, EPRS, European Parliament, December 2023.

7 The IA states that the PLD covers 'damage done by defective products, while other liability rules compensate also the harm caused for instance by services or any use of products. It covers the producer as liable person, while other liability rules cover the harm done by other actors like operators/users of AI systems. It covers certain damages, while other liability rules compensate also other harm suffered by victims like economic and non-economic loss' (IA, p. 5).

8 E. Kramer, Updating liability rules for defective products, EPRS, European Parliament, January 2023.

9 See subsidiarity grid, SWD(2022) 318, p. 7.

10 Strict liability rules assign liability for the relevant risk to a person, irrespective of fault.

11 SMEs developing, deploying or using AI technologies account for more than 95 % of companies active in this market; micro-enterprises represent over 80 % of all firms involved in AI research and software development (IA, p. 16).

This briefing, prepared for the Committee on Legal Affairs (JURI), analyses whether the principal criteria laid down in the Commission's own Better Regulation Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the impact assessment. It does not attempt to deal with the substance of the proposal.

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