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The Economic Burden of the Revised Product Liability Directive on EU and Non-EU Countries

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EXECUTIVE SUMMARY

Any manufacturer or innovator – whether headquartered in Munich, San Francisco, Zurich, or Mumbai – that places a product on the European market will soon face a spike in liability risk under the revised EU Product Liability Directive (PLD). Introduced as a consumer protection measure, the economic consequences of the Directive for enterprises, citizens, and the broader EU economy have been systematically underestimated. This study demonstrates that by fundamentally overhauling the regulatory landscape of the EU Single Market, the revised PLD imposes a dual economic burden: it acts as a structural drag on European economic output, while simultaneously raising new trade barriers that negatively impact non-EU countries. The threat to innovators and manufacturers is imminent: the PLD is currently being implemented across EU member states, before the December 2026 deadline.

Main Features of the New EU PLD

The PLD represents a critical departure from the principles that have underpinned the EU's regulatory approach for decades. Historically, the EU relied on a system anchored in ex-ante verification, supported by the European Testing, Inspection, and Certification (TIC) sector. Under this framework, obtaining a CE marking or a third-party declaration of conformity provided a robust defence against product liability claims, as it demonstrated compliance with established safety standards before a product reached the market.

The PLD abandons this model in favour of a system governed predominantly by ex-post litigation. The PLD introduces mandatory presumptions of defectiveness, effectively reversing the burden of proof. It is no longer up to the claimant to prove a product was defective. Rather, the obligation shifts to the defending party to prove the product is safe and did not cause harm. This forces European and non-EU enterprises alike to prove a negative, which is an expensive, time-consuming and technically difficult proposition that will drive most defendants to settle even meritless claims.

This shift is exacerbated by the dramatic expansion in the scope of covered products and liable actors under the revised PLD. Software, including cloud services and AI systems, is now classified as a product, exposing innovators and developers to liability for non-material damages such as data corruption. Routine post-marketing software updates can trigger liability, which now extends to actors along the entire supply chain including importers and authorised representatives in Europe. Furthermore, the PLD extends the maximum liability period to twenty-five years for latent injuries. This prolonged exposure forces domestic and foreign suppliers to maintain evidence and insurance coverage against future risks that are impossible to foresee today.

Crucially, these changes occur against a backdrop of rising mass litigation driven by the Representative Actions Directive (RAD) and the growth of unregulated Third-Party Litigation Funding (TPLF) in Europe. The resulting increase in legal and compliance costs for manufacturers reflects the opportunistic legal tactics of claimant lawyers and funders rather than any deterioration in the overall safety of products marketed in the EU. The PLD delivers fresh incentives for

collective action by removing the previous €500 property damage threshold, making aggregated, low-value claims highly lucrative for litigation funders. By combining a lowered evidentiary bar with these mechanisms for large-scale redress, the Directive creates a fertile environment for speculative litigation, further amplifying the risks for all economic operators.

Pricing the Risk of the New EU PLD Through the Insurance Market

The primary channel for the economic transmission of this regulatory shift is the insurance market. As the legal exposure of economic operators expands, insurers are being forced to translate this heightened risk into concrete financial cost estimates. The revised PLD creates a new landscape of unquantifiable liability, where judges must presume products that meet all regulatory requirements are defective, and liability is dispersed across complex global supply chains.

This heightened risk will materialise as a surge in baseline premiums for EU and non-EU firms that sell into the EU Single Market. Initial impact assessments by the European Commission severely underestimated these costs, often failing to account for the behavioural and market-level responses that the Directive is certain to trigger. Our analysis, which accounts for how insurance markets operate in the real world, projects astonishing increases in liability insurance costs: 40 per cent for sectors newly brought under the scope of the revised PLD, and as much as 10 per cent for sectors already covered. These soaring insurance costs act as the primary mechanism transmitting the revised PLD's burden across global supply chains, making the European market structurally more expensive to do business in for all enterprises.

The Burden of the New EU PLD on EU Output and Global Trade

Our economic modelling quantifies the economic costs of implementing the revised PLD, revealing a profoundly negative impact across the European economy and the economies of its trading partners. The revised PLD acts as a negative productivity and trading shock, forcing economic operators to divert resources from productive investment into defensive compliance, data logging, legal risk management and legal and settlement costs. The net result is a contraction on two fronts: a domestic drag that shrinks European output and erodes household welfare, and an external barrier that raises the cost of exporting to the EU for trading partners worldwide.

Impact on EU Countries

The PLD is projected to reduce EU GDP by between 0.17 and 0.24 per cent. This domestic economic loss is substantial since it exceeds the projected long-term gains from several of the EU's most significant recent free trade agreements, including the EU-Japan Economic Partnership Agreement and the EU-Mercosur agreement. This GDP contraction is driven by the weakened productive capacity of European innovators, manufacturers and other enterprises and also the surging costs of foreign goods and technologies on which they depend. Ultimately, this will undermine Europe's economic competitiveness.

The costs of less efficient domestic production and costlier imports will be borne by European citizens. As economic operators internalise higher insurance, compliance costs, these expenses

are passed on to consumers. The Directive will erode household purchasing power by an estimated total of €24 billion to €33 billion. For the average European family, this translates to an effective cost of between €119 and €163 per household, representing a material reduction in the European standard of living.

The EU public sector will face a €1.45 billion to €2.5 billion reduction in the imports it relies upon, threatening the delivery of high-quality public services. While the majority of public procurement in the EU is supplied by domestic enterprises, the portion of public procurement supplied by non-EU enterprises consists of highly specialised inputs for which no adequate European alternatives exist. As the PLD raises the cost of these imports, EU public authorities will likely pay a premium for the exact same goods – or they will have to accept lower-quality substitutes. In a context of constrained public finances, higher procurement costs translate directly into a diminished capacity to deliver public services.

Impact on Non-EU Countries

The economic consequences of the PLD will extend well beyond European borders. The Directive brings an additional 15.3 per cent of the EU's total imports within its scope, representing €586 billion in annual trade. To put this figure into perspective, the value of imports newly exposed to PLD liability exceeds the EU's total annual imports from China, its largest supplier.

The impact is concentrated in high-value, complex sectors. Consumer electronics and household products account for the largest share of affected imports at €222.7 billion, followed by automotive and vehicle systems (€137 billion), and IT services (€125 billion). Imports are projected to fall significantly across multiple economic sectors. Pharmaceuticals and life sciences face the steepest relative decline, with imports contracting by up to 0.73 per cent. Information and Communication Technology (ICT) imports are projected to fall by as much as 0.71 per cent.

As foreign suppliers absorb higher insurance premiums and face new barriers to entry in Europe, total EU imports from non-EU countries are projected to fall by between €21 billion and €36.5 billion in aggregate. While all of Europe's trading partners will be affected, our modelling isolates severe losses for certain economies:

- **United States:** The US faces the largest absolute contraction, losing up to €6.2 billion in annual exports to the EU (a 1.8 per cent decline).
- **Switzerland:** Swiss suppliers follow with estimated export losses of up to €1.7 billion (a 1.3 per cent decline).
- **United Kingdom:** UK enterprises face reductions of up to €1.5 billion in their exports to the EU (a 0.9 per cent decline).
- **India:** Indian economic operators will see their exports to the EU fall by up to €1.3 billion (a 1.8 per cent decline).
- **Canada:** Canadian suppliers face export losses of up to €432 million (a 1.5 per cent decline).

Ultimately, the revised PLD illustrates the hidden costs of significantly overhauling the regulatory

environment no matter how laudable the stated objective, in this case, consumer protection. By raising the cost of both European domestic production and international trade, the Directive risks undermining Europe's economic competitiveness, harming citizens' welfare, slowing adoption of new technologies, and straining relationships with key trading partners. EU policymakers must anticipate the new costs the Directive will impose on EU firms and citizens, and non-EU policymakers must take into account curtailed EU market access and the significant disruptions the Directive will trigger across global supply chains. Quantifying these costs, and making them visible to those who will bear them, is the central objective of this study.

1. INTRODUCTION

The European Union (EU) has long positioned itself as a champion of open, rules-based international trade. However, this commitment is increasingly tested by a parallel trend of stringent domestic regulation that carries significant impacts for both the internal European economy and non-EU countries. The new Product Liability Directive (PLD),[1] which entered into force in 2024 and is currently being implemented across EU member states, represents a prime example of this tension. While not a traditional trade barrier, the PLD fundamentally changes the conditions of doing business within the EU Single Market.

The PLD radically expands the scope and liabilities of the original 1985 framework, aiming to modernise EU product liability rules in response to the growing role of digital technologies. However, this paradigm shift introduces profound complexities for modern manufacturing and digital services, where final products often rely on global supply chains outside the direct control of the economic operator selling to the consumer.

To provide a comprehensive analysis of how these regulatory changes translate into economic impacts, this study is structured into two main parts. The first part is qualitative. Chapter 2 offers a detailed overview of the new PLD's key provisions, describing the expanded scope of covered products, liable actors, and new procedural thresholds. Chapter 3 examines the PLD's impact on the insurance market, detailing the mechanisms through which legal risk is translated into higher costs. Chapter 4 analyses how the PLD undermines the established third-party conformity assessment system, shifting the EU from a model of ex-ante verification to ex-post litigation.

The second part is quantitative. Chapter 5 assesses the methodology and scenario design used to estimate the economic impact, identifying which industries and import flows are most affected. Chapter 6 presents the results of our economic modelling, estimating the impact of the PLD on EU GDP, household welfare, public procurement, and non-EU exporters. Finally, Chapter 7 summarises the main conclusions of the study, highlighting the effects of the Directive on economic competitiveness.

[1] Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC (Text with EEA relevance). PE/7/2024/REV/1.

2. OVERVIEW OF THE NEW EU PRODUCT LIABILITY DIRECTIVE

The PLD entered into force in December 2024 and will apply to products placed on the EU market from December 2026 onwards. Significantly expanding the scope and liabilities of the 1985 Product Liability Directive, the new Directive aims to modernise EU product liability rules in response to the growing role of digital technologies. Since its adoption, several EU countries have already started preparatory steps towards putting the PLD into practice, while others are at different stages of the transposition process, with final implementation expected by December 2026.[2] This chapter presents the main features of the PLD and explains how they will affect EU and non-EU countries.

2.1 New Categories of Covered Products

The new PLD drastically extends product liability to a wider range of products compared to the old regime. Most notably, the Directive now includes software, whether integrated into movable products or installed in immovable property (Article 4(1)). Moreover, the PLD is applicable regardless of the delivery method, covering software stored on devices, accessed via communication networks, or provided through the cloud and software-as-a-service (SaaS) (Recital 13). This inclusion is directly linked to a broader definition of liability: because software is now a product, compensable harm has expanded to include not only physical injury but also non-material damage, such as the loss or corruption of personal data (Recitals 20–21; Article 6).

The Directive also extends liability to the digital ecosystem. Integrated or interconnected digital services, such as IoT environments, are treated as components of the product if they influence safety and remain under the manufacturer's control (Recital 17). Consequently, a hardware manufacturer can now be held liable for defects in a connected service, even if that service is supplied by a third party.

Finally, the Directive clarifies the status of open-source software and manufacturing files. While generally exempt, open-source software falls within the scope of the PLD if it is supplied commercially (Recital 15). In the case of digital manufacturing files, the Directive expressly classifies them as products. These files contain the functional data needed to produce tangible items using automated machinery, such as 3D printers. Their inclusion ensures that liability arises where defects in the digital file itself result in physical damage (Recital 16).

2.2 Expanded Scope of Liable Economic Actors

As the PLD extends its product coverage, it simultaneously expands the net of liable economic actors. This includes software developers, AI system providers, authorised representatives of

[2] CMS. (2025, November 17). Transposition Time – Update on the EU Member States' adoption of the new Product Liability Directive. Available at: https://cms-lawnow.com/en/ealerts/2025/11/transposition-time-update-on-the-eu-member-states-adoption-of-the-new-product-liability-directive

manufacturers, distributors, fulfilment service providers,[3] and providers of online platforms. It also encompasses third parties who substantially modify a product after it has been placed on the market, treating them as manufacturers for liability purposes (as detailed further in Section 2.5).

A specific expansion of liability also applies to online platforms (Recital 38, Article 8). Online platforms in certain circumstances will be exposed to liability, especially if they present products in a way that makes consumers think the platform is the seller, or if they fail to quickly identify an EU-based responsible operator when a claimant requests it. Platforms may also be treated as 'economic operators' where they act as the manufacturer, authorised representative, fulfilment provider, or distributor of the defective product.[4]

Crucially, many of these actors – from platforms to component manufacturers – are both EU and non-EU manufacturers deeply embedded in the global supply chains delivering goods and services into the EU Single Market. The allocation of liability in these supply chains is inherently complex. In modern manufacturing and digital services, the final product often relies on upstream components that are outside the direct control of the business selling to the consumer. For EU-based actors, this creates a precarious position. When a defect arises from an upstream non-EU supplier, the EU importer or distributor (Article 8(3)) absorbs the full liability through a fall-back mechanism. In cases where multiple responsible parties can be identified, the PLD provides that where two or more economic operators are liable for the same damage, they may be held jointly and severally liable (Article 12).[5]

To mitigate this exposure, EU-based intermediaries are expected to shift liability back onto non-EU manufacturers through defensive commercial measures. We anticipate a rise in demands for broad indemnities, stronger warranties, and higher insurance coverage. In extreme cases, EU intermediaries may simply refuse to carry products from non-EU jurisdictions unless margins are increased to cover the risk. Consequently, both EU manufacturers reliant on global supply chains and non-EU exporters will face higher costs and barriers to entry, even if their products are perfectly safe.

At the same time, these pressures can produce liability gaps[6]. Liability may be attributed to the incorrect actor, dispersed across multiple parties such that the most relevant actor cannot be identified or pursued, due to inaccessible technical evidence or cross-border barriers. These challenges are pronounced for digital products where firms may lack oversight over all providers involved in the design, development and supply of components. In this context, PLD's evidentiary presumptions are likely to amplify uncertainty by facilitating claims in situations where causation and fault are technically difficult to disentangle.

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[3] Their inclusion reflects the Directive's aim of ensuring claimants have access to an EU-based defendant, widening the range of economic actors exposed to claims.

[4] The PLD preserves liability protections for neutral online platforms under Article 6 DSA. However, this safeguard is conditional, and the risk of reclassification and litigation remains where a platform's conduct goes beyond mere intermediation.

[5] In practice, contribution claims may fail where upstream developers are located outside the EU, or where harm involves open-source components exempt from liability. This may leave EU-based firms carrying the full liability.

[6] A liability gap arises where harm occurs but legal responsibility cannot be clearly assigned. Bertolini, A. (2013). Robots as products: The case for a realistic analysis of robotic applications and liability rules. Law, Innovation and Technology, 5(2), 214–247. European Commission. (2019). Liability for artificial intelligence and other emerging digital technologies: Report from the Expert Group on Liability and New Technologies. European Commission. Johnson, D. G. (2015). Technology with no human responsibility? Journal of Business Ethics, 127(4), 707–715.

2.3 Prolonged Exposure and Uncapped Liability Levels

The Directive extends liability periods for specific categories of damage, replacing the previous ten-year limit with a maximum period of up to twenty-five years for latent personal injuries (such as slow-developing diseases). This prolonged exposure – a substantial increase from the old framework – affects domestic and foreign suppliers alike, forcing them to maintain records, evidence, and insurance coverage for at least a quarter of a century before they can consider their exposure to claims fully closed.

This extension is particularly risky given the rapid transformation of modern products. Due to the continuous evolution of emerging technologies, it is increasingly difficult to predict how a product will interact with the human body or the environment two decades from now. By extending liability to twenty-five years, the PLD forces manufacturers to insure against unknown future interactions and technological shifts that are impossible to model today.

Amplifying this temporal risk is the prohibition on financial limits. Article 11 of the PLD explicitly bans any contractual attempt to limit or exclude liability for defective products. Consequently, suppliers cannot use standard risk-management tools, such as liability caps or waivers, to define their maximum exposure.

2.4 New Procedural Thresholds and Presumptions of Liability

The PLD strengthens disclosure obligations (Article 9) beyond those in the 1985 Directive by allowing courts to order defendants to produce relevant evidence – including design documents, data sets, and product samples – once a claimant demonstrates that their claim is merely plausible. While courts may apply confidentiality safeguards, the disclosure process still increases the risk that defendants will have to disclose commercially sensitive information especially if the guardrails under national law are weak or even non-existent as is the case in several Member States.

Alongside these disclosure obligations, Article 10 of the PLD introduces mandatory rebuttable presumptions of defectiveness. PLD primarily targets the so-called David v. Goliath situation involving an individual claimant and ignores the growth of mass claims supported by specialised lawyers and litigation funders with deep pockets that make the David v. Goliath analogy no longer apt. With the David v. Goliath situation still in mind, PLD addresses the challenges raised by the complexity of modern products in liability cases by substantially lowering the evidentiary burden for the claimant: a court must presume a product is defective if the claimant merely shows it is likely that a defect exists. This effectively reverses the burden of proof. It is no longer up to the claimant to meet its burden of proving a fault; rather, the onus is on economic operators to actively disprove liability based on broad, vaguely defined and easily applied presumptions. Under the revised PLD defendants must prove a negative, an expensive and technically difficult undertaking, making the defence of even meritless claims significantly riskier, likely forcing defendants into abusive settlements.

2.5 Expanded Post-Market Obligations

The PLD expands the definition of defectiveness to account for the dynamic nature of digital products. Liability is no longer assessed solely on the product's condition at the time of sale. Instead, a product may be deemed defective based on its post-market evolution, specifically its ability to learn (AI capabilities), acquire new features via software updates, or interact with other devices (Article 7).

A product that is substantially modified and put back on the market is treated as a new product. And if a product is modified outside the original manufacturer's control, the person who made the change may be treated as the manufacturer and held liable (Recital 39). A modification is 'substantial' where it changes the product's function, affects compliance with safety requirements, or increases its risks. Where the original manufacturer (or someone acting under its control) makes the modification and this leads to a defect, the manufacturer remains liable and cannot argue that the defect arose only after the product was placed on the market.

Furthermore, for complex technologies, a product may be treated as defective not because of a technical malfunction or design failure, but merely because its risks were not properly explained. Therefore, liability may arise simply because the product's operation or risks were insufficiently disclosed to the user. This lowers the burden significantly for a finding of liability and creates unprecedented legal uncertainty for economic actors deploying novel technologies, especially where 'foreseeable misuse' is difficult to define.

To mitigate these risks, producers will be compelled to implement extensive logging, traceability, and post-market monitoring systems. They must maintain a continuous digital trail to prove the state of the software at the moment the harm was allegedly caused. This is because failing to meet mandatory safety rules, or refusing to disclose evidence may lead courts to presume a product is defective under Article 10(2) (see Section 2.4).

2.6 The Increased Risk of Mass Litigation

The PLD reforms must be viewed in tandem with the EU's Representative Actions Directive (RAD) and the push to make it easier to launch collective actions within the EU. While the PLD lowers the substantive threshold for winning a case (through new presumptions and disclosure rules as described earlier), the RAD provides the procedural vehicle to scale up these claims.

Two specific changes in the PLD fuel this trend. Firstly, the Directive removes the previous €500 threshold for property damage. This creates a new liability market for low-value, high-volume claims (e.g., a minor data loss or software glitch affecting millions of users), making the aggregation of such claims in a mass litigation suit an attractive proposition. Secondly, the PLD broadens the definition of who can sue. Claims can now be brought not only by the injured individual but by parties 'subrogated' to their rights such as Qualified Entities (QEs). This facilitates professionalised litigation where well-funded entities drive claims in principle (but, according to many, not always) on behalf of consumers.

These new PLD mechanisms will act as a force multiplier for an already expanding collective redress ecosystem in Europe. The combination of the RAD and other EU laws such as the General Data Protection Regulation (GDPR) and the Digital Markets Act (DMA), has already contributed to an increase in the number of collective actions across EU members.[7] This growth has been fuelled by the availability of funding for this type of litigation from third-party investors in exchange for a profitable share of litigation proceeds. Although a lack of EU regulatory oversight makes the number of third-party litigation funders is difficult to quantify, evidence from some EU member states shows that their numbers are significant and increasing.[8]

Finally, and related to the previously discussed expanded post-market obligations (see Section 2.5), claimants may attempt to frame post-market software updates as evidence of prior defectiveness. Even where an update is a responsible safety improvement, it risks being invoked in court to argue that the original version was unsafe. Although the PLD attempts to clarify that a better version does not imply an earlier defect, the practical distinction between responsible improvement and proof of defect remains uncertain. This creates a perverse incentive where responsible product evolution becomes a potential litigation trigger.

Ultimately, the rise of mass litigation delivers an economic blow because private enforcement translates into higher operating costs. As the risk of collective redress grows, companies face intense pressure to secure broader insurance cover and enforce stricter risk allocation throughout their supply chains. This dynamic sets the stage for a correction in the insurance market where premiums will increase in response to the new liability environment.

3. THE INSURANCE COST OF EXPANDED LIABILITY

Insurance companies translate legal risks into concrete financial costs. Where regulatory frameworks expand liability or lower evidentiary thresholds, particularly in consumer-facing sectors, the expected frequency, duration and severity of claims increase, forcing insurers to revise their risk calculations. Moreover, product-specific risk factors are also considered during pricing coverage, including the product's complexity, intended use, and likelihood of defects or misuse. To protect themselves, insurers will charge higher premiums, narrow the scope of coverage, or require businesses to bear a larger share of initial costs.

Insurers price expected litigation risk rather than past claims alone, meaning that regulatory changes such as the PLD which increase legal uncertainty or anticipated claim frequency result in disproportionate premium increases. Where these assessments result in elevated premiums or constraints on available coverage, participation by overseas manufacturers and suppliers in the EU Single Market may be discouraged. This may sound like an exaggeration, but there is a

[7] Erixon, F., Guinea, O., Pandya, D., Sharma, V., Sisto, E., du Roy, O., Zilli, R., & Lamprecht, P. (2025). The Impact of Increased Mass Litigation in Europe. ECIPE, Brussels, occ. paper 3/2025.

[8] Guinea, O., Pandya, D., & Sharma, V. (2025). Collective Action in the Netherlands: Why It Matters for the Transposition of the Product Liability Directive. ECIPE, Policy Brief, 11/2025; and Guinea, O., Pandya, D., & Sharma, V. (2025). The Economic Risks of Transposing the EU Product Liability Directive in Germany. ECIPE, Brussels, occ. paper 16/2025; also see: Lein, E., Bonzé, C., Salim, R., Alleweldt, F., & Kara, S. (2025). Mapping third party litigation funding in the European Union. European Commission. https://doi.org/10.2838/37951892

growing number of examples of non-EU companies postponing the introduction of a product due to regulatory uncertainty and risk.[9]

Higher liability premiums will also affect EU importers. Insurance policies from outside the EU often have limited coverage or are difficult to enforce. When this is the case, liability claims arising from defective or damaged products can be directed towards the importer or distributor.[10] As a result, insurers incorporate the risk of unrecoverable upstream liability into their pricing models, leading to higher product liability premiums for importers and distributors.

In these circumstances, authorised representatives will have a strong incentive to obtain product liability insurance where none previously existed, or to expand existing coverage to reflect the expanded scope of potential claims. The European Commission estimates that, as a result of the new PLD, authorised representatives could see their product liability insurance costs and other insurance-related costs increase by 15 per cent. These costs are likely to be partially or completely passed on to the non-EU producers they represent.[11]

As described in Section 2.2, in the case of complex products, such as software, fault attribution is often difficult to determine. This creates a significant challenge for insurance companies that may be unable to identify where product liability risk is most likely to materialise. To manage this uncertainty, insurers are likely to apply broad, conservative price increases across entire sectors rather than targeting specific risks. This will inevitably lead to higher insurance costs for entire categories of software-enabled products.

The uncertainty surrounding AI-related liabilities is already causing a retreat in the insurance market. Major insurers are actively seeking to introduce new policy exclusions for claims arising from the use of AI, viewing the technology as too much of a 'black box' to underwrite reliably. The insurance industry fears that a single flaw in a widely used AI model could trigger systemic, multi-billion-dollar losses, a risk they are unwilling to bear. It has been reported that businesses wanting to insure AI-enabled products will face significantly higher premiums and narrower coverage terms.[12]

Finally, the new PLD increases both the frequency and the expected value of claims, attracting third-party capital and supporting the growth of third party profit-driven mass litigation (see Section 2.6). The increase in claim activity raises insurers' expected losses beyond what would be implied by the merits of individual claims alone. Moreover, insurers' defence costs, as a share of incurred losses, are relatively high in product liability lines, reflecting the substantial legal and

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[9] In July 2024, Meta announced it would withhold its advanced multimodal AI models from the EU market, explicitly citing the 'unpredictable nature of the European regulatory environment. Source: https://www.theguardian.com/technology/article/2024/jul/18/meta-release-advanced-ai-multimodal-llama-model-eu-facebook-owner; Apple postponed the EU release of its Apple Intelligence features – including iPhone Mirroring and SharePlay due to 'regulatory uncertainties' brought about by the Digital Markets Act (DMA). Source: https://www.reuters.com/technology/artificial-intelligence/apple-delay-launch-ai-powered-features-europe-blames-eu-tech-rules-2024-06-21/

[10] Coyle, G. (2025, December 23). Product Liability Insurance Cost 2025. The Coyle Group. Available at: https://thecoylegroup.com/product-liability-insurance-cost-2025/#:~:text=Does%20business%20size%20influence%20product,calculating%20premiums%20for%20small%20businesses.

[11] Impact assessment study on the possible revision of the Product Liability Directive (PLD) 85/374/EEC Author: Centre for Strategy & Evaluation Services (CSES) Date: June 2022 Contract No: 887/PP/GRO/IMA/20/1133/11700. Source: https://op.europa.eu/en/publication-detail/-/publication/e4854516-728b-11ed-9887-01aa75ed71a1

[12] Harris, L., & Criddle, C. (2025, November 23). Insurers retreat from AI cover as risk of multibillion-dollar claims mounts. Financial Times. https://www.ft.com/content/insurers-retreat-from-ai-cover

technical resources required to contest such claims, especially in the discovery phase that is expanded by PLD.[13] As a result, insurance premiums are likely to rise still further.

This is not a theoretical argument but a pattern that has been observed in other markets where product liability has interacted with mass litigation. In the US, 28 per cent of product liability losses are driven by legal system abuse and social inflation, where rising costs reflect aggressive litigation tactics rather than underlying economic factors.[14] These escalating costs are increasingly fuelled by third-party litigation funding (TPLF), where hedge funds and private equity firms finance claimants' legal costs in exchange for a share of the settlement. This creates a self-reinforcing cycle: increased funding supports more litigation, which drives up claim costs and larger verdicts, which in turn attracts further speculative funding and places severe financial strain on insurers and policyholders.

This dynamic has already crossed the Atlantic. In the UK, social inflation contributed more than 10 per cent to the growth of liability claims in 2023. While continental Europe has historically been shielded from these costs, Swiss Re warns that the expansion of collective action and broader liability definitions introduced by the PLD could drive a similar surge in social inflation across the EU over the coming years.[15]

Ultimately, the cost of higher insurance, fuelled by the new PLD and its drive towards mass litigation, will lead to higher premiums that are passed on throughout the supply chain, raising the expected cost for EU and non-EU manufacturers and innovators selling products in the EU Single Market. By contrast, producers located in jurisdictions characterised by lower regulatory burdens or lower litigation intensity may benefit from comparatively lower liability-related costs, including reduced insurance expenses. Inevitably, this will increase the cost base of EU firms, large and small, that may export outside the EU but also sell their products within it, reducing their competitiveness in both domestic and international markets.

4. FROM EX-ANTE VERIFICATION TO EX-POST LITIGATION

The new EU PLD introduces several features that fundamentally conflict with the established regulatory framework of conformity assessment and diminish the commercial and legal value of the services provided by the Testing, Inspection, and Certification (TIC) sector. This paradigm shift – from a system anchored in ex-ante verification to one where ex-post litigation – represents a critical departure from the principles that have underpinned the EU's regulatory approach for decades.

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[13] In 2024, defence and cost containment expenses (DCCE) accounted for 33.6 per cent of incurred losses in product liability insurance in the US. This means that roughly one-third of insurers' total claim costs in this line arise from legal defence and claim-handling expenses, not from compensation payments alone. The relatively high DCCE ratio reflects the complexity and cost of defending product liability claims, and implies that increases in claim frequency can raise insurers' costs even where individual claims do not result in large payouts. See: Facts + Statistics: Product liability. Available at: https://www.iii.org/fact-statistic/facts-statistics-product-liability

[14] Insurance Information Institute, & Casualty Actuarial Society. (2025, October 30). Increasing inflation on liability insurance: Impact as of year-end 2024 [White paper]. Insurance Information Institute. https://www.iii.org/white-paper/increasing-inflation-on-liability-insurance-impact-as-of-year-end-2024-103025

[15] Boerlin, M., Finucane, J., Holzheu, T., Lechner, R., Vanolli, A., Wu, S., & Zhu, J. (2024). Social inflation: Litigation costs drive claims inflation (sigma No. 4/2024). Swiss Re Institute. https://www.swissre.com/institute/research/sigma-research/sigma-2024-04-social-inflation.html

The established framework relies on conformity assessment to verify compliance before products reach the market. Conformity assessment in the EU was based on the so-called 'New Approach' adopted by the EU in 1985. The New Approach established a system of checks to ensure products meet the required level of safety. For many lower-risk products, businesses can issue a Supplier's Declaration of Conformity (SDoC) and affix a CE Marking to declare the product complies with all essential requirements.

However, private enterprises do not have to undertake the conformity assessment themselves. They can buy the services of third-party conformity assessment firms in the TIC sector. These firms will determine the characteristics of a product (testing); examine the product to ensure it meets the specified criteria (inspection); and provide a formal written assurance that a product, service, or system meets specific requirements (certification).

A certificate of compliance served as a proof of compliance. However, under the PLD, this protection is substantially weakened because the formal status of approval that businesses have invested significantly to obtain can be invalidated during litigation, rendering the compliance verification process non-definitive. This new uncertainty directly undermines the commercial incentives for suppliers to buy the services provided by the TIC sector.

Even though certification was never a 'perfect shield' against a lawsuit, the PLD signals a fundamental shift in approach by introducing procedural mechanisms that systematically favour claimants (see Chapter 2). This de facto reversal of the burden of proof fundamentally alters the value of third-party certification. While TIC documentation remains relevant evidence, it is no longer as determinative as it once was.

Finally, it is important to acknowledge that the conformity assessment sector is distinctly European. Major global leaders such as SGS, Bureau Veritas, Intertek, and TÜV SÜD are all European-based organisations. This European dominance is not accidental but a consequence of the EU's market size and stringent regulatory standards. Exporters hire European-accredited labs to certify their products before shipping, creating a demand that has established Europe as the global centre of conformity assessment.

5. ESTIMATING THE ECONOMIC IMPACT: METHODOLOGY AND SCENARIO DESIGN

5.1 Transmission Channels for EU and Non-EU Producers

In its PLD Impact Assessment (IA), the European Commission estimates that liability insurance costs account for between 0.1 and 0.5 per cent of a product's value, depending on the product category and risk profile.[16] At the same time, the IA estimates that liability insurance costs for complex products could rise by 10 to 15 per cent. Moreover, in the IA accompanying the withdrawn AI Liability Directive, the European Commission estimated an increase in liability insurance premiums of around 25 per cent due to AI-related liability risks, rising to 35 per cent when combined with a mandatory insurance obligation.[17] While these estimates relate to a different Directive, they provide a useful benchmark for the likely scale of expanded insurance liability costs for stand-alone software, including cases where software is embedded in a product. This approach is consistent with the PLD's recognition that certain product categories beyond AI, such as life-sustaining medical devices, entail particularly high risks and, therefore, stricter safety and liability expectations.[18]

The figures put forward by the European Commission assume that insurers can accurately price liability risks. As explained in Chapter 3, in practice this is very challenging and insurers are likely to reflect this uncertainty in higher premiums. These cost effects are reinforced by the fact that the revised liability framework changes not only how risk is assessed but also how easily claims can succeed. In particular, as liability becomes easier to establish, for example through lowering of the burden of proof, insurers may raise the cost of insurance, especially where risks remain difficult to quantify.

While the new PLD fundamentally transforms liability for digital products, its regulatory reach also extends to traditional goods already governed by the 1985 Directive. In established sectors, the risk profile for non-complex products remains unchanged; however, the reform introduces procedural changes that amplify the cost and likelihood of litigation. In particular, the introduction of rebuttable presumptions of defectiveness and strengthened disclosure obligations significantly lower the evidentiary bar for claimants. Furthermore, extending the liability period to twenty-five years for latent injuries and removing the €500 threshold for property damage will heighten long-tail exposure and facilitate mass litigation across all economic sectors. Consequently, although the economic impact on traditional sectors is incremental compared to newly covered digital goods, these procedural modifications introduce a new layer of legal uncertainty and administrative friction that insurers will inevitably price into their premiums.

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[16] European Commission (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, p. 152. Based on the Commission's assessment, the benchmark data on product liability insurance costs could not be obtained from Europe, and was based on US data where commercial providers provided information about general product liability insurance costs.

[17] Commission Impact Assessment. (2022). Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence. Available at: https://commission.europa.eu/system/files/2022-09/1_4_197608_impact_asse_dir_ai_en.pdf

[18] Ibid.

Finally, the PLD will have effects on non-EU companies that go beyond insurance costs. The PLD reduces the value of certification by shifting the regulatory approach from ex ante verification to US-style ex post litigation. Certification should serve as a clear signal of product safety and compliance with rigorous EU standards; however, the PLD will allow courts to give less weight to such third-party certification. As a result, exporters are likely to face a more demanding contracting environment, with importers seeking stronger warranties, driving up costs and making trade with the EU more expensive and riskier.

Taken together, these mechanisms form a compounding regulatory structure in which higher insurance costs, lower evidentiary thresholds, and devalued certification reinforce one another. Table 1 summarises the principal channels through which the revised PLD translates into economic costs for EU and non-EU producers.

TABLE 1: SUMMARY OF ECONOMIC EFFECTS ON EU AND NON-EU PRODUCERS

Regulatory Trigger / Mechanism	Affected Economic Actor(s)	Transmission Channel	Primary Economic Effect
Expanded product scope covering standalone software, AI systems, and digitally integrated goods	EU and non-EU producers of digital products; software developers; AI system providers.	Products previously outside the liability regime of PLD now fall within it, creating entirely new insurable risk categories where no actuarial baseline exists	Emergence of a new liability insurance market characterised by high pricing uncertainty.
Reversal of the burden of proof via rebuttable presumptions of defectiveness (Articles 9–10)	All producers and importers (EU and non-EU); liability insurers.	Shifts evidentiary costs from claimants to defendants, lowering the threshold for successful claims and increasing expected litigation frequency.	Higher expected loss ratios for insurers, transmitted as increased insurance premiums; rise in defensive compliance expenditure (data logging, documentation).
Removal of the €500 property damage threshold	Producers of low-value, high-volume consumer goods; third-party litigation funders.	Eliminates the de minimis filter, making previously sub-threshold claims economically viable and enabling aggregation into mass litigation.	Expansion of the claimable loss pool; facilitation of third-party funded collective actions.
Extension of liability period to 25 years for latent personal injuries	Manufacturers of long-lifecycle goods (automotive, medical devices, industrial equipment); reinsurers.	Lengthens the tail of insurable risk exposure, requiring firms and insurers to provision for liabilities over a significantly longer time horizon.	Increased long-tail reserve requirements; higher cost of capital for affected sectors; upward pressure on product pricing to internalise extended liability windows.
Strengthened disclosure obligations (Article 8) compelling production of technical evidence	EU and non-EU producers (who must disclose proprietary data); EU importers acting as fallback defendants.	Creates information asymmetry costs: firms must either disclose commercially sensitive data or accept adverse evidentiary inferences in litigation.	Increased compliance and legal costs; potential erosion of intellectual property protection; higher transaction costs and insurance costs in cross-border supply chains.

Regulatory Trigger / Mechanism	Affected Economic Actor(s)	Transmission Channel	Primary Economic Effect
Shift from ex ante certification to ex post litigation as the dominant regulatory signal	Non-EU exporters; EU importers; third-party certification bodies	Reduces the signalling value of pre-market conformity assessments, forcing market participants to rely on contractual warranties.	Devaluation of certification as a trust mechanism; increased contracting costs; higher barriers to entry for exporters lacking litigation infrastructure in the EU.
Inclusion of post-market software updates and modifications within the liability perimeter	Software developers; OEMs; IoT platform operators.	Continuous product evolution (patches, algorithmic updates) extends the moment at which a defect can arise indefinitely, preventing liability from crystallising at the point of sale	Perpetual liability exposure; increased cost of ongoing product maintenance and monitoring; disincentive to issue safety-improving updates where each update reopens liability risk.

Source: ECIPE.

5.2 Defining the Affected Economic Sectors

5.2.1 Newly Covered Sectors

The legal and procedural shifts detailed in the preceding chapters do not apply uniformly across all product categories. As explained, the risks are most pronounced in sectors characterised by high technological complexity, deep integration of digital components, and long international supply chains.

Our analysis identifies five sectors principally affected by the new PLD: Automotive and Vehicle Systems, Medical Devices, Information Technology, Consumer Electronics and Household Products, and Industrial and Construction Equipment. Many products within these industries rely on continuous connectivity, regular updates, and adaptive learning processes, meaning their behaviour and functionality can evolve after being placed on the market. Consequently, potential harm arising from software modifications, algorithmic decision-making, or interactions between interconnected systems creates uncertainty over where responsibility lies and when it arises.

However, exposure to these new liability rules varies within each sector, depending on the extent of digital integration. The study narrows its focus to specific product categories that incorporate – or have the capacity to incorporate – software, AI, Internet of Things (IoT) technologies, and digital manufacturing files. In total, this paper identifies 73 product categories across the five sectors that are capable of integrating software and digital services (the full list is provided in Annex 1). Furthermore, the new PLD applies directly to standalone software as a product, our analysis also includes information technology (IT) services.

Table 2 illustrates the proportion of each sector captured by the expanded scope of the new PLD. Automotive and Vehicle Systems and Information Technology are fully included because

virtually all modern vehicles depend on embedded software and connectivity, and IT products are inherently digital by definition. In contrast, the remaining three sectors exhibit partial exposure. Within Medical Devices (29.9 per cent), Consumer Electronics and Household Products (36.1 per cent), and Industrial and Construction Equipment (12.1 per cent).

TABLE 2: SHARE OF SECTORAL TRADE FLOWS NEWLY COVERED BY THE DIRECTIVE (%)

Sector	Sector share of affected products (%)
Automotive and Vehicle Systems	100%
Medical Devices	29.9%
Information Technology	100%
Consumer Electronics and Household Products	36.1%
Industrial and Construction Equipment	12.1%

Source: ECIPE.

5.2.2 Traditional Sectors (Covered by the 1985 Directive)

For the wider economy already governed by the 1985 Directive, the impact of the revised PLD will be less transformative but remains economically significant. The new PLD therefore affects them primarily through procedural adjustments, heightened compliance requirements, and growing litigation risks.

These sectors include economic areas such as agriculture, food and primary products; mining and energy; chemicals, pharmaceuticals, basic metals; and textiles, and consumer goods. Additionally, the non-digital subsets of the five primary sectors identified previously, including Medical Devices (70.1 per cent), Consumer Electronics and Household Products (63.9 per cent), and Industrial and Construction Equipment (87.9 per cent) also fall into this secondary tier.

5.3 Modelling Assumptions and Scenario Design

Our economic modelling makes two important distinctions. First, it separates the effect of the PLD on the economic sectors newly affected by the Directive from the economic sectors that were already subjected to the 1985 Directive, but which will nonetheless see growing costs reflected in higher insurance premiums. The second distinction is between the effect of the new PLD in EU countries and non-EU countries. A description of the economic modelling and the scenarios is presented below.

5.3.1 Insurance Costs as a Baseline Percentage of Production

While the European Commission's own analysis for the PLD provides a useful starting point, its estimates for insurance cost increases do not fully capture the commercial realities of the insurance market. The European Commission's baseline, which assumes liability insurance costs of 0.1 to 0.5 per cent of a product's value, is a general benchmark. However, the product categories most affected by the PLD are inherently more complex and carry a higher risk profile than the average product. Moreover, the European Commission's IA did not account for many of the risks and economic costs described in Chapter 3 and Section 4.1. Therefore, a baseline insurance cost of 1 per cent of product value is a more realistic, albeit still conservative, assumption. For comparison, liability insurance costs in the US are generally higher than this assumption, reflecting higher litigation exposure.

5.3.2 Premium Growth for New Sectors

The European Commission's estimated premium increase of 10 to 35 per cent underestimates the compounding effect of several risk factors explained earlier. Insurers must price not only the expanded scope of liability but also the heightened uncertainty, the difficulty of fault attribution, and the increased likelihood of mass litigation, which drives costs far beyond the merits of individual claims. A 40 per cent increase in premiums is, therefore, assumed to better reflect this new, riskier legal environment. Critically, in cross-border supply chains, this cost is incurred at least twice: once by the non-EU producer and again by the EU importer, who must also secure liability coverage. This 'double incidence' of insurance costs is a practical reality of international trade that amplifies the total cost of the PLD.

5.3.3 Premium Growth for Traditional Sectors

For traditional manufacturing sectors, the economic impact will be more contained, primarily driven by new compliance requirements and procedural adjustments. While the PLD formally expands liability, its practical impact on these established sectors will be incremental. These industries have long faced claims under national tort law, meaning the physical risk profile of their products remains unchanged. Consequently, this study estimates that for sectors already covered under the previous PLD, insurance premiums will see an additional increase of 5 to 10 per cent. This projection has been validated by insurance industry experts, who confirm it aligns with their expectations.

5.3.4 Simulating Domestic Shocks (EU Countries)

To measure the regulatory burden of the revised PLD on the domestic EU economy, the study employs an "all-input augmenting technological change" shock, which captures how the new PLD increases the baseline cost of doing business within the Single Market. In economic modelling, this is represented as a percentage decrease in Total Factor Productivity (TFP).

Economically, this means that a sector now requires significantly more inputs to produce the exact same amount of final output.

In the real world, this shock translates the risks of the PLD into tangible economic costs. Instead of allocating capital toward product development, EU manufacturers and innovators are forced to divert critical resources to cover surging liability insurance premiums and implement extensive data logging and post-market monitoring systems to defend themselves against potential mass litigation. Consequently, they have fewer resources available for productive technology and are less incentivised to invest in new digital technologies or iterate on existing products. Over time, this increase in operational costs leads to diminished access to the technology frontier and lower economic growth.

5.3.5 Simulating Trade Shocks (Non-EU Countries)

In contrast to the domestic EU economy, to measure the regulatory burden of the revised PLD on non-EU countries, the study employs an "import-augmenting technological change" shock, which captures how the new Directive increases the baseline cost of exporting into the Single Market. In economic modelling, this is represented as a decrease in bilateral trade efficiency, often referred to as an "iceberg trade cost." This means that a foreign manufacturer now incurs higher transaction costs simply to deliver the exact same amount of final goods to the EU. Unlike EU-based producers who face unavoidable domestic cost increases, non-EU partners incur this friction only when interacting with the EU market.

In practice, this shock translates the extraterritorial risks of the PLD into tangible non-tariff trade barriers. It reflects the reality of the 'contractual squeeze' where EU importers and distributors demand stricter warranties, extensive technical documentation, and higher liability insurance from non-EU suppliers to offset their own legal exposure. In the long-term, this increase in market entry costs disincentivises non-EU entities from selling products in Europe, leading to diminished access to global innovation for EU businesses and consumers.

5.3.6 Scenario Outlines (Lower and Upper Bounds)

Based on these assumptions, the study sets out two scenarios, presented in Table 3, which underpin the computable general equilibrium (CGE) model used to estimate the costs of the PLD (see Annex 2 for a full description of the model).

The lower-bound Scenario 1 assumes that liability insurance costs for newly impacted sectors increase by 40 per cent, and by 5 per cent for economic sectors previously affected by the 1985 PLD. Importantly, under this Scenario the impact of the PLD through higher trade costs only affects exporters rather than both exporters and importers. The same increase in liability insurance costs is applied to the EU economy (see Section 6.1) and to non-EU countries (see Section 6.2).

Scenario 2 represents the upper bound. It assumes that higher insurance costs for the products and IT services newly affected by the PLD will be borne by both non-EU producers exporting to

the EU and EU enterprises importing these goods and services (see Section 4.3.5). This combined effect is captured by doubling insurance costs as a share of product costs – from 1 per cent in Scenario 1 to 2 per cent in Scenario 2 – while the assumed 40 per cent increase in liability insurance costs remains unchanged.[19] For economic sectors that were already in the scope of the 1985 PLD, Scenario 2 assumes that the increase in liability insurance costs is equal to 10 per cent, and this increase applies to both EU importers and non-EU exporters, again doubling the effect. In the case of the EU economy, because the effects of the PLD affect the domestic economy directly (see Section 4.3.4), the increase in liability insurance is equal to 40 per cent for economic sectors newly brought within the scope of the PLD and 10 per cent for economic sectors that were already in the scope of the PLD.

The total increase in product costs is calculated by multiplying insurance costs (as a share of product costs) by the assumed increase in liability insurance costs under each scenario. The actual coefficients entered into the economic model are adjusted by the share of affected products within each sector. For instance, while the Automotive and IT sectors have a 100 per cent share and receive the full 0.4 (Scenario 1) or 0.8 (Scenario 2) shock, Medical Devices has a share of 29.9 per cent, resulting in a lower shock coefficient (0.12 in Scenario 1) (see Annex 2 for a full list of the shocks per individual sector).

TABLE 3: MODELLING SCENARIOS AND SHOCK CALIBRATIONS

	Insurance cost as percentage of product costs (%)	Increase in liability insurance costs (%) (New Sectors)	Increase in liability insurance costs (%) (Old Sectors)	Increase in product costs (New Sectors)	Increase in product costs (Old Sectors)
Scenario 1 (lower bound primary)					
EU countries	1	40%	5%	0.4	0.05
Non-EU Countries	1	40%	5%	0.4	0.05
Scenario 2 (upper bound primary)					
EU countries	1	40%	10%	0.4	0.1
Non-EU Countries	2	40%	10%	0.8	0.2

Source: ECIPE.

[19] This is, however, an imperfect assumption. In practice, exporters and importers form part of the same value chain. The final cost burden would be shared according to the relative bargaining power of the parties and the availability of alternative suppliers. The cost is not automatically duplicated; rather, it is negotiated and shared. However, it is not uncommon for both sides of a transaction to take out insurance, much as all drivers purchase car insurance regardless of who is more likely to cause an accident. Taking these factors into account, Scenario 2 serves as the upper-bound estimate.

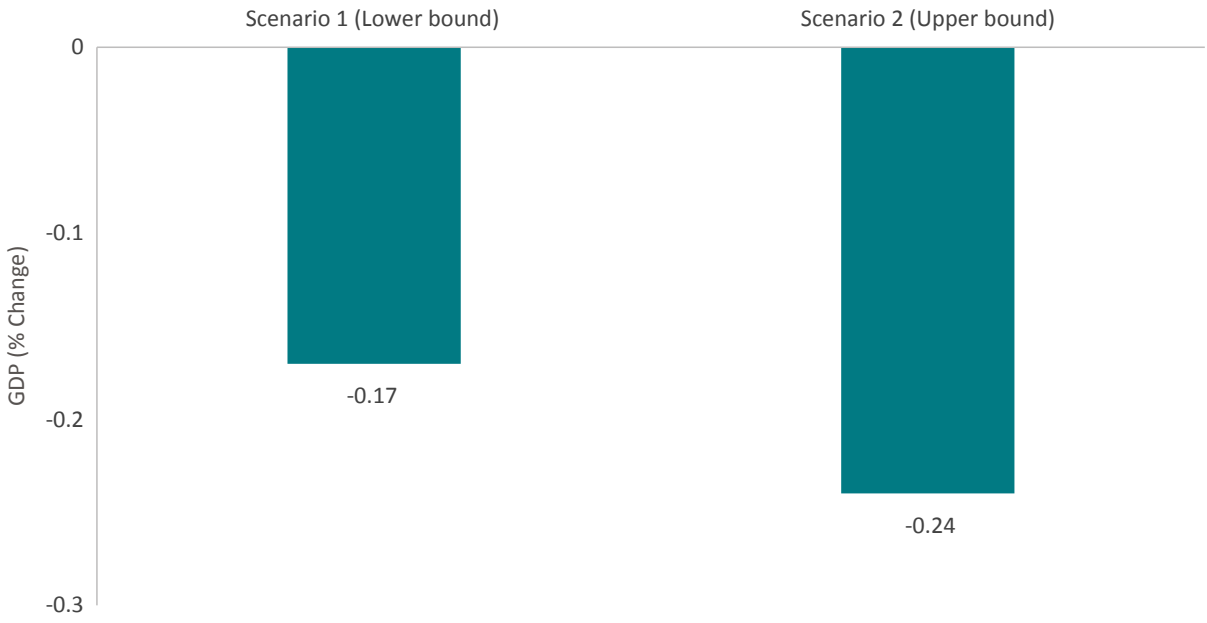
6. SIMULATION RESULTS: THE ECONOMIC IMPACT OF THE PLD

The analysis that follows focuses exclusively on the cost side of the regulation. The new PLD is expected to deliver benefits to consumers, including easier access to compensation for harm allegedly caused by defective software and AI systems. The quantitative analysis presented here does not seek to minimise these benefits, but rather to estimate the economic costs that are the necessary counterpart of those benefits, and which will be borne by EU and non-EU firms selling their products in the EU Single Market.

6.1 Economic Costs on EU Countries

The PLD is expected to have a significant negative impact on the EU economy. EU GDP is estimated to be 0.17 and 0.24 per cent lower in Scenarios 1 and 2, respectively, than it would be in the absence of the PLD (as shown in Figure 1). To put this in context, the estimated GDP cost of the PLD is larger than the projected gains from several of the EU's most significant recent trade agreements. The European Commission's own impact assessment for the EU-Japan Economic Partnership Agreement estimated a long-run GDP gain of 0.14 per cent for the EU.[20] The projected gains from the EU-Mercosur agreement, which took over two decades to negotiate, are estimated at around 0.05 per cent of EU GDP.[21]

FIGURE 1: ESTIMATED DECLINE IN EU GDP (% CHANGE)



Source: ECIPE, authors' calculations.

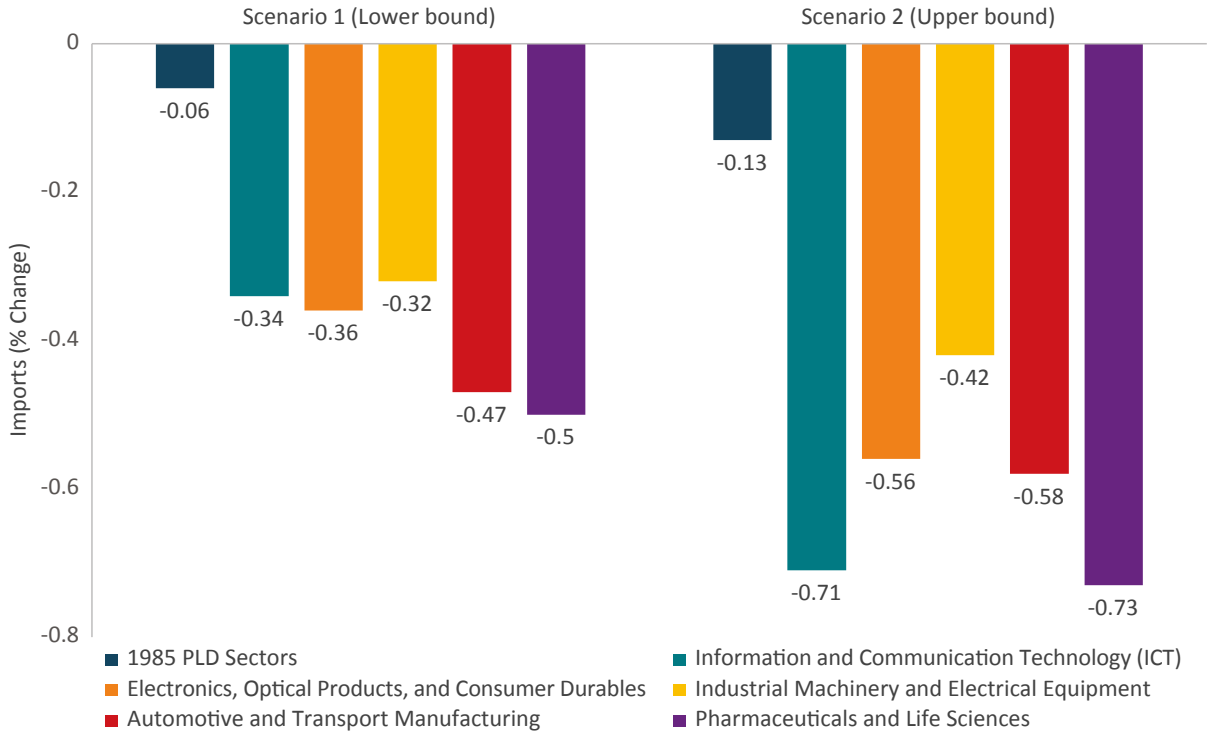
[20] European Commission (2012). Trade sustainability impact assessment of the free trade agreement between the European Union and Japan (Final Report). European Commission, Directorate-General for Trade. https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/japan/eu-japan-agreement_en

[21] European Commission (2025). Economic analysis of the negotiated outcome of the EU-Mercosur partnership agreement (EMPA). Publications Office of the European Union. https://op.europa.eu/en/publication-detail/-/publication/6f1a741f-677e-11f0-bf4e-01aa75ed71a1/language-en

The fall in GDP is the result of the combined effect of the two shocks described earlier. On the production side, PLD raises the cost of domestic output: EU firms that must allocate more resources to insurance, compliance, and legal risk management produce less per unit of input, lowering TFP across the affected sectors. On the trade side, the import-augmenting technological change shock increases the effective cost of trading with the EU. The net result is a contraction in real output: production becomes less efficient, imported inputs become more expensive, and the economy's overall capacity to generate value diminishes.

Figure 2 presents the estimated reduction in EU imports by sector under the new PLD. Pharmaceuticals and life sciences experiences the largest contraction across both scenarios, falling by 0.50 per cent under the lower bound and 0.73 per cent under the upper bound. Information and Communication Technology (ICT) follows a similar pattern, with import reductions ranging from 0.34 per cent in the lower bound to 0.71 per cent in the upper bound. The automotive and transport manufacturing sector and electronics, optical products, and consumer durables occupy the middle range with a fall between scenarios of 0.47 to 0.58 per cent and 0.36 and 0.56 per cent respectively, while industrial machinery and electrical equipment reports falls ranging between 0.32 and 0.42. Sectors already covered by the 1985 PLD face a smaller increase in liability insurance costs and, consequently, a more limited impact, ranging from 0.06 to 0.13 per cent.

FIGURE 2: ESTIMATED DECLINE IN EU IMPORTS BY SECTOR (% CHANGE)

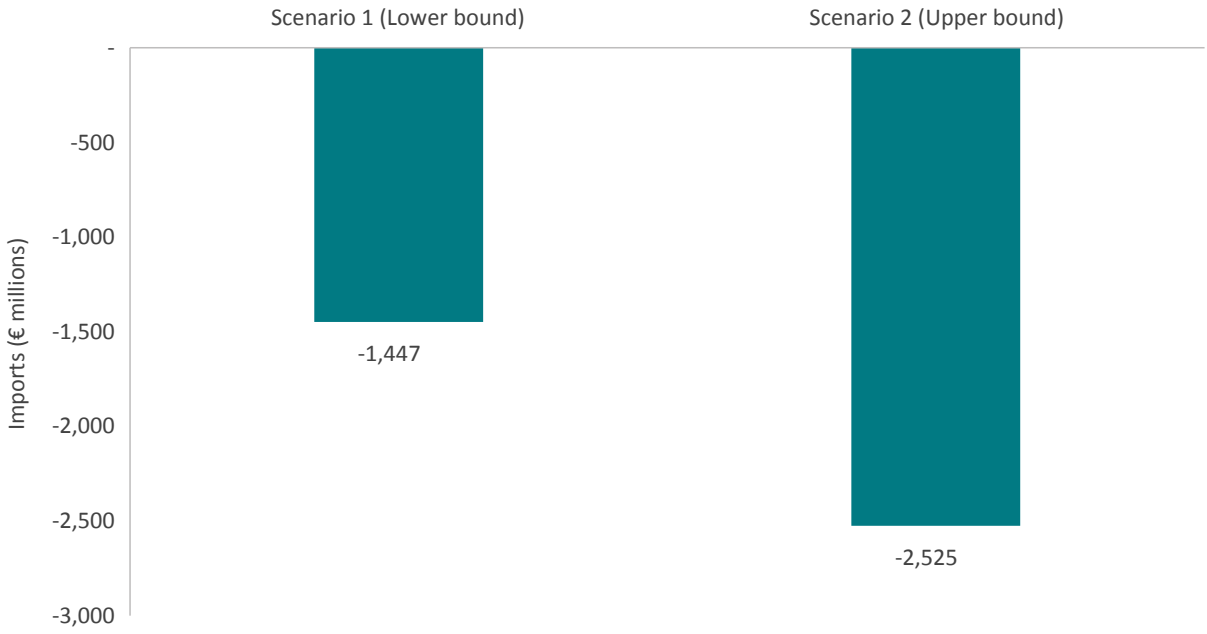


Source: ECIPE, authors' calculations.

In terms of public procurement, even though contracting authorities tend to source disproportionately from domestic suppliers, with only 3 per cent of public sector consumption coming from foreign imports, the EU public sector as a whole remains a large purchaser of

foreign products. In 2017, the EU's public sector imported goods and services worth €122 billion, amounting to 6.9 per cent of total goods and services imported by the EU.[22] Similar to other economic actors, rising import prices following the implementation of the PLD will lead public authorities to reduce import demand and pass part of these higher costs on to EU households and economic actors that rely on public services. As presented in Figure 3, the EU public sector's imports are projected to fall between €1.45 billion and €2.5 billion as a result of the PLD.

FIGURE 3: ESTIMATED DECLINE IN EU PUBLIC-SECTOR IMPORTS (€ MILLIONS)



Source: ECIPE, authors' calculations.

Ultimately, the increase in import prices and the fall in productivity will be borne by European households. For products with limited substitutes, where few domestic suppliers exist, households may be forced to cut spending elsewhere to absorb the higher costs induced by the new PLD. For other products, EU consumers may shift demand towards domestically produced alternatives, provided these are available at lower relative prices. However, the productivity shock weakens this substitution channel: because EU producers themselves face higher insurance and compliance costs, domestic alternatives are unlikely to offer meaningful price relief. The overall effect is likely to be a decline in European households' standard of living, driven by the combined pressure of costlier imports and less efficient domestic production.

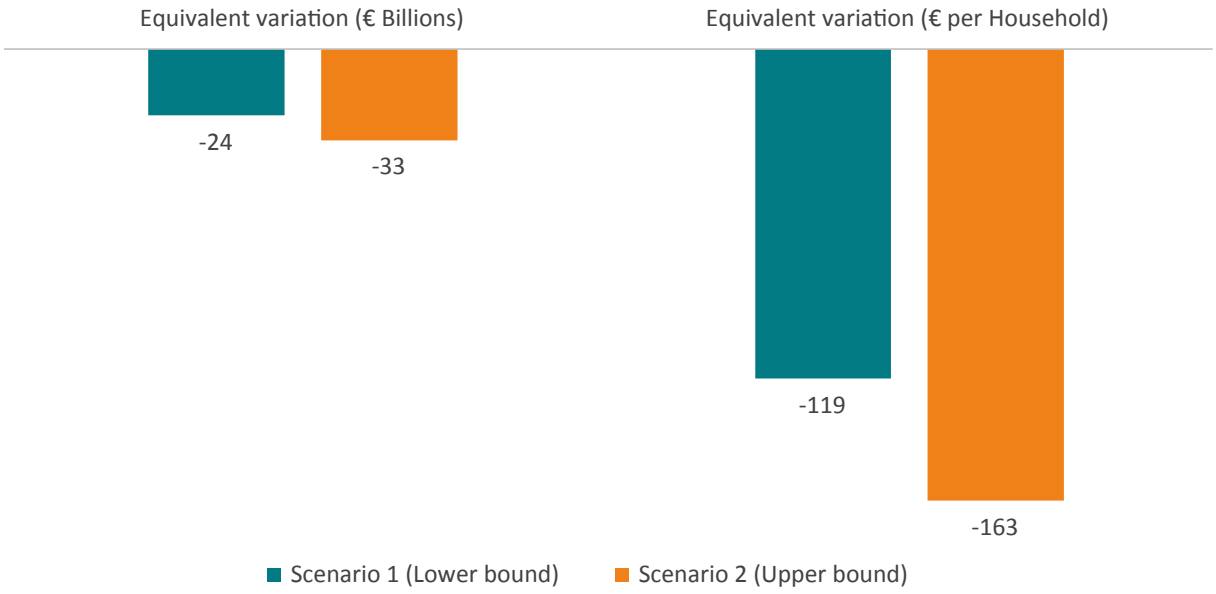
These effects are captured in our economic modelling results in the form of a variable that measures the equivalent variation.[23] This economic concept measures the monetary amount that households should receive to make them as well-off as they were before the implementation of the PLD. Figure 4 measures this amount as a cost to EU households, estimated to be between

[22] Prometeia SpA, BIP Business Integration Partners – Spa, Economics for Policy a knowledge Center of Nova School of Business and Economics Lisboa, (2021), Study on the measurement of cross-border penetration in the EU public procurement market. European Commission

[23] Hertel, T. W. (Ed.). (1997). Global Trade Analysis: Modeling and Applications. Cambridge University Press.

€24 billion (lower bound Scenario) and €33 billion (upper bound Scenario) in total, translating to €119 and €163 per EU household, respectively.

FIGURE 4: ESTIMATED COST BURDEN ON EU HOUSEHOLDS (€ BILLIONS AND € PER HOUSEHOLD)



Source: ECIPE, authors' calculations. Note: results are expressed in euros, converted using the 2025 exchange rate of 1 USD = 0.885 EUR. Source: European Central Bank.

The divergence between the cost estimates produced in this study and those of official bodies is not a matter of degree, but of methodology. Both the European Commission's Impact Assessment[24] and the German government's Ministerial Draft explanatory memorandum[25] restrict their analyses to the direct administrative and compliance mechanics of the Directive. These are real costs, but they represent only the visible surface of the PLD's economic impact. What these assessments do not capture, and what this study explicitly quantifies, are the behavioural and market-level responses that the Directive will trigger, as described in Section 5.1. As a result, the analyses conducted by the European Commission and the German government severely underestimate the economic cost of implementing the revised PLD.

[24] European Commission (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. Table 4.70. Under the preferred policy option, the study estimates incremental annual insurance costs for producers equal to €28.1 million and incremental enforcement costs equal to €1.59 million.

[25] Federal Ministry of Justice and Consumer Protection, Ministerial Draft (Referentenentwurf) of the new German Product Liability Act, 11 September 2025, Explanatory Memorandum. The memorandum estimates total national costs at approximately €72,000, of which the majority falls on the public sector (state and federal courts) for evidence disclosure processing and publication of decisions. For the private sector, the memorandum assumes "no change in compliance costs for the economy"; the only firm-level cost acknowledged is the time required to respond to court disclosure orders, estimated at 40 hours per case across 1,000 annual cases, yielding a total private sector cost of €26,000.

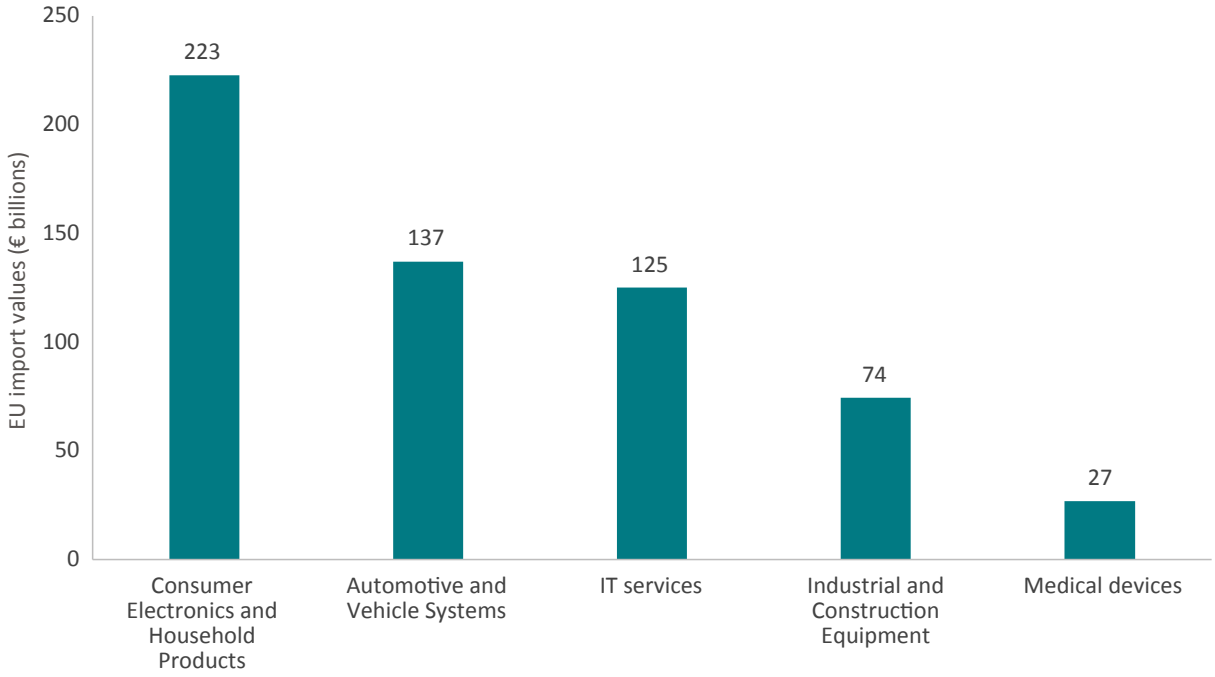
6.2 Economic Costs on non-EU Countries

6.2.1 Baseline Trade Values for Affected Non-EU Countries

As a Directive that applies to all products placed on the EU market, the new PLD will have a significant impact on the largest EU suppliers. Looking only at EU imports of the 73 product categories and IT services described in Section 4.2.1 and Annex 1, we find that the new PLD will impact 15.3 per cent of the EU's total imports, accounting for €586 billion. To put this into perspective, the €586 billion worth of imports affected by the Directive exceeds the EU's total imports from China, its largest supplier, which amounted to €522 billion in 2024.[26]

Across the five sectors (see Figure 5), consumer electronics and household products account for the largest import flows affected by the new PLD, at €222.7 billion, followed by automotive and vehicle systems (€137 billion) and the IT sector (€125 billion). Industrial and construction equipment, together with medical devices, account for a combined €101 billion in imports affected by the PLD.

FIGURE 5: VALUE OF EU IMPORTS IN NEWLY COVERED SECTORS (2024, € BILLIONS)



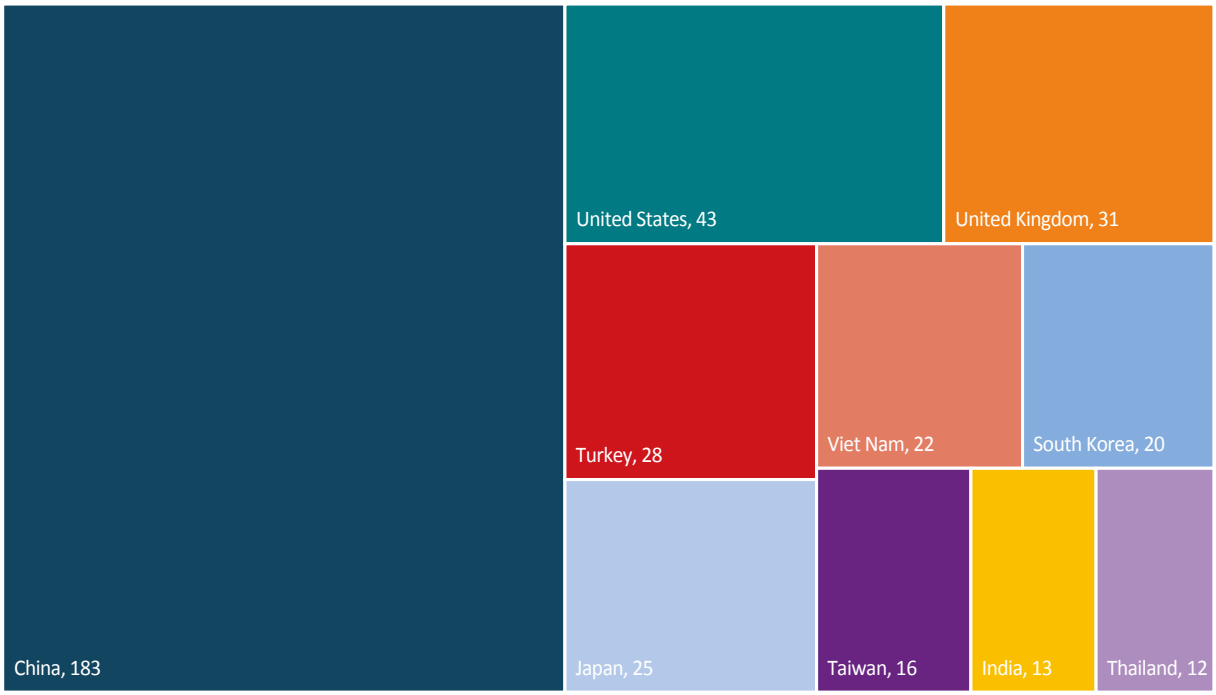
Source: Eurostat, author's calculations.

[26] Author's calculations based on Eurostat data

These EU imports of goods and services worth €586 billion were supplied by 213 countries and territories.[27] Figure 6 shows the ten largest exporters to the EU of the 73 affected goods in 2024, while Figure 7 presents the corresponding figures for IT services imports.

China was the largest supplier to the EU of the 73 goods directly affected by the new PLD, with exports worth €183 billion. This was followed by the US, the UK, Turkey, and Japan, with combined exports of affected goods to the EU worth €125 billion. Beyond the EU's traditional trade partners, newer and smaller partners will also see a significant share of their exports to the EU affected by the PLD. For example, Vietnam, Taiwan, and Thailand rank among the top ten countries most affected by the new PLD. Together, these countries export around €50 billion worth of goods to the EU that will fall within the scope of the new PLD.

FIGURE 6: TOP 10 NON-EU SUPPLIERS OF NEWLY COVERED GOODS (2024, € BILLIONS)

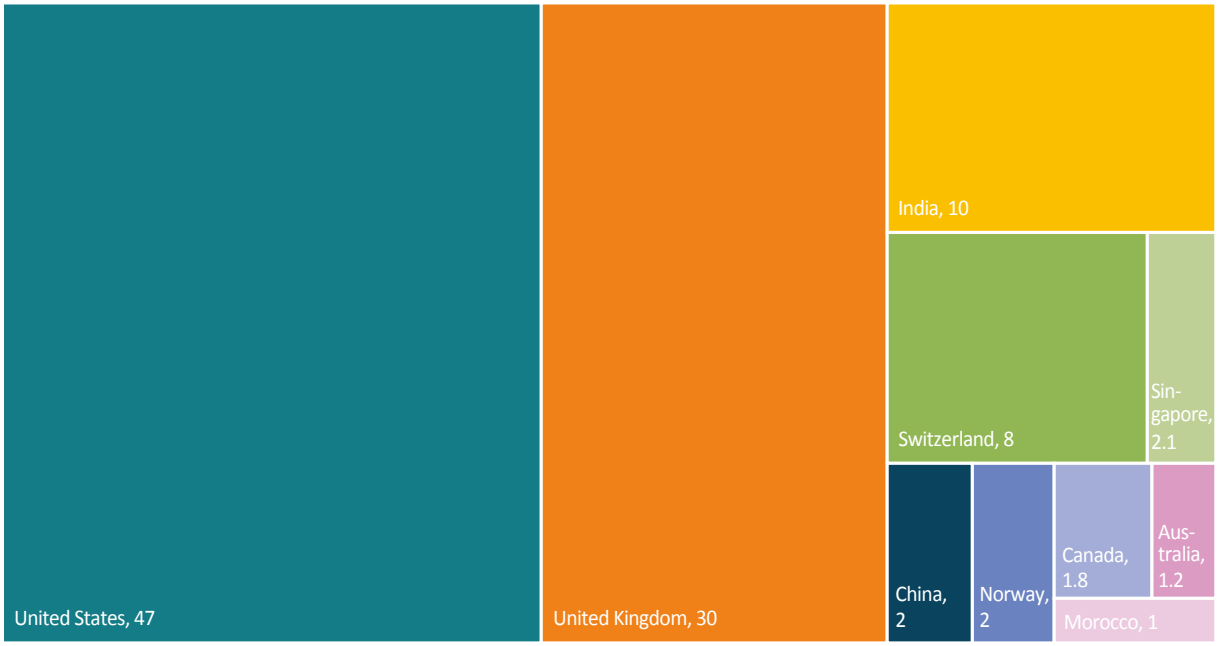


Source: Eurostat, author's calculations.

Looking at the import of IT services, Figure 7 shows the top 10 exporters to the EU impacted by the new PLD. The US and the UK were the leading suppliers of IT services to the EU with combined exports affected by the new PLD amounting to €77 billion. India ranked as the third-largest exporter of IT services to the EU in 2024, highlighting the broad and significant impact of the new PLD on both established and emerging trade partners. Even smaller economies, such as Singapore, would see services trade flows of around €2 billion affected by the new PLD.

[27] Eurostat data shows trade flows to partner countries as well as territories. Territories are usually offshore areas that might belong to a certain country but have their own trade and customs rules. Examples of territories included in the Eurostat database include French Southern Territories, British Indian Ocean Territories, Virgin Islands (British) and Virgin Islands (United States), etc.

FIGURE 7: TOP 10 NON-EU SUPPLIERS OF NEWLY COVERED IT SERVICES (2024, € BILLIONS)



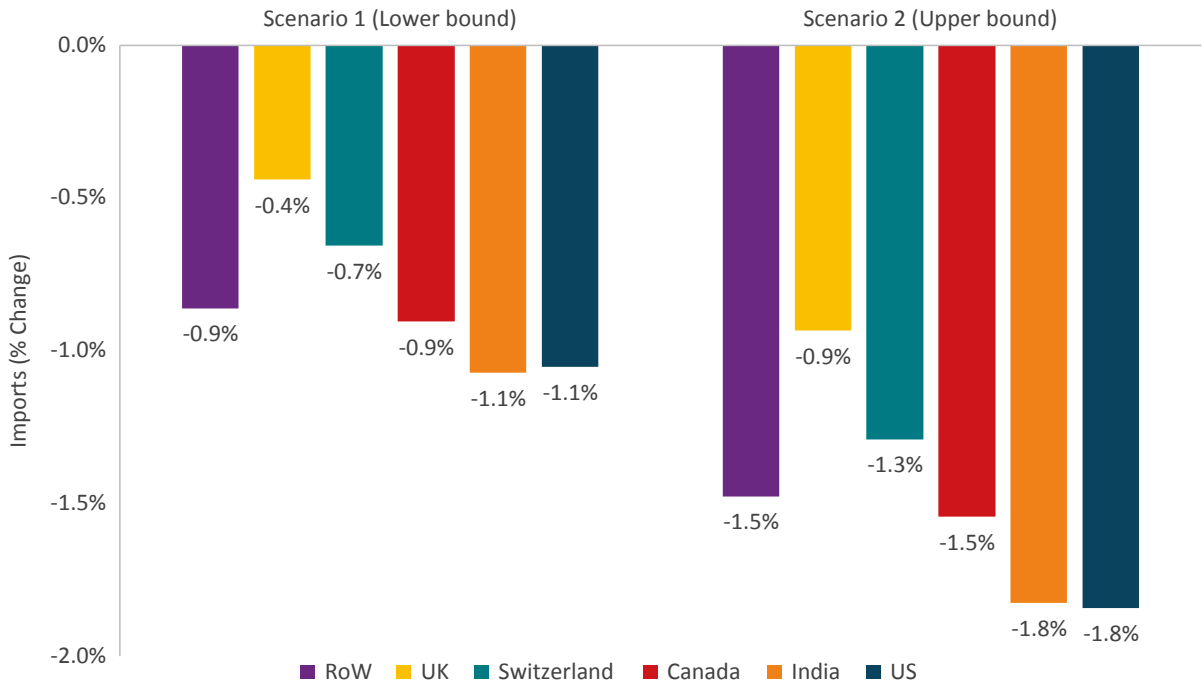
Source: Eurostat, author's calculations.

6.2.2 Projected Export Losses

As previously explained, as a result of the PLD, the EU will experience a drop in imports from non-EU countries. This fall in imports is estimated to be €21 billion under the lower bound scenario and €36.5 billion in the upper bound scenario. Figure 8 shows the percentage decrease in exports to the EU in the lower and upper bound scenarios for a selection of countries. India and the US face the largest relative decreases, with their exports to the EU falling by 1.1 per cent in the lower bound scenario and 1.8 per cent in the upper bound. Switzerland experiences the next largest reduction, with exports falling by 0.7 per cent under the lower bound and 1.3 per cent under the upper bound. Canada's exports to the EU decline by 0.9 per cent and 1.5 per cent in the lower and upper bound scenarios respectively. The Rest of the World (RoW) aggregate follows a similar pattern, with a 0.9 per cent reduction in the lower bound rising to 1.5 per cent in the upper bound. The UK records falling exports to the EU between 0.4 per cent in the lower bound and 0.9 per cent in the upper bound.

This reduction in exports is driven by the two compounding forces described previously. First, exporting to the EU becomes structurally more expensive as non-EU producers are forced to internalise higher liability insurance premiums and increased compliance costs. Second, as the EU economy absorbs its own negative shock, which makes domestic production less efficient, the EU becomes poorer in aggregate, leading to a contraction in overall demand for goods from abroad.

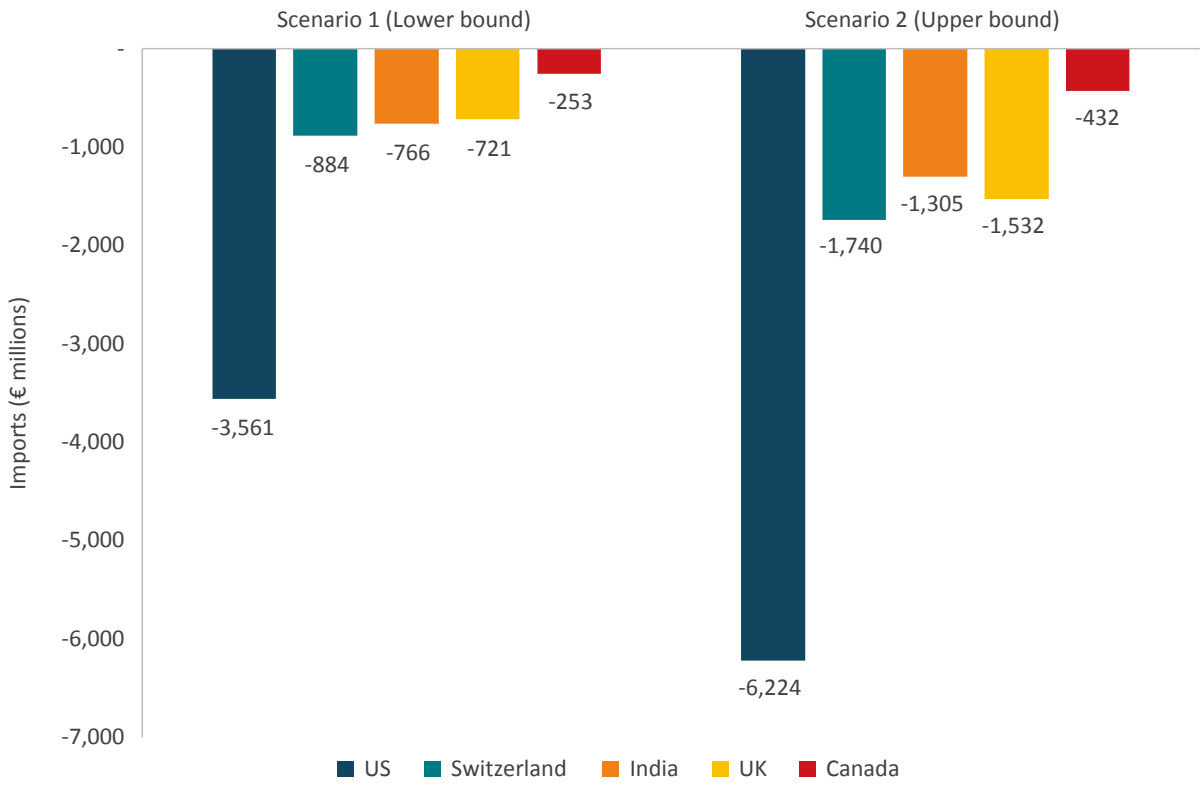
FIGURE 8: ESTIMATED DECLINE IN EU IMPORTS FROM KEY TRADING PARTNERS (% CHANGE)



Source: ECIPE, authors' calculations.

Because these reductions are expressed in percentage terms, countries with larger baseline trade volumes will experience significantly greater absolute losses. Figure 9 illustrates this clearly. Among the selected countries, the US faces by far the largest absolute contraction, with exports to the EU falling by €3.6 billion in the lower bound scenario and €6.2 billion in the upper bound. Switzerland and India follow, with estimated export losses of €884 million and €766 million respectively in the lower bound, rising to €1.7 billion and €1.3 billion in the upper bound. The UK records a loss of €721 million under the lower bound and €1.5 billion under the upper bound. Canada, despite facing one of the steeper percentage declines shown in Figure 8, records the smallest absolute loss among the five countries at €253 million in the lower bound and €432 million in the upper bound, a direct consequence of its comparatively smaller trade volumes with the EU in the affected product categories.

FIGURE 9: ESTIMATED DECLINE IN EU IMPORTS FROM KEY TRADING PARTNERS (€ MILLIONS)



Source: ECIPE, authors' calculations.

7. CONCLUSION

The revised Product Liability Directive (PLD) represents a fundamental shift in how the EU regulates the digital economy. While its stated objective is to modernise consumer protection, this study demonstrates that the Directive imposes a severe dual economic burden: it acts as a domestic drag on European economic output while simultaneously erecting new barriers for international trade.

This dual burden is driven by a structural shift in the rules that govern product liability in the EU. By expanding the definition of a product and of the types of damages that may be claimed, extending liability to new actors, and lowering the evidentiary bar for claimants, the PLD forces businesses to internalise unquantifiable legal risks. The inevitable result is a surge in liability insurance premiums and compliance costs. These costs impact both non-EU exporters and EU domestic industries selling their goods and services into the EU Single Market.

Our economic modelling quantifies the magnitude of this regulatory shift. The key empirical findings are:

EU Domestic Impact

- Contraction of the EU economy: The PLD is projected to reduce EU GDP by between 0.17 and 0.24 per cent. This domestic economic loss exceeds the projected long-term gains from several of the EU's most significant recent free trade agreements.
- Cost to European households: The Directive will erode European household purchasing power by an estimated €24 billion to €33 billion annually, equivalent to a cost of €119 to €163 per household.
- Strain on public services: The EU public sector faces a €1.45 billion to €2.5 billion reduction in the imports it relies upon to deliver public services to EU citizens.

Trade and Non-EU Impact

- Substantial volumes of affected trade: The new PLD brings 15.3 per cent of the EU's total imports within its scope, representing €586 billion in annual trade – a figure that exceeds the EU's total annual imports from China.
- Reduction in EU imports: Total EU imports from non-EU countries are projected to fall by between €21 billion and €36.5 billion as foreign producers absorb higher insurance and compliance costs.
- Export losses across trading partners: Every country exporting to the EU will see a reduction in its exports as a result of the PLD. Under the upper bound scenario, India and the US face the largest relative declines, with exports to the EU projected to fall by 1.8 per cent. Canada follows closely with an estimated reduction of 1.5 per cent, while Switzerland and the UK record projected declines of 1.3 per cent and 0.9 per cent respectively.

Sectoral Vulnerability

- Disproportionate impact on technology and health: Imports of pharmaceuticals and life sciences are projected to fall by up to 0.73 per cent, and ICT by up to 0.71 per cent. These sectors are central to Europe's long-term economic ambitions.

The revised PLD illustrates the hidden costs of aggressive unilateral regulation. While the intention to protect consumers in the digital age is legitimate, the chosen mechanism – relying on expanded liability and expensive litigation – creates profound inefficiencies. By raising the cost of both domestic production and international trade, the Directive risks undermining Europe's economic competitiveness, slowing its adoption of new technologies, and straining relationships with global trading partners.

ANNEX 1: TRADE CODES AND DESCRIPTIONS OF THE 73 NEWLY COVERED PRODUCTS

This annex lists the 73 product categories identified as falling within the scope of the new PLD's expanded product definition. These are products that either incorporate, or have the technical capacity to incorporate, software, artificial intelligence, Internet of Things (IoT) technologies, or digital manufacturing files. The product categories are drawn from five primary sectors: Automotive and Vehicle Systems, Medical Devices, Information Technology, Consumer Electronics and Household Products, and Industrial and Construction Equipment.

Each product is identified by its six-digit Harmonized System (HS) code, which provides the basis for calculating the volume of EU imports affected by the new PLD. These trade flows do not cover the entirety of each corresponding GTAP sector; the share of trade represented by the 73 categories within each sector is used to calibrate the shock coefficients applied in the CGE model, as described in Section 4.3 and Annex 2

TABLE A.1: LIST OF NEWLY COVERED PRODUCTS CLASSIFIED BY HS CODE

Product Code	Product Description	Sector
8470	Calculating machines and pocket-size data recording, reproducing and displaying machines with calculating functions; accounting machines, postage-franking machines, ticket-issuing machines and similar machines, incorporating a calculating device; cash register	Consumer Electronics and Household Products
8471	Automatic data processing machines and units thereof; magnetic or optical readers, machines for transcribing data onto data media in coded form and machines for processing such data, not elsewhere specified or included.	Consumer Electronics and Household Products
8472	Other office machines (for example, hectograph or stencil duplicating machines, addressing machines, automatic banknote dispensers, coin-sorting machines, coin-counting or wrapping machines, pencil-sharpening machines, perforating or stapling machines).	Consumer Electronics and Household Products
8474	Machinery for sorting, screening, separating, washing, crushing, grinding, mixing or kneading earth, stone, ores or other mineral substances, in solid (including powder or paste) form; machinery for agglomerating, shaping or moulding solid mineral fuels	Industrial and Construction Equipment
8475	Machines for assembling electric or electronic lamps, tubes or valves or flashbulbs, in glass envelopes; machines for manufacturing or hot working glass or glassware.	Industrial and Construction Equipment
8477	Machinery for working rubber or plastics or for the manufacture of products from these materials, not specified or included elsewhere in this Chapter.	Industrial and Construction Equipment
847950	Industrial robots, not elsewhere specified or included	Industrial and Construction Equipment
8501	Electric motors and generators (excluding generating sets).	Industrial and Construction Equipment
8504	Electrical transformers, static converters (for example, rectifiers) and inductors.	Industrial and Construction Equipment

Product Code	Product Description	Sector
8505	Electro-magnets; permanent magnets and articles intended to become permanent magnets after magnetisation; electro-magnetic or permanent magnet chucks, clamps and similar holding devices; electro-magnetic couplings, clutches and brakes	Industrial and Construction Equipment
8509	Electro-mechanical domestic appliances, with self-contained electric motor.	Consumer Electronics and Household Products
8510	Shavers, hair clippers and hair-removing appliances, with self-contained electric motor.	Consumer Electronics and Household Products
8513	Portable electric lamps designed to function by their own source of energy (for example, dry batteries, accumulators, magnetos), other than lighting equipment of heading 85.12.	Consumer Electronics and Household Products
8514	Industrial or laboratory electric furnaces and ovens (including those functioning by induction or dielectric loss); other industrial or laboratory equipment for the heat treatment of materials by induction or dielectric loss.	Industrial and Construction Equipment
8516	Electric instantaneous or storage water heaters and immersion heaters; electric space heating apparatus and soil heating apparatus; electro-thermic hair-dressing apparatus (for example, hair dryers, hair curlers, curling tong heaters) and hand dryers	Consumer Electronics and Household Products
8517	Electrical apparatus for line telephony or line telegraphy, including line telephone sets with cordless handsets and telecommunication apparatus for carrier-current line systems or for digital line systems; videophones.	Consumer Electronics and Household Products
8518	Microphones and stands therefor; loudspeakers, whether or not mounted in their enclosures; headphones and earphones, whether or not combined with a microphone, and sets consisting of a microphone and one or more loudspeakers; audio-frequency electric amplifiers	Consumer Electronics and Household Products
8521	Video recording or reproducing apparatus, whether or not incorporating a video tuner.	Consumer Electronics and Household Products
8523	Prepared unrecorded media for sound recording or similar recording of other phenomena, other than products of Chapter 37.	Consumer Electronics and Household Products
8524	Records, tapes and other recorded media for sound or other similarly recorded phenomena, including matrices and masters for the production of records, but excluding products of Chapter 37.	Consumer Electronics and Household Products
8525	Transmission apparatus for radio-telephony, radio-telegraphy, radio-broadcasting or television, whether or not incorporating reception apparatus or sound recording or reproducing apparatus; television cameras; still image video cameras and other video cameras	Consumer Electronics and Household Products
8526	Radar apparatus, radio navigational aid apparatus and radio remote control apparatus.	Consumer Electronics and Household Products
8527	Reception apparatus for radio-telephony, radio-telegraphy or radio-broadcasting, whether or not combined, in the same housing, with sound recording or reproducing apparatus or a clock.	Consumer Electronics and Household Products
8528	Reception apparatus for television, whether or not incorporating radio-broadcast receivers or sound or video recording or reproducing apparatus; video monitors and video projectors.	Consumer Electronics and Household Products
8531	Electric sound or visual signalling apparatus (for example, bells, sirens, indicator panels, burglar or fire alarms), other than those of heading 85.12 or 85.30.	Consumer Electronics and Household Products
87	Vehicles other than railways/tramways roll-stock, pts & access	Automotive and Vehicle Systems
901811	Electro-cardiographs	Medical devices

Product Code	Product Description	Sector
901812	Ultrasonic scanning apparatus	Medical devices
901813	Magnetic resonance imaging apparatus	Medical devices
901814	Scintigraphic apparatus	Medical devices
901819	Electro-diagnostic apparatus, incl. apparatus for functional exploratory examination or for checking physiological parameters (excl. electro-cardiographs, ultrasonic scanning apparatus, magnetic resonance imaging apparatus and scintigraphic apparatus)	Medical devices
901820	Ultraviolet or infra-red ray apparatus used in medical, surgical, dental or veterinary sciences	Medical devices
901849	Instruments and appliances used in dental sciences, n.e.s.	Medical devices
901850	Ophthalmic instruments and appliances, n.e.s.	Medical devices
901910	Mechano-therapy appliances; massage apparatus; psychological aptitude-testing apparatus	Medical devices
901920	Ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus, incl. parts and accessories	Medical devices
902110	Orthopaedic or fracture appliances	Medical devices
902121	Artificial teeth	Medical devices
902131	Artificial joints for orthopaedic purposes	Medical devices
902139	Artificial parts of the body (excl. artificial teeth and dental fittings and artificial joints)	Medical devices
902140	Hearing aids (excl. parts and accessories)	Medical devices
902150	Pacemakers for stimulating heart muscles (excl. parts and accessories)	Medical devices
902190	Articles and appliances, which are worn or carried, or implanted in the body, to compensate for a defect or disability (excl. artificial parts of the body, complete hearing aids and complete pacemakers for stimulating heart muscles)	Medical devices
902213	Apparatus based on the use of X-rays for dental uses	Medical devices
902214	Apparatus based on the use of X-rays, for medical, surgical or veterinary uses (excl. for dental purposes and computer tomography apparatus)	Medical devices
902221	Apparatus based on the use of alpha, beta or gamma radiations, for medical, surgical, dental or veterinary uses	Medical devices
902230	X-ray tubes	Medical devices
902290	X-ray generators other than X-ray tubes, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and the like, and general parts and accessories for apparatus of heading 9022, n.e.s.	Medical devices
902212	Computer tomography apparatus	Medical devices

Source: ECIPE.

ANNEX 2: ECONOMIC MODELLING APPROACH AND SCENARIO DESIGN

A2.1 CGE Model Specifications

CGE model simulations are conducted on the basis of the standard model by the Global Trade Analysis Project (GTAP) at the University of Purdue. CGE models are frequently used in economic impact assessments to estimate the magnitude of economic feedback effects, including structural changes in countries' international trade profiles for goods and services (see, e.g., European Commission 2019; Brockmeier 1996).[28]

The model applied in this analysis is static-comparative and has been applied frequently in studies on the impacts of various trade policy measures such as tariffs and non-tariff trade barriers (NTBs). We apply a multi-regional and multi-sector model, characterised by perfect competition, constant returns to scale and a set of fixed Armington elasticities. The modelling is conducted on the basis of the default macro-closure, which applies a savings-driven model, i.e., the savings rate is exogenous and the investment rate adjust accordingly.

The choice of a CGE modelling exercise, as opposed to a partial equilibrium simulation, is founded on the scope of economic analysis as the focus of our assessment is the global economy, including the EU and several other major trading partners as well as the rest of world category. In addition, the sectorial scope of our analysis is not limited to specific individual sectors, but covers the whole economy.

As concerns the economic base data on which we run the simulations, we apply the most up-to-date GTAP 11 database released in 2023. The database contains global trade data for 2004, 2007, 2011, 2014 and 2017 as reference years based on input output tables and recorded trade protection data.[29] The database covers 141 countries and 19 aggregate regions of the world for each reference year. The sectoral coverage includes a total of 65 sectors. The GTAP 11 dataset on the global economy was extrapolated to reflect the 'best estimate' of the global economy today.

With regard to the regional set-up, we distinguish between the 27 EU member states (EU27) and the US, UK, Switzerland, India, Canada and RoW as one block each. The model's sector aggregation is outlined in Table A.2. The overview of scenario assumptions is outlined in Table A.4.

The model separates the effect of the new PLD on the economic sectors newly affected by the Directive from the economic sectors that were already subjected to the 1985 PLD, but which will nonetheless see growing costs reflected in higher insurance premiums. The model therefore applies two levels of shocks to the 'new' and 'old' economic sectors.

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[28] A substantial number of economic impact assessments of EU free trade agreements (FTAs) and economic partnership agreements are carried out or accompanied by CGE models, which are the state of the art for comprehensive assessments of policy changes at regional and sector level (see, e.g., European Commission 2016).

[29] It is built on the most reliable international data sources (including Eurostat data for EU countries) and undergoes constant scrutiny by the different stakeholders and users such as the European Commission, the World Bank, OECD, IMF, WTO, United Nations, FAO, etc.

As seen in Annex 1, only 73 product categories fall under the new economic sectors, that can integrate technology such as AI, IoT into the products. As these selected trade flows do not capture the entire size of the respective GTAP sectors that the CGE model employs, we calculate the share that these trade flows represent of the total amount of trade covered by the GTAP sectors. These shares are used in the calculation of the shocks inserted into the CGE model and Table A.2 provides an overview of the respective shares.

In addition to the lower and higher bound scenarios presented in our study, we also performed two intermediary scenarios as robustness checks. This served to assess the overall robustness of all comparative scenario results, and to check for overshooting in the higher bound scenario used. The intermediary scenarios confirm that the model behaves consistently across the full range of assumptions: increases in the shock coefficients produce broadly proportional increases in the estimated economic effects, with no evidence of non-linear amplification or threshold effects that would suggest overshooting in the upper bound. The relationship between the magnitude of the insurance cost shocks and the resulting impacts on EU imports, GDP, and partner country exports is stable and monotonic across all four scenarios, lending confidence to the central estimates presented in the main analysis.

TABLE A.2: GTAP SECTOR AGGREGATION AND TRADE FLOW SHARES FOR NEWLY COVERED SECTORS

Sectoral aggregation	GTAP Sectors	HS Codes	Share of trade flows of total GTAP sectors (%)
Automotive and Vehicle Systems (incl. Software-Defined Cars, Autonomous cars)	43	87	100
Medical Devices (incl. IoT - AI & Software powered)	34	901811 901812 901813 901814 901819 901820 901849 901850 901910 901920 902110 902121 902131 902139 902140 902150 902190 902213 902214 902221 902230 902290 9022 902212	29.89
IT (incl. social media platforms, rideshare apps, and AI chatbots, software and AI)	56	Services: telecommunications, computer, and information services	100

Sectoral aggregation	GTAP Sectors	HS Codes	Share of trade flows of total GTAP sectors (%)
Consumer Electronics and Household Products	40; 45	8415 8416 8418 8422 8423 8424 8450 8452 8470 8471 8472 8509 8510 8513 8516 8517 8518 8521 8523 8524 8525 8526 8527 8528 8531	36.1
Industrial and Construction Equipment	41; 42	8413 8414 8417 8419 8420 8421 8425 8426 8427 8428 8429 8430 8457 8464 8465 8468 8474 8475 8477 847950 8501 8504 8505 8514	12.06
Sectors under 1985 PLD	34		70.11
Sectors under 1985 PLD	40; 45		63.9
Sectors under 1985 PLD	41; 42		87.94
Sectors under 1985 PLD	1 – 33; 35 – 39; 44; 46 – 48		100

Source: ECIPE, authors' calculations.

A2.2 Underlying Assumptions of the CGE Model

CGE simulation results are sensitive to various features of the model and assumptions underlying of the modelling approach, including the quality of the trade and production data, the model closure (the parameterisation of casual economic relationships), and the actual quantification of economic shocks (e.g., the increase in costs as a result of the PLD). The outcomes in terms of changes in economic variables also depend on the set-up of the model and the assumptions underlying the modelling approach which translates real world legal obligations to quantitative inputs for the model. These include assumptions about the nature of competition, substitutability of goods and services, trade elasticities, scale economies, firm heterogeneity and productivity.

Like any applied economic model, the model used in this analysis is based on a number of assumptions which simplify complex behavioural economic relationships and the policy framework governing the reality of domestic production and international commerce. The results of the estimations therefore only have indicative character as it is not possible to forecast the precise economic impacts of regulatory changes on macro-economic variables, mainly due to lack of empirical data, the influence of policy and non-policy factors and causal relationships that change over time (the Lucas critique).[30]

The applied model is comparative-static, i.e., the simulation results reflect two equilibria at different points in time.[31] As concerns the timeframe for the economic impacts to evolve, the time horizon generally depends on the nature of the simulated policy shock and a reasonable assessment of agents' behavioural responses, i.e., adjustments in consumption, production, trade and investment. The timeframe also depends on the nature of the policy change and is generally sensitive to industry characteristics. The timeframe for economic impacts to unfold thus needs to be assessed and discussed on a sector-by-sector basis. In addition, the assumption of full factor mobility and full employment of factors of production, i.e., all factors of production including labour will adjust until they are fully absorbed by other sectors after the policy changes, has critical implications for the modelling and the assessment of the time horizon within which policy-induced economic impacts will unfold.

A2.3 Simulating Cross-Sector Productivity Shocks (Domestic Economy)

Standard CGE modelling covers effects on the whole economy resulting from shocks on trade (i.e. imports/exports). It is also possible to shock the domestic EU economy directly, via the avenue of productivity shocks. Increased insurance costs resulting from the PLD are relevant for domestic EU producers as they translate into an increase in production cost from them. We measure the impacts of these costs for the EU economy through a set of productivity shocks employed in the CGE model which allows us to capture efficiency losses for the EU economy as a result of higher costs and resulting lower production of productive technologies. In the EU economy, increased production costs result in a decrease of production by domestic producers which in turn leads

[30] The Lucas critique is a criticism of econometric policy assessment approaches that fail to recognize that optimal decision rules of economic agents vary systematically with changes in regulation. It criticizes using estimated statistical relationships from past data to forecast the effects of adopting a new policy, because the estimated regression coefficients are not invariant but will change along with agents' decision rules in response to a new policy context.

[31] Most CGE models are "comparative-static" by default, i.e. the results of the modelling to not have a preset time dimension indicating how long it would take the economy to adjust to a new equilibrium.

to efficiency losses in the economy because of lower quantities available or worse access to productive technologies and innovation at the technology frontier. The link between productivity and availability of productive technologies in the economy is demonstrated in the literature by Gal et al. (2019). Gal et al. assess how the adoption of a variety of technologies impacts on firm-level productivity. Based on varying specifications of econometric models, it is estimated for EU countries that increases in the adoption of certain technologies by firms translate into total factor productivity (TFP) changes.[32] The CGE model employed allows us to estimate the impact of these efficiency losses for the EU economy, due to decreased availability of technology, through a set of productivity simulations. For each of the productivity simulation sets, productivity losses are estimated on the basis of percentage decreases in output of productive technologies and total factor productivity estimates.

A2.4 Simulating Bilateral Trade Efficiency Shocks (Trade Friction)

Standard CGE modelling evaluates how regulatory changes impact international trade flows and the broader economy. To capture the specific friction faced by non-EU exporters entering the Single Market, it is possible to shock cross-border trade efficiency directly. Increased liability risks, demands for stronger warranties, and higher insurance coverage resulting from the PLD are relevant for non-EU producers as they translate into a direct increase in the cost of exporting to the EU. We measure the impacts of these non-tariff barriers through a set of trade shocks employed in the CGE model, which allows us to capture efficiency losses in bilateral trade as a result of higher cross-border transaction costs. For non-EU partners, these increased export costs act as an "iceberg trade cost," meaning a portion of the product's value is effectively lost to compliance and legal friction before reaching the EU consumer. This in turn leads to reduced import volumes into the EU, restricted access to global innovation, and potential trade diversion away from the Single Market. The CGE model employed allows us to estimate the impact of these cross-border frictions for both the EU and its trading partners through a set of trade simulations. For each of the trade simulation sets, efficiency losses are estimated on the basis of percentage decreases in import-augmenting technological change, reflecting the higher baseline cost of delivering foreign goods to the EU market.

The use of import-augmenting technical change shocks to measure the trade-related impacts of PLD is well-established in the academic and policy literature. Table A2.3 summarises six studies that apply this approach to model regulatory compliance costs, border frictions, and trade facilitation measures, confirming that the methodology adopted in this study is consistent with standard practice in CGE-based trade analysis.

[32] Gal, P. et al. (2019), "Digitalisation and productivity: In search of the holy grail – Firm-level empirical evidence from EU countries", OECD Economics Department Working Papers, No. 1533, OECD Publishing, Paris, https://doi.org/10.1787/5080f4b6-en.

TABLE A.3: USE OF AMS SHOCKS IN GTAP MODELLING OF REGULATORY AND NON-TARIFF BARRIERS

Study / Source	Regulatory Context	Use of AMS Shock
Andriamananjara, Ferrantino, and Tsigas USITC, 2003	Non-tariff measures (NTMs): customs procedures, technical regulations, and SPS barriers	Explicitly uses the ams parameter to model NTMs as an import-augmenting technical change shock. The regulatory burden is represented as a technological wedge reducing the effective quantity of imports.
Fugazza and Maur ‚Non-tariff barriers in a non-tariff world'	TBT/SPS-type barriers; compliance costs arising from differing regulatory standards	Links ams shocks to mutual recognition, harmonisation, and compliance costs. Explains how ams enters the GTAP treatment and provides the efficiency interpretation of the iceberg-cost approach.
JRC (2019) ‚Exploring alternative approaches to estimate the impact of non-tariff measures and further implementation in simulation models'	Methodological review of NTM treatment in simulation models	States explicitly that in GTAP, the iceberg-type approach to NTMs is represented by a shock to ams. Compares this approach with alternative NTM treatments.
Nicita and Koloskova UNCTAD, 2025 ‚Non-tariff measures at the border: a GTAP level analysis'	Border NTMs; quantification of border compliance-type costs in a GTAP framework	Explicitly describes the iceberg parameter ams in the model discussion. Reviews prior GTAP NTM papers and applies ams to quantify border compliance costs.
Zamani and Pelikan (2026) ‚Deforestation-free trade: the impact of border regulations on trade, production and land use in the forestry and agricultural sectors'	EU Deforestation Regulation (EUDR); new EU border regulatory requirement converted into trade-cost shocks	Converts tariff-equivalent measures arising from a new EU regulatory requirement into AMS shocks within a MAGNET/GTAP-family modelling framework.

Source: ECIPE.

A2.5 Scenario Design and Shock Parameters

The study sets out two scenarios, presented in Table A.4, which underpin the computable general equilibrium (CGE) model used to estimate the costs of the PLD.

The lower-bound Scenario 1 assumes that liability insurance costs for newly impacted sectors increase by 40 per cent, and by 5 per cent for economic sectors previously affected by the PLD. Importantly, the impact of the PLD through higher trade costs only impacts exporters rather than both exporters and importers.

Scenario 2 represents the upper bound. It assumes that these higher insurance costs for the products and IT services newly affected by the PLD will be borne by both non-EU producers exporting to the EU and EU entities importing these goods and services. This combined effect is captured by doubling insurance costs as a share of product costs – from 1 per cent in Scenario 1 to 2 per cent in Scenario 2 – while the assumed 40 per cent increase in liability insurance costs remains unchanged. For economic sectors that were already subjected to the 1985 PLD, Scenario

2 assumes that the increase in liability insurance costs is equal to 10 per cent, and this increase applies to both EU importers and non-EU exporters, doubling the effect. In the case of the EU economy, because the effects of the PLD affect the domestic economy directly, the increase in liability insurance is equal to 40 per cent for economic sectors newly affected by the PLD and 10 per cent for economic sectors that were already subjected to the PLD.

At the same time, the coefficients are also adjusted by the share of affected products within each sector. For instance, 36.1 per cent of the consumer electronics and household products sector falls under the new economic sector and under Scenario 1 faces a shock coefficient of 40 percent, which will lead to a lower shock coefficient of 36.1 x 0.4 = 0.144 percent. At the same time, the remaining 63.9 per cent of the consumer electronics and household products sector falls under the old economic sector and under Scenario 1 faces a shock coefficient of 5 percent. This will lead to a lower shock coefficient of 63.9 x 0.05 = 0.032 percent. Table A.4 provides a full list of the shocks per individual sector.

TABLE A.4: SCENARIO CALIBRATIONS FOR EU AND NON-EU EXPORTERS

Scenario 1 (lower bound primary)	Increase in product costs (%)	Sector share of affected products (%)	Shock coefficient for CGE model
New economic sectors			
Automotive and Vehicle Systems	0.40%	100%	0.4
Medical Devices	0.40%	29.89%	0.11956
Information Technology	0.40%	100%	0.4
Consumer Electronics and Household Products	0.40%	36.10%	0.1444
Industrial and Construction Equipment	0.40%	12.06%	0.04824
Old economic sectors			
Medical Devices	0.05%	70.11%	0.0351
Consumer Electronics and Household Products	0.05%	63.90%	0.032
Industrial and Construction Equipment	0.05%	87.94%	0.044
Sectors under 1985 PLD (every sector under 1985 PLD with the exception of 34; 40; 41; 42; 43; 45; 56)	0.05%	100%	0.05

Scenario 2 (upper bound primary)	Increase in product costs (%)	Sector share of affected products (%)	Shock coefficient for CGE model
New economic sectors – Non-EU			
Automotive and Vehicle Systems	0.80%	100%	0.8
Medical Devices	0.80%	29.89%	0.23912
Information Technology	0.80%	100%	0.8
Consumer Electronics and Household Products	0.80%	36.10%	0.2888
Industrial and Construction Equipment	0.80%	12.06%	0.09648
Old economic sectors – Non-EU			
Medical Devices	0.20%	70.11%	0.140
Consumer Electronics and Household Products	0.20%	63.90%	0.128
Industrial and Construction Equipment	0.20%	87.94%	0.176
Sectors under 1985 PLD (every sector under 1985 PLD with the exception of 34; 40; 41; 42; 43; 45; 56)	0.20%	100%	0.200
New economic sectors – EU			
Automotive and Vehicle Systems	0.40%	100%	0.4
Medical Devices	0.40%	29.89%	0.11956
Information Technology	0.40%	100%	0.4
Consumer Electronics and Household Products	0.40%	36.10%	0.1444
Industrial and Construction Equipment	0.40%	12.06%	0.04824
Old economic sectors – EU			
Medical Devices	0.10%	70.11%	0.0701
Consumer Electronics and Household Products	0.10%	63.90%	0.0639
Industrial and Construction Equipment	0.10%	87.94%	0.0879
Sectors under 1985 PLD (every sector under 1985 PLD with the exception of 34; 40; 41; 42; 43; 45; 56)	0.10%	100%	0.1

Source: ECIPE.

ANNEX 3: DISAGGREGATED IMPORT IMPACT CALCULATIONS

A3.1 Calculating Reductions in Bilateral Imports

The CGE model estimates the percentage change in bilateral exports to the EU from Canada, India, Switzerland, UK, US, and the Rest of the World (RoW) per sector as a result of the shocks arising from the PLD. This information helps estimate the fall in total EU imports from these countries as a result of the PLD. For instance, to estimate the change in total exports from the US to the EU, we firs found concordance between the GTAP sectors used in the CGE model and trade flows classified under the CPA 2.1 (Classification of Products by Activity). The concordance for the selected sectors is given below in Table A.5.

TABLE A.5: CONCORDANCE TABLE: MAPPING GTAP SECTORS TO CPA CLASSIFICATIONS

Sectoral aggregation	GTAP Sectors	GTAP Description	CPA 2.1	CPA 2.2 Description
Automotive and Vehicle Systems (incl. Software-Defined Cars, Autonomous cars)	43	Manufacture of motor vehicles, trailers and semi-trailers	29	Motor vehicles, trailers and semi-trailers
Medical Devices (incl. IoT - AI & Software powered)	34	Manufacture of pharmaceuticals, medicinal chemical and botanical products	21	Basic pharmaceutical products and pharmaceutical preparations
Consumer Electronics and Household Products	40	Manufacture of computer, electronic and optical products	26	Computer, electronic and optical products
Consumer Electronics and Household Products	45	Other manufacturing: includes furniture	31, 32, 33	Furniture; Other manufactured goods; Repair and installation services of machinery and equipment
Industrial and Construction Equipment	41	Manufacture of electrical equipment	27	Electrical equipment
Industrial and Construction Equipment	42	Manufacture of machinery and equipment n.e.c.	28	Machinery and equipment n.e.c.

Source: ECIPE.

For instance, by mapping the concordance table to Eurostat data, we determine the value of US exports to the EU for the selected sectors. In 2024, the US exports to the EU in the consumer electronics and household products sector was €45 billion. In order to calculate the absolute change in the US exports to the EU in the consumer electronics and household products sector under the lower bound scenario, we multiply €45 billion with -0.91 per cent which is equal to a fall of €410 million. Similar calculations were done for partner country exports to the EU for Canada, India, Switzerland, UK, and the Rest of the World, for each sector.

A3.2 Calculating Reductions in Public-Sector Imports

From Annex A3.1, we have information on the total fall in EU imports from abroad. Under the lower bound scenario this amount is €21 billion and in the upper bound scenario, the total fall is €36.5 billion. From the European Commission (2021)[33], we also know that in 2017, 6.9 per cent of EU's total imports were by the public sector.

In order to calculate the impact of the PLD on government imports, we multiply the 6.9 per cent value with the lower and upper bound falls in EU's total imports. See Table A.6 below for the calculations.

TABLE A.6: ESTIMATED DECLINE IN EU PUBLIC-SECTOR IMPORTS

	Fall in imports	Share of public sector imports	Fall in public sector imports
Lower Bound	- €20.97 billion	6.9%	- €1.45 billion
Upper Bound	- €36.59 billion	6.9%	- €2.52 billion

Source: ECIPE.

[33] Prometeia SpA, BIP Business Integration Partners – Spa, Economics for Policy a knowledge Center of Nova School of Business and Economics Lisboa, (2021), Study on the measurement of cross-border penetration in the EU public procurement market. European Commission