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# The Proposal to Revise the Product Liability Directive: A Call for More Facts and Evidence

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*The European Union is reforming its Product Liability Directive (PLD). A proposal from the European Commission is now working its way through the European Parliament and the Council. This note underlines that the changes to the PLD and the promotion of a U.S.-style mass litigation culture will have huge consequences for the European economy and that these impacts have not been analysed. The Impact Assessment covered some of the economic effects, but grossly underestimated the cost to businesses. No one has considered the effect on consumer prices. Innovation will be harmed by the proposed liability regime, and it is highly likely that it will lead to market exclusion of Small and Medium-sized Enterprises. These effects are not intended and underscore the need for more analysis before policymakers can make informed decisions.*

## 1. Introduction

In 2022, the European Commission proposed to revise the 1985 Product Liability Directive (PLD), with the intention of updating the Directive in light of new technological and product developments. A key objective of the initiative, communicated strongly during the preceding consultation, was to provide more legal certainty for manufacturers and consumers – ending some confusions and providing better legal definitions that could be applied consistently across the EU.

These objectives are valid and the decision to initiate a new process to revise the PLD is a good opportunity to review the development of the liability framework for faulty products that cause harm including both in-court and out-of-court settlements. Considering other legislative developments – such as the General Data Protection Directive (GDPR) and the Medical Device Regulation/In Vitro Diagnostic Medical Devices Regulation – it is also an opportune moment to reflect on how overlapping and potentially conflicting regulations can be avoided and unnecessary legal confusion reduced.

Product safety and liability regimes have been subject to significant change since 1985, not least in the past ten years during which the practice of collective litigation established itself more firmly in Europe. However, we do not know much about this development and what it implies for consumers and producers. Obviously, the incomplete knowledge we have of how liability regimes have been managed in practice can undermine the ambition to have a balanced liability regime that provides legal protection for both consumers and producers, promotes both product safety and innovation and ensures that the market remains open for all sizes of firms.

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<sup>1</sup> This is a write-up of a presentation in September 2023 at an ECIPE workshop.

The European Commission declared an ambitious approach in its Impact Assessment. However, it is notable that ensuing discussions about the Commission's proposal have been shorn of actual facts and evidence and that officials in EU institutions and national governments hold very different views about the actual meaning of the PLD proposal. In spite of the Commission's good intentions, the consequences of the proposed PLD for stakeholders and for the economy remain uncertain, and in many cases unknown.

There are some fundamental discrepancies between the contents of some recitals and the actual legislative articles in the proposal. Moreover, what the Commission has proposed does not always correspond with the conclusions from outlined scenarios in the Impact Assessment, and it is not clear why. The disjointed documents underscore the need to collect more evidence to enable policymakers to make informed decisions.

Indeed, a first warning that knowledge gaps and confusion would disrupt the legislative debate can be seen in the regulatory review from the EU's own Regulatory Scrutiny Board which noted that the "report is not sufficiently clear about the size and evolution of the problem" that it aims to address. The Board observed that "(t)he 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>2</sup>

One example illustrating this point can be found in the full Impact Assessment of the revised PLD. The report makes the claim, for reasons of technological complexity, that it is increasingly difficult to establish that a product is defective. It cites some sectors, including medical technology. The report goes on to give soft support to the proposition that the burden of proof should be changed to make it easier for claimants to make their case. However, then it says that "the challenges associated with the burden of proof in the context of new technological developments have not yet appeared in national courts".<sup>3</sup>

This is a significant admission and suggests that more evidence is needed. However, this evidence is not provided. The Impact Assessment report only cites a European Parliament study on AI and civil liability and says that there is academic analysis pointing to future problems related to AI and how to establish that a final product is defective. While this may be true, these studies largely neglect the fact that there are already many court cases that have dealt with exactly these types of problems and that the Court of Justice has already given some significant opinions about how courts should manage cases that include products with complex technology.

There are several areas in the PLD that require a much deeper factual understanding before informed decisions can be taken about the desired policy developments and outcomes. Reasonable people can hold different opinions about the design of a liability regime and how different and sometimes competing objectives should be balanced – i.e., how unavoidable trade-offs should be managed. With PLD, the EU is ushering in to law a liability regime that is distinctly different from the current regime. However, many of the officials that are involved dismiss the risk that these changes will have economic impacts that have not been mapped or estimated in the Impact Assessment. This is not a good basis for decision-making and

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<sup>2</sup> Regulatory Scrutiny Board Opinion on the Impact Assessment underlying the reform of the Product Liability Directive. SEC (2022) 343. 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>3</sup> Centre for Strategy and Evaluation Services (2022) Impact assessment study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC – No. 887/PP/GRO/IMA/20/1133/11700 Final Report.

especially not in the sensitive area of product liability. The proposed changes to the PLD will assist the development of U.S.-style mass litigation in Europe, though we have not figured out yet what this implies for the European economy. This should deeply concern involved stakeholders and prompt them to request a much better factual basis for the decisions that they are asked to make related to PLD.

## **2. The “Known Unknowns” – Necessary Economic Analysis to Guide the PLD Revision**

The revised PLD brings several new additions that warrant further analysis. A first observation is that there has not been a plausible motivation for fundamentally changing the PLD if the original purpose was merely to update it to take into account technological developments.<sup>4</sup> The underlying intentions have been to avoid allowing new (digital/software) products to escape no-fault liability and to ensure that injured parties can adequately claim compensation for damages caused by defective products. However, it is still unclear what specific flaws in the current PLD required a wholesale change, rather than making specific and discrete updates based on evidence from the real-life operation of liability regimes and handling of injury claims in the EU countries. After all, digital products (or the inclusion of digital components in other products) do not have unregulated liability regimes. Nor is it obvious that there is a so-called “right” amount for liability settlements or that the EU is generally below that level. Liability settlements vary substantially between sectors and products, depending on the harm that can be established.

The more specific issues that will have a stronger impact on liability regimes and that will lead to economic consequences are changes to the burden of proof, the inclusion of psychological harm and the loss or corruption of data, and the ambiguous treatment of various types of software in the PLD. The point here is not re-litigate concerns that have been widely identified – or discuss why specific changes are of concern in the first place.<sup>5</sup> The purpose is rather to underline that these changes will have an economic impact and call for better economic evidence that will allow policymakers to make informed decisions.

Three types of economic impacts warrant a much better understanding: increasing costs on businesses and consumer prices; effects on innovation and investments in innovation; and market exclusion effects.

### **A. Increases in general costs of doing business and effects on consumer prices**

The Commission, and the consultancy firm that made the Impact Assessment, rightly point out that changes to the PLD will increase costs for businesses. 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

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<sup>4</sup> The Inception Impact Assessment, like the proposal and the full Impact Assessment that was commissioned by the European Commission, includes motivations that are specific to the inclusion of digital products/technologies/software/applications and draw on previous work in expert groups and consultations. This work may be based on correct observations, but no one really knows. Importantly, this work does not include specific motivations (nor underlying evidence) for all the other changes that are proposed and that have little or nothing to do with digital products/technologies/software/applications. See European Commission, Inception Impact Assessment, Ref. Ares(2021)4266516 - 30/06/2021 and European Commission, 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

<sup>5</sup> Colleagues of mine have already discussed them in Matthias Bauer and Elena Sisto (2023) *Increasing Systemic Legal Risks in the EU: The Economic Impacts of Changes to the EU’s Product Liability Regime*. Brussels: the European Centre for International Political Economy.

prevalence, success rate and cost of legal disputes. It should be noted that the quantitative assumptions were developed by the authors in the absence of data, based on subjective "evaluative judgements" derived from "stakeholder feedback". These calculations are then used for different scenarios – based on different developments in increases in claims in the future.

The 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 report 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. The inclusion of all stand-alone software within the product scope is estimated to increase liability insurance costs by 15% on average for software developers. The removal 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).

Notably, there are several changes in the PLD that do not form part of the Impact Assessment – at least not the economic part. There is no economic analysis of the consequences of the changes related to the burden of proof. Nor is there any general economic analysis of the extension of the scope of the definition of injury to include psychological harm. Even the coverage in the Impact Assessment of those changes that are included is incomplete. For instance, the report does not account for digital services marketed by companies in the manufacturing and services sectors – companies that are not providing "standalone" software. In addition, the impact assessment does not assess situations in which companies are denied liability insurance coverage. This issue – a very important one – was highlighted by the insurance industry in its response to the Commission consultation.<sup>6</sup>

All these aspects are important for obtaining a realistic understanding of the cost to business of the proposed changes. Ultimately, these costs will affect the price of products and lead to effects on consumers. However, the incidence of increasing business costs is not estimated and the report largely identifies consumers as only having one interest – to obtain better compensation for injuries. Indeed, this is a consumer interest, but it is not the only one and it is just implausible that consumer prices would not be affected by an increase in business costs.

## **B. Effects on innovation and investments in innovation**

The proposed changes in the PLD will particularly have an impact on technology-intense sectors: this is part of the rationale for the revised PLD. The Impact Assessment does not have much to say about the consequences of the PLD changes on innovation. Remarkably, what it suggests is that the only effect on innovation is positive: liability rules will become clearer and make it easier for firms to innovate.

This is a grossly inadequate analysis. Liability risks are known to have a distinct impact on

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<sup>6</sup> See, for instance, Insurance Europe, <https://www.insuranceeurope.eu/publications/2788/key-messages-on-the-ec-proposal-for-a-revision-of-the-pld/>

innovation – both investments in innovation and the placing of new products on the market – and it is not a positive one. There is a rich research literature that has identified the impact of various forms of liability risks on innovation strategies and investment in different regulatory environments, and for different sectors. Surprisingly, none of that literature features in the Impact Assessment.

Moreover, there is experience both in Europe and internationally of a liability litigation culture that is important to understand from the viewpoint of innovation, and some of these experiences were shared with the Commission in the consultation that preceded the new PLD proposal. These responses seem to have fallen off the map because they are not accommodated in the proposal or analysed in the Impact Assessment.

Liability risks are often about uncertainty which is difficult to manage and insure against. Such risks are, therefore, steering innovation and innovation-investment allocations within firms. Risks are usually known and quantifiable while uncertainty, in this case, essentially implies that potential liabilities and damages are difficult to apprehend and structure in accordance with classic risk analysis and metrics. Many of the sectors that are likely to be disproportionately impacted by the new PLD – such as pharmaceuticals and medical devices – are known to respond to these types of uncertainties by reallocating their business and innovation strategies. Unfortunately, this reallocation is not beneficial for the general intensity of innovative activity – and especially genuinely new innovation.

Generally, innovation that is exploring new frontiers and aims at putting very new categories of products on the market tend to be particularly affected by liability risks and legal uncertainties. These consequences need to be better understood before policymakers can take informed decisions.

### **C. Market exclusion effect for SMEs**

The economic consequences of new liabilities may have a disproportionate impact on Small and Medium-sized Enterprises (SMEs). In fact, it is likely that new liabilities will affect them more than large companies, which have longer and deeper experience of product liability risks and stronger relationships with insurance companies that can help to manage the financial aspects of liability risks. For instance, studies have shown that, in the United States, small businesses carry a disproportionate part of the total costs of the tort system. Analysing the costs of commercial liabilities in 2018, the U.S. Chamber of Commerce found that, while small businesses represented less than 20 percent of the business revenues, they “bore 53 percent of the costs of the commercial tort system.”<sup>7</sup> The insurance costs for small businesses are also vastly higher per unit of revenue.

The fact that various EU stakeholders have explored ideas and proposals for excluding SMEs from the new rules is indicative: it signals awareness that the economic effects on SMEs may be very strong. However, this awareness has not been reflected in the actual development of the proposal – at least by providing SMEs with a full carve out from the liabilities. More efforts need to be made to better understand how SMEs will be affected – both for SMEs that are developing new products that may become commercially successful and SMEs that are providing input goods and services to manufacturers that later place the product on the market.

Unlike large companies, SMEs have a much greater challenge to find insurance companies

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<sup>7</sup> U.S. Chamber of Commerce Institute for Legal Reform (2020) *The Liability Costs for Small Businesses*.

that can offer them appropriate insurance protection. In such scenarios, the effect of incurring additional liability risks is basically market exclusion: these firms cannot take part in the market anymore because, without liability insurance, the financial risks can be fatal. The only viable option is to not put the firm in a position where it will have to carry the liability risks. The result is that important parts of the market will be closed for SMEs. Considering that some of the sectors that are likely to be impacted by the new PLD have significant SME presence (e.g., medical devices and software developers), the result of the PLD on firm size and profile may be significant.

### 3. Conclusion

This note has a simple conclusion: before policymakers can make informed decisions about the new PLD, more economic analysis is needed. There are significant risks that the EU is about to make changes to its liability regime that will cause confusion and lead to significant changes in the market, for producers and consumers, and the climate of innovation. Indeed, many of these outcomes may be unintended. These economic consequences are real and not speculative. By applying a better decision-making framework based on facts and analysis, the unintended consequences of PLD can be mitigated.

Before policymakers now make decisions about the PLD they should ask for more and deeper analysis of these factors:

- The total cost on producers from all the changes that are proposed in the PLD – not just the selective changes covered in the Impact Assessment.
- The cost to consumers in the likely scenario that businesses will pass on the increasing business costs to consumers.
- The effects on innovation when liability risks are increasing, especially for technology-intensive sectors.
- The effects on small businesses from increasing liability risks and the risk of market exclusion when they cannot insure against these risks.