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# Increasing Systemic Legal Risks in the EU: The Economic Impacts of Changes to the EU's Product Liability Legislation

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## EXECUTIVE SUMMARY

The EU's Product Liability Directive (PLD) determines the rules for strict product liability in the EU. It establishes a framework in which manufacturers' liability is determined solely based on the presence of defects in the product, regardless of the manufacturer's fault. The PLD is intended to serve as a "safety net" when fault-based or contractual liability rules do not offer sufficient compensation to consumers. It operates independently from contractual arrangements between businesses and consumers, and it cannot be weakened by contractual agreements between businesses and consumers.

The PLD is a horizontal regulation that applies to a wide range of industries in the EU because it applies to all products available on the EU market. The recently proposed changes by the European Commission would increase systemic legal uncertainty for producers and sellers of technology-intensive goods and services in the EU. The impact assessment of the European Commission does not sufficiently account for changes to the PLD proposed in 2022. Nor does it sufficiently account for the major impacts of increased legal uncertainty for European businesses. Legislators in the Council and the European Parliament should slow negotiations to allow time for policymakers to collect more evidence on the impacts on businesses, insurers, and courts we detail in this paper. This would be an opportunity to improve regulatory quality in light of the high levels of legal uncertainty associated with the changes proposed by the Commission.

**Most of the proposed changes would bring new legal risks to manufacturers of technology products, software developers and services providers specialising in the development and commercialisation of digitally provided services.** We identified six key determinants of new legal risks. These have largely been overlooked in the European Commission's impact assessment regarding the reform of the PLD. The impact assessment presented by the Commission is well-researched. However, it suffers from multiple problematic aspects, resulting in a systematic neglect and underestimation of effects of new legal risks on businesses and consumers in the EU.

**Technology-intensive sectors are investment-intensive and therefore particularly sensitive to legal risks.** Applying econometric techniques, we find that legal uncertainty has a significant impact on the creation of value-added in the EU. The impact of legal risks on value-added production is strongest in EU industries with high digital and technological intensities, such as Europe's software industry or budding AI ecosystem, but also, for example, the motor vehicles and transport equipment industry. We observe strong significant relationships between legal uncertainty and economic activity of small and large firms. Even if the proxy indices used in our analysis reflect a broad spectrum of legal risks perceived by businesses, the results demonstrate that even a small increase in risk perception would have a significant negative impact on the output of technology-intensive industries in the EU, reducing available supply. Existing companies may be forced to stop providing products or services in the EU, harming consumers.

**Most of the proposed changes to the PLD systematically increase the legal risks in the EU.** Legal uncertainty always impacts economic activity. The proposed changes to the PLD are

meant to provide clarification regarding the scope of strict liability requirements. However, they conversely increase legal uncertainty for companies providing technology-intensive products, components or services in the EU.

**Major sources of additional legal risks are as follows:**

- 1. Inclusion of stand-alone software:** The treatment of software offerings, including AI-based applications, as products, is problematic because of the particularities of software development and the complexity of industrial partnerships in the development of technology-intensive products and components. Software applications have a fundamentally different risk profile than physical and movable goods. Stand-alone software cannot physically act upon any person or property. Software bugs are generally accepted as inherent to software development and can be readily fixed through remote wireless updates. The biggest challenge stemming from strict liability under the proposed PLD is that software and app developers can be held liable regardless of their intent or knowledge of defectiveness. Software developers often lack control over how their software is integrated along the supply chain. Imposing strict liability for standalone software is not justified nor proportionate as it does not pose the same risks of severe damage to persons or property.

Under a revised PLD, all companies contributing software to a product or component could still be held liable for no-fault-based errors even if they had limited their liability risks in contractual arrangements with the buyers or users of their software solutions. For complex product and software solutions, fault is extremely difficult or even impossible to assign to an individual entity in the value chain. This poses a major problem for insurance companies, which may not be able to assess which part of the value chain contains the greatest product liability risk.

Insurance companies will base their (pricing) decision on whether to insure a software provider on aspects that influence the risks facing that company. The European Commission's own (rough) estimates indicate that the inclusion of stand-alone software, the extension of compensable damage, and the easing of the burden of proof would increase company's liability insurance premia by 25% on average. In reality, these numbers will vary significantly between individual companies depending on company size, portfolio diversification, and the risk profiles of products and services offerings. Insurers' assessment of risks related to no-fault-based claims would have to account for risks related to particular use cases. This will be difficult and, in many cases, impossible to be done in a reliable way, especially in the case of general-purpose software, i.e., code that is mass-produced for a broad range of common business applications such as word-processing, graphics, payroll, and accounting software. Difficulties in assessing the risks of use cases will also arise from software that is deployed in conjunction

with open-source code or software deployed to run interfaces used for the provision of web-based digital services, e.g., software underlying intermediation services, search engines, and online platforms.

The difficulties of assessing new no-fault-based risks will negatively impact companies' ability to obtain affordable and/or full insurance coverage. Currently, liability claims are dealt with such that product manufacturers and software developers have contractual arrangements, which are not covered by the PLD. This reflects the reality that contracting parties in many cases have asymmetrical information or discretion over how a contributor's technology is going to be operated or placed into a product by another party, causing parties to contractually assign certain responsibilities or apportion potential exposure in a more equitable manner. Higher exposure to no-fault-based liability risks implies that software developers at the beginning of a new development project must be aware that there are persistent risks which may be outside their control. Businesses, small and large, will be deterred by these risks.

- 2. Inclusion of related (digital) services:** The inclusion of software-based services also fails to account for fundamental differences between product and software-based services offerings. Contrary to most movable products, digitally provided services typically do not have distinct uses with a foreseeable range of associated risks. Many digital services can be considered general purpose services, e.g., smart voice assistants, (AI-assisted) search engines, and AI-enabled services such as fraud detection, content moderation, chatbots, and the creation of smart content, which can be used in a vast range of scenarios. The inclusion of services whose areas of application are not foreseeable has a deterrent effect on services development placement in the EU. Many companies, small and large, may decide not to or no longer offer a certain service in the EU because of too many possible liability risks and because insurers offer no or only limited insurance coverage.
- 3. Inclusion of damage related to psychological health:** New legal risks from the inclusion of software and digital services would be tremendously amplified if policymakers decided to extend liability risks to damage to psychological health, as the Commission proposes. Psychological health and mental illness are very complex types of damage to assess and the opinions of medical professionals frequently differ. As concerns "medically recognised psychological harm", interpretations of what it exactly constitutes vary greatly, making it close to impossible to interpret the rules in a consistent way across the 27 Member States. The combination of including software and damage related to psychological health would lead to an increase in litigation and, as a result, increased insurance premiums for insurable risks.

The impacts of Social Inflation and collective redress have been, to date, disregarded by policymakers. Social inflation in liability insurance reflects the trend of an increasing number of claims with high amounts of compensation

claimed for damage. Social inflation, activist plaintiffs and class action would disproportionately hit companies developing and commercialising software and AI systems in the EU. Although it is difficult to assess the impact of Social Inflation on the number of immaterial damage claims, cases involving environmental standards and social media suggest that social inflation in EU liability litigation could pick up substantially if mental health becomes a compensable damage under the PLD. Anticipating increases in litigation and associated costs, companies may decide not to develop and commercialise certain software products and digital services in EU Member States.

- 4. Inclusion of damage related to loss or corruption of data:** The inclusion of data loss and the corruption of data would tremendously increase risks of being exposed to claims related to no-fault-based liability claims. The value of personal data is usually subjective. Damages from the loss of personal data are extremely difficult to define and, as a result, it is very difficult to objectively quantify it in courts. Similar to assessments of damages related to mental health, a rather unlimited expansion of individuals' legal interests will likely result in differences in enforcement across EU Member States. Anticipating or responding to increases in litigation and associated costs, software companies and providers of data-driven digital services may decide to leave or discontinue offerings in Member State markets.
- 5. Reversal of burden of proof and evidence disclosure obligations:** The Commission proposes to alleviate the burden of proof for complex technologies, including AI-based systems and services. This constitutes a de facto reversal of the burden of proof for many technology-intensive product and service providers – despite the Commission's impact assessment advising against a reversal in the burden of proof. As argued in the European Commission's impact assessment, reversing the burden of proof “would expose manufacturers to significantly higher liability risks and could hamper innovation, leading also to potentially higher product prices and reduced access to innovative products.” In addition to higher exposure to no-fault-based liability risks, companies must consider the possibility of being mandated to disclose essential trade secrets. Plaintiffs would have greater incentives to launch frivolous or speculative claims due to greater leverage over defendants, which in turn may opt for out-of-court settlement rather than disclosing information or incurring the costs of court proceedings.
- 6. Vague definitions or concepts that go undefined:** Despite the clarification of product scope and damage, significant legal uncertainties remain as to the applicability of the revised Product Liability Directive to companies that develop and commercialise software and technology products. Due to unspecified applications and use cases, the Commission's proposal would likely lead to more fragmentation as interpretations would be left to the discretion of Member States' courts, for, e.g., the concept of related service, the application of disclosure orders, and decisions on what constitutes a scientifically and technically complex product, etc.

## **Impacts on businesses, R&D and consumers in the EU**

For any business, the biggest challenge of strict liability is that they can be held liable regardless of their intent or knowledge of defectiveness. Policymakers do not address how companies will in the future manage, allocate or insure risks from no-fault-based liability. Companies commercialising software, AI code, AI data, and software-based services or contributing them to a product or component could still be held liable for no-fault-based errors even if they had limited their liability risks in contractual arrangements with users of their solutions. The exposure to new and unforeseeable liability risks will probably result in many technology companies no longer marketing their products and services in the EU, or only doing so to a limited extent. The effects on research and development (R&D) and innovation in Europe are difficult to predict. However, the revised PLD would have a dampening effect on investments, production and innovation in technology-intensive industries in the EU. It can be expected that innovative technology-based products and services will be (initially) marketed primarily outside the EU and that the development of these products will also increasingly take place in these markets, above all in the US.

The EU's software and technology innovation ecosystem would be systemically disrupted. The direct impacts on the relevant sectors would be the largest in the Member States which are home to a large number of companies pursuing the development of software and app solutions. As shown in this paper, Europe's software and app development sector is to a very large extent driven by small business activity. The termination of development projects by small companies could result in a comparatively high drop in value added in the Member States. It should be noted that the European Commission's impact assessment underlying its PLD reform proposal does not account for impacts in industries other than ICT services (NACE sectors J62-J63). Impacts on manufacturing and services businesses, which also develop and commercialise software products and related services, have been ignored. These include carmakers and manufacturers of electrical equipment or consultancies, which engage in customised software development and solutions that are sold to other businesses and final customers.

### **Impacts on European consumers**

A first impression of the proposed changes to the PLD may be that it provides stronger rights and benefits for consumers. However, there is only weak evidence of why it is a problem that software and mental health are not covered by strict product liability today, and why the inclusion of software should go beyond safety-relevant applications. The Commission's impact assessment remains largely silent about why consumers have difficulties making specific claims or why their claims are rejected by the courts. The European Commission's Regulatory Scrutiny Board states that the European Commission's impact assessment "report is not sufficiently clear about the size and evolution of the problem".

Even small changes in the perception of legal uncertainty and actual legal risks have a significant impact on companies operating in investment-, knowledge-, and technology-intensive industries in the EU. Some companies will simply stop serving EU markets, resulting in a decrease in the supply of technology-intensive products and services, which in turn results in less consumer choice, less

access to cutting-edge innovation, and higher prices for remaining and potentially inferior offerings. Higher provisions for no-fault-based liability risks and higher cost of liability insurance would be passed on to consumers, resulting in higher prices for affected goods and services.

### Policy recommendations:

- 1. Software, AI systems and related digital services should per se not fall under the scope of the strict liability regime of the EU's PLD.** Including software and software-based services to the PLD's no-fault-based liability regime should be strictly limited to critical applications that can cause serious harm to consumers.

The evidence base for including damages created by all defective software or apps is weak. Other liability regimes, fault-based and/or contractual are more appropriate. For example, software developers can already be held accountable on the basis of Directive 2019/770<sup>1</sup> and Directive 2019/771<sup>2</sup> covering rules applicable to "digital content", "digital services", and the "sales of goods with digital elements".

The European Commission has also proposed, alongside the PLD, an AI Liability Directive, which provides common rules for a non-contractual, fault-based liability regime for damage caused by AI, particularly high-risk AI systems (HRAIS). At the time of writing, it is still too early to endorse the AI Liability Directive as a solution, as it is yet to move through the legislative process. AILD may be better suited to handle AI than the PLD – and they are intended to co-exist anyway. However, the AILD proposal also includes a rebuttable presumption for establishing causation, which (as is alluded to in this paper) is a potential problem for many upstream providers of software and AI applications when considering the unforeseeable scope of potential harms.

- 2. Damage from psychological health and loss/corruption of data should both be excluded from the scope of the PLD.** It is very difficult for courts to objectively assess the nature and origin of damages. It is, for example, very difficult to establish the no-fault-based impacts of a software app or consumed digital services on psychological health. Including damages from psychological health and loss/corruption of data would lead to differences in implementation and enforcement as well as speculative claims and associated forum shopping. Social inflation in no-fault-based liability claims, activist plaintiffs and collective redress would disproportionately hit companies developing and commercialising software in the EU.

<sup>1</sup> Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and digital services. Available at [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32019L0770#:-:text=Directive%20\(EU\)%202019%2F770,\(Text%20with%20EEA%20relevance\).](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32019L0770#:-:text=Directive%20(EU)%202019%2F770,(Text%20with%20EEA%20relevance).)

<sup>2</sup> Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC. Available at [https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32019L0771#:-:text=Directive%20\(EU\)%202019%2F771,\(Text%20with%20EEA%20relevance\).](https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32019L0771#:-:text=Directive%20(EU)%202019%2F771,(Text%20with%20EEA%20relevance).)

- 3. If the burden of proof is to be reversed for reasons of technical or scientific complexity, then this should be within tightly controlled limits set out for national courts to apply.** Additional safeguards are needed for the disclosure of evidence to address the likelihood of businesses preferring to settle to avoid litigation costs and keep information and trade secrets confidential. The type of evidence eligible for disclosure orders must be more clearly defined. Assessments of publicly available documentation and evidence should be performed prior to resorting to a disclosure order. Furthermore, defendants should be granted reciprocal rights to request a defined set of evidentiary materials from claimants with regard to their habitual product use, proof of purchase, health records, and other relevant information. Without these safeguards and reciprocal treatment of all parties, companies potentially liable under the PLD may be inclined to settle rather than disclose trade secrets or invest in costly legal proceedings.
  
- 4. The EUR 500 threshold should be maintained to prevent a disproportionately high number of claims, which could overstrain courts and insurance companies. The upper limit of EUR 70 million should also be maintained to encourage insurability of strict liability risks.** The maximum threshold was not mandatory in the original PLD and was not considered a priority by the European Commission. It has been excluded from the Commission's impact assessment. However, given the potential revisions proposed by the Commission regarding product scope and damages, these thresholds are arguably even more important than before. For example, one small unknown defect could become the basis of a strict liability claim by, potentially, millions of customers.



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## 1. INTRODUCTION

The European Commission has proposed a revision of the existing EU product liability framework, which consists of the Product Liability Directive 85/374/EEC (PLD)<sup>3</sup> and national liability rules. Major changes proposed by the Commission have been endorsed by Member States in the Council. In the European Parliament, the situation is more nuanced with Members and the co-rapporteurs taking steps to adjust the text to address in part the legal uncertainty described above.<sup>4</sup>

The major objective of the proposed revision is “to take account of the characteristics and risks of new technologies and of new digital and circular business models, including AI-equipped products and services”. Intended to address legal uncertainty, the most significant changes proposed by the Commission include the extension of the PLD’s legal scope by widening the definition of “product”, additions to the list of no-fault-based damages, and a reversal of the burden of proof for scientifically and technically complex products.

Legal uncertainty regarding the application of PLD requirements to software was initially considered a shortcoming of the existing regime.<sup>5</sup> Indeed, extending the scope of the PLD from “all movables” to “electricity, digital manufacturing files and software” would, from the perspective of a consumer, improve prospects of successful liability claims under the PLD. However, the general inclusion of software applications and AI systems in the product scope of the PLD creates significant new legal uncertainties and increased costs of doing business for companies that commercialise software in the EU, costs which will ultimately result in less choice and increased prices for consumers and harm digital innovation in the EU, contrary to EU’s digitalisation ambitions.

New legal risks are amplified by additional changes proposed by policymakers, namely the treatment of “digital services” as products, the inclusion of psychological health and loss of data as (immaterial) damage, and the shift in the burden of proof as well as an easing of conditions for plaintiffs to access evidence and a strict liability claim for scientifically and technically complex products. Taken together, and accounting for the weak evidence base underlying the rationale of the European Commission, these changes represent a disproportionate and marked expansion of the current strict liability regime. It is noteworthy that, for example, the impact assessment conducted by the European Commission does not illuminate why claimants have difficulties in making claims under the existing PLD, or why their claims are rejected by the courts. Without these details, it is difficult to justify a far-reaching reform of the existing rules, which intentionally only cover serious cases of harm to physical health and damage to property. The 2018 PLD Evaluation, which is an analysis of data for the period 2000-2016, indicates that 40% of the total number of cases are dismissed to the detriment of consumers because of lacking evidence.

<sup>3</sup> Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31985L0374>.

<sup>4</sup> European Parliament Draft report on the proposal for a directive of the European Parliament and of the Council on Liability for defective products (COM(2022)0495 – C9-0322/2022 – 2022/0302(COD)). Available at [https://www.europarl.europa.eu/doceo/document/CJ24-PR-745537\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/CJ24-PR-745537_EN.pdf).

<sup>5</sup> Software is not explicitly mentioned in the PLD as it did not play a prominent role in (movable) products in 1985. Claims regarding software are traditionally dealt with through contractual law.

However, it is also found that evidence issues are mainly involved in cases related to medical and pharmaceutical issues.<sup>6</sup>

The analytical components provided in this paper account for but also go beyond the (2022) impact assessment by the European Commission.<sup>7</sup> The impact assessment by the Commission is well-researched. However, we note multiple problematic aspects, which lead to an underestimation and neglect of legal risks, costs and adverse economic implications for European businesses. The central problem areas of the impact assessment are as follows:

1. The European Commission's impact assessment and quantification of businesses' costs arising from several policy options suffer from profound data gaps. Highlighted by the authors of the impact assessment, these include the number of damages, injuries and deaths caused by defective products in the EU and whether they had fallen under the exclusive scope of the PLD's strict liability regime or alternative legal regimes such as contract and tort law. Data gaps were also identified for a number of legal cases in the EU that had exclusively fallen under the scope of the PLD and the volume of PLD-related compensation claims.

For liability insurance policies, data was unavailable or rudimentary on the distribution and nature of liability insurance coverage, the prevalence of strict liability insurance coverage, and the share of insurance premiums linked to strict product liability coverage. The impact assessment's study team considered several data sources and explained in detail the assumptions made to derive estimates. However, the economic impacts of policy options on businesses, particularly changes in insurance costs resulting from changes to the PLD are contestable. In addition, the important issue of "insurability" of liability risks has been ignored.

2. The European Commission's impact assessment only investigates a limited set of policy changes (options). These options do not fully reflect the changes to the PLD that the European Commission has ultimately proposed.
  - The inclusion of "software and digital elements" to the product scope of the PLD and impacts on "software developers" are covered in the impact assessment. However, the impacts of the inclusion of related digital services have not been researched. This includes software that is offered as a service to consumers irrespective of whether the software was developed by the services provider or externally by software developing companies.<sup>8</sup>

<sup>6</sup> See European Commission (2018). Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products. Final Report. Available at <https://op.europa.eu/en/publication-detail/-/publication/d4e3e1f5-526c-11e8-be1d-01aa75ed71a1/language-en>.

<sup>7</sup> See Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

<sup>8</sup> It should be noted that a non-paper by the Commission clarifying "a number of digital-related elements of the proposal for a new PLD" was only published in February 2023. See Commission non-paper on digital elements of the proposal for a new Product Liability Directive. Interinstitutional File: 2022/0302(COD). Available at <https://data.consilium.europa.eu/doc/document/ST-6201-2023-INIT/en/pdf>.

- The impacts of extending immaterial damage to psychological health issues have not been sufficiently addressed by the impact assessment. The risk of excessive litigation for software-based service providers has been ignored. Quantitative estimates regarding the number of mental health-related claims brought forward by consumers are not provided. The impacts of social inflation, the key driver of escalating costs in the commercial liability market, have been ignored.<sup>9</sup>
3. A major rationale of the PLD reform initiative was to reduce legal uncertainty-related risks and to promote technological innovation. However, despite their importance, no or very little attention has been paid to these aspects in the EU's impact assessment.<sup>10</sup> A general finding is that the addition of software and AI systems to product scope and psychological health and data loss/corruption to damages would increase legal certainty on the side of businesses and lead to safer products in the EU. The impact assessment does not attempt to quantify the impacts of new legal uncertainties for software-intensive products and services suppliers resulting from the interplay between products and software and the extension of the definition of damages to psychological health. The assessment does not look into the impacts of new legal uncertainties from the inclusion of related digital services and legal risks from the inclusion of psychological health. This is surprising given the significant negative impact of legal risks on investment in the production of technology-intensive industries.
  4. The inclusion of software and related digital services in the product scope and psychological health to the definition of damages disproportionately increase operating costs and legal risks for SMEs. This is generally acknowledged or downplayed by the authors of the impact assessment. A far-reaching revision of the PLD should properly account for the specific needs of SMEs, namely limited financial and personal resources to manage technological and legal risks, imbalances in negotiation power in contractual arrangements with large businesses, the inability to acquire insurance coverage for liability risks, and the risk of bankruptcy in case of excessive litigation.

The analytical parts of this paper focus on the potential economic impacts of the key changes proposed for the PLD. These include impacts on businesses' costs including the availability and costs of product liability insurance coverage, impacts on SMEs, impacts on consumers, and impacts on the development of technology-intensive goods and services in EU Member States.

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<sup>9</sup> The term "social inflation" refers to the impact of legal advertising, litigation funding, expanding class-action lawsuits, public distrust of corporate defendants, and other factors, which tend to increase the number of liability insurance claims, jury awards, and settlements. See, e.g. MunichRe (2023). The impact of social inflation on US commercial liability claims. Available at <https://www.munichre.com/topics-online/en/economy/the-impact-of-social-inflation-on-us-commercial-liability-claims.html>.

<sup>10</sup> "The objectives of the liability framework are to (i) provide legal certainty to industry about the risk they take in the course of their business, (ii) encourage the prevention of damage and (iii) ensure injured parties are compensated. Liability rules must strike a delicate balance between these objectives and promoting innovation." See Inception Impact Assessment of the initiative on Adapting liability rules to the digital age and circular economy. Available at [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Product-Liability-Directive-Adapting-liability-rules-to-the-digital-age-circular-economy-and-global-value-chains\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Product-Liability-Directive-Adapting-liability-rules-to-the-digital-age-circular-economy-and-global-value-chains_en).

The paper is organised as follows. Section 2 outlines the rationale of the PLD and its proposed revision and discusses the major impacts found by the European Commission's impact assessment. Section 3 discusses key legislative changes proposed by the Commission and how they impact legal uncertainty, particularly legal risks for companies related to liability claims under a revised PLD. Based on an econometric assessment, Section 4 explores the potential impacts of new legal uncertainties, created by a reform of the PLD, on the production of technology-intensive industries in the EU economy. Impacts on innovation and consumers in the EU as discussed in Section 5. Section 6 concludes with general recommendations.

## **2. PROPOSED CHANGES TO THE PLD AND POTENTIAL ECONOMIC IMPACTS**

The PLD is widely considered a balanced system offering a high level of protection to persons sustaining serious damage by a defective product, while at the same time taking into account the legitimate interests of producers and, thus, promoting innovation and commerce in the EU.

One main objective of the revision is "to take account of the characteristics and risks of new technologies and of new digital and circular business models, including AI-equipped products and services". The European Commission proposes several significant changes to the current regime, notably the definition of what constitutes a product under the PLD, expanding the types of eligible damages and shifting the burden of proof for products considered scientifically or technically complex. Additional changes include the removal of minimum and maximum compensation thresholds, and the new considerations courts can account for to presume defectiveness, some of which are quite subjective.

### **2.1. EU Product Liability in Light of Technological Developments**

The existing PLD is widely considered a balanced system offering a high level of protection to persons sustaining damages by a defective product. According to stakeholder feedback in EU's consultations, current PLD provisions account for legitimate interests of consumers and producers. Industry stakeholders regardless of sector or size consider that the existing PLD is helpful in promoting product developments and technological innovation in the EU, while not risking consumer safety.

The Commission proposal now challenges this view. Technological advancements have contributed to the dissemination of software-based services, automation and (increasingly) artificial intelligence (AI) in the economy. The European Commission argued the Product Liability Directive (PLD) from 1985 may not be suited to effectively address liability issues arising from the malfunctioning of software, software-powered products, and novel technologies such as AI.

The original PLD was designed to provide a framework for the liability of manufacturers for defective products that cause serious harm to consumers. However, as the original text was drafted some 30 years ago, it does not specifically address potential risks associated with software

and digital technologies. However, nothing prevents the existing PLD from applying to smart products. Policymakers claim that this could lead to producers not being held accountable for accidents caused by software- and AI-powered products, since the Directive does not provide clear guidance on how to establish liability in such cases.

It is also argued that a nationally fragmented liability regime may evolve inside the EU's Single Market if the PLD does not keep up with ongoing changes to the national product safety frameworks. This, according to policymakers, could result in different standards of protection for consumers across the EU, particularly for digital products where the legal landscape is said to be complex and uncertain. However, as outlined below, vague formulations of definitions and concepts and decisions left to the discretion of the courts would likely lead to more fragmentation in implementation and enforcement across Member States. In addition, the EU's recent initiative deviates from approaches to liability taken in other mature economies, for which major features are outlined in Appendix I: Regulation of Product Liability in other Mature Economies.

## 2.2. Major impacts identified by the European Commission

The European Commission's impact assessment from 2022 provides a deep dive into the potential economic impacts of the key features of the proposed PLD revision.<sup>11</sup> Comparing the status quo with a set of broad policy options, it provides a comprehensive account of potential impacts on producers and consumers. Its findings reveal that the extension of product scope to "immovables" and new measures intended to overcome difficulties in claiming compensation for damages would have negative consequences for producers of goods, software and digital services. However, the general conclusion is that these impacts must be accepted to ensure greater legal certainty for consumers in the EU.

To begin with, the impact assessment addresses a number of broadly formulated policy options that address two major problems identified by the European Commission:

**Problem 1:** "Certain products, economic actors and types of damages in the digital and circular economy escape no-fault liability."

**Problem 2:** "Injured parties face difficulties in claiming compensation for damages caused by defective products."

The policy options developed by the Commission include provisions ensuring the coverage of different types of software (all embedded software, all stand-alone but product safety-relevant software, and all stand-alone software) and products originating from circular economy business models. In addition to product scope, additional changes include the extension of damage to immaterial damage, the alleviation of the burden of proof, and liability concerns related to products bought from third countries.

<sup>11</sup> Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

Regarding product coverage, a summary of options and proposed revisions is provided by Table 1 below. Concerning difficulties in claiming compensation, a summary of options and proposed revisions is provided by Table 2. It should be noted that this study focuses on key digital economy implications of the proposed changes. The impacts from the coverage of circular economy products and business models are not addressed in this study.

**TABLE 1: OVERVIEW OF POLICY OPTIONS CONSIDERED TO ADDRESS PROBLEM 1 (PRODUCT COVERAGE)**

Policy option	PLD product coverage	Compensable damage covered by the PLD	Ensure presence of an EU-based liable person
1a	Inclusion of strict liability to software/digital elements <b>necessary for tangible products</b> to operate.  The final producer or the software producer would also be made liable for <b>defective updates and upgrades</b> and for the <b>failure to provide a required software (security) update</b> to keep the product safe.	Keeping the status quo: Status quo: Immaterial damage could be compensated in all MSs should the particular MS choose to do so, but would not be mandatory.	Make the producer's <b>authorised representative</b> liable if there is no importer.
1b	Coverage of stand-alone software: In addition to 1a, inclusion of strict liability to safety-relevant <b>software as a product in its own right</b> when it a) influences the operation of a <b>tangible product</b> ; or b) cause <b>harm itself</b> .	Same as 1a.	In addition to Option 1a, treatment of <b>fulfilment service providers</b> (operators who provide warehousing, packaging or dispatching services) as "importers.
1c	In addition to Option 1b, also apply <b>strict liability to software even if not intended to be used with a tangible product</b> .	Same as 1a.	Same as 1b.

Source: European Commission DG Grow.<sup>12</sup>

<sup>12</sup> Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

**TABLE 2: OVERVIEW OF POLICY OPTIONS CONSIDERED TO ADDRESS PROBLEM 2 (CLAIMING COMPENSATION)**

Policy option	Easing of burden of proof	Lowring of restrictions on making claims
2a	<p>Oblige the producer to <b>disclose necessary technical information to the injured party</b> to better enable the latter to prove their claim.</p> <p>Ensure that national <b>courts can infer/presume that a product is defective or caused the damage under certain circumstances</b> (e.g., non-compliance with safety standards, product subject to a recall or product clearly malfunctioned).</p> <p><b>Development risk defence would remain except that the producer would remain liable if a defect became discoverable after the moment of putting a product into circulation</b> while the producer has control over the product.</p> <p>The later defect defence exemption would be abolished as products change post-market placement (for circular economy).</p>	<p><b>Abolish the EUR 500 threshold</b> for property damage.</p> <p>Extend 10-year liability to <b>15 years for latent health-related injuries only</b>.</p> <p><b>Keep a 3-year time limit for starting legal proceedings.</b></p>
2b	<p><b>Reversal of the burden of proof.</b> In the event of damage, it would be for the producer to prove the product was not defective if causality was determined by national courts as being difficult for a plaintiff to reasonably establish. Keep producer liable for all undiscoverable defects (i.e. remove development risk defence).</p>	<p><b>Abolish EUR 500 threshold</b> for property damage.</p> <p><b>Extend 10-year liability for personal injury for all defective products to 15 years.</b></p> <p>Extend the 3-year limit to <b>5 years for starting legal proceedings.</b></p>

Source: European Commission DG Grow.<sup>13</sup>

Table 1 and Table 2 illustrate that the European Commission evaluated policy options in its impact assessment that do not exactly correspond to the changes presented in the September 2022 draft law.<sup>14</sup>

Several economic impacts and industries in-scope of the new PLD are therefore not part of the analysis. Indeed, the Commission proposed extensive changes to the status quo, which go beyond the inclusion of "software and digital elements" to the definition of products under the existing PLD. Software development activities in industries other than ICT services (NACE sectors J62-J63) have not been covered in the impact assessment. The impact assessment does not consider related digital services as a specific product category. Whereas the assessment accounts for "software and digital elements", companies in services sectors other than ICT services, which are known to create and commercialise software (as-a-service) solutions, such as professional services, maintenance and repair services, retail services, or healthcare services, are not considered in the impact assessment. The abolishment of the maximum threshold of

<sup>13</sup> Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

<sup>14</sup> COM(2022) 495 - Proposal for a directive of the European Parliament and of the Council on liability for defective products. Available at [https://single-market-economy.ec.europa.eu/document/3193da9a-cecb-44ad-9a9c-7b6b23220bcd\\_en](https://single-market-economy.ec.europa.eu/document/3193da9a-cecb-44ad-9a9c-7b6b23220bcd_en).



EUR 70 million for claims has not been considered a policy priority by the Commission and is therefore not covered by the impact assessment. While the impacts of the extension of damage to psychological health and data loss are covered, the impact on related digital services, of which many are provided by services sectors other than ICT services, has not been analysed by the Commission. Overlaps and differences between the impact assessment and the draft law are set out in Table 3.

**TABLE 3: MAJOR GAPS IN THE EUROPEAN COMMISSION'S IMPACT ASSESSMENT OF CHANGES TO THE PLD**

Major proposed changes affecting technology-intensive products and digital services	Covered in impact assessment	Explanation
The proposed PLD would allow strict product liability claims to be made due to <b>defective software, AI systems, AI-enabled goods and digital manufacturing files</b> (such as those used for purposes of 3D printing) (see explained context of the proposal and Article 4).	Partly.	These proposed changes are largely accounted for by policy option 1c (in the digital economy part).  However, the impact assessment only assesses impacts on 17 industries of which 16 cover the manufacturing of products. Impacts from the inclusion of software are only assessed for one sector, "Computer programming, consultancy, and information service activities (generally ICT services; NACE sector J62-J63). <sup>15</sup> Software that is developed by companies in services sectors other than ICT services, such as professional services, maintenance and repair services or healthcare services, are not considered in the impact assessment.
<b>Related digital services</b> (such as a digital service interconnected with a product that is required for the product's functions to be performed) are <b>considered a component part of a product</b> (see explained context of the proposal, recital 17, and Article 4).  <b>Providers of software and providers of digital services can be considered manufacturers</b> and can face liability under the PLD (see Article 4).	No.	The proposed definitions of "component" (Article 4.3) and "related services" (Article 4.4) are intended to cover "digital services", as stated in recital 15. This proposed change is not covered in the impact assessment, which only accounts for "software and digital elements". Similar to the assessment of "software", companies in services sectors other than ICT services, which are known to create and commercialise software solutions, such as professional services, maintenance and repair services or healthcare services, are not considered in the impact assessment.
Damage includes material losses from <b>personal injury</b> , which <b>includes medically recognised harm to psychological health</b> . (see recital 17 and Article 4).	Partly.	This proposed change is largely accounted for by policy option 1c (in the immaterial harm part). However, it is stated that the sectors affected would only correspond to the overall scope of the PLD. Related digital services, of which many are provided by services sectors other than ICT services, have not been considered affected sectors.

<sup>15</sup> The European Commission's impact assessment covers seventeen industries (based on the statistical classification of economic activities in the European Community – NACE Rev. 2). Computer programming, consultancy, and information service activities (J62-J63) is the only services sector accounted for in the analysis. See page 223 of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

Major proposed changes affecting technology-intensive products and digital services	Covered in impact assessment	Explanation
For complex cases, the burden of proof is eased in order to achieve a fairer balance of industry and consumer interests. The burden of proof has not been reversed, but the proposed PLD would allow the burden of proof to be alleviated <b>when a claimant faces excessive difficulties in proving defect or causation due to the technical or scientific complexity of a claim</b> (see explained context of the proposal, recitals 33 to 36, and Article 9).	Yes.	This proposed change is largely accounted for by policy option 1c (in the immaterial harm part).
<b>Abolishment the EUR 500 minimum threshold</b> for property damage	Partly.	This proposed change is accounted for by policy option 2a. However, a significant shortcoming is that impacts on digital services are out of the scope of the analysis of the impact assessment.
<b>Abolishment the EUR 70 million maximum threshold</b> for compensation. The optional cap of not less than EUR 70 million for damage resulting from death or personal injury and caused by identical products (implemented by some member states) has been removed.	No.	This policy option was discarded as other options were prioritised. <sup>16</sup>
<b>Inclusion of fulfilment services providers to potentially liable economic operators</b> where the manufacturer of the defective product is established outside the EU and importer of the defective product and the authorised representative of the manufacturer can be held liable for damage caused by that product. <b>Exclusion of postal services, parcel delivery services, freight transport services, and any other postal services</b> (Article 4).	Partly.	This proposed change is accounted for by policy option 1b and option 1c.  However, while postal services, parcel delivery services, freight transport services, and any other postal services are explicitly excluded from the definition of fulfilment providers, the impact assessment treats postal services, parcel delivery, storage, and warehousing services as fulfilment services.  It should be noted that one policy option intended to make "make online marketplaces (acting in an intermediary capacity) strictly liable" was discarded in the impact assessment as other options were prioritised.

Source: own compilation and assessment based on the original PLD proposal and the European Commission's Full Impact Assessment Study on the possible revision of the Product Liability Directive.

For companies operating in the EU, the Commission's impact assessment provides a range of quantitative estimates of changes in the annual compensation paid to victims, the annual cost of liability insurance costs, and annual enforcement costs. The calculations are based on several critical assumptions regarding the prevalence, success rate and cost of legal disputes. These assumptions are outlined in Table 4. It should be noted that the quantitative assumptions were

<sup>16</sup> See page 422 of Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

developed by the authors in absence of data, based on subjective “evaluative judgements” derived from “stakeholder feedback”.

**TABLE 4: CRITICAL ASSUMPTIONS UNDERLYING THE ESTIMATION OF COST OF COMPENSATION IN THE IMPACT ASSESSMENT OF THE EUROPEAN COMMISSION’S DG GROW**

Determinant	Assumption
Total number of in-court cases under the PLD in the EU27 per year	Between 209 and 452
Total number of out-of-court cases under the PLD in the EU27 per year	Between 1,255 and 3,165
Share of damage types in in-court and out-of-court cases under the PLD <sup>17</sup>	- 20% of cases under the PLD are assumed to be related to deaths - 40% related to personal injuries - 40% related to property damages
Share of success rate for in-court and out-of-court cases under the PLD <sup>18</sup>	60% for both in-court and out-of-court cases
Number of successful in-court cases under the PLD in the EU27 per year, by damage type	Based on the assumed proportion: - Between 25.1 and 54.3 in-court cases related to deaths - Between 50.2 and 108.5 in-court cases related to personal injuries - Between 50.2 and 108.5 in-court cases related to property damages
Number of successful out-of-court cases under the PLD in the EU27 per year, by damage type	Based on the assumed proportion: - Between 150.6 and 379.8 out-of-court cases related to deaths - Between 301.2 and 759.7 out-of-court cases related to personal injuries - Between 301.2 and 759.7 out-of-court cases related to property damages
Average compensation paid for deaths caused by defective products	Between 20,000 and 1,500,000 EUR
Average compensation paid for personal injuries caused by defective products Average compensation paid for damages to property caused by defective products per year	Between 1,500 and 700,000 EUR
Average compensation paid for damages to property caused by defective products per year	Between 5,000 and 25,000 EUR

Source: European Commission DG Grow.<sup>19</sup>

For each policy option (see Table 1 and Table 2), the European Commission's assessment outlines key impacts compared to the status quo (the baseline).

<sup>17</sup> Simplified assumptions due to lacking data on the shares of legal cases related to the different types of damage covered under the PLD.

<sup>18</sup> In line with 2018 PLD evaluation.

<sup>19</sup> Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

As concerns the number of legal disputes related to deaths, personal injury, and property damage, estimated changes are outlined in Table 5 below. For the inclusion of software to the scope of product (policy option 1c), the Commission's estimates indicate that the highest increase in legal disputes can be expected for inclusion of all stand-alone software to the PLD. The increase in the total number of legal disputes is estimated to amount to 1% for cases related to deaths, and 4% each for cases related to personal injuries and cases related to property damage. It should be noted, however, that the estimation methodology only accounts for one (statistical) sector of the economy, "Computer programming, consultancy, and information service activities (J62-J62)". This sector accounts for 16% of the gross value added of all other sectors that are considered to be included in the scope of the new PLD. Excluding non-relevant economic operators that are not considered software providers, results in a total estimated industry share affected by the inclusion of stand-alone software of 10%. This share, however, gravely underestimates the value-added generated by software development in the EU. Statistically, software development is indeed mainly covered by sector J62 (computer programming, consultancy, and related activities) and J63 (computer programming, consultancy and related activities). However, many manufacturing and services industries, which are recorded in different statistical categories, also engage in the development and marketing of stand-alone software. Take carmakers and manufacturers of electrical equipment or consultancies, which engage in customised software development that is sold to other businesses. Similarly, applications based on artificial intelligence are of increasing importance for Europe's pharmaceutical industry, e.g., in early-stage disease detection and accelerated drug and treatment development. Many pharmaceutical companies develop and deploy in-house applications.<sup>20</sup>

Moreover, related digital services, which are covered by the Commission's PLD reform proposal, are not sufficiently covered by the Commission's impact assessment.<sup>21</sup> In its non-paper<sup>22</sup> clarifying digital elements of the proposal for a new PLD, including related services, it is clearly stated that such services include, amongst others, continuous supply of traffic data, the continuous supply of AI training data for machine learning, voice control assistant services, health monitoring services, data backup services, and in certain circumstances, even telecommunication services. These activities, which are regularly supplied by companies operating in manufacturing and services industries have not been accounted for in the Commission's impact assessment.

The inclusion of harm related to privacy infringements, discrimination and emotional harm (extension of policy option 1c) is estimated to cause an additional 25% increase in the number related to personal injuries and an additional 15% increase in cases related to property damage. It is stated that the increase in the number of cases related to personal injuries would be driven by the increasing use of digital products that have a higher risk of non-material harm. Referring to stakeholder feedback, it is argued that the inclusion of non-material harm would significantly increase the level of litigation.

<sup>20</sup> See, e.g., EFPIA (2022). The future of product liability in the EU. EFPIA position paper. June 2022.

<sup>21</sup> A non-paper by the Commission clarifying "a number of digital-related elements of the proposal for a new PLD" was only published in February 2023. See Commission non-paper on digital elements of the proposal for a new Product Liability Directive, Interinstitutional File: 2022/0302(COD). Available at <https://data.consilium.europa.eu/doc/document/ST-6201-2023-INIT/en/pdf>.

<sup>22</sup> See Commission non-paper on digital elements of the proposal for a new Product Liability Directive, Interinstitutional File: 2022/0302(COD). Available at <https://data.consilium.europa.eu/doc/document/ST-6201-2023-INIT/en/pdf>.

Similarly, the abolishment of the EUR 500 threshold for the initiation of claims (policy option 2a) is estimated to have a higher impact on the number of legal disputes than the inclusion of stand-alone software. Cases relating to deaths, personal injuries and property damage are estimated to increase by 7%.

Given that the Commission's impact assessment does not account for related digital services and software and digital services marketed by companies in manufacturing and services sectors, the Commission's estimates for impacts from the inclusion of non-material harm and the abolishment of the EUR 500 threshold significantly understates the overall rise in legal disputes from a revised PLD.

**TABLE 5: KEY IMPACTS FROM CHANGES TO AFFECTING SOFTWARE AND DIGITAL SERVICES BUSINESS MODELS AS ESTIMATED IN THE IMPACT ASSESSMENT OF THE EUROPEAN COMMISSION'S DG GROW**

Policy option	Annual number of in-court and out-of-court PLD cases related to deaths	Annual number of in-court and out-of-court PLD cases related to personal injuries	Annual number of in-court and out-of-court PLD cases related to property damage
1a	- Expected increase: 1% increase for software developers - Share of industry under PLD scope: 10%	- Expected increase: 1% increase for software developers - Share of industry under PLD scope: 10%	- Expected increase: 1% increase for software developers - Share of industry under PLD scope: 10%
1b	- Expected increase: 1% for software developers - Share of industry under PLD scope: 10%	- Expected increase: 2% for software developers - Share of industry under PLD scope: 10%	- Expected increase: 2% for software developers - Share of industry under PLD scope: 10%
1c (inclusion of stand-alone software)	- Expected increase: 1% for software developers - Share of industry under PLD scope: 10%	- Expected increase: 4% for software developers - Share of industry under PLD scope: 10%	- Expected increase: 4% for software developers - Share of industry under PLD scope: 10%
1c (inclusion of damage to digital assets and harm related to privacy infringements, discrimination and emotional harm)	- No change	- Expected increase: 25% - Share of industry under PLD scope: 16%	- Expected increase: 15% - Share of industry under PLD scope: 16%
2a	Ease of burden of proof: - Expected increase: 7% - Share of industry under PLD scope: 20%  Ease of restrictions: - Expected increase: 2% - Share of industry under PLD scope: 100%	Ease of burden of proof: - Expected increase: 7% - Share of industry under PLD scope: 20%  Ease of restrictions: - Expected increase: 2% - Share of industry under PLD scope: 100%	Ease of burden of proof: - Expected increase: 7% - Share of industry under PLD scope: 20%  Ease of restrictions: - Expected increase: 2% - Share of industry under PLD scope: 100%

Policy option	Annual number of in-court and out-of-court PLD cases related to deaths	Annual number of in-court and out-of-court PLD cases related to personal injuries	Annual number of in-court and out-of-court PLD cases related to property damage
2b	Ease of burden of proof: - Expected increase: 12% - Share of industry under PLD scope: 100%  Ease of restrictions: - Expected increase: 5% - Share of industry under PLD scope: 100%	Ease of burden of proof: - Expected increase: 12% - Share of industry under PLD scope: 100%  Ease of restrictions: - Expected increase: 5% - Share of industry under PLD scope: 100%	Ease of burden of proof: - Expected increase: 12% - Share of industry under PLD scope: 100%  Ease of restrictions: - Expected increase: 5% - Share of industry under PLD scope: 100%

Source: European Commission DG Grow.<sup>23</sup>

The European Commission's impact assessment also investigated effects on the cost of liability insurance, which should be interpreted with caution. First of all, it is difficult to obtain detailed data on product liability insurance policies in different countries. Liability insurance policies are typically sold within larger types of contracts. In addition, claims that are specifically about product liability are not always registered as such, but instead, they are registered under the larger name of the type of bundled insurance package. The Commission acknowledges that the inclusion of stand-alone software and lower thresholds for initiating claims as well as the inclusion of immaterial harm would require an extension of insurance coverage to include strict liability. This is reflected in the estimates, which indicate that insurance costs will increase for companies that fall under the PLD's requirements (Table 6). The inclusion of all stand-alone software to product scope is estimated to increase liability insurance costs by 15% on average for software developers. The abolishment of the EUR 500 threshold for the initiation of claims is estimated to result in a 3-4% increase in liability insurance costs across industries. The rise in liability insurance costs from the inclusion of immaterial harm is estimated to amount to 2-3% for software developers and manufacturers of hardware (including PCs, laptops, and external data storage devices).

It should be noted that the Commission's impact assessment does not account for related digital services and software and digital services marketed by companies in the manufacturing and services sectors. In addition, the impact assessment does not assess situations in which companies are denied liability insurance coverage, which was highlighted by the insurance industry.<sup>24</sup> Due to their size it is generally more challenging for SMEs to acquire liability risk insurance coverage than for large companies, which can rely on several business models (equivalent to internal insurance risk subsidisation) and maintain accruals for risks from sales. With so many unknowns, such as the number of claims less than EUR 500 and the level of compensation for psychological harm, many SMEs may not be able to insure against strict liability claims. At the same time,

<sup>23</sup> Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

<sup>24</sup> Insurance Europe argues that "[f]or insurers to be able to provide insurance coverage tailored to policyholders' needs, the scope of the Directive should be clarified by including provisions that clearly refer to the products that fall under the liability framework." It is also argued that "[w]ithout a harmonised definition of psychological harm, it will be very hard for insurers to assess damage, inevitably leading to litigation." See Insurance Europe (2023). Key messages on the European Commission's proposal for a revision of the Product Liability Directive (PLD). Available at <https://www.insuranceeurope.eu/publications/2788/key-messages-on-the-ec-proposal-for-a-revision-of-the-pld/>.

larger businesses might face the same challenge, especially those selling software or providing free or paid applications that are used by a large number of customers. Disregarding these consequences, Table 7 provides an overview of aggregate quantitative estimates for costs and benefits resulting from the policy options considered in the Commission's impact assessment, indicating that the most profound impacts on businesses stem from the inclusion of all stand-alone software and the inclusion of immaterial harm to compensable damage.

It is noteworthy that, contrary to the Commission's PLD reform proposal, the impact assessment identified policy options 1b (inclusion of all software able to influence the operation of a tangible product, including when a producer does not supply needed safety upgrades) and 2a (no reversal of proof) as the preferred combination of options.

**TABLE 6: QUANTITATIVE ESTIMATES OF CHANGE IN LIABILITY INSURANCE COST AND JUSTIFICATIONS**

Policy option	Expected change in liability insurance costs	Share of EU industry under scope	Share of EU industry under scope and justification of determination of estimated change
1a	Concerning the inclusion of software/digital elements necessary for tangible products to operate: <b>+ 3% for software developers</b>	- Share of industry under PLD scope: 10% <sup>25</sup>	- Different software and digital elements are <b>covered for the first time</b> and more operators are included within the scope of the definition of producer. The increase in insurance costs for software developers is estimated to be low, as although they are not presently covered under the PLD, they <b>ought to already have general product liability insurance</b> . The increase in insurance costs for software developers, therefore, derives from the need to upgrade their existing insurance.
1b	Concerning the inclusion of strict liability to safety-relevant software as a product in its own right: <b>+ 10% for software developers</b>	- Share of industry under PLD scope: 10%	- Different software in its own right (relevant for safety) is <b>covered for the first time</b> and more operators are included within the scope of the definition of producer. Some <b>increase in insurance costs for software developers</b> is expected. Although they are not presently covered under the PLD, they <b>ought to already have general product liability insurance</b> . The increase in insurance costs for software developers, therefore, derives from the <b>need to upgrade their existing insurance</b> .
1c	Concerning the inclusion of software even if not intended to be used with a tangible product: <b>+ 15% for software developers</b>	- Share of industry under PLD scope: 10%	- Different stand-alone software (even if not relevant for safety or intended to be used with a tangible product) are covered for the first time and more operators are included within the scope of the definition of producer. Increases in insurance costs for software developers are expected. Although they are not presently covered under the PLD, they <b>ought to already have general product liability insurance</b> . The <b>increase in insurance costs for software developers derives from the need to upgrade their existing insurance</b> .

<sup>25</sup> It is assumed in the impact assessment of DG GROW that "Computer programming, consultancy, and information service activities" (NACE code J62-J63) represent 16% of the gross value added of industries under the scope of the revised PLD. A share of 10% is chosen as lower proxy estimate to exclude software developers that are considered "non-relevant".

Policy option	Expected change in liability insurance costs	Share of EU industry under scope	Share of EU industry under scope and justification of determination of estimated change
1c	Concerning the inclusion of damage to digital assets and harm related to privacy infringements, discrimination and emotional harm <b>+2-3% for software developers, manufacturers of hardware (including PCs, laptops, external data storage devices)</b>	- Share of industry under PLD scope: 16%	- <b>Minor increase in insurance costs derives from the need to upgrade the existing insurance.</b> EOs would need to ensure that their general liability insurance coverage includes data loss, corruption and destruction (generally, this appears to be the case presently, e.g. if a data storage device is damaged).
2a	Concerning the burden of proof: <b>4% for software developers, manufacturers of hardware (including PCs, laptops, external data storage devices), consumer IoT products and pharmaceutical products</b>  Concerning the ease of restrictions: <b>+ 3 to 4% across industries considered to be in-scope of the PLD by the authors of the impact assessment</b>	- Share of industry under PLD scope: + 4% for software developers, manufacturers of hardware (including PCs, laptops, external data storage devices), consumer IoT products, and pharmaceutical products  - Share of industry under PLD scope: 100%	- An easing of the burden of proof through a more homogenous use of presumptions is <b>expected to expose product liability insurers to increased risks</b> , which will be reflected onto the overall insurance costs producers will have to pay. As presumptions, in this case, concern <b>mainly complex cases</b> , many producers will be unaffected. The <b>small increase in insurance costs derives from the need to upgrade their existing insurance.</b>  - <b>Insurers' exposure to risk increases</b> with the extension of the liability period and damage threshold, across sectors. However, this impact is limited by the fact that claims for property damages of > 500 EUR would continue to be eligible under the PLD.
2b	Concerning the burden of proof: <b>+ 6 to 8% across industries considered to in-scope of the PLD by the authors of the impact assessment</b>  Concerning the ease of restrictions: <b>+ 5 to 6% across industries considered to be in-scope of the PLD by the authors of the impact assessment</b>	- Share of industry under PLD scope: 100%  - Share of industry under PLD scope: 100%	- A reversal of the burden of proof would lead to an <b>increase in insurance costs for companies seeking product liability cover</b> , across sectors, as the <b>reversal of the burden of proof would put pressure on the insurability of products.</b>  - The current product liability insurance premiums have been designed with the existing periods in which an injured party may bring forward claims. Any increase to these periods is expected to have <b>ripple effects on the insurability of certain products (across sectors) and lead to increased insurance costs.</b>

Source: European Commission DG Grow.<sup>26</sup>

<sup>26</sup> Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.



**TABLE 7: QUANTITATIVE ESTIMATES OF COST AND BENEFITS, BY POLICY OPTION, AS ESTIMATED BY THE EUROPEAN COMMISSION**

Policy option	Incremental annual compensation paid to victims (assumed to be covered by insurance in most cases)			Incremental annual product liability insurance costs			Incremental annual legal enforcement costs		
	Incremental benefits, compared to baseline			Incremental costs, compared to baseline			Incremental costs, compared to baseline		
	low estimate	medium estimate	high estimate	low estimate	medium estimate	high estimate	low estimate	medium estimate	high estimate
Policy option 1a	0.07	7.26	14.47	1.21	1.81	2.41	0.41	0.72	1.01
Policy option 1b	0.15	11.14	22.13	4.35	6.52	8.69	1.12	1.93	2.75
Policy option 1c	0.17	23.94	47.7	6.56	9.82	13.09	1.83	3.17	4.49
Policy option 2a	0.2	21.86	43.54	14.35	21.54	28.71	0.41	0.72	1.02
Policy option 2b	0.99	109.34	217.7	41.73	62.59	83.46	6.9	11.93	16.95
<b>Costs and benefits after excluding estimated impacts from the inclusion of circular economy products</b>									
Policy option 1a	0.07	6.69	13.33	0.61	0.91	1.21	0.41	0.72	1.01
Policy option 1b	0.15	10.57	20.99	3.75	5.62	7.49	1.12	1.93	2.75
Policy option 1c	0.17	23.37	46.56	5.96	8.92	11.89	1.83	3.17	4.49
Policy option 2a	0.2	21.29	42.4	13.75	20.64	27.51	0.41	0.72	1.02
Policy option 2b	0.99	108.77	216.56	41.13	61.69	82.26	6.9	11.93	16.95

Source: European Commission DG Grow.<sup>27</sup>

<sup>27</sup> Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

### 3. SOURCES OF NEW LEGAL RISKS CREATED BY CHANGES PROPOSED TO THE EU PLD

Legal uncertainty always impacts economic activity. The proposed changes to the EU's PLD would empower consumers, and their legal representatives, regarding the scope of no-fault-based liability requirements. However, they would increase legal risks for a very large number of companies in the EU with respect to future claims on the basis of strict liability.

Strict liability is an exemption from the general liability framework. It is intended to address occasions when a legally sold product could result in damage to other persons or property. As such, since 1985 the common understanding was that it should be limited only to safety-related situations where its use is really warranted. Given the lack of evidence regarding harm caused by defective software or applications, the decision to include software in the revised PLD does not address a clearly defined or evident problem. There are currently no real-world examples of liability problems that would call for a far-reaching broadening of the existing scope of no-fault-based liability.

Indeed, the European Commission's Regulatory Scrutiny Board states that the European Commission's impact assessment "report is not sufficiently clear about the size and evolution of the problem. [...] The report should be clear to what extent the analytical assumptions and results (in both the baseline and impact analyses) have been validated by experts and stakeholders. More generally, the report should deal better with uncertainty, for instance by considering sensitivity analysis when assessing the scale of the (remaining) problem and comparing the options in terms of costs and benefits."<sup>28</sup>

From a legal point of view, several changes proposed by the European Commission would increase "parameter uncertainty", i.e., they would change legal parameters that systematically affect legal disputes about technology-intensive products and services. The extension of product scope and compensable damage would impact Member States' case law. In addition, given the complexity of software and interlinkages with products, on the one hand, and subjective views on psychological harm, data loss and technological complexity, on the other hand, the revisions would increase "decision uncertainty", referring to the fact that decisions of judges are no longer as predictable as they were in the past.<sup>29</sup>

These new uncertainties impact companies whose products and services might fall under the revised PLD. New uncertainties also impact the decisions of insurance companies as to whether to provide strict liability insurance coverage (companies' ability to obtain insurance) and at which terms (the level of premia and deductibles).

Below we discuss major proposed changes to the PLD and the extent to which they create new legal uncertainties / risks for technology-driven businesses operating in the EU. A summary

<sup>28</sup> Regulatory Scrutiny Board Opinion on the Impact Assessment underlying the reform of the Product Liability Directive. SEC(202). Available at [https://www.parlament.gv.at/dokument/XXVII/EU/114039/imfname\\_11180579.pdf](https://www.parlament.gv.at/dokument/XXVII/EU/114039/imfname_11180579.pdf).

<sup>29</sup> See, e.g., Lee et al. (2023). The Economics of Legal Uncertainty. Available at [https://www.law.nyu.edu/sites/default/files/Schoenherr%20LU\\_20221216.pdf](https://www.law.nyu.edu/sites/default/files/Schoenherr%20LU_20221216.pdf).

of changes and potential impacts is provided in Figure 1 below. In this context, we also discuss implications for decisions to invest, innovate, produce and trade in the EU, as well as businesses' ability to obtain required liability insurance protection.

**FIGURE 1: OVERVIEW OF SOURCES OF NEW LEGAL RISKS CREATED BY CHANGES PROPOSED TO THE EU PLD**

Sources of new legal risks regarding the nature and size of liability claims faced by businesses in the EU27					
Inclusion of stand-alone software	Inclusion of related (digital) services	Inclusion of damage related to psychological health	Inclusion of damage related to loss or corruption of data	Reversal of burden of proof for complex products / services and evidence disclosure obligations	Vague definitions or concepts that go undefined
<ul style="list-style-type: none"> <li>• Very broad scope</li> <li>• No limitation to safety-relevant software</li> <li>• Specific consumer use cases often unknown to software providers</li> <li>• Liability risks difficult to manage in B2B contracts</li> <li>• Limitations to obtain strict liability insurance</li> </ul>	<ul style="list-style-type: none"> <li>• Very broad scope</li> <li>• No limitation to safety-relevant services</li> <li>• Concrete consumer use cases often unknown to software providers</li> <li>• High exposure to risks from collective redress</li> <li>• Limitations to obtain strict liability insurance</li> </ul>	<ul style="list-style-type: none"> <li>• Psychological health very complex types of damage</li> <li>• Damage very difficult to assess and quantify</li> <li>• Challenge of Social inflation</li> <li>• High risk of activist plaintiffs and mass claims</li> <li>• Limitations to obtain strict liability insurance</li> </ul>	<ul style="list-style-type: none"> <li>• Value of personal data is subjective</li> <li>• Damages from the loss of personal data extremely difficult to define</li> <li>• Damage difficult to quantify objectively by courts</li> <li>• Limitations to obtain strict liability insurance</li> </ul>	<ul style="list-style-type: none"> <li>• Higher exposure to no-fault-based liability risks</li> <li>• Potential disclosure of essential trade secrets</li> <li>• Greater leverage (threat potential) for claimants</li> <li>• Higher incentives to launch claims</li> <li>• Larger incentives for out-of-court settlement rather than disclosing information or incur the costs of court proceedings</li> <li>• Larger number of cases</li> <li>• Limitations to obtain strict liability insurance</li> </ul>	<ul style="list-style-type: none"> <li>• General amplification of liability risks</li> <li>• Additional risks from differences in national implementation and differences in enforcement</li> <li>• Risk of forum shopping, e.g., in case of collective redress</li> <li>• Limitations to obtain strict liability insurance</li> </ul>
Impacts on companies' decisions to develop, produce and commercialise complex technology product and services in the EU					
Impacts on EU consumers in B2B and B2C markets: less supply, less choice, and higher prices for remaining offers					

Source: compilation by authors.

### 3.1. New legal risks from the inclusion of stand-alone software

Stand-alone software is considered a "product" under the proposed PLD (Article 4). It also states that companies that develop software or applications are considered "manufacturers". As outlined in the European Commission's non-paper on clarifying "a number of digital-related elements of the proposal for a new PLD", the proposal maintains the same definition for product but demands that software is to be understood as a product. At the same time, the non-paper states that software remains an open concept. Defining software, it is said, would not be "future-proof" given its "different forms". Narrowing the scope of software could "accidentally limit the application of the [PLD] regime to future types of software."<sup>30</sup>

A broad definition of software is, however, provided in recital 12, stating that:

*"[...] Software, such as operating systems, firmware, computer programs, applications or AI systems, is increasingly common on the market and plays an increasingly important role for product safety. Software is capable of being placed on the market as a standalone product and may subsequently be integrated into other products as a component, and is capable of causing damage through its execution. In the interest of legal certainty it should therefore be clarified that software is a product for the purposes of applying no-fault liability, irrespective of the mode of its supply or usage, and therefore irrespective of whether the software is stored on a device or accessed through cloud technologies."*

Accordingly, the PLD proposal does not rule out certain modes of supply. Software-as-a-service business models explicitly fall under the scope of the proposed PLD. Moreover, recital 37 states that companies can be held liable for defectiveness and damages resulting from software updates or machine learning.

According to the European Commission, there are over one million software companies in Europe, which makes the inclusion of stand-alone software a non-negligible part of the proposed PLD.<sup>31</sup> Currently, standalone software is not covered by no-fault liability. The existing PLD takes a technology neutral approach, making sure that compensation for damage caused by a defective tangible product is generally possible regardless of how the damage has been caused. The existing PLD already ensures that consumers can seek remedies directly from a product manufacturer. Under the current regime, software developers are subject to contractual and extra-contractual liability through fault-based liability under national tort laws.<sup>32</sup>

<sup>30</sup> Non-paper by the Commission clarifying "a number of digital-related elements of the proposal for a new PLD" was only published in February 2023. See Commission non-paper on digital elements of the proposal for a new Product Liability Directive, Interinstitutional File: 2022/0302(COD). Available at <https://data.consilium.europa.eu/doc/document/ST-6201-2023-INIT/en/pdf>.

<sup>31</sup> Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

<sup>32</sup> Contractual liability is a civil liability that arises from a contract (e.g., the refusal to honour the terms of a contract) while extra-contractual liability stems from a person's actions.

The treatment of software and software-as-a-service as products is particularly problematic because of the particularities of software development and the complexity of industrial partnerships in the development of technologies and software-as-a-service applications, including IoT and use cases in industrial production.

According to the PLD proposal, no-fault-based liability would in the future cover software which is considered a “product of its own”. Medical devices software is highlighted by the Commission as an intuitive example in addition to mapping and navigation apps.<sup>33</sup> Other types of software and their use in B2C context and B2B use cases, which also impact final consumers, have largely been neglected in the Commission’s thinking behind the reform. The impact assessment by the Commission nevertheless concludes that the inclusion of stand-alone software would incentivise innovation because the liability between the different economic operators would be shared. It is further argued that the regulatory environment surrounding software development would in the future be more conducive to competitiveness in the internal market. However, the Commission does not substantiate these claims, and it does not lay out and account for the complexity and software development and the deterrent effect of persistent liability risks between developers and product manufacturers and developers and consumers respectively.

### **3.1.1. Management of liability risks in complex value chains**

The European Commission’s 2020 investigation into the “safety and liability implications of Artificial Intelligence, the Internet of Things and robotics” indeed recognises the complexity of value chains in technology-intensive industries. It is stated that the “Union product safety legislation [already] takes into account the complexity of the value chains, imposing obligations on several economic operators following the principle of “shared responsibility”.<sup>34</sup> However, as concerns the inclusion of stand-alone software in the product scope under the PLD, the report does not address how companies would effectively manage, allocate or insure risks from strict liability.

Deaths and cases of personal injury from defective software are most likely to occur when the software controls the aspects necessary to the functioning of a tangible product, such as a medical device. However, cases of damage to property are likely to arise for a very wide spectrum of embedded or stand-alone software.<sup>35</sup> Examples include smart home metering devices, smart heating systems, and home security systems. In addition, damages to property may also result

<sup>33</sup> Non-paper by the Commission clarifying “a number of digital-related elements of the proposal for a new PLD” was only published in February 2023. See Commission non-paper on digital elements of the proposal for a new Product Liability Directive, Interinstitutional File: 2022/0302(COD). Available at <https://data.consilium.europa.eu/doc/document/ST-6201-2023-INIT/en/pdf>.

<sup>34</sup> See European Commission (2020). Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0064>.

<sup>35</sup> The 2018 evaluation of the PLD identified that comparatively more legal cases falling under the PLD are registered for medical devices and equipment. The European Commission’s impact assessment states that including all “software and digital elements” will only have a small impact on the volume of cases related to deaths. See pp. 238. It is further stated that “it is generally accepted that software either embedded or crucial to the operation of a product is already included within scope; 2) software developers are already liable under other grounds of liability; 3) software rarely causes physical damage except in certain circumstances. There will be a shift in liability as consumers could pursue compensation for defective software under the PLD. The producer would then counter-claim under either contractual liability or through a recourse claim.”

from a broad spectrum of (typically cloud-based) software-as-a-service applications, which also fall under the scope of the new PLD. Examples include bookkeeping and tax administration software as well as banking and automated finance apps when deployed for personal use. In addition, web portals that offer recruitment services or online intermediation services would also fall under the scope of a revised PLD. Software, including AI applications, cannot be expected to be completely free from error. Therefore, companies offering software and software-based services in partnership with others, which is common in markets for software services, have to reconsider their legal relationships in order to account for new legal risks from no-fault-based liability.

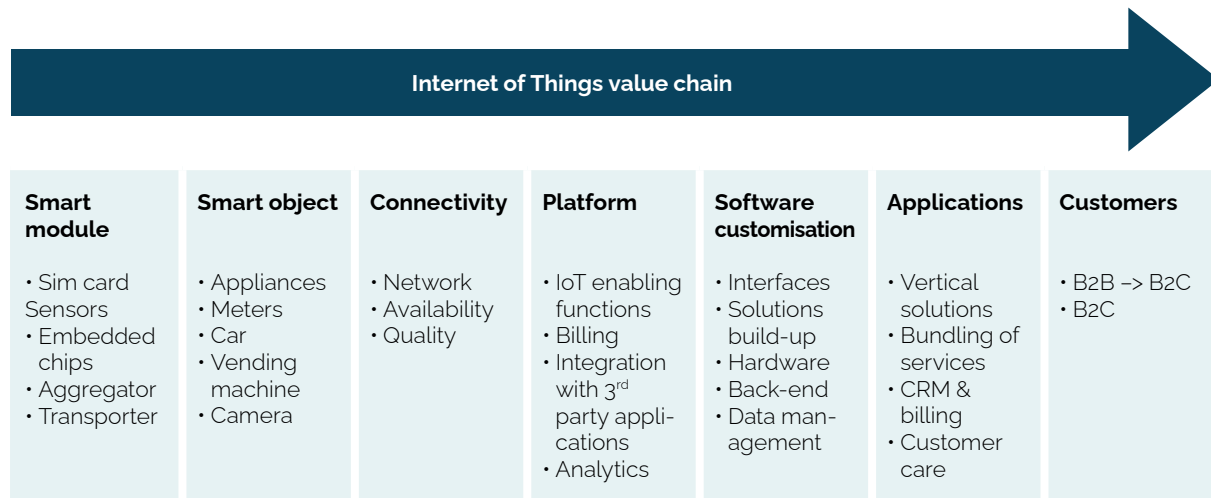
Collaboration in Internet of Things (IoT) applications is another case in point. IoT-related products and services rely on several building blocks or input components, which add value to the overall IoT solution for the end user. Companies participating in the IoT value chain can have three distinct roles: they can be orchestrators, which typically are larger companies that have the resources and capability to invest and operate a platform and effectively contribute to establish a platform-centric ecosystem. Contributors, on the other hand, are the companies that develop and sell solutions on an IoT platform by bringing unique data sets or unique software solutions to the platform. Finally, enabler companies provide user-facing services based on additional technological solutions, such as cybersecurity and connectivity services. In sum, this results in a complex mix of technical components and a multitude of software solutions including connectivity services, integration services, interface services, and back-end services (see Figure 2).

For companies in complex value chains, the fundamental question arises as to who ultimately has to pay compensation in the event of damage and the amount of compensation that has to be paid. Moreover, the question arises as to whether certain product liability risks can still be contractually excluded or shared (apportioned across the value chain) at all, and how to deal with strict liability as a consortium when a software developer no longer has control over how the software is deployed or used by a buyer. The latter applies to corporate customers who sell software and components together as a product and it applies to the use of software by a final customer.

Due to the complexity of cooperation between software developers and between software developers and product manufacturers, risks from strict liability may be jointly shared (via contractual arrangements) in the future, especially for complex software or product solutions where fault is difficult or even impossible to assign to an individual entity in the value chain.<sup>36</sup> Thus, it can pose a major problem for insurance companies, because "from the outside" they can only poorly assess which part of the value chain contains the greatest product liability risks. And it can pose a major problem for courts, leading to contestable judgements and lengthy legal proceedings.

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<sup>36</sup> This would be in line with Article 11 of the proposed PLD, stating that "Member States shall ensure that where two or more economic operators are liable for the same damage pursuant to this Directive, they can be held liable jointly and severally."

**FIGURE 2: THE INTERNET OF THINGS VALUE CHAIN**

Source: own illustration based on Global IoT Network (2020).<sup>37</sup>

### 3.1.2. Deterrent effect of persistent exposure to strict liability risk

Errors in code or defectiveness of components can both, individually or together, result in damages from malfunction or cyber-attacks, which are major areas where product liability can arise in the IoT industry.<sup>38</sup> Due to the complexity of technology-intensive value chains, courts may consider apportioning liability between relevant entities involved in the IoT product and network chain, regardless of their fault. This, however, is not an easy task and it may result in liability apportioned to technology contributors whose software or components did not cause defectiveness. For example, in the case of a hack of a WIFI router, a court would have to decide if liability for damage due to immaterial loss lies with the router manufacturer, the internet service provider, or just the actual hacker. In the case of an erroneous data measurement, a court may have to decide if liability lies with the software of a sensor, a cloud-based data aggregation software, or the power management system. Cars are also good examples of software being bundled with several physical products, e.g., automatic brakes, and guided driving systems. It is also unclear whether individual technology contributors can be separately held liable for the same damage.

For any business, the biggest challenge of strict liability is that they can be held liable regardless of their intent or knowledge of defectiveness. Currently, liability claims are dealt with such that product manufacturers and software developers have contractual arrangements, which are not covered by the PLD. Under a revised PLD, all companies contributing software to a product or component could still be held liable for no-fault-based errors even if they had limited their liability risks in contractual arrangements with the buyers or users of their software solutions.

<sup>37</sup> Global IoT Network (2020). IoT – the disruption champion in the 5G landscape. Available at <https://www.iotglobalnetwork.com/iotdir/2020/12/15/iot-value-chain-analysis-27925/>.

<sup>38</sup> See, e.g., Mason, Hayes and Curran (2016). Untangling the Web of Liability in the Internet of Things. Available at <https://www.mhc.ie/latest/insights/untangling-the-web-of-liability-in-the-internet-of-things>.

This risk remains even if software developers discontinue partnerships with component or device manufacturers, i.e., when contracts expire or when products will not receive updates anymore. This means that software developers at the beginning of a new development project must be aware that there are persistent risks which are out of their control. Small businesses in particular will be deterred by these risks. This effect is amplified when small software developers cannot share or reduce the risks, e.g., through value chain apportionment or strict liability insurance.

The deterrent effect is reinforced when software developers cannot know or control which hardware components of other software the buyer (e.g., a component manufacturer) or user will connect its software to. Accordingly, applying strict product liability to stand-alone software could create persistent and unpredictable liability risks for software developers. Depending on the individual assessment of a company, persistent and unpredictable liability risks would result in companies no longer participating in development projects or terminating contracts with technology development partners, reducing research and innovation.

In this context, it is striking that the European Commission's PLD proposal aims to exclude open-source software from the PLD's product scope. According to Recital 13, "[i]n order not to hamper innovation or research, [the new PLD] Directive should not apply to free and open-source software developed or supplied outside the course of a commercial activity. This is in particular the case for software, including its source code and modified versions, that is openly shared and freely accessible, usable, modifiable and redistributable."

Contrasting with this is the legal approach that software developers can only be held accountable if they know who is using the software and how it is being used. Indeed, the 2019 amendment of Directive 2019/771 covering rules applicable to the "sales of goods with digital elements" limits the obligations of sellers and developers of software and digital services to commitments in contractual relationships. As concerns updates, for example, a company is only required to install updates when a contractual relationship exists when the seller has data on the customers of its software allowing it to install updates on the customers' devices.

### **3.2. New legal risks from the inclusion of "related" digital services**

The inclusion of related digital services would impact companies that provide software-as-a-service and companies supplying cloud-based or other interface-based services. The European Commission's impact assessment failed to assess the impacts on these companies. This is striking since companies supplying such services are operating in a wide spectrum of manufacturing and services industries in the EU, and they deploy software sourced from other companies and software developed in-house.

The inclusion of software-based services fails to account for fundamental differences between product and service offerings. Movable products typically have distinct uses with a foreseeable range of associated risks. By contrast, many digital services can be considered general purpose services, e.g., smart voice assistants, (AI-assisted) search engines, AI-enabled services, such as



fraud detection, content moderation, chatbots, the creation of smart content etc. can be used in a vast range of scenarios. The inclusion of services whose areas of application are not foreseeable can lead to companies no longer offering a digital service, since there are too many possible liability risks from the various possible uses. The deterrent effect can be expected to be strongest for small and medium-sized enterprises which lack financial resources and provisions for risk and, in addition, may not be able to insure against risks from strict liability. Larger companies that deliver services at a highly scalable level for widespread use also need to be able to calculate their risks.

It is important to acknowledge that the PLD does not exist in a legal vacuum. It is crucial to align with existing EU product safety and liability laws. In the case of defective software, consumers are already protected under the existing EU warranty laws. Directive 2019/770 concerning contracts for the supply of digital content and digital services include a shift of the burden of proof for at least one year (depending on the Member State this can even be longer) from delivery of the goods or supply of digital content or digital services. Recital 59 of Directive 2019/770 explicitly states that “[d]ue to the specific nature and high complexity of digital content and digital services, as well as the trader's better knowledge and access to know-how, technical information and high-tech assistance, the trader is likely to be in a better position than the consumer to know why the digital content or digital service is not supplied or is not in conformity. The trader is also likely to be in a better position to assess whether the failure to supply or the lack of conformity is due to the incompatibility of the consumer's digital environment with the technical requirements for the digital content or digital service. Therefore in the event of a dispute, while it is for the consumer to provide evidence that the digital content or digital service is not in conformity, the consumer should not have to prove that the lack of conformity existed at the time of supply of the digital content or digital service or, in the event of continuous supply, during the duration of the contract. Instead, it should be for the trader to prove that the digital content or digital service was in conformity at that time or during that period. That burden of proof should be on the trader for a lack of conformity which becomes apparent within one year from the time of supply where the contract provides for a single act of supply or a series of individual acts of supply, and for the duration of the contract where the contract provides for continuous supply over a period of time.”

The EU's digital contract rules already guarantee a very high level of consumer protection for faulty software and digital services. Recognising the huge number of potential use cases for many digital services and the lack of empirical evidence on safety-relevant legal gaps, there are no founded reasons for additional no-fault liability.

### **3.3. New legal risks from the inclusion of psychological health**

The existing PLD covers only cases of material damage, such as physical injury or damage to property. In addition, some Member States cover mental health issues related to personal injury. The revision of the PLD now seeks to extend the scope of damages to include “medically recognised harm to psychological health”. However, the concepts are fundamentally subjective

and not properly defined in the draft directive, which in turn would pose many legal challenges, including Social Inflation, and increased legal uncertainty for companies.

### 3.3.1. The inclusion of damage from psychological health

In Sections 3.1 and 3.2, we outlined that under a revised PLD, companies providing software and digital services would be exposed to new legal uncertainties from complexities in the value chains of technology-intensive products, persistent and unpredictable no-fault-based liability risks, and liability risks that are hard or impossible to foresee because of different types of use by consumers. These risks would be amplified if policymakers extend liability risks to "damage to psychological health".

The creation of new legal risks through the PLD is especially recognised by insurers who are highly critical of the inclusion of damage to psychological health in association with the inclusion of software and digital services (including AI) to product scope.

For example, Germany's insurers' association stated that "[t]he PLD's scope on personal injury and property damage should be retained. Psychological harm/emotional pain and suffering are already compensable if consequential to personal injury. To preserve consistency and coherence between the various legislative instruments, infringements of basic rights (data protection, discrimination, privacy) should continue to be dealt with exclusively in existing dedicated EU legislation such as the GDPR."<sup>39</sup>

Similarly, Insurance Europe argues that "the proposed changes would, if adopted in their current form, compromise insurers' ability to price risk, most notably the risk of personal injuries, including 'medically recognised damage to psychological health' and the proposed extended liability risks for producers." It is also stated that "[f]or insurers to be able to provide insurance coverage tailored to policyholders' needs, the scope of the Directive should be clarified by including provisions that clearly refer to the products that fall under the liability framework." And it is highlighted that "[w]ithout a harmonised definition of psychological harm, it will be very hard for insurers to assess damage, inevitably leading to litigation."<sup>40</sup>

Industry associations (e.g., BusinessEurope<sup>41</sup>, ORGALIM<sup>42</sup>, and DigitalEurope<sup>43</sup>) also raised concerns, showing the range of industries and sectors for which the proposed PLD would increase uncertainty rather than reduce it because the nature of immaterial damage makes it difficult to quantify. Businesses would be unable to assess no-fault-based liability risks from discrimination (from an AI recruitment software), lost income from an app, and privacy infringement. Moreover,

<sup>39</sup> See feedback of Gesamtverband der Deutschen Versicherungswirtschaft e.V. to the consultation of the European Commission.

<sup>40</sup> Insurance Europe (2023). Key messages on the European Commission's proposal for a revision of the Product Liability Directive (PLD). Available at <https://www.insuranceeurope.eu/publications/2788/key-messages-on-the-ec-proposal-for-a-revision-of-the-pld/>.

<sup>41</sup> See BusinessEurope (2023). Product liability and AI liability directives - a BusinessEurope position paper. Available at <https://www.bussinesseurope.eu/publications/product-liability-and-ai-liability-directives-bussinesseurope-position-paper>.

<sup>42</sup> See ORGALIM (2023). Orgalim comments on the Legislative Proposal for a Directive on liability for defective products. Available at [https://orgalim.eu/sites/default/files/attachment/Orgalim%20comments%20on%20the%20Legislative%20Proposal%20for%20a%20Directive%20on%20liability%20for%20defective%20products\\_070323..pdf](https://orgalim.eu/sites/default/files/attachment/Orgalim%20comments%20on%20the%20Legislative%20Proposal%20for%20a%20Directive%20on%20liability%20for%20defective%20products_070323..pdf).

<sup>43</sup> Digital Europe (2023). Creating a proportionate Product Liability Directive. Available at <https://cdn.digitaleurope.org/uploads/2023/03/DIGITALEUROPE-PLD-position-March-2023.pdf>.

industries expect a higher number of legal disputes including class action, which could result from the abolishment of the EUR 500 threshold for the initiation of claims.

The European Commission's impact assessment acknowledges higher legal costs related to liability claims in or out of court, and the cost of potential compensation. However, the impact assessment still concludes that a regulatory change would lead to more certainty regarding what damage is covered by the PLD (as opposed to how potential damages are compensated). This is a gross oversimplification. Psychological health and mental illness are very complex and subjective to assess, and the opinions of medical professionals frequently differ. As concerns "medically recognised psychological harm", interpretations of what it exactly constitutes vary greatly from one EU Member State to another, making it close to impossible to interpret the rules in a consistent way across the 27 Member States.<sup>44</sup> At the same time, mental health is already covered by fault-based liability regimes, which raises the question whether the suggested extension to no-fault-based liability is appropriate at all.

As concerns mental harm and discrimination, it is worth noting that the existing PLD leaves compensation for moral damage to national law. In France, for example, there are legal provisions for so-called moral prejudice. They deal with claims from the relatives of a victim of an accident. The parents of a child that has been severely handicapped have the right to claim compensation for the moral suffering as a result of the accident. Essentially the prejudice applies to the pain and suffering from the loss of a close relative, and it does not include damage to physical property.<sup>45</sup> In the context of online platforms, if a person is targeted by a defamatory publication (harassment, prejudice to human dignity, glorifying violence, etc.) she can ask for the publication to be removed or file a lawsuit against the author and the platform's owner. The latter is sanctioned if he has deliberately agreed to the release of the illicit publication.<sup>46</sup> In Belgium, under the Product Liability Act compensation can be awarded to the consumer for personal injury including moral damages for pain and suffering.<sup>47</sup> In Germany too, psychological damage is recoverable in principle but because of the difficulty to quantify such non-material damage, courts allow for discretionary payments.<sup>48</sup>

The combination of including software and damage related to psychological harm would lead to an increase in litigation and, as a result, increased insurance premiums for insurable risks. However, depending on the nature of a company's software or digital service offering, the combination of measures would also result in more uninsurable risks. If companies fail to acquire proper insurance coverage, they are likely to abstain from product and services development, or might even decide to withdraw from the development of software and digital services.

<sup>44</sup> It is noteworthy that the World Health Organisation (WHO) provides some guidance on aspects related to mental health. See, e.g., WHO (2023). Key facts on mental health. Available at <https://www.who.int/news-room/fact-sheets/detail/mental-health-strengthening-our-response>.

<sup>45</sup> See, e.g., Association Aide Indemnisation Victimes de France (2023). Available at <https://association-aide-victimes-france.fr/accueil-association-daide-a-lindemnisation-victimes/differents-postes-prejudice-corporel/prejudices-corporels-victimes-indirectes/prejudice-affection-moral>.

<sup>46</sup> See, e.g. Government of France (2023). Responsabilité des contenus publiés sur internet : quelles sont les règles ? Available at <https://www.service-public.fr/particuliers/vosdroits/F32075>.

<sup>47</sup> See, e.g., Thomson Reuters (2023). Product Liability and Safety in Belgium: Overview. Available at [https://uk.practicallaw.thomsonreuters.com/w-013-1575?transitionType=Default&contextData=\(sc.Default\)&firstPage=true](https://uk.practicallaw.thomsonreuters.com/w-013-1575?transitionType=Default&contextData=(sc.Default)&firstPage=true)

<sup>48</sup> See, e.g., Thomson Reuters (2023). Product Liability and Safety in Germany: Overview. Available at [https://uk.practicallaw.thomsonreuters.com/Document/I8ba560fd9bc11e79bf099c0ee06c731/View/FullText.html?transitionType=SearchItem&contextData=\(sc.Search\)](https://uk.practicallaw.thomsonreuters.com/Document/I8ba560fd9bc11e79bf099c0ee06c731/View/FullText.html?transitionType=SearchItem&contextData=(sc.Search))

### 3.3.2. Negative impacts from Social Inflation

An additional aspect, which has been entirely ignored by the European Commission, is "Social Inflation" in liability insurance markets. Social inflation in liability insurance refers to the trend of an increasing numbers of claims that are deemed "abnormal", with high amounts of compensation claimed for damage. Although it is a phenomenon that occurs particularly in the US insurance sector, EU Member states are not immune to it, e.g., through the expansion of collective redress rights in the EU.<sup>49</sup> With mental health issues potentially being covered by the EU's revised no-fault-based liability regime, social inflation may end up affecting European insurers' costs and liability risk coverage.<sup>50 51</sup>

The Geneva Association, a study group on insurance economics, identifies three drivers of social inflation, which could become much more relevant in the EU when damage related to psychological health is included in the PLD:

- Aggressive strategies of plaintiffs' attorneys who strengthened their activities throughout the litigation process from client acquisition, pre-trial discovery and evidence gathering through to tactics at the trial itself.
- The development of third-party litigation funding and collective redress mechanisms in a number of jurisdictions, which are changing the economics of litigation and the appetite and ability of claimants to file lawsuits.
- Shifts in judge/public attitudes, on the back of growing recognition of social and income inequalities, about who should bear the risk and the appropriate duty of care that firms and institutions should extend to individuals.<sup>52</sup>

Though it is difficult to assess what the impact of social inflation will have on the number of immaterial damage claims resulting from a revised PLD, we can make educated comparisons with similar litigations. For example, industry stakeholders raised concerns that some online social media platforms could potentially be held liable for immaterial damage under strict

<sup>49</sup> The EU Directive on representative actions for the protection of the collective interests of consumers was adopted on 24 November 2020. It enables mass claims and provides redress and injunctive measures for group of consumers that have been affected by a breach of EU legislation in a range of policy areas. It provides a list of EU laws to which an action can be brought (referred to in Annex 1). The collective redress Directive encompasses a variety of policy areas such as health, cosmetics, food information, data protection, environment, energy and the rights of passengers. See Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC. Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020L1828>.

<sup>50</sup> See, e.g., Zurich (2023). Tackling social inflation head on. Available at <https://www.zurich.com/en/products-and-services/protect-your-business/commercial-insurance-risk-insights/tackling-social-inflation-head-on>.

<sup>51</sup> In the US, the Insurance Information Institute has found that social inflation contributed to a \$30 billion increase in commercial auto liability claims between 2012 and 2021, an increase by 18-20%. It is important to note that social inflation is a growing trend and a much discussed issue in the US, therefore evidence disproportionately reflect a situation that is specific to that region and its legal environment. In other words, it's not clear whether social inflation will affect product liability claims in the same fashion as in the US. One of the reasons is that third-party litigation funding, a key driver of social inflation, is a practice that is not common in Europe. Insurance Information Institute (2023). Latest research on social inflation in the auto liability reveals that a USD 20 billion increase in claims. Available at [https://www.iii.org/insuranceindustryblog/latest-research-on-social-inflation-in-commercial-auto-liability-reveal-a-30bn-increase-in-claims/#:~:text=Social%20inflation%20contributed%20to%20a,Casualty%20Actuarial%20Society%20\(CAS\)](https://www.iii.org/insuranceindustryblog/latest-research-on-social-inflation-in-commercial-auto-liability-reveal-a-30bn-increase-in-claims/#:~:text=Social%20inflation%20contributed%20to%20a,Casualty%20Actuarial%20Society%20(CAS)).

<sup>52</sup> The Geneva Association (2021). Social Inflation: Navigating the evolving claims environment. Available at [https://www.genevaassociation.org/sites/default/files/social\\_inflation\\_brief\\_web.pdf](https://www.genevaassociation.org/sites/default/files/social_inflation_brief_web.pdf).

liability because the applied software or recommender systems may suggest content which may trigger an adverse reaction from one individual when millions more may be completely unaffected.

As concerns the role of social inflation, lessons can be drawn from the significantly increased number of climate-related litigations. Because climate change is at the heart of the public debate and policy actions, there has been a doubling of related cases since 2015. Not only is the number of cases growing, but it is also argued that they are increasingly made up of litigations where the “aim is to influence policy and society beyond the interests of the immediate parties to the litigation”.<sup>53</sup> In other words, there might be some appetite from groups of activists to hold major companies accountable for environmentally damaging activities. That trend could extend to social media platforms, though no evidence currently exists in the literature. The hypothesis would be that growing concerns about the negative aspects of social media on mental health issues, especially among younger individuals, and its wider implications for society drive larger claims directed at social media companies.

### **3.4. New legal risks from the inclusion of loss and corruption of data**

Like damages related to psychological health, the inclusion of data loss and the corruption of data would tremendously increase risks of being exposed to claims related to no-fault-based liability claims. The inclusion of data loss raises several questions regarding situations that could give rise to no-fault-based liability claims, which would increase legal uncertainty for businesses that store and process all sorts of consumer data.

New legal risks also stem from the risk that Member States interpret situations of damage differently, leading to a fragmented EU level playing field. Generally, damages from the loss of personal data are extremely difficult to define and, as a result, very difficult to objectively quantify for courts. The value of personal data is usually subjective. A rather unlimited expansion of individuals' legal interests will likely result in differences in enforcement across EU Member States.

Anticipating or responding to increases in litigation and associated costs, software companies and providers of data-driven digital services may decide to leave or discontinue offerings in Member State markets. The adverse effects from Social Inflation, as outlined in Section 3.3.2, also apply for damage related to the loss or corruption of data, e.g., activist claims, speculative claims, and mass claims.

Importantly, EU legislation does already offer sufficient protection against the misuse of data and data loss. Violations of data privacy and data-related personal rights are already sufficiently addressed outside of strict liability, notably in data privacy law (GDPR), anti-discrimination law and tort liability. Several sanctioning mechanisms in EU law would only increase legal risks for

<sup>53</sup> See, e.g. International Bar Association (2021). The rising tide of climate litigation. Available at <https://www.ibanet.org/The-rising-tide-of-climate-litigation>.

companies. Generally, data loss should only lead to product liability in the case of severe material damage to a consumer.

### **3.5. New legal risks from the de facto reversal of the burden of proof**

The Commission proposes to alleviate the burden of proof for complex technologies, including AI-based systems and related services. This constitutes a de facto reversal of the burden of proof for many technology-intensive product and service providers – despite the Commission's impact assessment advising against a reversal in the burden of proof.

The proposal on the revision of the burden of proof would de facto establish a situation of “guilty until proven innocent”. The reversal of the burden of proof for product and services deemed “complex” can become an open invitation to activist plaintiffs. It constitutes a deviation from the fundamental rule of litigation where a claimant must provide proof and fault must be proven. Deviating from this rule should be limited to a few exceptional cases, e.g., products and services that can cause serious harm to consumers. Some medical services, such as software assisted surgeries, spring to mind.<sup>54</sup>

Reversing the burden of proof for all products that may be deemed complex would significantly increase legal risks for any developer and provider of a technology-intensive product and service whose technical features are unknown to the public. For example, the sometimes criticized opacity of software code and algorithms would by default be to the great disadvantage of developers and producers, as they would have to credibly prove that no fault in the systems they placed on EU markets was responsible for any damage that occurred. This can be painstaking, and more so if there is no reciprocal disclosure obligation for consumers with regard to their habitual product use, proof of purchase, health records, and other relevant information.

In addition to higher exposure to no-fault-based liability risks, companies must consider the possibility of being mandated to disclose essential trade secrets. Plaintiffs would have greater incentives to launch frivolous or speculative claims due to greater leverage over defendants. Companies subject to litigation may in turn opt for out-of-court settlement rather than disclosing information or incur the costs of court proceedings.

The European Commission initially aimed to avoid negative impacts from the reversal of proof on businesses. As argued in the European Commission's impact assessment, reversing the burden of proof “would expose manufacturers to significantly higher liability risks and could hamper innovation, leading also to potentially higher product prices and reduced access to innovative products.” Importantly, the 2018 PLD Evaluation of the Commission already concluded that the consumer's burden of proof does not affect the effectiveness of the PLD. While providing evidence may be a problem for any technically complex product this should be considered in

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<sup>54</sup> It should be noted that under the EU Medical Devices Regulation standalone software is classified as a product to reflect the specificity of this critical area of application.

light of the fact that in the past most cases were amicably settled, and evidence did not present an obstacle to amicable settlement.<sup>55</sup>

### **3.6. New legal risks from vague definitions and concepts**

Despite the clarification of product scope and damage, significant legal risks remain as to the applicability of the Product Liability Directive to any company that develops and commercialises software and technology products in the EU. Due to unspecified applications and use cases, the Commission's proposal would lead to more fragmentation as interpretations would be left to the discretion of Member States' courts regarding, e.g., the concept of related service, the application of disclosure orders, and decisions on what constitutes a scientifically and technically complex product, etc.

There are many practical questions related to how courts interpret definitions and concepts, including the understanding of:

- Injuries and damages to property related to software and where to locate a liable economic operator in complex value chains (also see Section 3.1),
- What constitutes a "related service" despite the attempt by the Commission to provide clarification.<sup>56</sup>
- What constitutes a complex technology product or service and when to order disclosure of which type of evidence.
- What constitutes a substantial modification, e.g., in the context of updates and upgrades. Whether a substantial modification has caused or contributed to a damage should in the first place be measured by reference to instructions, warnings, guides, and other ancillary materials from the original manufacturer that apply to the unmodified product that guide consumers in the safe use and modification of the product.

### **3.7. Consequences of the inability to obtain liability insurance**

The new legal risks outlined above affect the ability of companies to acquire liability insurance protection. Liability insurance policies generally differ based on the types of business activity (products and services portfolios) that are insured, the size of the firm, and the jurisdiction in which a firm operates. Because of the different nature of software and manufacturing products and the associated risks, product manufacturing, software development and digital services are insured in different ways and at different prices.

<sup>55</sup> See Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products. Available at <https://op.europa.eu/en/publication-detail/-/publication/d4e3e1f5-526c-11e8-be1d-01aa75ed71a1/language-en>.

<sup>56</sup> See Commission non-paper on digital elements of the proposal for a new Product Liability Directive, Interinstitutional File: 2022/0302(COD). Available at <https://data.consilium.europa.eu/doc/document/ST-6201-2023-INIT/en/pdf>.

Software developers increasingly sell their software and related services to users (B2B and B2C) in the form of software-as-a-service offerings. These can be platform-based or app-based and made for end users or other companies. The fact that software may become a critical component of another business activity, e.g., data-intensive product bundles that are sensitive to privacy concerns, implies that insurers must factor in several risks which are difficult to assess. Amongst these are data breaches resulting from a cyber-attack, professional negligence if the client realises that the software is actually unfit for purpose after some time and it wants to be reimbursed, financial losses for the client due to errors in the software, and other risks.<sup>57</sup> Insurance companies will base their (pricing) decision on whether to insure a particular software product on aspects that influence the risks facing that company. Variables like the number of employees, revenue, the nature of the service provided, its history of claims, and the volume of personal information stored are common characteristics taken into consideration.<sup>58</sup> Risk premia and coverage will also differ depending on the nature of the software and its use: risks associated with Errors and Omissions (E&O)<sup>59</sup> in a SaaS like Microsoft 365 will likely be different from a bug in a software that is used for medical purposes. This is also reflected in EU product safety law: medical software is part of the category of harmonised products which requires specific legislation given their high-risk levels, while non-harmonised products only have to comply with general rules, i.e. the General Product Safety Regulation (GPSR), which stops short of including standalone software in scope and instead addresses the higher risk profile of embedded software.

For insurance companies, the assessment of risks related to no-fault-based claims would be based on the factors mentioned above, but also should account for risks related to particular use cases. This will be difficult and, in many cases, impossible to be done in a reliable way, especially in the case of general-purpose software, i.e., code that is mass-produced for a broad range of common business applications such as word-processing, graphics, payroll, and accounting software. Difficulties in assessing the risks of use cases will also arise from software that will be deployed in conjunction with open-source, or software deployed to run interfaces used for the provision of web-based digital services, e.g. software underlying intermediation services, search engines, and social media platforms.

It is also difficult how risks from no-fault-based liability will be addressed in businesses contractual relationships, and how these complex relationships are judged by insurance companies. For the inclusion of stand-alone software, the European Commission's impact assessment states that "the pool of liable persons among producers that would assume joint and several liability within the value chain would be expanded." It is also argued that "[t]he apportionment of liability would continue to be addressed through recourse claims." And it is stated that the inclusion of "harm related to privacy infringements, discrimination and emotional harm", potential effects are much more difficult to assess. The impact assessment

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<sup>57</sup> See, e.g., Embroker (2023). Managing the Risks of Software Development with Software Development Insurance. Available at <https://www.embroker.com/blog/software-development-insurance/>. Also see Insureon (2023). Why do software developers need business insurance? Available at <https://www.insureon.com/technology-business-insurance/software-developers>.

<sup>58</sup> See, e.g., Embroker (2022). Identifying Insurance Needs for SaaS Companies. Available at <https://www.embroker.com/blog/saas-insurance/>

<sup>59</sup> Professional Liability insurance, also known as Errors and Omissions (E&O) coverage, is designed to protect a business against claims that professional advice or services caused a customer financial harm due to actual or alleged mistakes or a failure to perform a service.



by the Commission acknowledges that “[i]nsurance providers would find it difficult to reconcile the notion of immaterial harm and the need to quantify economic losses, given its complexity and potential for subjectivity.” It is argued that “[t]he precise increase in [insurance] costs is difficult to assess as this would depend on the scale of compensation pay-outs for immaterial damage established through case law in future which would establish precedents.” Average estimates provided by the European Commission, which are based on rough assumptions (due to the lack of data), indicate that for software developers on average, the strongest rise in liability insurance risk premiums would stem from the combination of including software to product scope, the inclusion of damage from immaterial harm, and the abolition of the EUR 500 threshold (see Figure 3). It should be noted that these estimates are average numbers, which do not account for SMEs and the difficulties SMEs face in trying to obtain insurance coverage. In addition, the estimates do not reflect impacts on manufacturing and services companies in the EU that also engage in the development and commercialisation of software products.

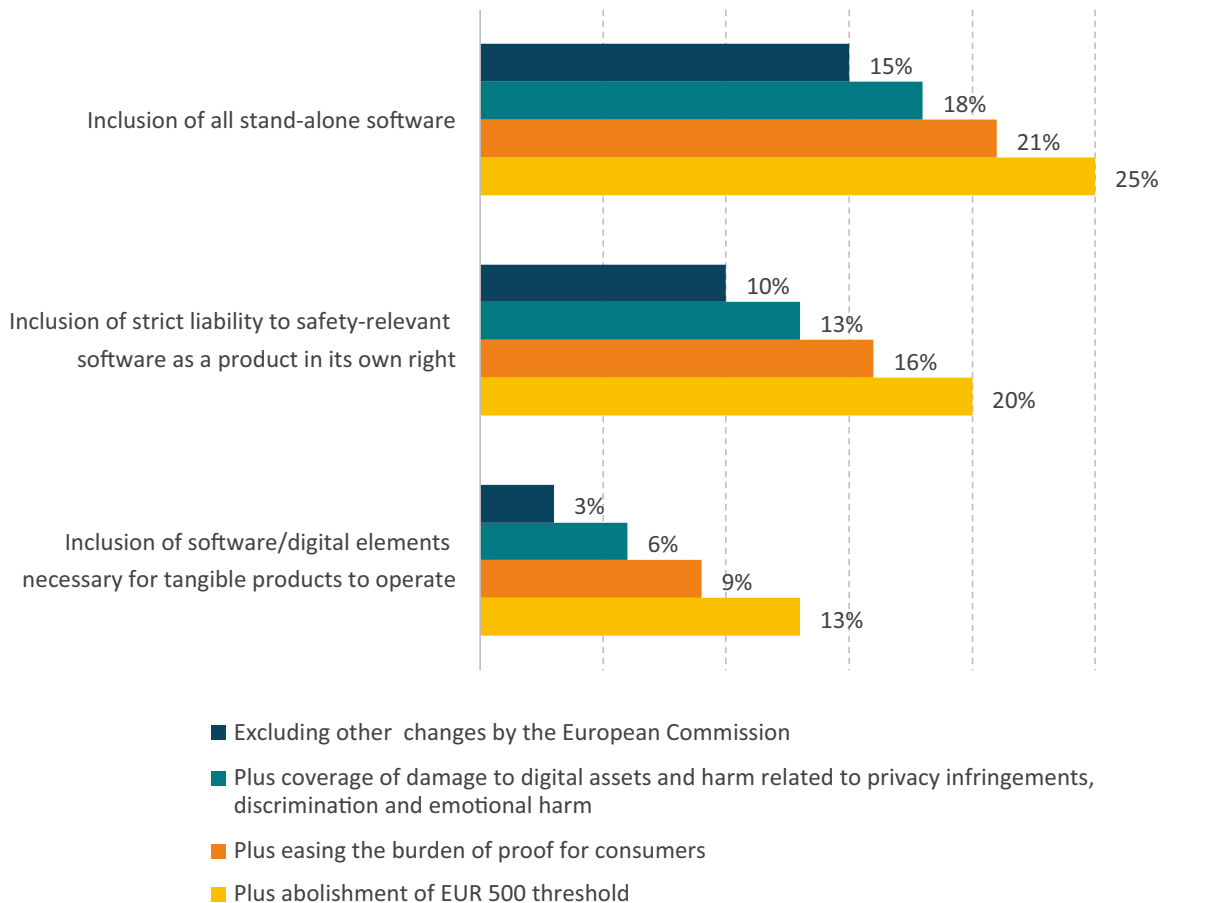
The difficulties of assessing new no-fault-based risks will have an impact on SMEs ability to acquire affordable insurance coverage. The fact that insurance policies for product liability are already relatively more expensive for small businesses puts SMEs that are financially constrained at an even greater disadvantage compared to larger firms. This is recognised by the European Commission’s impact assessment, outlining that “uncertainties concerning the estimation of losses and in establishing insurance costs may in particular affect SMEs ability to purchase appropriate product liability insurance cover, given the potential for increased insurance premium costs.” Accordingly, a small firm may choose less or more expensive coverage than optimal. Reducing the scope of the insurance coverage increases risks in general, including legal uncertainties regarding very high claims if the compensation is outside of the coverage.

It should be noted that the Regulatory Scrutiny Board in its assessment of the quality of the European Commission’s impact assessment explicitly concludes that “there is an underestimation of the compensation costs borne by businesses not covered by insurance. This is because there is insufficient data on liability insurance coverage.” Referring to the “high relevance of SMEs in the discussion” the Board explicitly calls for an extension of “the analysis of impact on that category of firms. More specifically on the fact that they are facing direct compensation costs due to less insurance coverage.”<sup>60</sup>

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<sup>60</sup> Regulatory Scrutiny Board Opinion on the Impact Assessment underlying the reform of the Product Liability Directive. SEC(202). Available at [https://www.parlament.gv.at/dokument/XXVII/EU/114039/imfname\\_11180579.pdf](https://www.parlament.gv.at/dokument/XXVII/EU/114039/imfname_11180579.pdf). See, e.g., Lee et al. (2023). The Economics of Legal Uncertainty. Available at [https://www.law.nyu.edu/sites/default/files/Schoenherr%20LU\\_20221216.pdf](https://www.law.nyu.edu/sites/default/files/Schoenherr%20LU_20221216.pdf).

**FIGURE 3: ESTIMATED CUMULATIVE AVERAGE PERCENTAGE CHANGE IN LIABILITY INSURANCE COSTS FOR SOFTWARE DEVELOPERS IN THE EU (EXCLUDING MANUFACTURING AND SERVICES COMPANIES THAT ALSO ENGAGE IN THE DEVELOPMENT AND COMMERCIALISATION OF SOFTWARE PRODUCTS), BY PROPOSED CHANGES TO EXISTING EU PLD**



Source: Cumulative numbers based on estimates by European Commission DG Grow.<sup>61</sup>

#### **4. IMPACTS OF LEGAL UNCERTAINTY ON THE PRODUCTION OF TECHNOLOGY-INTENSIVE PRODUCTS**

Legal risks from regulation impact on managerial decisions and can significantly affect economic outcomes, such as patterns in production, trade, R&D and innovation. In this chapter, we provide an econometric analysis aimed at demonstrating how legal uncertainty impacts companies and industries that develop and produce technology-intensive products and services.

<sup>61</sup> Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

## 4.1. Methodological considerations underlying the econometric analysis

As outlined in Section 3, the proposed changes to the PLD would systematically increase legal uncertainty / risks for manufacturers of technology products, software developers and companies that develop and commercialise software and digital services. Empirical analysis of the impacts of liability laws is very rare. One study on the economic impacts of reforms of tort liability laws demonstrates that reforms which restricted “the scope of products liability” improved economic conditions and resulted in increases in the “number of businesses, employment, and production in the industries that face most of the products liability claims: the manufacturing, retail, distribution, wholesale, and insurance industries.”<sup>62</sup> Another study about the impacts of product liability on the pharmaceutical industry concludes that product liability can have undesirable economic effects, resulting, e.g., in discontinued product offerings and price increases, but these effects are not ubiquitous.<sup>63</sup>

Due to lacking data about product liability legislation, e.g., systematic recordings of the stringency of national product liability legislation, cases and impacts, we pursue an indirect way studying the impacts from changes in regulatory quality, reflected by well-recorded and widely used indices that amongst other aspects include various sources legal uncertainty.<sup>64</sup>

“Shocks of uncertainty” include several sources of increased economic uncertainty such as government policy changes and financial instability.<sup>65</sup> While there have been studies investigating the influence of legal uncertainty on investments, particularly in emerging markets and developed countries<sup>66</sup>, the examination of the effects of legal uncertainty on economic indicators remains limited.

One of the primary challenges in quantifying legal uncertainty lies in the complexity of measuring its certainty and uncertainty including the perception of legal risks.<sup>67</sup> This is also true for the measurement of risks related to product liability rules. Although there are several indexes available to explore for impacts of legal risks, it is difficult to precisely determine the specific impact of liability-related regulations within the broader context of legal uncertainty. However, it is well-established in academic literature that an inadequate regulatory framework, lacking in property rights protection, uncertainties over law enforcement, or vulnerability to external

<sup>62</sup> Shepherd, J. M. (2023). Products Liability and Economic Activity: An Empirical Analysis of Tort Reform's Impact on Businesses, Employment, and Production. Available at <https://scholarship.law.vanderbilt.edu/vlr/vol66/iss1/4/>.

<sup>63</sup> Garber, S. (2013). Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals. Available at <https://www.rand.org/pubs/monographs/MG1259.html>.

<sup>64</sup> When it comes to a clear cut examples of the impacts of a change in liability laws, there is no data enabling us to pinpoint the precise changes in national laws that could enable us to use, e.g., a difference in difference model (that would be at the firm level rather).

<sup>65</sup> Bloom, N. (2009). The impact of uncertainty shocks. *econometrica*, 77(3), 623-685.

<sup>66</sup> Jardet, C., Jude, C., and Chinn, M. (2022). Foreign direct investment under uncertainty evidence from a large panel of countries. *Review of International Economics*. Choi, S., Furceri, D., & Yoon, C. (2021). Policy uncertainty and foreign direct investment. *Review of International Economics*, 29(2), 195-227.

<sup>67</sup> Lee, J., Schoenherr, D., and Starmans, J. (2022). The Economics of Legal Uncertainty (SSRN Scholarly Paper No. 4276837). <https://doi.org/10.2139/ssrn.4276837>

influences, can impede investments, production, and international trade.<sup>68</sup> In our analysis, we consider ample cross-industry stakeholder feedback (see Section 3) demonstrating that the lack of clarity or increased uncertainty resulting from new rules can have a significant impact on production, innovation, and trade. Legal uncertainties can be a major deterrent for companies to invest, produce or trade certain products and services. Legal uncertainties can arise from a variety of sources, such as unclear or ambiguous laws and regulations, conflicting legal frameworks, or changes in legal requirements or interpretations. Inconsistent enforcement of laws and regulations can also add to confusion and impact managerial decisions. These uncertainties can cause delays, increased costs, and reduced innovation, as companies hesitate to invest in new technologies, products, or markets due to uncertainty about their legal obligations. On an aggregate level, legal uncertainty can slow down economic growth and create market distortions that give an advantage to firms with more legal resources and expertise, first and foremost large or very large companies.

In the context of product safety and liability laws, such as the EU PLD, legal uncertainties with regard to realistic liability risks are particularly relevant. The reform of the PLD aims to include new, untested or vaguely formulated concepts within its scope. This creates uncertainty throughout the businesses' value chains. Companies must adapt to new regulatory requirements and ensure compliance with the updated rules. Moreover, provisions allowing Member States to adopt diverging national rules may result in fragmentation rather than harmonisation. Small companies or producers of intangibles will be particularly exposed to additional legal uncertainties resulting from the proposed reform of the PLD as they typically lack the resources and expertise to navigate complex legal frameworks and will be subject to the proposed shift in the burden of proof. Small businesses are also more vulnerable to legal uncertainty due to their limited revenues and limited business model diversification and a resulting lack of liability insurance coverage.<sup>69</sup> At the same time, medium-sized and larger companies that provide scalable software solutions and services are at greater risk of facing new claims and, resulting from the extension of damages to psychological health and data loss, activist mass litigation.

As a result, technology-intensive companies may opt for a more cautious approach to avoid legal risks, including market withdrawals, restricted offerings, and the discontinuation of research, production and product placements in the EU. Everything else being equal, this would translate to lower levels of production of related products and services in EU Member States, and potentially higher prices for consumers as companies try to compensate for increased liability risks.

Our aim is to explore how changes in legal uncertainty, stemming from the intended reform of the existing PLD could impact the production and creation of value added in EU Member States. Considering the above, the impacts on businesses are likely to vary depending on the size of a company and the sectors a company is operating in. It should be noted that there is very little analysis of the impacts of liability laws on SMEs and larger companies or different industries, e.g., technology-intensive manufacturing sectors or industries with high digital intensities.

<sup>68</sup> Blind, K. (2012). The influence of regulations on innovation: A quantitative assessment for OECD countries. *Research policy*, 41(2), 391-400.

<sup>69</sup> This is also highlighted at several places in the European Commission's impact assessment (and other regulatory impact assessments). See Final Report of the Full Impact Assessment Study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC (No. 887/PP/GRO/IMA/20/1133/11700) commissioned by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) from June 2022.

Due to the availability of solid industrial data, we have chosen to focus our analysis on sectoral production and production by company size class to examine this relationship. The proxy we use for economic activity is gross value added (or generally production) as data on value added in the EU is readily available for the period 2014 to 2020 and, with a few exceptions, broken down by company size class.<sup>70</sup> Moreover, production data implicitly reflects investment behaviour and the effects from/on product and services development (innovation). A decrease in production is regularly accompanied by a fall in investment in capacities and decreasing investment in research activities, which in turn can lead to a decline in production, i.e., a feedback loop where an initial fall in production leads to further declines in production.

To examine the impact of legal uncertainty, we first assess observable legal and administrative barriers that inhibit the production of goods and services, particularly in highly digital industries where many governments are currently implementing new regulations. Second, we establish an empirical link between legal uncertainty and industry performance across a set of countries. We focus on the impact on value added at the sectoral level and show that legal uncertainty tends to affect production in industries that rely heavily on digital services and goods in the countries we consider.

Aiming to quantify legal uncertainty at the national level, we use a subset of existing indices centred around legal enforcement quality, regulatory quality, and regulatory clarity. These factors are included in the Regulatory Quality Indicator of the World Governance Indicators (WGI), which measures the ability of national authorities to formulate and implement sound policies and regulations allowing private sector development.<sup>71</sup> It should be noted that the index itself is an aggregation of a wide spectrum of sources.<sup>72</sup> For a robustness check, we also consider the Strength of Legal Rights index encompassed in the Doing Business indicator of the World Bank.<sup>73</sup>

Given that the Regulatory Quality Index incorporates certain output-based sources, it is important to interpret the findings of this paper with caution, recognising them as indicative of a trend or correlation rather than a definitive causal impact, which is standard in any econometric analysis. Furthermore, as outlined by the European Commission's impact assessment of changes to the existing PLD, it is worth noting that the overall limitation of available data regarding legal uncertainty and the perception of legal risks by companies in different sectors and size classes poses a constraint on the study's findings.

As concerns available industry-level data, we use the value-added at factor costs (log) from the Eurostat Structural Business Statistics<sup>74</sup>, which provides data by employment size class. Our

<sup>70</sup> The following countries are included: Austria, Belgium, Bulgaria, Cyprus, Czechia, Germany, Denmark, Spain, Estonia, Finland, France, Greece, Croatia, Hungary, Ireland, Italy, Lithuania, Luxembourg, Latvia, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, and Sweden.

<sup>71</sup> Kaufmann, D., Kraay, A., and Mastruzzi, M. (2011). The worldwide governance indicators: Methodology and analytical issues. *Hague journal on the rule of law*, 3(2), 220-246.

<sup>72</sup> Thomas, M. A. (2010). What do the worldwide governance indicators measure? *The European Journal of Development Research*, 22, 31-54.

<sup>73</sup> World Bank Doing Business Index. Methodological considerations. Available at <https://archive.doingbusiness.org/en/methodology/getting-credit#:~:text=The%20strength%20of%20legal%20rights%20index%20measures%20the%20degree%20to,unitary%20secured%20transactions%20system%20exists>.

<sup>74</sup> Eurostat. (2023). Structural business statistics: Employment by sex, age and economic activity (NACE Rev. 2) [Data set]. European Commission. For an overview of sectors, see Appendix II: Sectoral classification underlying econometric analysis.

analysis focuses on the impact of legal uncertainty, as proxied by the World Bank's Regulatory quality, on gross value added (GVA). While the rule of law significantly reduces legal uncertainty, legal uncertainty remains a feature of any legal system due to, for example, judicial discretion and changes in the law over time. To ensure robustness, we employ country, year, and sector fixed effects, which control for time-invariant country/sector-specific differences in levels of gross value added and time-series shocks. By comparing the gross value added across countries and sectors within the same year, we can examine the effects of legal uncertainty on the gross value added.

To specifically capture the impact of regulatory quality, we consider the influence of factors that are country, year, and sector specific (using fixed effects). This approach helps us isolate the effect of regulatory quality on value-added while accounting for consistent differences across countries and sectors over time. Additionally, it allows us to account for any unexpected changes that may have occurred throughout the time period studied. Our analysis of gross value-added and legal uncertainty encompasses all EU countries and the period 2014 to 2020, excluding Romania, and compares the effects across countries and sectors within the same year.

## 4.2. Empirical findings of econometric analysis

We use regression analysis to understand the relationship between legal uncertainty and gross value-added in the EU countries.<sup>75</sup> We aim to determine the impact of legal uncertainty on gross value-added, specifically focusing on companies and industries that supply knowledge- and technology-intensive products and services. For an overview of sectors and sector aggregations, see Appendix II: Sectoral classification underlying econometric analysis.

Firstly, we find a positive and statistically significant relationship between a higher regulatory quality (based on the WGI sub-indicator) and gross value added in the EU (see Table 8).<sup>76</sup> Notably, this relationship is stronger when considering time lag effects, suggesting that changes in the judicial system take time to manifest their impact on the economy.<sup>77 78</sup>

Delving into the sectors with a high digital intensity as per column 2 of Table 9<sup>79</sup>, we observe an even more significant relationship, particularly for very small and large firms with 250 or more employees. Conversely, the coefficients exhibit a smaller or insignificant effect for entities positioned at the lower end of the digital intensity ranking. One should be careful while delving into the size class analysis for a particular industry as the number of observations decreases and may impact the robustness of the findings.

<sup>75</sup> In our regression analysis, the independent variable is regulatory quality, which captures the level of legal uncertainty, while the dependent variable is gross value-added, a measure of economic output.

<sup>76</sup> Our analysis employs logarithmic transformation for both the dependent and independent variables, resulting in coefficients that represent elasticities rather than simple numerical changes. This allows us to measure the proportional impact of the independent variable on the dependent variable

<sup>77</sup> Additional calibrations of models are provided in Appendix III: Econometric set-up and model robustness.

<sup>78</sup> It is standard in this type of analysis to take at least the first lag to identify the impact of any policy or regulation on economic indicators.

<sup>79</sup> Digital intensity can be gauged by considering the following indicators: the share of ICT tangible and intangible investment, the share of purchases of intermediate ICT goods and services, the stock of robots per hundreds of employees, the share of ICT specialists in total employment, and the share of turnover from online sales.

**TABLE 8: REGRESSION ANALYSIS OF GROSS VALUE ADDED BY REGULATORY QUALITY AND COMPANY SIZE, ALL INDUSTRIES UNDER THE SCOPE OF THE PLD**

	(1)	(2)	(3)	(4)	(5)	(6)
	ALL	0-9 empl.	10-19	20-49	50-249	GE250
Lag 1-year Regulatory quality	0.462*** (0.002)	0.630*** (0.000)	0.351*** (0.003)	0.455*** (0.000)	0.324*** (0.000)	0.498*** (0.000)
Constant	4.083*** (0.000)	3.894*** (0.000)	3.309*** (0.000)	3.816*** (0.000)	4.695*** (0.000)	4.856*** (0.000)
Obs	36334	8464	7790	7505	7013	5562
R2	0.039	0.032	0.024	0.043	0.036	0.100

p-values in parentheses

\* p < 0.10, \*\* p < 0.05, \*\*\* p < 0.01

**TABLE 9: REGRESSION ANALYSIS OF GROSS VALUE ADDED BY REGULATORY QUALITY FOR HIGH DIGITAL INTENSITY INDUSTRIES**

	(1)	(2)	(3)	(4)	(5)	(6)
	ALL	0-9 empl.	10-19	20-49	50-249	GE250
Lag 1-year Regulatory quality	0.532*** (0.000)	0.679*** (0.000)	0.483*** (0.006)	0.416*** (0.006)	0.460*** (0.009)	0.568*** (0.000)
Constant	3.832*** (0.000)	4.091*** (0.000)	3.067*** (0.000)	3.122*** (0.000)	4.304*** (0.000)	4.749*** (0.000)
Obs	11041	2580	2480	2325	2095	1561
R2	0.049	0.051	0.031	0.062	0.039	0.098

p-values in parentheses

\* p < 0.10, \*\* p < 0.05, \*\*\* p < 0.01

Next, we narrow our focus to the software-intensive ITC sector, specifically considering the third column of the sectoral classification table.<sup>80</sup> This industry, being deeply interconnected with both hardware and software aspects of product liability, occupies a central position in the value chain of technology-intensive products, making it highly susceptible to the impacts of any changes in the PLD framework. In this context, we discover an even larger positive association between a higher regulatory quality and gross value added, particularly for small businesses (very small firms with 0-9 employees and medium-sized firms with 20-49 employees). The numbers for the ITC sector, when analysed in isolation, should be interpreted with caution as the dataset available for analysis is relatively limited in size.

<sup>80</sup> For an overview of sectors, see Appendix II: Sectoral classification underlying econometric analysis.

These findings are important for policymakers to understand how software-intensive sectors and producers of technology-intensive products are impacted by changes in legal certainty or risks related to product and software liability risks. As these sectors are generally knowledge- and technology-intensive, and therefore investment-intensive, they are particularly sensitive to legal risks.

As outlined in detail in Section 3, the PLD reform would increase legal uncertainty for businesses due to higher liability risks, especially in technology-intensive sectors. As concerns our econometric findings, even if the regulatory quality index only reflects only a small part of numerous sources of legal uncertainty and risks perceived by a company, changes in legal uncertainty would have a significant impact on aggregate economic output in the EU. For example, a 10% decrease in overall regulatory quality is associated with a 4.6% drop in gross value-added overall size of companies in the IT industries. The estimate would jump to 10.2% for the small companies in Europe's ICT (software) industry.<sup>81</sup>

As concerns the robustness of results, shifting our attention to increases in the strength of legal rights perceived by businesses, we find it to be an influential factor in boosting gross value-added.<sup>82</sup> Interestingly, the impact is strong for small and large firms. As for the regulatory quality index, the importance of legal certainty is even stronger for digitally intensive industries.

The direct impacts on the relevant sectors would be the largest in Member States which are home to a large number of companies pursuing the development of software and app solutions. The sectoral composition of companies pursuing relevant activities is provided in Table 10 and Table 11. Despite lacking statistical records, the numbers indicate that the creation of value added in Europe's software and app development sector is to a very large extent driven by small business activity. As many of the proposed revisions would disproportionately impact legal uncertainty perceived by SMEs, the termination of development projects and the withdrawal of products and services by small companies could result in a comparatively high drop in value added in the Member States.

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<sup>81</sup> See Table Gross Value Added and regulatory quality for IT industries in the Annex. IT services include Computer programming, consultancy, and information service activities (J62-J63).

<sup>82</sup> See Appendix II: Sectoral classification underlying econometric analysis.



**TABLE 10: DISTRIBUTION OF MAJOR SOFTWARE PRODUCING INDUSTRIES, BY COMPANY SIZE CLASS, SOFTWARE PUBLISHING & INFORMATION SERVICES**

Number of firms	Software publishing					Information service activities				
	Size class	>250	50 to 249	20 to 49	2 to 9	Total	>250	50 to 249	20 to 49	2 to 9
<b>EU27</b>	108	623	942	5,290	24,000	243	1,050	1,817	33,700	140,000
<b>Belgium</b>	:	:	3	68	482	:	17	50	:	3,744
<b>Bulgaria</b>	:	:	4	35	132	10	32	47	626	2,490
<b>Czechia</b>	:	:	:	:	1,090	11	24	58	296	4,891
<b>Denmark</b>	4	23	39	250	849	4	29	52	298	1,281
<b>Germany</b>	9	51	104	757	1,472	64	250	356	3,445	10,847
<b>Estonia</b>	0	1	1	20	281	0	8	13	185	1,068
<b>Ireland</b>	:	:	:	:	:	:	:	:	:	:
<b>Greece</b>	:	:	10	97	303	:	:	:	569	3,427
<b>Spain</b>	9	25	62	343	3,880	19	85	132	1,552	6,981
<b>France</b>	34	269	353	1,228	5,882	24	121	208	1,153	11,023
<b>Croatia</b>	0	0	5	63	195	1	7	17	191	993
<b>Italy</b>	0	9	7	73	285	27	125	310	15,011	37,365
<b>Cyprus</b>	:	:	:	35	86	0	:	:	:	112
<b>Latvia</b>	0	0	1	15	40	3	15	20	490	1,741
<b>Lithuania</b>	0	1	3	26	154	5	8	18	203	1,395
<b>Luxembourg</b>	0	1	6	34	128	0	5	11	54	218
<b>Hungary</b>	:	:	27	239	1,084	6	14	36	877	7,167
<b>Malta</b>	0	0	:	17	47	:	:	:	42	150
<b>Netherlands</b>	0	1	4	56	241	2	51	122	1,822	9,869
<b>Austria</b>	2	14	23	77	230	13	41	68	1,170	4,146
<b>Poland</b>	5	16	38	468	2,169	21	63	67	2,637	10,752
<b>Portugal</b>	5	10	20	143	422	7	18	18	281	1,396
<b>Romania</b>	8	39	47	282	1,078	5	32	57	951	4,501
<b>Slovenia</b>	0	0	1	13	49	0	7	7	109	975
<b>Slovakia</b>	:	0	:	:	:	4	:	:	:	5,584
<b>Finland</b>	5	15	12	36	130	1	20	31	251	824
<b>Sweden</b>	14	75	84	539	2,841	5	32	45	443	3,261

Source: Eurostat.

**TABLE 11: DISTRIBUTION OF MAJOR SOFTWARE PRODUCING INDUSTRIES, BY COMPANY SIZE CLASS, DATA PROCESSING, HOSTING, AND RELATED ACTIVITIES & COMPUTER PROGRAMMING, CONSULTANCY AND RELATED ACTIVITIES**

Number of firms	Data processing, hosting and related activities; web portals					Computer programming, consultancy and related activities				
	Size class	>250	50 to 249	20 to 49	2 to 9	Total	>250	50 to 249	20 to 49	2 to 9
<b>EU27</b>	214	858	1,526	28,379	108,436	1,466	7,000	13,027	126,095	728,484
<b>Belgium</b>	:	14	43	:	2,389	38	182	394	4,592	28,811
<b>Bulgaria</b>	7	15	24	293	1,184	32	171	288	2,689	9,570
<b>Czechia</b>	:	:	:	:	3,885	49	197	403	2,682	38,773
<b>Denmark</b>	4	25	43	243	1,061	19	153	332	2,112	12,179
<b>Germany</b>	55	168	228	1,611	3,707	377	1,998	3,591	30,443	88,751
<b>Estonia</b>	0	6	11	136	743	9	49	53	734	4,768
<b>Ireland</b>	:	:	:	:	:	34	184	247	2,615	10,927
<b>Greece</b>	:	:	:	426	2,042	13	64	125	1,684	7,990
<b>Spain</b>	:	:	98	1,019	5,984	133	501	946	8,829	39,050
<b>France</b>	:	:	192	1,013	9,151	157	584	1,351	9,126	89,819
<b>Croatia</b>	1	5	14	170	840	8	63	141	1,498	7,924
<b>Italy</b>	:	112	:	14,181	33,294	115	645	998	10,087	52,073
<b>Cyprus</b>	0	:	:	29	96	:	:	39	507	1,744
<b>Latvia</b>	3	13	17	390	1,324	5	42	82	1,492	4,343
<b>Lithuania</b>	5	7	14	149	960	10	64	106	1,163	6,050
<b>Luxembourg</b>	0	4	11	45	189	4	51	69	403	2,049
<b>Hungary</b>	6	:	:	692	5,490	29	140	245	4,021	31,896
<b>Malta</b>	:	:	:	23	87	:	15	61	265	1,048
<b>Netherlands</b>	2	47	115	1,676	8,274	82	491	951	9,393	73,846
<b>Austria</b>	11	34	61	1,090	3,681	25	152	346	4,149	13,000
<b>Poland</b>	17	50	60	2,290	8,797	76	301	556	10,738	106,127
<b>Portugal</b>	6	17	17	237	1,148	47	185	299	2,899	13,482
<b>Romania</b>	3	30	53	876	4,202	76	225	369	3,686	16,311
<b>Slovenia</b>	0	7	7	101	880	2	42	90	900	6,957
<b>Slovakia</b>	4	:	:	:	:	17	74	118	1,371	15,925
<b>Finland</b>	1	17	27	172	559	34	183	304	2,603	7,557
<b>Sweden</b>	4	28	41	359	2,577	70	278	523	5,414	37,514

Source: Eurostat.

## 5. IMPACTS ON INNOVATION AND CONSUMERS IN THE EU

Considering the analysis above, this Section provides a discussion on impacts on innovation and consumers.

### 5.1. Impacts on innovation

Economic policymaking, including consumer protection regulation, is typically intended to improve the efficiency of markets in delivering goods and services to consumers.<sup>83</sup> This requires regulators to have a profound understanding of the different tools available and the capacity of these tools to achieve certain policy objectives. Governments are also required to improve regulatory quality through impact assessments, stakeholder engagement, and ex post evaluations.<sup>84</sup> EU legislators have indeed assessed the effectiveness of the PLD over the past few years, for example in the 2018 Evaluation of the Commission, and in the European Commission's impact assessment. However, there are major discrepancies in the conclusions of the two documents. In addition, the Commission's Impact Assessment lacks relevant effects that have been emphasised by various stakeholders from different industries.

For any business, the biggest challenge of strict liability is that they can be held liable regardless of their intent or knowledge of defectiveness. Policymakers did so far not address how companies will in the future manage, allocate or insure risks from no-fault-based liability. Companies commercialising software, AI code, AI data, software-based services or contributing them to a product or component could still be held liable for no-fault-based errors even if they had limited their liability risks in contractual arrangements with users of their solutions. The European Commission's impact assessment underlying the PLD reform proposal does not account for impacts in industries other than ICT services (NACE sectors J62-J63). Impacts on manufacturing and services businesses, which also develop and commercialise software products and related services, have been ignored. These include carmakers and manufacturers of electrical equipment or consultancies, which engage in customised software development and solutions that are sold to other businesses and final customers.

The exposure to new and unforeseeable liability risks may result in many technology companies no longer marketing their products and services in the EU, or only doing so to a limited extent, or delayed after having them introduced in other jurisdictions. The effects on research and development (R&D) and innovation in Europe are difficult to predict. However, the revised PLD would have a dampening effect on investments, production, and innovation in technology-intensive industries in the EU. It can be expected that innovative technology-based products

<sup>83</sup> OECD (2012b). Organisation for Economic Co-operation and Development, "Regulatory Reform and Innovation", 2012, <https://www.oecd.org/sti/inno/2102514.pdf>.

<sup>84</sup> OECD (2021). Organisation for Economic Co-operation and Development, Recommendation of the Council for Agile Regulatory Governance to Harness Innovation, October 2021, <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0464>.

and services will be (initially) marketed primarily outside the EU and that the development of these products will also increasingly take place in these markets, above all in the US.<sup>85</sup>

The EU's overall attractiveness to R&D- and technology-intensive industries would decline, and as such likely increase the innovation gap between the EU and the US. The EU is already underperforming with regard to companies' ability to scale an EU-headquartered company whose business model has proven to be successful in its home market. Europe's underperformance is, for example, reflected in the number of technology-driven unicorns and asset market capitalisation ratios, reflecting investors' expectations about the robustness of new business models and business growth respectively. At the end of 2022, for instance, EU technology companies only accounted for 7% of Europe's total market capitalisation. In the US, by comparison, technology companies accounted for 33% of total regional market capitalisation across all industries.<sup>86</sup> In addition, survey data indicates that the greatest risks founders and financial partners face in Europe are challenges related to (EU and national) government responsibilities and initiatives, and here essentially legal uncertainty due to new regulation for products, services and technology (see Figure 4).<sup>87</sup>

With increasing risks from no-fault-based liability, the EU's software and technology innovation ecosystem would further deteriorate. The direct impacts on the relevant sectors would be the largest in Member States which are home to a large number of companies pursuing the development of software and app solutions. Europe's software and app development sector is to a very large extent driven by small business activity. The termination or relocation of development projects by small companies could therefore result in a comparatively high drop in value added in the Member States.

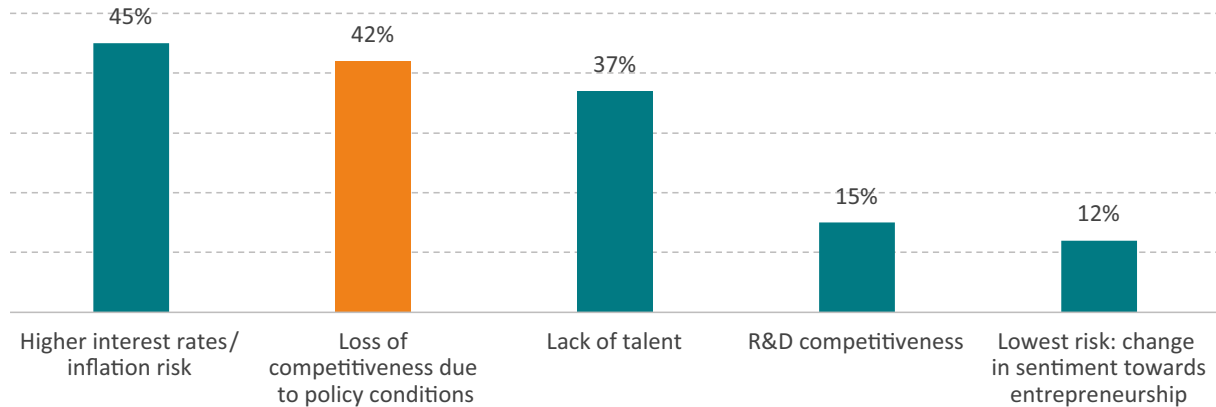
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<sup>85</sup> European companies are to a substantial extent lagging behind global leaders in technological development, commercial innovation, and international competitiveness. This gap can be attributed to markets for products and services that are organised along Member States' national lines. Structural determinants of lagging productivity and competitiveness include a range of sector-specific and horizontal "cross-sectoral" policies, leading to a strong home-market bias in most Member States. As a result, market churn, especially in Euro Area countries, is low – and behind comparable economies like the US. See Bauer, M (2023). What is Wrong with Europe's Shattered Single Market? Lessons from Policy Fragmentation and Misdirected Approaches to EU Competition Policy. ECIPE Occasional Paper 02/2023.

<sup>86</sup> Bauer, M (2023). What is Wrong with Europe's Shattered Single Market? Lessons from Policy Fragmentation and Misdirected Approaches to EU Competition Policy. ECIPE Occasional Paper 02/2023.

<sup>87</sup> Atomico (2022). The State of European Tech 2022. November 2022. Available at [https://prismic-io.s3.amazonaws.com/atomico-2022/cdfde802-3ed7-4248-b5db-b4b981741f29\\_Atomico-Report22\\_ready-to-upload.pdf](https://prismic-io.s3.amazonaws.com/atomico-2022/cdfde802-3ed7-4248-b5db-b4b981741f29_Atomico-Report22_ready-to-upload.pdf).

**FIGURE 4: MAJOR MACRO RISKS THAT COULD LEAD TO AN OVERALL SLOWDOWN OF VC ACTIVITY IN EUROPE OVER THE NEXT 5 YEARS**



Source: Atomico (2022).<sup>88</sup> Note: survey respondents include company founders and venture capital professionals.

## 5.2. Impacts on consumers

A first impression of the proposed changes to the PLD may be that it provides stronger rights and benefits for consumers. However, there is only weak evidence of why it is a problem that software and mental health are not covered by strict product liability today, and why the inclusion of software should go beyond safety-relevant applications. The Commission's impact assessment remains largely silent about why consumers have difficulties to make specific claims or why their claims are rejected by the courts. The European Commission's Regulatory Scrutiny Board states that the European Commission's impact assessment "report is not sufficiently clear about the size and evolution of the problem", reflecting the findings from the European Commission's 2018 PLD Evaluation.

Even small changes in the perception of legal uncertainty and actual legal risks have a significant impact on companies operating in investment-, knowledge-, and technology-intensive industries in the EU. Some companies will simply stop serving EU markets or delay offerings based on new (cutting-edge) technologies, resulting in a decrease of supply of technology-intensive products and services, which in turn results in less consumer choice, less access to cutting edge innovation, and higher prices for remaining and potentially inferior offerings. Higher provisions for no-fault-based liability risks and higher cost of liability insurance would be passed on to consumers, resulting in higher prices for affected goods and services.

<sup>88</sup> Atomico (2022). The State of European Tech 2022. November 2022. Available at [https://prismic-io.s3.amazonaws.com/atomico-2022/cdfde802-3ed7-4248-b5db-b4b981741f29\\_Atomico-Report22\\_ready-to-upload.pdf](https://prismic-io.s3.amazonaws.com/atomico-2022/cdfde802-3ed7-4248-b5db-b4b981741f29_Atomico-Report22_ready-to-upload.pdf).

## 6. CONCLUDING REMARKS AND GENERAL RECOMMENDATIONS

The proposed changes to the EU's PLD would increase systemic legal risks for a large number of companies in the EU. Important impacts have been ignored by the European Commission and policymakers in the Council and the European Parliament. Policymakers should reconsider legislative proceedings and slow institutional negotiations to reconsider their positions carefully. While more clarity on how to apply strict liability for safety-relevant technologies may be needed to address risks of serious harm to consumers, more evidence - and improved - assessments are needed. A set of more detailed policy recommendations are provided in the Executive Summary of this paper. In addition, it is imperative to engage in targeted consultations with:

- legal experts to assess the impacts on contractual arrangements to share liability risks in complex technology-driven value chains;
- insurance companies to better understand the impacts on insurance premia and ability of companies, small and large, to obtain liability insurance coverage; and
- businesses to better understand the impacts on relationships with commercial and private customers.

The differences in the conclusions drawn from the 2018 Evaluation of the Commission and its 2022 impact assessment, and the critique raised by the EU's Regulatory Scrutiny Board regarding the scope of the problem, raise concerns about adherence to good regulatory standards, particularly the EU's Better Regulation Guidelines.

Slowing the legislative procedure would be an opportunity to improve regulatory quality in light of the shortcomings outlined above, notably the high levels of legal uncertainty associated with the changes proposed by the Commission. EU policymakers should make a new call to objectively assess the functioning of the existing PLD and revisions needed to address current shortcomings. The OECD's recent "Recommendation of the Council for Agile Regulatory Governance to Harness Innovation"<sup>89</sup> could further guide EU policymakers to better account for the risks and opportunities from rapid innovation and technological change.<sup>90</sup>

<sup>89</sup> OECD (2012b). Organisation for Economic Co-operation and Development, "Regulatory Reform and Innovation", 2012, <https://www.oecd.org/sti/inno/2102514.pdf>.

<sup>90</sup> Similarly, the WEF's "Toolkit for Agile Regulation for the Fourth Industrial Revolution" takes on board a large body of OECD work to outline regulatory challenges and principles for policy approaches that allow economies to realise new opportunities from technology and innovation. The challenges identified in this report include lack of transparency and participation in regulatory design, regulatory decisions made on a subjective and inconsistent basis and, with regard to technology and innovation, delayed regulatory responses, and absent coordination across jurisdictions. See WEF (2021). Agile Regulation for the Fourth Industrial Revolution A Toolkit for Regulators, December 2020.

## APPENDIX

### Appendix I: Regulation of Product Liability in other Mature Economies

While it is important to ensure consumer protection and hold producers accountable, overly prescriptive regulation could stifle innovation and hinder economic growth in the digital sector and in sectors where products increasingly consist of software and digital connectivity components. Therefore, a nuanced approach to regulation is necessary to balance consumer protection with innovation.

In Canada, the Product Liability Act (PLA) is the main piece of legislation that governs product liability. While the PLA has not undergone any significant recent amendments, Canadian courts have been active in interpreting the legislation, particularly in cases involving complex technologies. One recent trend is the increasing use of class action lawsuits in product liability cases, particularly in cases involving defective products.

In the UK, the Consumer Protection Act 1987 is the primary legislation governing product liability. However, following Brexit, the UK has left the jurisdiction of the European Court of Justice, which means that UK courts may no longer be bound by EU case law on product liability. The UK is currently in the process of reviewing its product liability legislation to ensure that it remains fit for purpose.

In the US, product liability is governed by state law, rather than federal law. There is generally no federal product liability common law. For product liability, most of the US law is common law that has developed in each state. It is court-made law and is based on prior case law from the trial courts and appellate courts.<sup>91</sup>

In Japan, product liability is governed by the Product Liability Act, which was introduced in 1995. While the legislation has not undergone any significant recent amendments, Japanese courts have been active in interpreting the legislation in cases involving complex technologies, such as IoT-powered products. One recent trend is the increasing use of alternative dispute resolution mechanisms, such as arbitration, in product liability cases.

When comparing the product liability laws of the US, Canada, Japan, and the EU, it is important to consider how each jurisdiction approaches the following factors:

- **Scope of coverage:** Which products and types of harm are included in the scope of each jurisdiction's product liability laws?
- **Standard of liability:** What level of legal responsibility must manufacturers meet to be found liable for harm caused by their products?

<sup>91</sup> There are federal laws that affect product safety and three main government agencies that deal with it: the Consumer Product Safety Commission, the National Highway Traffic Safety Administration, and the Food and Drug Administration.

- **Burden of proof:** Who holds the burden of proof in product liabilities case
- **Defences available to manufacturers:** What defences are available to manufacturers to protect them from liability?
- **Limitation periods:** How long do consumers have to bring a claim against a manufacturer?
- **Remedies available to consumers:** What types of remedies are available to consumers who are harmed by a defective product?

### 1. Scope of coverage:

The EU's product liability directive covers damage suffered by natural persons. It has the broadest scope, covering all movable products and personal injury. The US and Canada have similar coverage, including all products and personal injury or property damage. Japan's product liability law only applies to consumer goods and covers personal injury, property damage, and economic loss.

### 2. Liable of sellers and distributors:

The liability of sellers and distributors varies across jurisdictions. In the EU and the UK, sellers and distributors may be liable if they fail to identify the manufacturer or provide the name and address of the manufacturer to the injured party. In the US, sellers and distributors are generally not held strictly liable, but may be held liable if they played a role in the design, manufacture, or marketing of the product. In Canada, sellers and distributors may be held liable if they knew or ought to have known of the defect, and failed to take reasonable steps to prevent the harm. Japan does not impose strict liability on sellers and distributors, but they may be held liable for negligence or breach of contract.

### 3. Burden of proof:

The burden of proof in product liability cases also differs across jurisdictions. In the EU, the burden of proof rests with the injured party to prove that the product was defective and caused harm. In the US, the burden of proof is also on the plaintiff to show that the product was defective and caused harm, but the burden shifts to the manufacturer once the plaintiff establishes a prima facie case.<sup>92</sup> In Canada, the plaintiff must establish a causal link between the defect and the injury, but the burden of proof may shift to the defendant in certain circumstances. In Japan, the plaintiff must prove that the product was defective and that the defect caused the injury, but the burden of proof may shift to the defendant in cases of manufacturing defects.

### 4. Standard of liability:

Strict liability, which imposes liability on manufacturers regardless of fault, is a key feature of product liability regimes in the EU, the US, and Canada. In the UK, strict liability is combined with

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<sup>92</sup> A prima facie case is the establishment of a legally required rebuttable presumption. A prima facie case is a cause of action or defence that is sufficiently established by a party's evidence to justify a verdict in his or her favour, provided such evidence is not rebutted by the other party.



negligence-based liability. Japan does not have a strict liability regime, but allows for product liability claims based on negligence or breach of warranty.

#### **5. Defences available to manufacturers:**

Manufacturers may be able to assert certain defences to product liability claims. In the EU and the UK, manufacturers can avoid liability if they can prove that the state of scientific and technical knowledge at the time the product was put on the market was not such as to enable the defect to be discovered, commonly known as the “development risks defence”. In the US, manufacturers may be able to assert a defence of “state of the art” or argue that the product was used in an unforeseeable manner. Canada also allows for a development risk defence, which absolves manufacturers of liability if they can show that the defect was unknown at the time of production despite having taken all reasonable steps to discover it. Japan also allows for certain defences, such as contributory negligence on the part of the plaintiff and features a development risk defence, but narrowly interpreted.<sup>93</sup>

#### **6. Limitation periods:**

In the EU and the UK, consumers have 3 years from the time they discover the harm to bring a claim. In the US, limitation periods vary by state, but are generally 2-4 years. Canada and Japan both have a 2-year limitation period.

#### **7. Remedies available to consumers:**

The EU, the UK, and Japan allow for compensation and damages, while the US and Canada also allow for punitive damages. The amount of damages awarded can vary widely between jurisdictions.

These comparisons illustrate the diversity of product liability laws across different jurisdictions. The EU's strict liability standard and lack of defences for manufacturers may increase consumer protection, but may also have implications for innovation and competition. The US' and Canada's allowance of punitive damages may provide consumers with greater compensation, but could also increase the risks and costs of doing business. Japan's more limited scope of coverage may reflect a different approach to balancing consumer protection and industry competitiveness. Overall, these comparisons provide valuable insights for policymakers and stakeholders who are interested in understanding the trade-offs involved in different product liability systems.

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<sup>93</sup> Article 4 of the Product Liability Act (Law No. 85) of 1994. Available at <https://www.cas.go.jp/jp/seisaku/hourei/data/PLA.pdf>

## Appendix II: Sectoral classification underlying econometric analysis

**TABLE 12: SECTORAL CLASSIFICATION SCHEME FOR PLD REFORM EVALUATION**

All sectors covered in PLD impact assessment (NACE Rev. 2)	Highly digital intensive <sup>94</sup>	Highly Exposed ICT Industries
<p>Manufacture of food products; beverages and tobacco products (C10–C12)</p> <p>Manufacture of textiles, wearing apparel, leather and related products (C13–C15)</p> <p>Manufacture of wood, paper, printing and reproduction (C16–C18)</p> <p>Manufacture of coke and refined petroleum products (C19)</p> <p>Manufacture of chemicals and chemical products (C20)</p> <p>Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21)</p> <p>Manufacture of rubber and plastic products (C22)</p> <p>Manufacture of other non-metallic mineral products (C23)</p> <p>Manufacture of basic metals (C24)</p> <p>Manufacture of fabricated metal products, except machinery and equipment (C25)</p> <p>Manufacture of computer, electronic and optical products (C26)</p> <p>Manufacture of electrical equipment (C27)</p> <p>Manufacture of machinery and equipment n.e.c. (C28)</p> <p>Manufacture of motor vehicles, trailers and semi-trailers (C29)</p> <p>Manufacture of other transport equipment (C30)</p> <p>Manufacture of furniture; other manufacturing (C31–C32)</p> <p>Computer programming, consultancy, and information service activities (J62–J63)</p>	<p>C29: Motor vehicles, trailers and semi-trailers</p> <p>C30: Other transport equipment</p> <p>J61: Telecommunications</p> <p>J62: Computer programming, consultancy, and related activities</p> <p>J63: Data processing, hosting, and related activities; web portals</p> <p>M69: Legal and accounting activities</p> <p>M70: Activities of head offices; management consultancy activities</p> <p>M71: Architectural and engineering activities; technical testing and analysis</p> <p>M72: Scientific research and development</p> <p>M73: Advertising and market research</p> <p>M74: Other professional, scientific, and technical activities</p> <p>M75: Veterinary activities</p> <p>N77: Rental and leasing activities</p> <p>N78: Employment activities</p> <p>N79: Travel agency, tour operator, and other reservation service and related activities</p> <p>N80: Security and investigation activities</p> <p>N81: Services to buildings and landscape activities</p> <p>N82: Office administrative, office support, and other business support activities</p> <p>S95: Repair of computers and personal and household goods</p>	<p>Computer programming, consultancy, and information service activities (J62–J63)</p>

<sup>94</sup> Calvino, F., Criscuolo, C., Marcolin, L., & Squicciarini, M. (2018). A taxonomy of digital intensive sectors. <https://www.oecd-ilibrary.org/content/paper/f404736a-en>

## Appendix III: Econometric set-up and model robustness

In our empirical framework, we aim to address potential biases by incorporating country, year, and sector fixed effects to account for unobserved heterogeneity and time-specific variations. We also cluster at the country-sector level. Additionally, we include GDP per capita as a control variable to capture economic disparities across countries.

**TABLE 13: DESCRIPTIVE STATISTICS**

Value added at factor costs					
Size class (employee)	Mean	SD.	Min.	Max.	Obs.
0-9	773.5	2,655.0	-520.7	50,976.8	12,644
10-19	307.8	1,025.8	-253.2	22,901.8	12,375
20-49	423.5	1,230.6	-127.8	23,848.2	11,967
50-249	779.2	2,067.9	-804.7	45,721.9	11,581
GE250	1955.5	5,772.1	-3,026.1	104,868.5	11,030
Total	826.4	3,056.2	-3,026.1	104,868.5	59,597
Legal rights index	45.75	17.58	16.67	75	59,597
Regulatory quality	0.76	0.11	0.5	1	59,597

## Regulatory quality

**TABLE 14: GROSS VALUE ADDED AND REGULATORY QUALITY FOR LOW DIGITAL INTENSIVE INDUSTRIES**

	(1)	(2)	(3)	(4)	(5)	(6)
	ALL	0-9 empl.	10-19	20-49	50-249	GE250
Lag 1-year Regulatory quality	0.516*** (0.000)	0.342** (0.002)	0.110*** (0.009)	0.479*** (0.000)	0.198 (0.142)	0.555** (0.028)
Constant	4.324*** (0.000)	4.081*** (0.000)	3.706*** (0.000)	4.057*** (0.000)	4.710*** (0.000)	5.359*** (0.000)
Obs	10478	2536	2199	2159	2011	1573
R2	0.030	0.029	0.018	0.040	0.032	0.057

p-values in parentheses

\* p &lt; 0.10, \*\* p &lt; 0.05, \*\*\* p &lt; 0.01

**TABLE 15: GROSS VALUE ADDED AND REGULATORY QUALITY FOR ITC INDUSTRIES**

	(1)	(2)	(3)	(4)	(5)	(6)
	ALL	0-9 empl.	10-19	20-49	50-249	GE250
Lag 1-year Regulatory quality	0.462** (0.026)	1.022*** (0.000)	-0.341 (0.615)	0.935*** (0.010)	0.120 (0.680)	0.639** (0.045)
Constant	3.628*** (0.000)	3.300*** (0.000)	3.119*** (0.000)	3.348*** (0.000)	4.083*** (0.000)	4.257*** (0.000)
Obs	1838	385	399	389	374	291
R2	0.083	0.208	0.023	0.134	0.058	0.170

p-values in parentheses

\* p &lt; 0.10, \*\* p &lt; 0.05, \*\*\* p &lt; 0.01

## Strength of legal rights

**TABLE 16: REGRESSION ANALYSIS OF GROSS VALUE ADDED AND STRENGTH OF LEGAL RIGHTS BY COMPANY SIZE**

	(1)	(2)	(3)	(4)	(5)	(6)
	ALL	0-9 empl.	10-19	20-49	50-249	GE250
Lag 1-year Strength of legal rights	0.135***	0.146*	0.055	0.052	0.160***	0.290***
	(0.000)	(0.079)	(0.383)	(0.437)	(0.001)	(0.000)
Constant	3.471***	3.221***	3.039***	3.504***	4.009***	3.630***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Obs	36334	8464	7790	7505	7013	5562
R2	0.032	0.020	0.020	0.033	0.033	0.096

p-values in parentheses

\* p &lt; 0.10, \*\* p &lt; 0.05, \*\*\* p &lt; 0.01

**TABLE 17: REGRESSION ANALYSIS OF GROSS VALUE ADDED AND STRENGTH OF LEGAL RIGHTS FOR HIGH DIGITAL INTENSITY INDUSTRIES**

	(1)	(2)	(3)	(4)	(5)	(6)
	ALL	0-9 empl.	10-19	20-49	50-249	GE250
Strength legal rights	0.165***	0.233***	0.050	0.105	0.080	0.426***
	(0.000)	(0.003)	(0.546)	(0.196)	(0.281)	(0.000)
Constant	3.118***	3.092***	2.825***	2.690***	3.810***	3.052***
	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)	(0.000)
Obs	12845	2984	2894	2717	2441	1809
R2	0.058	0.052	0.036	0.075	0.053	0.122

p-values in parentheses

\* p &lt; 0.10, \*\* p &lt; 0.05, \*\*\* p &lt; 0.01

**TABLE 18: REGRESSION ANALYSIS OF GROSS VALUE ADDED AND STRENGTH OF LEGAL RIGHTS FOR LOW DIGITAL INTENSITY INDUSTRIES**

	(1)	(2)	(3)	(4)	(5)	(6)
	ALL	0-9 empl.	10-19	20-49	50-249	GE250
Strength legal rights	0.163*** (0.004)	0.107 (0.568)	0.179 (0.127)	0.066 (0.521)	0.210*** (0.002)	0.299*** (0.000)
Constant	3.668*** (0.000)	3.602*** (0.000)	2.893*** (0.000)	3.773*** (0.000)	3.925*** (0.000)	4.319*** (0.000)
Obs	12249	2957	2577	2526	2356	1833
R2	0.031	0.015	0.027	0.042	0.046	0.061

**TABLE 19: REGRESSION ANALYSIS OF GROSS VALUE ADDED AND STRENGTH OF LEGAL RIGHTS FOR ITC INDUSTRIES**

	(1)	(2)	(3)	(4)	(5)	(6)
	ALL	0-9 empl.	10-19	20-49	50-249	GE250
Lag 1-year Strength of legal rights	0.344*** (0.000)	0.387*** (0.001)	0.171 (0.122)	0.302* (0.065)	0.380** (0.027)	0.553*** (0.000)
Constant	2.154*** (0.000)	1.503** (0.043)	2.600*** (0.001)	1.812* (0.054)	2.601*** (0.006)	1.803*** (0.008)
Obs	1838	385	399	389	374	291
R2	0.083	0.165	0.021	0.101	0.068	0.178

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