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IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Directive of the European Parliament and of the Council

on liability for defective products

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Glossary

Term or acronym	*Meaning or definition*
ADR	Alternative dispute resolution
AI	Artificial intelligence
AI Act	Proposal for an AI Act (COM(2021)206)
BaU	Business as Usual costs (costs that would be incurred anyway by business regardless of whether there is new legislation).
DSA	Proposal for a Digital Services Act (COM(2020) 825)
EU AR	Authorised Representative serving as a legally-authorised person within the EU
FSP	Fulfilment service provider
GDPR	General Data Protection Regulation (EU) 2016/679
GPSD	General Product Safety Directive (Directive 2001/95/EC)
GPSR	Proposal for a General Product Safety Regulation (COM(2021)346)
IA	Impact Assessment
IIA	Inception Impact Assessment
IoT	Internet of Things
PLD	Product Liability Directive: Council Directive 85/374/EEC
PO	Policy option(s)

1. INTRODUCTION

1.1. Political context

The Product Liability Directive[1] (PLD) provides a system at European level for compensating people who suffer physical injury or damage to consumer property due to defective products. Since the adoption of the Directive in 1985, there have been significant changes in the way products are produced, distributed and operated, and key transformations to Europe's economy are underway.

The President of the Commission stressed in her political guidelines[2] the need for Europe to lead the transition to a healthy planet and a new digital world. This twin challenge of a green and digital transformation must go hand in hand. It requires, as set out in the European Green Deal, more sustainable solutions that are resource-efficient, circular and climate-neutral, such as extending the life of materials and the possibility to upgrade and repair products and components. It also requires, as set out in the Communication on Shaping Europe's Digital Future[3], that everyone have a fair chance to reap the benefits of our increasingly digitised society, such as those offered by innovative products using artificial intelligence and the internet of things.

But these benefits do not come entirely without risks.

When it comes to digital technologies, in order to minimise these risks and improve the safety of products that are placed on the market, the EU is in the process of modernising rules on machinery, radio equipment and general product safety, as well as creating new rules on safe and trustworthy artificial intelligence systems[4]. This initiative complements this modernisation drive by ensuring that when products do cause harm, consumers can be confident that their right to compensation will be respected and that businesses have legal certainty about the liability risks they face in the course of doing business. Taken together, these modernisation efforts should better enable Europe to pursue its own path towards a digital transformation that works for the benefit of people. They should contribute to a fair and competitive economy and a frictionless single market, where companies of all sizes and in any sector can compete on equal terms, and can develop, market and use digital technologies, products and services at a scale that boosts their productivity and global competitiveness.

The European Parliament has also highlighted the need to ensure that liability rules are adapted to the digital world, in order to ensure a high level of effective consumer protection, and a level playing field with legal certainty for all businesses, while avoiding high costs and risks for SMEs and start-ups [5].

When it comes to the circular economy, business models in which products are repaired, refurbished or upgraded are increasingly common and central to the EU's efforts to achieve sustainability and waste-reduction goals. This initiative aims to reinforce such

[1] Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).
[2] political-guidelines-next-commission_en_0.pdf (europa.eu).
[3] Communication-shaping-europes-digital-future-feb2020_en_4.pdf (europa.eu).
[4] See section 1.2.3 for more details.
[5] Texts adopted - Civil liability regime for artificial intelligence - Tuesday, 20 October 2020 (europa.eu).

efforts as the Sustainable Products Initiative[6] by ensuring consumers have just as clear rights to compensation for harm caused by defective refurbished products as they do for entirely new products and creating the legal clarity about liability risks that industry needs to embrace circular business models.

Due to the PLD's very broad scope, covering potentially thousands of product types, it has relevance beyond the Digital Age and Green Deal. Pharmaceuticals are a product type that has generated considerable case law, and this initiative takes into account the objectives of the Commission's Pharmaceutical Strategy and the upcoming evaluation of Union pharmaceutical legislation[7].

The evaluation of the PLD[8] in 2018 concluded that the Directive was on the whole an effective and relevant instrument, but had several shortcomings: it was legally unclear how to apply the PLD's 35-year-old definitions to products in the modern digital and circular economy; the burden of proof was challenging in the case of complex products; and the rules excessively limited the possibility of making claims. Its shortcomings in the area of emerging digital technologies were further analysed in the White Paper on AI[9], the accompanying Report on Liability for AI, IoT and Robotics[10] and the report of the Expert Group on Liability and New Technologies[11].

Three Sustainable Development Goals ('SDGs') have been identified as relevant to the PLD and to this initiative: SDG 3 (healthy lives and well-being) linked to promoting safe products and compensating victims of harm, SDG 9 (fostering innovation) linked to giving businesses legal certainty and SDG 12 (responsible consumption and production) linked to circular economy, enhancing product safety when substantial modifications are made.

1.2. Legal context (see annex 7 for more details)

1.2.1. Main features of the PLD

The PLD lays down common rules at EU level for strict liability (i.e. liability irrespective of fault or negligence) of producers for damage caused by defective products. It allows any person who has been injured by a defective product, whether the owner or a bystander, to claim financial compensation for death, personal injuries or for damage to consumer property where the property damage amounts to more than EUR 500.

Product: A product is defined very broadly as "any movable, even though incorporated into another movable or into an immovable, including electricity". The PLD does not cover the liability of service providers[12] but it does apply to products used while providing services[13].

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[6] Sustainable products initiative (europa.eu).
[7] Revision of the EU general pharmaceuticals legislation (europa.eu).
[8] Evaluation of Product Liability Directive, SWD(2018)157.
[9] European Commission, *White Paper on Artificial Intelligence - A European approach to excellence and trust*, COM(2020) 65 final, 2020.
[10] European Commission, *Report on safety and liability implications of AI, the Internet of Things and Robotics*, COM(2020) 64 final, 2020.
[11] Expert Group on Liability and New Technologies (2019), Report on Liability for artificial intelligence and other emerging digital technologies.
[12] CJEU, Judgment of 10 June 2021, *Case C-65/20*; CJEU, Judgement of 21 December 2011, *Case C-495/11*.
[13] CJEU, Judgment of 10 May 2001. *Case C-203/99.*

Defect: A product is defective when it does not provide the safety a person is entitled to expect, taking all circumstances into account, including the presentation of the product, the reasonably expected use and the time when the product was put into circulation. The concept of "defect" is designed broadly since it has to apply to a huge range of products, and its interpretation dynamically adapts to changing levels of safety expectations, in particular as new product legislation brings in new safety rules.

Producer: A producer means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who puts their trade mark on the product, as well as importers. The term "producer" is deliberately broad so that an injured person can easily find a liable person. If the producer is not known, the supplier (e.g. seller) will be held liable unless he informs the injured person of the producer's identity.

Burden of proof: The claimant has the burden of proving the damage, the defect and the causal relationship between defect and damage in order to get compensation. The Court has endorsed national evidentiary rules intended to ease the burden of proof[14].

Exemptions: Producers may be exempted from liability if they prove certain circumstances, for example, that they did not put the product into circulation, that the defect probably emerged after the product was put into circulation ("later-defect defence", Art. 7(b)), or that the defect was undiscoverable based on the state of scientific and technical knowledge at the time the product was put into circulation ("development risk defence", Art. 7(e)).

Time-limits: Producers are also released from liability under the PLD 10 years after they put a product into circulation, and claimants have to start legal proceedings within three years of identifying the damage, the defect and the producer.

1.2.2. Interplay of PLD with other liability regimes

National fault-based liability regimes

The distinctive feature of the PLD regime is that claimants do not have to prove the producer's fault to get compensation, because this proved to be very challenging for claimants as production became more technologically complex during the 20th century. Instead of proving fault, claimants have to prove the product was defective.

The PLD does not exist in isolation and is embedded into Member States' national liability regimes, where it is applied alongside national rules[15]. These unharmonised regimes allow compensation claims against a broader range of liable persons for a broader range of damages, covering not only products but services, and for longer periods of time. But victims of harm have to prove the wrongdoer's fault[16], which is more challenging to prove than defectiveness. The PLD does not affect these rights, so the PLD sits coherently within the broader national regimes. Whenever the PLD does not apply, for example because the cause of the harm was not a product but a service or the

[14] CJEU, Judgment of 21 June 2017. *Case C-621/15*.
[15] Evaluation of Product Liability Directive, SWD(2018)157, p. 11.
[16] Depending on the circumstances, victims may also have a strict liability claim at national level for which they do not have to prove fault, for example claims against vehicle owners in most Member States.

property damage was below the threshold, victims of harm will normally be able to make a fault-based liability claim at national level.

Table 1. Difference between the PLD and national fault-based liability

	PLD	**National fault-based liability**
Scope	Products	Any human action or omissions, including manufacturing and using products and providing services
Liable person	Producer (manufacturer, importer) and, in some cases, supplier/seller	Any wrongdoer: producer, service provider, users (both businesses and private persons), owner etc.
Type of victim protected	Private persons	Any victim: private persons, businesses, public entities
Type of damage	Death, personal injury, damage to consumer property worth more than EUR 500	Death, personal injury, damage to consumer property also under EUR 500; damage also to business property; pure economic loss, discrimination, pain and suffering (in some Member States)
What victim needs to prove	Defect in product irrespective of fault	Fault – wrongful behaviour of a person[17]
Period of liability	10 years after putting product into circulation	Various periods, but generally much longer

The Sale of Goods Act[18] and Digital Content and Services Directive[19] gives consumers the right to remedy, i.e. replacement, repair or reimbursement, when digital content or a digital service is not in conformity or does not work properly. That concerns contractual liability, whereas the PLD concerns extra-contractual liability of producers for injuries/damage caused by a lack of safety – a complementary tool. The General Data Protection Regulation (GDPR)[20] concerns liability of data processors and controllers for material or non-material damage caused by data processing that infringes the GDPR, whereas the PLD provides compensation only for death, personal injury and damage to consumer property. The Environmental Liability Directive[21] establishes a framework to prevent and remedy environmental damage. It deals with pure ecological damage such as damage to protected species and natural habitats as distinct from damage to privately owned property, which is covered by the PLD.

1.2.3. Interplay of PLD with other EU legislation

Product safety framework: EU product safety legislation aims to ensure that only safe products are placed on the internal market. If they are covered by sectoral legislation (e.g. on machinery, pharmaceutical products, toys, radio equipment) they have to comply with essential health and safety requirements set out there. Otherwise they fall under the General Product Safety Directive[22] and are required to be safe[23]. Safety rules are

[17] Note that alongside fault-based liability, all Member States have strict liability regimes where fault does not need to be proven, for example regimes covering the ownership of dangerous things such as motor vehicles.
[18] Directive (EU) 2019/771 on certain aspects concerning contracts for the sale of goods.
[19] Directive (EU) 2019/770 on certain aspects concerning contracts for the supply of digital content and digital services.
[20] Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR).
[21] Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage.
[22] Council Directive 87/357/EEC and Directive 2001/95/EC
[23] Beyond sectoral legislation and the GPSD, there is also technology-specific but horizontal product safety legislation, notably the proposed AI Act, see section 1.2.5.

enforced by market surveillance rules[24], which ensure consumer protection by stopping non-compliant products circulating or by bringing them into compliance. Product safety legislation does not contain specific provisions on liability of manufacturers, but make reference to the fact that the PLD applies when a defective product causes damage. Product safety and product liability are therefore complementary mechanisms for achieving a functioning single market for goods that ensures high levels of safety.

Cybersecurity: The Cybersecurity Act[25] and the recently adopted delegated act[26] under the Radio Equipment Directive[27] are intended to mitigate cybersecurity risks, but they do not regulate the liability of producers. In addition, the Commission is preparing a Cyber-resilience Act[28], which would build on existing rules to encourage manufacturers and software developers to mitigate cybersecurity risks, but is not expected to touch on liability.

1.2.4. Interplay with ongoing initiatives

The proposed Machinery Regulation[29] and proposed General Product Safety Regulation[30] (GPSR) aim, in their respective fields, to address the risks of digitalisation in the area of product safety, but not liability. The proposed Digital Services Act[31] (DSA) sets out rules for online intermediary services, including online marketplaces. The proposal for a GPSR imposes additional obligations on them to tackle the sale of unsafe products online. None of these measures concern liability for defective products under the PLD.

The Circular Economy Action Plan 2020[32] announced a sustainable products policy framework intended to provide high-quality, functional and safe products designed for reuse, repair, remanufacturing and high-quality recycling. The Action Plan does not contemplate measures on liability for defective products.

1.2.5. Specific interplay with the Artificial Intelligence Act and the impact assessment on AI liability

The proposed Artificial Intelligence Act[33] aims to ensure that high-risk AI-systems comply with safety and fundamental rights requirements (e.g. data governance, transparency, human oversight) before being placed on the market or put into service within the EU. However, there is no corresponding liability of the AI-system provider under the PLD when an AI system is defective and causes harm, because they do not fall clearly under definition of "producer" in the PLD. This is because AI systems themselves

[24] Established by Regulation (EU) 2019/1020 on market surveillance
[25] Regulation (EU) 2019/881 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (Text with EEA relevance), OJ L 151, 7.6.2019, pp. 15-69.
[26] Commission Delegated Regulation (EU) 2022/30 of 29 October 2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive
[27] Radio Equipment Directive 2014/53/EU, Article 3(3)(e) and Article 3(3)(f).
[28] How a European Cyber Resilience Act will help protect Europe, European Commission (europa.eu).
[29] COM(2021) 202 final.
[30] COM(2021)346 final.
[31] Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC, COM(2020) 825 final
[32] Circular economy action plan, March 2020

[33] Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (AI Act), COM(2021)206 final.

do not fall clearly within the outdated definition of "product" in the PLD, which is true of other software too, not only AI systems. And, while products that make use of AI systems, such as robots, are obviously products within the meaning of the PLD, the PLD is not well adapted to dealing with such products, nor other products in the digital age (see Problem 1 below).

The Commission is taking a holistic approach to liability through the revision of the PLD on the one hand (the subject of this impact assessment), and AI-specific measures concerning national liability rules on the other (the subject of the AI liability impact assessment). The interplay between the two impact assessments is depicted in the table below and the rationale is explained in section 1.2 of the AI liability impact assessment.

Table 2. Interplay between PLD impact assessment and AI impact assessment

	PLD IA: horizontal (i.e. not AI-specific) problems & measures	AI IA: AI specific problems & measures
Scope	All products (including AI-enabled products and AI systems themselves)	AI-enabled products and AI-systems themselves, and actions or omissions linked to AI, including AI-enabled services
Liable person	Producer (manufacturer, importer)	Any wrongdoer: producer, service provider, user (both businesses and private persons), owner, etc.
Current type of liability (see table 1 above)	Harmonised no-fault liability based on defect	Non-harmonised national liability based on fault and, in some cases (e.g. for dangerous things like vehicles or drones) strict liability

The current PLD applies to a vast range of products from raw materials to cancer medicines. It also applies to AI-enabled products, like robots, but the PLD is not well adapted to dealing with them. The revised PLD will adapt the rules for such products and ensure people injured by defective software, including AI software, can get compensation from software producers. The AI liability initiative also covers AI-enabled products and AI software, so the product scope of two impact assessments overlap. However, **the two initiatives apply in different legal situations: The PLD, which is the EU's harmonised no-fault liability regime, exists in parallel to Member States' fault-based liability regimes.** The AI liability initiative creates no new route to compensation, it only facilitates the existing national route based on fault, and hence does not introduce any overlap with claims under the PLD.

The two impact assessments address measures to ensure legal certainty and effectiveness of all routes to compensation: both under the PLD and under national liability rules. Cross-references are made throughout the impact assessments where necessary to explain the interplay.

2. PROBLEM DEFINITION

2.1. What are the problems?

The evaluation of the PLD found that, while the Directive was on the whole effective, its effectiveness was hampered by outdated concepts that are unclear when applied to the modern economy and by an unfair balance of interests between producers and consumers in some respects.

The PLD reinforces the EU's product safety rules by providing an additional incentive for producers to place only safe products on the market in order to avoid liability (product liability law's "deterrent effect"[34]). If, despite all the precautionary safety rules, a product is not safe and causes damage, the PLD helps injured parties to get compensation.

The PLD has a wide scope, potentially affecting the entire manufacturing sector as defined in the NACE classification. However, according to the 2018 evaluation study, in the reporting period (2000-2016), there were only 798 court cases based on product liability rules in EU27, with 50-60 cases per year. Around 60% (476 out of 798) of claims for defective products were successful for injured parties from 2000 to 2016[35]. The other cases were decided in favour of producers. The evaluation study acknowledged that this was likely an underestimate[36]. This is due to the difficulty of obtaining comprehensive data on the use of the PLD: out-of-court settlements are often on confidential terms, arbitration or mediation cases and many lower-court cases are often not published at all, and there is no monitoring at national level. This impact assessment and the accompanying study confirmed the lack of data on the number of cases of harm caused by defective products as well as the lack of a common injury database with meaningful information[37]. More information and estimates are provided in section 5.1 and in annex 4.

The evaluation study found that 52% of cases relate to products in the categories of raw materials, pharmaceutical products and vehicles. In general, the parties settle product liability-related claims through direct negotiation in 46% of cases, whereas 32% are resolved in court and 15% through mechanisms for alternative dispute resolution. Only a small share (7%) of claims under the Directive is decided through other means, such as settlements with the insurer of the responsible party[38].

The 2018 evaluation found that, in total, 79% of producers overall have product liability insurance[39]. This means that if a producer is found liable for a defective product and has to compensate a victim, the compensation pay-out will be covered by product liability insurance for c.a. 80% of all producers.

Based on the evaluation findings, two main problems have been identified. They are summarised in the below table with respective drivers and consequences of the problems.

Drivers - regulatory failures	Problems	Consequences
1.Liability rules unclear for products in the digital age - no liability for defects that emerge after product is marketed, including defective updates and cybersecurity vulnerabilities - unclear application to software and ancillary digital services - new types of damages such as damage to digital property are not covered	**1. Certain products, economic actors and damage in the digital and circular economy escape no-fault liability**	FOR INTERNAL MARKET 1. Less incentive to market safe products for economic actors who impact safety but are not covered by regime. (Driver 1) 2. Unequal levels of consumer protection across EU (D1) 3. Consumers who are unsure of rights may not adopt innovative or "circular" products. (D1, 2) FOR BUSINESSES 4. Businesses unable to assess risk of liability due to

[34] John C.P. Goldberg, Twentieth-Century Tort Theory, 91 GEO. L.J. 513 (2003).
[35] The evaluation study found that there was no particular difference in the level of success of injured parties if the case is settled in court rather than out of it.
[36] Evaluation of Product Liability Directive, SWD(2018)157, p. 21.
[37] Geiss, O. et al. (2016), Injury and accident data collection efforts in Europe in support of consumer product safety policy.
[38] Evaluation of Product Liability Directive, SWD(2018)157.
[39] Evaluation of Product Liability Directive, SWD(2018)157. General product liability insurance policies covers products' strict liability, contractual liability and fault-based liability, such as negligence.

2.Liability rules unclear for refurbished/remanufactured products **3.**No liable person under PLD when consumer purchases product from a 3rd country directly		uncertainty and different interpretations in every MS (D1,2) 5. Businesses face unfair competition from 3rd-country producers who are beyond the reach of the PLD (D3) FOR CONSUMERS 6. Consumers less able to get compensation for defective products using digital technologies or "circular" products. (D1, 2) 7. Consumers left without compensation when purchasing from a 3rdcountry directly (D3) ENVIRONMENT Uncertainty may have negative impact on growth of circular economy (D2)
4.Proving defectiveness and causal link with damage is very difficult and costly for complex products: - No right for victims to access necessary technical information held by producer - No explicit possibility to ease the burden of proof under the PLD - Liability for undiscoverable defects is uncertain (e.g. machine learning) Liability claims are subject to a number of restrictions: **5.**Liability ends after 10 years; need to start legal proceedings 3 years after damage **6.**No liability for property damage worth less than EUR 500	**2. Consumers face obstacles to getting compensation**	FOR INTERNAL MARKET 1.Unequal levels of consumer protection across EU (including divergent national implementation) (Drivers 4,6+D1) FOR BUSINESSES 2.Uncertainty due to fragmentation could chill willingness to place innovative products on the market (D4+D1,2) FOR CONSUMERS 3. Difficult and costly to get compensation for harm caused by complex products (D4) 4.Invidual victims may unfairly bear risk of damage from undiscoverable defects (D4) 5.Victims of harm that emerges after 10 years get no compensation. (D5) 6.Victims of harm who miss 3-year deadline to start legal proceedings get no compensation. (D5) 7.Consumers who suffer property damage less than EUR 500 get no compensation. (D6)

1. Products, economic actors and damage escaping no-fault liability in the digital and circular economy

No-fault liability of producers was introduced as a necessary response to the risks inherent in technological production in the 20th century. Products and technologies have continued to develop since the PLD was enacted in 1985 but the rules have not. The safety of products, be they robotic lawnmowers, connected or autonomous vehicles or smart home systems, is determined more and more by software and digital services that may be supplied once a product is already on the market. As the evaluation has shown, the PLD is no longer adapted for products in the digital age in a number of respects. In the digital age, the features of a product are not set in stone when it is put into circulation, but are determined by software and digital services after that moment, which may be provided by economic operators other than the producer of the "finished product".

Clarity on how liability rules apply to software is all the more important considering the software industry is a growth sector: the industry in Germany was expected to grow from EUR 18 billion to EUR 20 billion between 2018 and 2021[40]. The safety of products with digital elements also depends on cybersecurity: lack of adequate cybersecurity is one of the barriers that limits the uptake of new technological developments. According to Eurostat, one person out of ten in the EU-27 does not use IoT devices due to cybersecurity concerns, while in Austria, Germany, Finland and Portugal the percentage

[40] Annual growth rate of 2.9%; Netherlands: EUR 5.4 billion to EUR 6 billion (3.7%); Poland: EUR 2.1 billion to 2.4 billion (4%). See CSES with Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive, section 2.1.1.1.

is over 20%.[41] The PLD's ill-adaptedness to new technologies is in part evidenced by the fact that the evaluation found only one case relating to new technological developments in the reporting period[42]. As these developments gather pace, the lack of future-proof rules is likely to further undermine the effectiveness of the PLD (see section 2.3).

In the circular economy too, products may be modified by refurbishers and remanufacturers and placed back on the market, but the PLD is silent on whether such economic operators are subject to no-fault liability. Uncertainty makes it difficult for businesses to assess their liability exposure and may have negative effects on the growth of the circular economy.

And new global supply chains that make it possible for consumers to purchase products directly from non-EU producers have led to a situation where no EU-based economic operator is subject to no-fault liability in the event of defective products causing harm. This leaves consumers with no one to get compensation from under the PLD and creates an uneven playing field between EU producers and non-EU producers who are beyond the reach of the PLD.

The consequences of all the above economic operators escaping no-fault liability are various: the deterrence function of the PLD[43], designed to encourage producers to do their best to make products safe, is missing; no-fault liability is shouldered instead by other economic operators (principally hardware manufacturers) who may not be best placed to minimise software-related safety risks; competition between market operators is distorted, since producers of hardware products and components *are* subject to no-fault liability; levels of consumer protection across the EU are unequal, since some Member States do impose no-fault liability outside of the PLD regime for digital services necessary for products to operate; and consumers face uncertainty about how to get compensation for harm caused by digital and refurbished or remanufactured products and from whom. Nevertheless, it is worth mentioning that the effect of certain products, economic actors and damage falling outside of the PLD's no-fault liability regime does not mean a complete absence of compensation for victims of harm: national regimes provide for extra-contractual liability for fault or negligence. But the difficulties involved in proving fault were precisely the rationale for introducing no-fault liability for producers in the first place by the PLD (see section 1.2 for more details). The existence of alternative routes to compensation makes consumer protection more comprehensive, but it makes it very difficult to quantify the added value of no-fault liability. At the same time, economic operators usually have an insurance policy covering all type of potential liability claims. (The impact assessment on AI liability looks at challenges in proving fault specifically when certain AI systems are involved.)

1. Consumers face obstacles to getting compensation

The PLD seeks to achieve a fair balance of interests between consumers and producers, and the importance of this balance has been stressed in every application report since 2001. Whereas producers shoulder liability irrespective of fault, claimants shoulder the burden of proof and face time limits and thresholds. The 2018 evaluation found that the

[41] Eurostat, Internet of Things - barriers to use, 2020 (consulted on 22 November 2021).
[42] Evaluation of Product Liability Directive, SWD(2018)157, p. 12.
[43] Confirmed in Joined Cases C-503/13 and C-504/13, Boston Scientific Medizintechnik GmbH; see also P. Machnikowski (ed.), European Product Liability: An Analysis of the State of the Art in the Era of New Technologies (2016), p. 100.

balance struck in the current PLD was not always fair to consumers, due to the difficulties in proving liability when complex products cause harm, and due to the time limits and thresholds that disproportionately restrict the number of claims[44].

Stakeholders have deeply conflicting views, with a sharp divide between consumer and industry positions. Industry stakeholders, exemplified by Business Europe[45], consider the current balance to be just right. They acknowledge that complex products may present challenges for consumers, but argue that national courts have the possibility to ease the burden of proof where necessary, although the pharmaceuticals industry organisation EFPIA considers some national courts have gone too far, thus undermining the balance[46]. Consumer organisations, on the other hand, argue it is difficult and costly to get compensation for harm caused by complex products; that individual victims unfairly bear the risk of damage from new technologies whose defects are undiscoverable when the product is put into circulation; and that time limits and thresholds prevent access to justice. They also argue that the challenges for consumers will only get worse as products become ever more complex.[47].

2.2. What are the problem drivers?

2.2.1. Problem 1: Certain products, economic actors and damage in the digital and circular economy escape no-fault liability

1.1.1.1. Liability rules not adapted for products in the digital age

The PLD allows a producer to escape liability if the producer can prove that a defect that causes damage probably came into being after the product was put into circulation[48]' (the "later-defect defence"), because it is traditionally at that moment that the product leaves the producer's control. This logic no longer reflects the reality of products in the digital age. Producers of such products often retain control of them after they are put into circulation, either by providing updates, delivering new functionalities through upgrades, or supplying digital services in the form of continuous updates in order to make, say, an autonomous vehicle or smart domestic appliance function. Software updates themselves can be defective, and have been identified by the EU Agency for Cybersecurity as the main causes of non-malicious security threats to IT systems and applications[49].

While providing defective updates can compromise product safety, so too can failure to provide them, especially when it comes evolving cybersecurity threats. For example, a cyber-attack may target a vulnerability in a machinery product's software that makes the machinery malfunction and injure the user. Lack of adequate cybersecurity is one of the barriers that limits the uptake of new technological developments. In recognition of this, economic operators are now required to provide software and security updates to ensure the ongoing safety of products after they are placed on the market[50]. So software updates

[44] Evaluation of Product Liability Directive, SWD(2018)157, p. 61.
[45] Position paper of Business Europe in response to public consultation, p. 4.
[46] EFPIA, European Federation of Pharmaceutical Industries and Associations, Position paper in response to public consultation, p. 8.
[47] BEUC (2020). Product Liability 2.0 - How to make EU rules fit for consumers in the digital age. BEUC-X-2020-024 - 07/05/2020.
[48] Article 7(b) of the PLD.
[49] European Union Agency for Cybersecurity (ENISA) (2021). ENISA threat landscape 2021, p. 82
[50] Directive (EU) 2019/771 on certain aspects concerning contracts for the sale of goods, Art. 7(3). Other legislation requires manufacturers to take corrective measures if a product is no longer safe, which could include corrective

are not only necessary to keep products safe, they are also required by legislation, yet the later-defect defence exonerates producers from liability under the PLD. The digital security industry (Eurosmart) has argued that the "later-defect defence" makes the concept of no-fault liability meaningless when applied to smart/connected products and AI systems that could let vulnerabilities emerge only after the placement of a product on the market.[51]

But who *is* liable for harm caused by defective software, software updates and digital services that make products work[52]? BEUC, the consumer organisation, considers the uncertainty around this question most problematic when it comes to 3rd-party software downloaded separately and added to hardware, for example a software upgrade or an entirely new software module in a domestic robot[53]. The hardware manufacturer could invoke the later-defect defence, and the software manufacturer could argue that software is not a product and that no-fault liability therefore does not apply to him. This crucial question of whether software is a product is ambiguously answered by the PLD, which defines products simply as "movables". This led two Member States (Austria and Belgium) to interpret the PLD as applying only to tangible items: "tout bien meuble *corporel*"[54]. And this question around tangibility has generated decades of intense academic debate[55]. Economic operators too argue variously that only software physically embedded at the time the tangible product is put into circulation is covered, but not any subsequently downloaded software (e.g. updates/upgrades)[56]; some insist that software, even if provided separately from a tangible product, is already covered[57]; some insist software developers themselves currently qualify as producers; some argue the opposite[58].

This lack of clear liability for software providers undermines the original intention of the PLD to make "all producers involved in the production process liable[59], and is inconsistent with recent EU legislation and proposals which place obligations on software providers to ensure the safety of products[60]. For example, there are requirements for placing on the market software that is a medical device[61], separately marketed safety components for machinery[62] and AI systems[63]. (See also section 1.2).

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software updates, e.g. Regulation (EU) 2017/745 on medical devices, Art. 83(3)(e); Radio Equipment Directive 2014/53/EU, Article 3(3)(e) and Article 3(3)(f); COM(2021)346 final, Art. 7(1)(h) and recital 23.

[51] Position Paper of Eurosmart (2020) in response to public consultation, p. 3.

[52] Expert Group on Liability and New Technologies (2019), Report on Liability for artificial intelligence and other emerging digital technologies, p. 41.

[53] European Commission (2020), Report on the Safety and Liability Implications of Artificial Intelligence, the Internet of Things and Robotics. P.13; Vellinga, N. (2019), Automated Driving: Liability of the Software Producer and the Producer of the Automated Vehicle. University of Groeningen. Social Science Research Network Electronic Paper Collection; Wagner, G., (2018) Robot Liability, p.11.

[54] Duncan Fairgrieve (2020), Product Liability, 3rd edition, p. 292.

[55] See P. Machnikowski (ed.) (2016), European Product Liability: An Analysis of the State of the Art in the Era of New Technologies, p. 46 for an overview.

[56] Response to inception impact assessment, June 2021: BSA – Software Alliance.

[57] Response to inception impact assessment, June 2021: MedTech Europe, Siemens Healthineers.

[58] Response to inception impact assessment, June 2021: Google.

[59] Product Liability Directive, 4th recital.

[60] Christiane Wendehorst (2020), Study on Safety and Liability Related Aspects of Software, p. 82.

[61] Regulation (EU) 2017/745 on medical devices.

[62] COM(2021) 202 final.

[63] COM(2021)206 final.

Manufacturers of finished products and of hardware components[64] have argued that subjecting only hardware producers to no-fault liability is unfair, given that today's products operate in an ecosystem composed of hardware, software and ancillary services, which are difficult to distinguish one from another[65]. They argue that the safety of 3rd-party software updates or of a control app downloaded to a user's smartphone is outside of their control and they point to the key principle of product liability: that liability should be imposed on the party best able to minimise safety risks[66]. Industry associations in the automotive industry have noted that services and data can be crucial to the operation of a vehicle and its safety, such as geolocation data and its supply on a continuous basis in an autonomous vehicle[67]. Legal experts have pointed out that excluding software providers from no-fault liability is especially incongruous when the digital component is more important for the overall functioning of the product than the physical part itself. [68] This might be the case in IoT ecosystems, for example a smart home system, where software and digital services have a greater role in determining how safely the system works than the individual hardware components. It essentially leads to a narrowing the scope of the PLD as more and more products on the market are of a type that can be influenced by software or that relies on updates or digital services to operate[69]. This may explain why the evaluation identified only one court case in the period 2000-2018 in which a consumer sought compensation under the PLD for software-related harm[70].

Representatives of the software industry, however, have argued that shielding software providers from no-fault liability is justified since software providers cannot control how their software will be used[71]. It seems the same could be said of any component, however. They have also argued that a hardware manufacturer who has paid out compensation can claim that back from software providers through contractual agreements, if the software was to blame for the harm. Hardware manufacturers, however, have stressed that it can be difficult to pursue such claims under contract law since software producers may insist on liability being excluded by contract[72].

While the focus above has been on software and digital services responsible for the safe operation of hardware, software itself may also cause personal injury or property damage. For example, a medically-approved smartwatch app intended to send an alarm notification to the user or doctor when it recognises irregular heartbeats could defectively fail to do so, leading to injury[73], or a defective app or computer programs could cause a

[64] For example ACEA (car manufacturers), APPLiA (domestic applicance manufacturers), CLEPA (automotive suppliers).
[65] European Commission (2020), Report on the Safety and Liability Implications of Artificial Intelligence, the Internet of Things and Robotics, p.61; For more detailed information about servitisation of the European economy: European Commission (2018), Study on the potential of servitisation and other forms of product-services provision for Eu SMEs
[66] Gerhard Wagner, Robot Liability (2018), Paper based on a presentation at the Münster Colloquium on EU Law and Digital Economy, Liability for Robotics and the Internet of Things
[67] Feedback to inception impact assessment from: CLEPA (European Association of Automotive Suppliers) (europa.eu).
[68] Twiggs-Flesner, C., (2021), Guiding Principles for Updating the Product Liability Directive for the Digital Age. ELI Innovation Paper Series, p. 5
[69] P. Machnikowski (ed.) (2016), European Product Liability: An Analysis of the State of the Art in the Era of New Technologies, p. 691, and at ELI Webinar on Guiding Principles for Updating the Product Liability Directive for the Digital Age, 23 February 2021.
[70] EY, Technopolis, VVA (2018), Study accompanying Evaluation of Product Liability Directive, p. 24.
[71] Response to inception impact assessment, June 2021: Bitkom and BSA – Software Alliance.
[72] Interview with representative of automotive suppliers in the context of the supporting impact assessment study.
[73] Christiane Wendehorst (2020), Study on Safety and Liability Related Aspects of Software, p. 50.

computer battery to overheat or explode[74]. In neither case could the software manufacturer currently be held liable under the PLD.

What about types of harm other than personal injury and property damage? The 2018 evaluation highlighted that products using digital technologies are capable of causing a broader range of harm than traditional products, in particular **a)** damage to a user's digital property, and **b)** infringement of personality rights such as privacy or discrimination[75].

Damage to digital property[76]: The PLD covers damage to items of consumer property, but not all Member States' legal systems treat intangible goods as property[77]. For example, if an external hard-drive is defective and erases all digital content from the computer's hard-disk without physically damaging the computer itself, in some Member States the consumer can seek compensation under the PLD for the resultant economic loss e.g. restoring the digital content or purchasing new software licences[78], but in others only if the hard-disk itself were physically damaged[79]. In a case in Bulgaria, a defective hard-drive erased digital content from the claimant's computer and the damage was in principle deemed recoverable by the court, although the claimant could not prove the digital content had been stored on the computer[80]. The increasing prevalence of connected devices and cybersecurity risks may make this sort of damage to digital property more common[81], although EU rules on product safety[82] and on cybersecurity[83] should mitigate these risks through tougher cybersecurity requirements. It should be recalled, however, that the PLD acts as a safety net when, despite the safety rules, harm occurs. BEUC, the consumer organisation, considered the lack of common approach to compensating such losses problematic, because of the unequal protection of consumers across the Union[84].

Losses due to infringement of fundamental rights: A novelty of products in the digital age, in particular wireless/IoT products, such as connected toys like the Cayla doll[85], or smart meters, is their use of personal data, which, if not protected, could cause harm such as mental suffering[86]. The impact assessment study found that in almost all scenarios of data protection failings, a controller would be identifiable and the GDPR would provide a route to compensation. This might, however, not be the case if, say, a baby monitoring

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[74] Position paper in response to public consultation: Civil liability – adapting liability rules to the digital age and artificial intelligence.
[75] Evaluation of Product Liability Directive, SWD(2018)157, p. 56.
[76] Protection of personal data, which is not considered as property under Union law, is addressed under "losses due to infringements of fundamental rights".
[77] Under German law (Art. 90 BGB) a thing must be corporeal, whereas under Austrian law (Art. 285 ABGB) a thing may also be intangible; See also Expert Group on Liability and New Technologies (2019), Report on Liability for artificial intelligence and other emerging digital technologies, p. 19.
[78] Expert Group on Liability and New Technologies (2019), Report on Liability for artificial intelligence and other emerging digital technologies, p. 59
[79] Position paper of Insurance Europe in response to public consultation, p. 2: Civil liability – adapting liability rules to the digital age and artificial intelligence
[80] Bulgarian case no. 20942/2012. Reported in Evaluation of Product Liability Directive, SWD(2018)157, p. 12.
[81] See for instance:
https://www.taylorwessing.com/en/insights-and-events/insights/2021/04/product-liability-for-an-iot-data-breach
[82] COM(2021)346 final, Art. 7(1)(h).
[83] Regulation (EU) 2019/881; Also GDPR mandates data accuracy and integrity (Art. 5(1)(d) and (f).
[84] BEUC (2020). Product Liability 2.0 - How to make EU rules fit for consumers in the digital age. BEUC-X-2020-024 - 07/05/2020, p. 15.
[85] German regulator bans spying doll Cayla | www.beuc.eu.
[86] e.g. due to a stranger communicating with a child through a doll.

camera were operated by a natural person without personal data being processed by a responsible controller/processor. In such a situation, if a security vulnerability made it possible for other individuals to watch the live feed from this device, the processing of personal data might fall under the GDPR's so-called household exemption[87], meaning no compensation under the GDPR. Manufacturers of IoT products – in that example the producer of the camera – will be obliged under a recently adopted delegated act[88] to equip their devices with features to guarantee the protection of personal data and privacy. BEUC, the consumer organisation, has argued that the PLD should apply in such cases and whenever flaws in IoT products lead to privacy infringements[89]. Industry stakeholders have pointed out that the victim would have a claim under national tort law or contract law against the camera manufacturer.

Besides privacy, digital technologies can lead to infringements of other fundamental rights. The draft AI Act lays down rules to minimise the risk of AI systems taking erroneous or biased decisions in critical areas such as education, training or employment that could lead to economic loss or emotional harm, e.g. failure to get a job due to biased AI recruitment software or failure to get a loan due to biased credit-rating software. Several stakeholders considered it would be difficult to get compensation for software-induced discrimination, although they pointed to the significant role of the user of the software and not only the producer, and therefore questioned whether this was a problem to be addressed under the PLD[90]. (The impact assessment on AI liability looks more closely at liability rules for discrimination caused by AI-systems.) Also concerning damages: See annex 5 concerning a clarification for psychological harm damages.

1.1.1.2.Liability rules unclear for refurbished/remanufactured products

Circular business models in which products are refurbished or remanufactured are increasingly common and central to the EU's efforts to achieve sustainability and waste-reduction goals. However, as explained in section 2.2.1.1, under the PLD the original manufacturer is not liable for defects that emerge after a product is put into circulation and the PLD is silent on whether economic operators who modify products and put them back on the market can themselves be treated as producers and therefore subject to no-fault liability. The aerospace, automotive and heavy-duty equipment sectors make up more than 80% of the European remanufacturing industry, and electrical and electronic as well as medical equipment have witnessed an expansion in demand[91]. In the medical devices sector alone, the market for refurbished and remanufactured products is estimated to be EUR 600 million/annum in the EU, and is divided roughly equally between original equipment manufacturers and 3rd-party refurbishers[92].

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[87] Article 2(2) of GDPR; Example scenario provided by JRC.

[88] Commission Delegated Regulation (EU) 2022/30 of 29 October 2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive.

[89] BEUC (2020). Product Liability 2.0 - How to make EU rules fit for consumers in the digital age. BEUC-X-2020-024 - 07/05/2020, p. 15.

[90] Position paper in response to public consultation of Austrian Bundesarbeitskammer; Civil liability – adapting liability rules to the digital age and artificial intelligence; and feedback on inception impact assessment from: Future of Life Institute.

[91] ERN (2015), Remanufacturing Market Study (for Horizon 2020, grant agreement No 645984), p. 42

[92] Estimate provided by COCIR, European trade association representing the medical imaging, radiotherapy, health ICT and electro-medical industries; see case study on medical devices in the circular economy annexed to supporting impact assessment study.

Remanufacturing and refurbishing are industrial practices in which a product is returned to at least its original performance to match the original manufacturers' specifications[93], and involves various steps such as disassembly, cleaning, repair/replacement of components, reassembly and testing, before the product is put back into circulation[94]. Stakeholder feedback confirmed that both original manufacturers and refurbishers/remanufacturers face legal uncertainty as to the extent of their liability exposure[95]. The home appliance industry noted that clearer rules would give original manufacturers confidence to allow independent third-party operators to carry out refurbishments[96].

The question of who is responsible for the safety of modified products has been addressed in the Commission's "Blue Guide" on the implementation of EU product safety legislation: an economic operator who makes important changes to or who overhauls a product should be seen as putting a new product into circulation and should be responsible for safety compliance[97]. This concept of "substantial modification" has been integrated into legislation and legislative proposals in recent years[98] and the Medical Devices Regulation explicitly includes economic operators who fully refurbish devices in its definition of manufacturer[99]. While there is no evidence of victims currently going uncompensated for damage caused by substantially modified products, the existing liability rules are not future proof or coherent with this legislation, as the notion of substantial modification is absent from the PLD.

In contrast to situations of substantial modification, the mere repair of products does not create uncertainty for the application of liability rules. A repair is rather an individualised service, in which a product is returned to working order and then typically given back to the owner. There is no new product and there is no new distribution, so no grounds for product liability to be triggered. Repairers can of course be found liable under national fault-based rules, however, for undertaking a faulty repair.

1.1.1.3. No liable person under the PLD when consumer purchases product from a 3rd country directly

Alongside the producer, which includes own-branders, importers are also liable for product defects under the PLD. The rationale for this is that enforcing a compensation claim against a producer in a third country would present consumers with insurmountable difficulties.[100]

The emergence of e-commerce is a major global development of the last few decades, but for the most part buying online is analogous with buying offline and the PLD applies equally well: producers and importers are treated the same whether a purchase was made online or offline. However, online marketplaces now also make it possible for consumers to purchase products directly from non-EU producers without the involvement of an EU-

[93] ERN (2015), Remanufacturing Market Study (for Horizon 2020, grant agreement No 645984), p. 7; BS 887-Part2.
[94] PWC for DG GROW (2017), Refurbishment of medical equipment (report on promising KETs-based product nr. 4)
[95] See for example position papers of Business Europe, Mouvement des Entreprises, European Law Institute and Finnish Competition and Consumer Authority in response to the public consultation.
[96] Response to targeted survey: APPLiA, trade association representing manufacturers of home appliances.
[97] Commission Notice (2016), The 'Blue Guide' on the implementation of EU products rules 2016, p. 15 to 17.
[98] Proposal for a Regulation of the European Parliament and of the Council on machinery products, COM(2021)202; proposal for a Regulation on General Product Safety (GPSR), COM(2021)346.
[99] Regulation (EU) 2017/745 on medical devices, Art. 2(1)(30).
[100] Explanatory Memorandum of PLD, Supplement Bulletin EEC 1976_11, para 10.

based importer. In such cases, if a product is defective and causes harm, there is no EU-based liable person from whom to seek compensation under the PLD. 64% of respondents in the public consultation agreed there was a need to adapt liability rules where there is no EU importer[101].

Such "direct imports" have increased in recent years: around 150 million small consignments are imported free of VAT into the EU each year[102] and it has been reported that in 2017 there were 150 000 private consignments coming from China to individual consumers per day[103]. The problem is expected to be mitigated by upcoming legislation. To better ensure the safety of "directly imported" products, the draft Digital Services Act[104] requires online marketplaces that intermediate sales between sellers and consumers to collect information on sellers using their marketplace and suspend services to the seller if they fail to disclose requested information. The already in force Market Surveillance Regulation[105] requires an responsible person (either a manufacturer, importer, authorised representative or fulfilment service provider) to be established in the EU in order for certain products within its scope to be placed on the market, and the proposal for General Product Safety Regulation proposes to extend this requirement to all products. These measures can be expected to reduce the risk of dangerous products reaching the internal market. However, if harm does occur, compensation would not be available under the PLD as authorised representatives and fulfilment service providers are not among the liable persons covered by the PLD. Other means of compensation could be available under national liability rules, but only on grounds of fault or negligence.

See Annex 5 for details of clarifications needed on the role of online marketplaces.

2.2.2. Problem 2: Consumers face obstacles to getting compensation

1.1.1.4. Proving defectiveness and causal link with damage is very difficult and costly for complex products

The most significant condition for an injured person to get compensation under the PLD is proving that the product was defective and that this defectiveness caused the damage suffered. Failure to discharge this burden of proof is the most frequent reason for a claim to be rejected (accounting for 53% of total rejections)[106].

There is by and large consensus among stakeholders that the more complex a product is, the greater the asymmetry of information between the producer and consumer. This can make it harder for claimants to produce the evidence needed to prove the producer's liability: whereas proving a collapsed garden chair is defective might be straightforward, proving a pharmaceutical is defective may require considerable expertise, which the producer has at its disposal but the claimant does not. Stakeholders disagree on the extent of the problem: 98% of consumer and NGO respondents and members of the public

[101] 63.9% (179 out of 280) agreed or strongly agreed; 20% (56 out of 280) disagreed or disagreed strongly.
[102] European Commission (2017), Modernising VAT for e-commerce
[103] Eurocommerce (2019), Creating a level-playing field for retail in Europe.
[104] COM(2020) 825 final, Art. 5.
[105] Regulation (EU) 2019/1020 on market surveillance.
[106] Evaluation of Product Liability Directive, SWD(2018)157, p.23

consider that technically complex products present, to a large or very large extent, difficulties for proving liability, whereas as only 45% of business respondents do[107].

Difficulties getting information. Claimants have no right under the PLD to get technical information from producers in court[108]. However, the ECJ has noted that access to information makes it easier for a claimant to produce the necessary evidence to prove the producer's liability, and has endorsed national rules that give claimants this right. Based on data from 24 Member States, the support study for this impact assessment found that all but one (CZ) had some rules in place for disclosure of documents in court. The rules vary, however, in terms of what can be requested: in SE any document can be requested, whereas in DE, EL, IT, NL and PL the specific document has to be named; failure to disclose information can result in a penalty in FR and PL, whereas in DE the element the claimant was seeking to prove can be presumed by the court. The level of consumer protection in terms of information rights is therefore divergent across the EU[109].

Difficulties proving liability. Even if a claimant gets the information, proving liability can still be difficult. This is demonstrated by the fact that national courts make use of various mechanisms to make it easier for claimants to come up with the proof. National courts have, for example, held that products that do not comply with safety requirements can be presumed to be defective[110], and claimants do not need to show *how* a defect was caused or what specific defect led to the lack of safety[111]. National courts have referred questions on how to apply the PLD's burden-of-proof rules three times in the last 10 years[112]. In response, the ECJ has endorsed national rules that allow courts to presume the existence of a causal link even if there is no conclusive evidence, so long as the factual evidence available was sufficiently robust[113]. It has also ruled that a pacemaker could be considered defective without proof of actual defect by virtue of being from the same production series as another pacemaker already proven to be defective[114]. The ECJ has therefore endorsed efforts of national courts to make it easier for claimants to produce the evidence needed to prove the producer's liability.

Industry stakeholders such as Business Europe[115] argue that national courts have shown they have the tools they need to ease the burden of proof where necessary. EFPIA argues that some national courts have already gone too far in easing the burden of proof and the inconsistency of approaches is negative[116]. Consumer organisations[117] argue that while the ECJ judgments on information obligations and easing the burden of proof are to be welcomed, they do not go far enough in helping consumers to prove liability, especially

[107] 97.1% (135 out of 139) compared with 44.6% (45 out of 101).
[108] CJEU, Judgment of 20 November 2014, *Case C-310/13*.
[109] CSES, Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive, Annex 4.2.
[110] European Commission (2020), Report on the Safety and Liability Implications of Artificial Intelligence, the Internet of Things and Robotics. P.14
[111] Defectiveness could be inferred by the fact that the susceptibility (in this case brakes that seized without warning) was not present in other bikes of the same type; see Baker v KTM Sportmotorcycle UK Ltd and another (2017), EWCA Civ 378.
[112] CJEU, Judgment of 20 November 2014, *Case C-310/13*; CJEU, Judgment of 21 June 2017, *Case C-621/15*; CJEU, Judgment of 5 March 2015, Joined Cases *C-503/13* and *C-504/13*.
[113] CJEU, Judgment of 21 June 2017, *Case C-621/15*; the case turned on whether a causal link between a vaccine and the onset of multiple sclerosis could be inferred from the fact that the disease manifested itself shortly after injection and there were no family antecedents related to the disease.
[114] Joined Cases C-503/13 and C-504/13.
[115] Position paper of Business Europe in response to public consultation, p. 4.
[116] Position paper of EFPIA, European Federation of Pharmaceutical Industries and Associations in response to public consultation, p. 8.
[117] Position paper of BEUC, the consumer organisation, in response to public consultation, p. 7.

in complex cases – consumer protection is therefore insufficient and uneven across the internal market. The European Group on Tort Law consider the fact that courts take divergent approaches makes future court decisions unpredictable, which is a problem for legal certainty. See also Annex 8 concerning products that carry risks but are not defective.

Development risk defence: The development risk defence allows the producer to escape liability when the product was defective when put into circulation but the *'state of scientific and technical knowledge' at that time* did not allow for the particular defect to be discovered[118]. The PLD allows Member States to derogate from applying the defence: Finland and Luxembourg derogate entirely, while Spain, France and Hungary derogate in respect of certain categories of product[119].

Consumer organisations have, over many years, argued that the defence should be removed, since producers are always better placed than individual consumers to mitigate and insure against risks caused by their products, even if they were undiscoverable at the time the product was put into circulation[120]. Industry stakeholders have argued equally strongly in support of the defence designed to encourage innovation. The defence itself has rarely been used in practice though – successful use of the defence accounted for 4% of rejected claims [121]. The 2018 evaluation found that the development risk defence was an important factor for guaranteeing the relative stability of product liability insurance costs within the internal market while avoiding significant increases in litigation levels. It also found that whether or not a Member State had a derogation had little impact on the number of product liability cases in that country[122].

However, the Expert Group pointed out that assessing the state of scientific knowledge at the moment of putting into circulation fails to take account of the fact that producers retain control over digital products beyond that moment and therefore have the means to address defects that become discoverable[123]. This is true of many digital products, including IoT and AI-enabled products, as discussed in section 2.1.1.1.

1.1.1.5. Liability ends after 10 years; need to start legal proceedings 3 years after damage

Producers are released from liability under the PLD 10 years after putting the product into circulation: an unlimited period would be unreasonable, given that products age and higher safety standards are developed over time[124]. In addition, victims are required to start legal proceedings within three years of the day on which they became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.

The length of the periods, 10 years and three years respectively, represents an effort to balance the interests of producers and consumers. In respect of most products, the time limits does not seem to hamper the effectiveness of the PLD. The percentage of claims

[118] Art. 7(e), PLD.
[119] ES: pharmaceuticals and foodstuffs; FR: products of the human body, such as blood products; HU: pharmaceuticals.
[120] BEUC (2020). Product Liability 2.0 - How to make EU rules fit for consumers in the digital age. BEUC-X-2020-024 - 07/05/2020, p. 17.
[121] Evaluation of Product Liability Directive, SWD(2018)157, p.23
[122] Evaluation of Product Liability Directive, SWD(2018)157, p.31
[123] Expert Group on Liability and New Technologies (2019), Report on Liability for artificial intelligence and other emerging digital technologies, p. 6; also response of European Law Institute to the public consultation.
[124] Product Liability Directive, Article 11 and 11th recital.

rejected once proceedings were started is low: in respect of the 3-year time limit, 4%, and in respect of the 10-year time limit, residual[125]. However, this will certainly be an underestimate, since a claim would not be admissible in the first place if it could be shown that the 10-year period had expired.

In the public consultation 69% of non-business respondents argued the 10-year time limit presented obstacles to compensation to a moderate, large or very large extent, while 49% said the same of the 3-year time limit[126]. For business respondents the figures were 14% and 11% respectively[127]. BEUC and a French patient organisation[128]argue that the 10-year time limit is too short in respect of products capable of damage to health that becomes evident only after a long time, such as pharmaceuticals, chemicals, foodstuffs or construction materials like asbestos, and that this disproportionately limits access to justice. Pharmaceuticals, chemicals and foodstuffs account for 26.3% of product liability cases[129], or an average 12 cases per year, but long latency periods are very rare[130]. One example that representatives of pharmaceutical victims have pointed to is Sodium Valproate (Depakine), a medicine prescribed to pregnant women until 1971, has severe adverse effects, including for subsequent generations, which emerge after expiry of the 10-year period[131]. In such cases it is not possible to make a compensation claim under the PLD and a claimant would have to rely on fault-based national rules to seek compensation. The European Court on Human Rights too has ruled that time limits have consequences for access to justice. In respect of a Swiss law that set a 10-year limit for claiming compensation for diseases caused by asbestos, the Court ruled that applying the time limit "to persons suffering from diseases which could not be diagnosed until many years after the triggering events, was liable to deprive those persons of the opportunity to assert their claims before the courts"[132].

In respect of the three-year time limit to start legal proceedings, personal-injury lawyers[133] and a French patient organisation[134] argued it can be too short in the case of personal injuries, since gathering evidence before starting proceedings takes considerable time, and victims may be recovering from injuries during that period. However, the extent of this problem is mitigated by the fact that the PLD permits Member States to suspend or interrupt the three-year period according to their national rules, for example in the case of disability or where it is otherwise equitable to do so. No such possibility exists to extend the 10-year time limit.

1.1.1.6. No liability for property damage worth less than EUR 500

Producers do not have to provide compensation under the PLD for damage to consumer property amounting to less than EUR 500. The purpose of the threshold was to avoid excessive litigation and was conceived as part of the balance of producers' and consumers' interests. The 2018 evaluation found that the threshold overly limited claims

[125] Evaluation of Product Liability Directive, SWD(2018)157, p.28: 4 cases out of 798 reported cases.
[126] 125 and 90 out of the total 181 non-business respondents respectively.
[127] 14 and 12 out of the total 110 business respondents respectively.
[128] Responses of BEUC and France Assos Santé to the public consultation.
[129] 144 cases out of 547.
[130] Law Insider, Latent Injury Definition.
[131] France Assos Santé, response to Inception Impact Assessment, June 2021.
[132] Howald Moor and Others v Switzerland – 52067/10 and 41072/11 (ECHR 069-2014).
[133] Interviews conducted as part of the IA support study.
[134] Response of France Assos Santé to the public consultation.

for property damage, which undermined the effectiveness of the PLD in protecting consumer property[135].

BEUC[136], the consumer organisation, has argued that the threshold denies victims of property damage an effective remedy, a right enshrined in Article 47 of the Charter of Fundamental rights. The threshold also appears to be at odds with the objectives of the Directive on representative actions[137], which seeks to ensure an effective remedy for infringements that harm the collective interests of consumers, especially where individual claims might be considered small in isolation. That Directive explicitly lists PLD claims as falling within its scope[138], and yet the EUR 500 threshold excludes smaller claims from the outset.

In the public consultation, 78% of non-business respondents considered the threshold an obstacle to getting compensation to a moderate, large or very large extent, compared to only 16% of businesses respondents[139]. Indeed industry stakeholders have argued that consumers have other routes to effective remedies, such as under national tort law or contract law. This suggests, however, that the threshold has not achieved its aim of reducing overall litigation, but has merely displaced it away from the PLD[140].

In terms of consequences for the internal market, Romanian authorities have raised the concern that the impacts on consumer protection of a single fixed threshold across the EU vary widely depending on price levels for consumer goods in each Member State, because more consumer property falls below the threshold in cheaper Member States. In 2020 prices levels of consumer goods were almost three times higher in the most expensive Member State compared to the cheapest[141]. Besides objections to the threshold per se, the provision has been transposed divergently at national level. Most Member States allow the total amount of damages to be recovered once the claim exceeds EUR 500. Other Member States (AT, DE, DK, ES, FI, FR, IT) reduce all damages awarded by EUR 500. On the former interpretation, a claimant who has suffered EUR 800 worth of damage would be compensated for the full amount; on the latter interpretation only EUR 300. The different interpretations of this threshold evidently create differing levels of consumer protection within the internal market. Business stakeholders did not raise the different interpretations as a problem for them.

2.3. How will the problems evolve?

The transition to a digital economy is still in its infancy. As automation and digitalisation continue to advance, the role of software and digital services in determining the safety of products will increase. For example, the global market for autonomous cars amounted to USD 508 billion in 2015 and has grown at a compound annual growth rate (CAGR) of

[135] Evaluation of Product Liability Directive, SWD(2018)157, p.25. The impact assessment study could not find data on how many cases under the PLD concern property damage.
[136] BEUC (2020). Product Liability 2.0 - How to make EU rules fit for consumers in the digital age. BEUC-X-2020-024 - 07/05/2020, p. 16.
[137] Directive (EU) 2020/1828 on representative actions for the protection of the collective interests of consumers
[138] Annex I of Directive (EU) 2020/1828.
[139] 131 out of 167, and 16 out of 102 respectively.
[140] Chatzipanagiotis, M. P., Leloudas, G., (2020), Automated Vehicles and Third-Party Liability: A European Perspective, University of Illinois Journal of Law, Technology & Policy, pp. 109-199. P. 127.
[141] See Eurostat data from 2020, according to which Denmark has the highest price level (141% of EU average) and Romania the lowest (55%); see also Fourth report on the application of Council Directive 85/374/EEC, COM(2011)547.

12.7% since then. The market is forecast to amount to USD 3195 billion by 2030[142]. As automation increases in cars and numerous other products, an increasing proportion of accidents will be caused by defectiveness compared to the negligence or fault of a driver or user. The prominence of the producer for liability purposes will therefore increase[143], and with it the importance of a future-proof PLD. The lack of clarity on what products, producers and damage fall within the PLD would exacerbate the lack of a level playing field between economic operators who put hardware into circulation and those who put software into circulation. As the EU product safety framework continues to be modernised to address new digital risks, the PLD would be left behind, no longer coherently mirroring safety rules, and therefore no longer providing an effective safety net when harm involving digital technologies occurs. The growth of digital economy and the potential increase in the number of injuries related to these products could lead to greater divergence as courts adopt their own interpretations of outdated definitions or Member States or introduce parallel liability regimes to cover defects that occur after a product is put into circulation.

The transition to a circular economy is also in its infancy. As it becomes increasingly possible to extend the life of materials through industrial processes, uncertainty about the liability of original manufacturers and remanufacturers could make it difficult for businesses to assess their liability exposure and get appropriate insurance.

The growing trend of buying products directly from 3rd countries, especially through online marketplaces, will compound difficulties getting compensation for lack of an EU-based liable person for consumers to turn to under the PLD,

As for the burden of proof, the divergent approaches to disclosure obligations and to easing the burden of proof in complex cases would continue to be taken by national courts. This would perpetuate an unequal level of consumer protection and undermine the predictability of court decisions. Importantly, consumer organisations and legal academics believe that emerging digital technologies will exacerbate existing difficulties[144]. The Commission's Report on safety and liability implications of Artificial Intelligence, the Internet of Things and robotics identified the same concerns[145]. This may especially be the case in complex IoT environments and cyberphysical systems, such as smart home systems where many different connected devices and related services interact and AI-enabled products (see case study in section 2.2. of AI liability impact assessment). This view is not shared by industry stakeholders, who point to the absence of empirical evidence that new technologies will exacerbate evidentiary difficulties. More information on evidentiary difficulties due to features specific to AI technologies can be found in the parallel AI liability impact assessment.

The effects of time limits and thresholds on limiting claims are not expected to evolve – these restrictions would simply continue.

[142] CSES with Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive, section 2.1.1.1.
[143] Gerhard Wagner (2020), Verantwortlichkeit im Zeichen digitaler Techniken, Versicherungsrecht, p. 738.
[144] BEUC (2020), Product Liability 2.0 - How to make EU rules fit for consumers in the digital age, p. 17; European Commission (2020), Report on the Safety and Liability Implications of Artificial Intelligence, the Internet of Things and Robotics.
[145] European Commission (2020), Report on the Safety and Liability Implications of Artificial Intelligence, the Internet of Things and Robotics.

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

The PLD fully harmonises the matters it explicitly covers and is based on Article 114 TFEU (ex-Article 95 TEC, ex-Article 100 EEC Treaty), the objective of which is the establishment and functioning of the internal market by approximating national rules. Any revision of the PLD would build on the current objectives of free movement of goods and creating a level playing field for companies in the internal market, while ensuring consumer protection, and so would have the same legal basis.

3.2. Subsidiarity: Necessity of EU action

This initiative addresses the issues identified in the evaluation of the PLD, which was carried out as part of the Commission's regulatory fitness and performance (REFIT) programme[146]. The evaluation concluded that the PLD was on the whole relevant, effective, efficient, coherent and had EU added value, despite some shortcomings concerning ease of application in the digital and circular economy and the balance of producer-consumer interests in some cases.

In the public consultation conducted for the evaluation, more than 85% of respondents considered the PLD was advantageous for consumers and producers, and stakeholders across the board considered the advantages could not be achieved with national legislation alone. This is because goods circulate freely within the internal market and are capable of being defective and causing harm irrespective of the Member State in which they were produced or used. Furthermore, the problems identified do not have any particular national or sub-national specificities.

Since the PLD fully harmonises the matters it explicitly covers, Member States are not allowed to make changes to the scope, outdated definitions or rules of the PLD: they must be made at EU level. In the absence of a uniform set of rules on compensating victims harmed by defective products, manufacturers would be faced with 27 different sets of rules, leading to different levels of protection for consumers and distorted competition among market operators from different Member States.

3.3. Subsidiarity: Added value of EU action

The evaluation concluded that the added value of having EU-level product liability rules to complement EU-level product safety rules was uncontested[147]. Indeed rules on compensating victims harmed by defective products reinforce EU product safety rules, and both pursue the same policy goal of a functioning internal market for goods that ensures a high level of consumer protection.

Regulatory action at EU level would ensure coherent implementation of product liability rules. It would provide legal certainty about what products, economic operators and types of harm fall within the PLD's scope, and about the appropriate balance of interests between producers and consumers across the EU. This would in turn help ensure the free

[146] Evaluation of Product Liability Directive, SWD(2018)157.
[147] Evaluation of Product Liability Directive, SWD(2018)157, p. 60.

movement of goods, a level playing field for all market operators, and a high and consistent level of consumer protection.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

The PLD fully harmonises the matters it explicitly covers and is based on Article 114 TFEU (ex-Article 95 TEC, ex-Article 100 EEC Treaty), the objective of which is the establishment and functioning of the internal market by approximating national rules. The revision of the PLD pursues two general objectives to address the problems identified, both of which build on those of the current PLD:

1) Continue to ensure the functioning of the internal market, free movement of goods and undistorted competition between market operators;
2) Continue to ensure a high level of protection of consumers' health and property.

4.2. Specific objectives

This initiative pursues five specific objectives (SOs).

In order to adapt product liability rules to the digital age and circular economy:

- **SO 1: Ensure liability rules reflect nature and risks of products in the digital age**

The aim here is to ensure that not only traditional products that were commonplace in the 1980s are adequately covered by product liability rules, but that digital products are too. Adapting or clarifying definitions will bring product liability rules into line with EU safety legislation already adapted to digital technologies, and will help reduce uncertainties in the implementation of the PLD.

The aim is also to reflect the reality that product safety is nowadays impacted after the formal production process, including through updates/upgrades or through evolving cybersecurity threats.

The aim is also to ensure any new and relevant types of damage that products using digital technologies may cause are appropriately covered, with the goal of ensuring consistent interpretation (e.g. of digital property) and avoiding overlaps with other regimes (e.g. GDPR, non-discrimination legislation).

- **SO 2: Ensure liability rules reflect nature of products in the circular economy**

The aim here is to ensure that products produced according to circular business models and placed on the market are adequately covered.

- **SO 3: Ensure there is always an EU-based liable person for defective products bought from producers outside the EU**

The aim here is to ensure that when a consumer purchases a product directly from a non-EU producer, there is an economic operator based in the EU from whom to seek compensation if the product is defective and causes harm. The aim is also to ensure

consumer protection no matter how a product is purchased and to guarantee a level playing field for EU and non-EU businesses alike.

In order to reduce disproportionate obstacles to getting compensation:

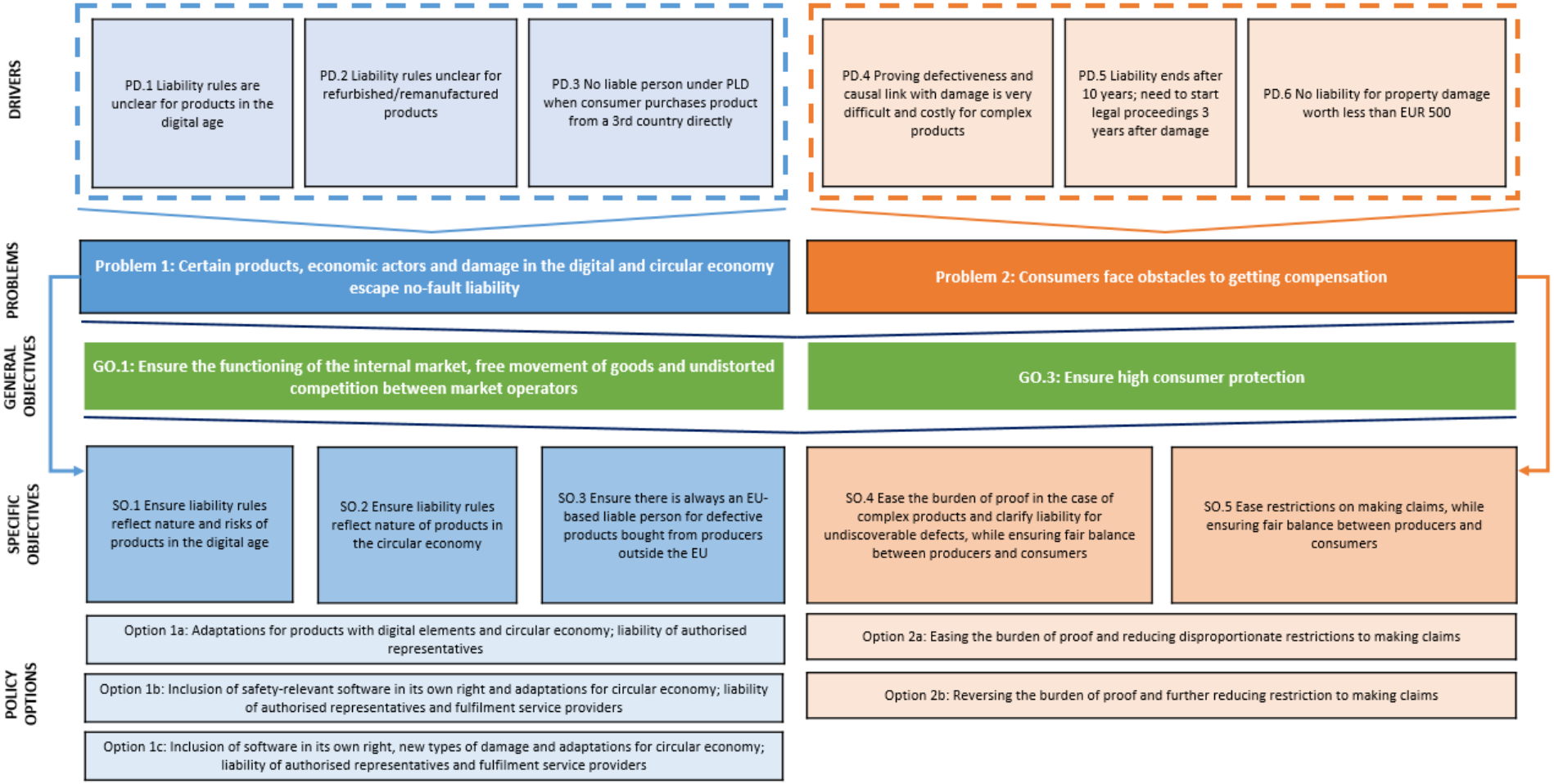
- **SO 4: Ease the burden of proof in the case of complex products and clarify liability for undiscoverable defects, while ensuring fair balance between producers and consumers**

The aim here is to alleviate difficulties that consumers face in proving producers' liability in the case of complex products, and so achieve a fairer balance of interests. The aim is also to provide legal certainty regarding defects that were undiscoverable when the product was put into circulation.

- **SO 5: Ease restrictions on making claims, while ensuring fair balance between producers and consumers**

The aim here is to ease restrictions that currently disproportionately limit consumers' ability to make claims.

Intervention logic



5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. What is the baseline from which options are assessed?[148]

The baseline – "policy option 0" – consists in no EU action, meaning no change to the current PLD. This would lead to the continuation of the shortcomings identified in the evaluation of the PLD, and the problems and consequences described in Section 2. It is assumed, however, that ongoing legislative proposals would be enacted and implemented. Proposals to make the product safety framework fit for the digital age (in particular the Machinery Regulation, GPSR and AI Act) principally by setting safety requirements for placing products on the market, are expected to improve product safety and therefore reduce product-related harm in real terms as well as avoiding a future rise in such harm due to novel risks brought about by digital technologies (see also section 1.2.4). These safety requirements will help courts decide whether a product is defective, i.e. whether it provided the level of safety the public was entitled to expect. But victims of harm would still need to rely on the outdated PLD to seek compensation or fall back on national fault-based liability rules if the product, producer or harm falls out of the PLD's scope.

With respect to products from 3rd countries, it is similarly assumed that the proposed DSA and GPSR will be enacted and implemented (see also section 1.2.5). Both proposals will set out due diligence obligations on online marketplaces and the GPSR will require there to be a responsible person for product safety purposes based in the EU. Neither proposal concerns the question of whether such economic operators should be treated as producers for product liability purposes.

This same baseline is used in the impact assessment on AI liability. To a small extent, the options analysed in that IA impact the evolution of the problems described in this IA. In cases where the PLD cannot currently be used effectively (e.g. to get compensation from an AI-system provider), a victim of harm will have to use national liability rules requiring proof of fault. The challenge of proving fault would be mitigated by the measures considered in the AI impact assessment, by easing the burden of proof in limited circumstances. However, the AI impact assessment does not have any impact on how the options of this IA are defined, since any change to national fault-based rules would only complement and not substitute a digitally fit PLD based on no-fault liability. This is also because this impact assessment is relevant not only for AI but for digital technologies in general (see section 1.3).

The PLD potentially affects almost the entire manufacturing sector (see section 2.1). However, according to the evaluation study, there are only around 50-60 court cases based on product liability rules per year in EU27[149]. As acknowledged by the study itself, this number is likely not complete, and more realistic figures have been extrapolated using information from selected Member States' databases, pointing to a range between

[148] Annex 4 provides details over assumptions as well as the estimation methodology used to assess the baseline scenario.
[149] Evaluation of Product Liability Directive, SWD(2018)157, p. 21.

209 and 452 for the annual number of court cases across the EU27. In extrapolating these figures, the expected modest reduction in product-related harm as a result of ongoing product safety-related legislative proposals has been taken into account by making conservative assumptions about the lower range, even if the reduction is not directly quantifiable and does not directly affect the size of the remaining problem (see more details in Annex 4).

The evaluation found that most liability-related claims were settled out of court[150] and interviews with industry associations and product liability lawyers as part of the IA study suggested that there might be as many as 6-7 times the number of cases settled out-of-court compared with cases that actually go to court[151]. Thus, it is estimated a range between **1,255 and 3,165 for the annual number of out-of-court proceedings** across the EU27.

Evidence collected through stakeholder consultation confirms the 2018 evaluation's finding that the financial size of compensations to victims varies widely depending on the product and sector, the nature and extent of the damage, and the circumstances of individual cases. For the purpose of the impact assessment, the compensation paid for deaths in the EU27 is estimated in the range of 20,000-1,500,000 EUR; the compensation paid for personal injuries is estimated in the range 1,500-700,000 EUR; and the compensation paid for property damages is estimated in the range 5,000-25,000 EUR.

Economic operators covered by liability insurance would not have to directly compensate victims since their liability insurance would cover pay-outs to victims in case they are found liable for a defective product. The liability insurance premiums faced by these economic operators are, however, assumed to increase[152]. The total value of product liability insurance premiums in the EU27 in 2021 is estimated to be equal to 33.38 billion EUR. Out of this, only a small share relates the risk of no-fault liability under the PLD (estimated around 1-2% of the total premiums).

Finally, there is considerable variance in the costs of legal cases involving PLD compensation claims, depending on (1) the product and its complexity (2) the circumstances of the case and (3) the Member State concerned and the prevailing differences in legal costs. Legal costs for court proceedings across Europe is estimated in the range of 500 EUR – 40,000 EUR. Legal cost per out-of-court proceedings across Europe is estimated in the range of 500 EUR – 25,000 EUR (proxies for the average values have been used in the calculation, only for the purpose of an overall rough estimation). See annex 4 for details concerning baseline assumptions.

5.2. Description of the policy options

Three policy options were identified to address problem 1 and two policy options to address problem 2. In order to address all problems that the initiative aims to tackle, option 1a, 1b or 1c (addressing problem 1 relating to the digital age and circular economy

[150] Evaluation of Product Liability Directive, SWD(2018)157, p.11: with 46% settled in direct negotiation, 32% in court, 15% through alternative dispute resolution and a residual 7% solved through other means, such as the insurance of the responsible party.

[151] CSES with Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive, section 4.4.1.2.

[152] According to the Evaluation of Product Liability Directive, SWD(2018)157, 79% of producers overall have either a general (57%), or a specific (22%) product liability insurance policy, covering pay-outs to victims in case they are found liable for a defective product. See section 6.

and concerning mainly the **scope of the regime**) would have to be combined with option 2a or 2b (addressing problem 2 related to obstacles in getting compensation and concerning mainly the **internal balance within the regime**).

The combinations of measures in each policy option were developed based on stakeholder input during the impact assessment study and were also presented to stakeholders, notably at the Stakeholder Workshop in December 2021, with no calls for exploring alternative combinations.

Each measure was analysed separately in the impact assessment study and this analysis informed the choice of combinations. Since each problem is independent from the other, the options for each problem are analysed separately. For greater transparency on the impact of different elements within each option, the costs and benefits (increase of insurance premiums and compensations for victims) related to each measure are shown separately in section 6 of the impact assessment.

5.2.1. Policy options to adapt liability rules to the digital age and circular economy

Option 1a – Adaptations for products with digital elements and circular economy

Digital: Under PO1a, manufacturers of products with digital elements would be liable, as now, for defects in the overall product, but this would include liability for updates to software and for digital services that are *necessary* for the product to operate. They would also be liable if harm results from an unreasonable failure to provide a security update[153]. If the defect lay in the digital elements themselves, a victim of harm would also be able to seek compensation directly from the providers of such software or digital services – they would be treated as producers (like any other manufacturers of a *tangible* components today) – or from the manufacturer of the overall product. Applying joint and several liability would ensure a victim of harm does not have to seek compensation from both parties[154]. There would be no change to the types of damage that are compensable: personal injury and damage to consumer property. The revised PLD would, however, in all policy options clarify that medically diagnosed psychological damage is included in the concept of personal injury (see annex 5 for details).

Circular: The revised PLD would make explicit that economic operators that make a substantial modification to a product and place it back on the market, such as refurbishers and remanufacturers, fall within the concept of "producer". The original producer would remain jointly and severally liable for its contribution, in the same way that component manufacturers are liable for flaws in their components that make a product defective. The option would bring the PLD into line with the trend in the product safety framework to take account of substantial modifications (see section 2.2.1.2).

3rd-country products: Under this option, when a defective product is bought from a 3rd country in the absence of an importer, and it causes harm, it would be possible to hold the

[153] This would not create an obligation to provide updates. Where such obligations do exist, (e.g. in Art. 7(3) of Directive (EU) 2019/771 on certain aspects concerning contracts for the sale of goods, , that would provide a yardstick for courts to assess what level of safety a person is entitled to expect in respect of updates.

[154] As is the case today, if ultimate responsibility for the defect lies with the component producer (in this case, the software provider), the manufacturer of the overall product could make a recourse claim against them to recoup the costs of compensating the victim.

producer's "authorised representative" liable if one has been appointed. Authorised representatives are already subject to liability under the Medical Devices Regulation, and the Market Surveillance Regulation and proposed GSPR[155] should ensure that when there is no importer an authorised representative is appointed in a majority of cases.

The revised PLD would in all policy options clarify that while providers of online marketplaces are subject to a liability exemption when they merely intermediate sales, if they play the role of producer, importer or seller for a given product, they may be liable under the PLD (see annex 5 for details).

Option 1b – Inclusion of safety-relevant software in its own right and adaptations for circular economy

This option includes measures envisaged under option 1a.

Digital: This option builds on option 1a and would mean a broader scope of the PLD. Whereas option 1a would cover only component software necessary for a tangible product to operate, option 1b would recognise safety-relevant software as a product in its own right. This would include 3rd-party add-on software that is not necessary for, but nevertheless influences, the operation of a tangible product (such as a downloaded 3rd-party software module for a service robot) and standalone software that itself may cause harm (such as medical device software). While a producer of add-on software and the manufacturer of the overall tangible product would be jointly and severally liable for harm caused by defective software, the manufacturer of the overall product would, unlike under PO1a, be able to use the later-defect defence by showing that that add-on software was outside of its control. The types of damage that are compensable would remain limited to personal injury and damage to consumer property, but the text would clarify that material loss[156] resulting from damage to digital property (such as digital content wiped from a hard drive) is also compensable.

Circular: Same as option 1a.

3rd-country products: Under this option, in the absence of an EU-based producer or importer, and where a non-EU producer has not appointed an authorised representative, a victim of harm would be able to seek compensation from a fulfilment service provider[157]. Although there is no precedent for holding fulfilment service providers liable for defective products, this option would provide an extra safeguard compared to option 1a, justified by the fact that the Market Surveillance Regulation and proposed GPSR do envisage responsibilities for fulfilment service providers in those cases where an authorised representative has not been appointed.

Option 1c – Inclusion of software in its own right, new types of damage and adaptations for circular economy

[155] The appointment of an authorised representatives (a natural or legal person who has a written mandate from a manufacturer to act on its behalf) is regulated in Regulation (EU) 2019/1020 on market surveillance, Art. 4(2)(c) and Art. 3(12) and in the proposed GPSR, Art. 15.

[156] e.g. the cost of restoring destroyed music or video files or software programs. This would not cover non-material losses such as emotional harm resulting from, say, the loss of family photos.

[157] "Any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching…and any other postal services or freight transport services": Article 3(11) of Regulation (EU) 2019/1020 on market surveillance.

This option includes measures envisaged under option 1b.

Digital: This option would build on option 1b and would involve a more significant expansion in the types of damage covered. Not only safety-relevant software would be recognised as a product in its own right, but also software with fundamental rights implications, which would in particular be relevant for AI systems (such as discriminatory recruitment software). The types of damage that are compensable would be expanded to include material and non-material damage flowing from fundamental rights infringements: data protection breaches, privacy infringements or discrimination.

Circular: Same as option 1a.

3rd-country products: Same as option 1b.

5.2.2. Policy options to reduce disproportionate obstacles to getting compensation

In policy options 2a and 2b, measures to ease the burden of proof have been packaged together with measures to reduce restrictions on making claims according to the level of ambition of the potential intervention. However, for full transparency of the assessment, the specific impacts related to measures restricting on making claims are spelled out separately in section 6.

Option 2a –Easing the burden of proof and reducing disproportionate restrictions to making claims, while ensuring a fair balance of interests

Easing the burden of proof: Under this option, a) the revised PLD would harmonise rules on when producers are obliged to disclose necessary technical information to the injured person in court (e.g. clinical trials data concerning a drug or data logs from an autonomous vehicle). The obligation would be limited to proportionate disclosure and would protect confidential information. In addition, b) the revised PLD would harmonise rules on easing the burden of proof: defectiveness/causality would be presumed by courts on certain conditions (e.g. the product did not comply with safety standards, if it clearly malfunctioned or if it is disproportionately difficult to prove liability due to technical complexity[158]). The producer would have the opportunity to rebut any presumption. In addition, c) the development risk defence, which exempts producers from liability when a product's defective nature was not discoverable according to state-of-the-art knowledge at the moment it was put into circulation, would be adapted to take account of producer control beyond that moment: for example, if a producer has provided a software update for an AI-enabled robot, then that should be the moment taken into account when applying the defence.

Restrictions on making claims: The EUR 500 threshold for property damage would be removed. The 10-year period of producer liability would be extended to 15 years, but only for latent personal injury[159], meaning injury that existed but did not become apparent in the first 10 years. The 3-year limit for starting legal proceedings would not be changed.

[158] A balance would need to be struck between setting clear conditions and allowing flexibility for courts to take account of all facts of the case before it.
[159] Law Insider, Latent Injury Definition.

Option 2b – Reversing the burden of proof

Reversing the burden of proof: Under this option, a) in the event of harm caused by a product, it would be for the producer to prove the product was not defective and did not cause the harm. In addition b) the development risk defence would be removed, meaning that producers would be liable when a product was defective, even if the defectiveness was not discoverable according to state-of-the-art knowledge. Elements a) and b) were combined as a coherent higher-intervention alternative to option 2a, in light of the fact that both stakeholders in favour of the option and those against saw the two elements as interconnected.

Restrictions on making claims: As in option 2a, the EUR 500 threshold would be removed. But the time limits would be extended more generously than under option 2a: the 10-year period of producer liability would be extended for all personal injury, not only latent personal injury; and the 3-year limit would be extended to 5 years to give victims of harm more time to start legal proceedings.

5.3. Options discarded at an early stage

Several other potential policy options were discarded at an early stage.

Guidance only: Although an overall majority of all respondents to the public consultation were in favour of legislative change to adapt the PLD to the digital and circular economy, 65% of businesses or business associations were opposed[160]. A number of them called for guidance instead[161]. Guidance would, however, require consensus by all stakeholders and would therefore be limited to minimum changes. In 2018 the Commission set up the Expert Group on liability and new technologies (PLD formation)[162] to develop such guidance. However, experts had conflicting interpretations of the current text of the PLD, particularly on the extent to which software and digital elements are within scope, how to deal updates or other product changes and the extent to which presumptions could be used to ease the burden of proof. As a result, no consensus could be reached[163] and the guidance was not completed. Substantive changes, such as recognising software as a product in its own right, changes to time limits and the EUR 500 threshold, would in any event not be possible through guidance. Despite being discarded, given there was stakeholder support for guidance, the assessment of this option is presented in Annex 6.

Repeal of the PLD: The Evaluation of the PLD concluded that the PLD provides EU added value and no stakeholder suggested repealing it. Repeal would mean that each Member State would design their own national rules on producers' liability for harm caused by defective products. A majority of businesses agree that the level playing field achieved would not be possible with individual Member State action. In addition, almost all consumer associations considered that the protection of consumers achieved would not be feasible with only national action. The vast majority of public authorities and civil

[160] 56% overall (excluding members of the public) (92 out of 168) in favour of legislative change; 75% of members of the public (93 out of 123) in favour of legislation change; 65% of businesses or business associations (71 out of 110) prefer no legislative change.
[161] For example, responses to the public consultation by Business Europe, Orgalim, Digital Europe, AmCham EU.
[162] Register of Commission expert groups and other similar entities (europa.eu).
[163] See also minutes of Expert Group on Liability and New Technologies (PLD formation) of 18 February 2019 and 5 November 2019.

society representatives deem that the Directive added value to the EU legal framework and policies[164].

Converting the PLD into a regulation: Given that the PLD's liability rules interact closely with national civil codes and are deeply embedded into diverse national legal systems, the option of converting the PLD into a regulation was discarded. A directive allows more flexibility to seamlessly embed the PLD's rules into national systems. Neither the evaluation nor the impact assessment study identified additional benefits of a regulation. There is also no stakeholder support for converting the PLD into a regulation.

Sector- or technology-specific approach to easing the burden of proof: The measures on easing the burden of proof (PO2a and PO2b) could have been applied only to certain specific product types identified as creating difficulties to prove liability. The PLD evaluation identified pharmaceuticals as such a product type, and the expert group on liability and new technologies identified AI-enabled products and other emerging digital technologies like IoT products as problematic[165]. Indeed, a French patients' association called for stricter rules for pharmaceuticals products[166] and several NGOs called for stricter rules for harm caused by AI systems[167]. However, most stakeholders expressed support for a product liability regime that applies neutrally to all product types. This was reflected in the public consultation: while very clear majorities of respondents did identify AI-enabled products, IoT products and pharmaceuticals as examples of products for which it is difficult to prove liability, 77% of respondents[168] also replied that it was (to a moderate, large or very large extent) technical complexity, as a product characteristic in general, that made it difficult to prove liability. Focussing on pre-defined sectors or technologies would be too rigid an approach, leading to over-inclusion, since not all products in a given category are highly complex (e.g. an AI-enabled toothbrush) and under-inclusion, since technical complexity can be a feature of many other different products types (e.g. chemicals, machinery). It risks not being future proof and unfairly benefitting some victims of harm and not others[169].

Lowering the EUR 500 threshold: Stakeholders were either in favour of keeping the threshold for damage to consumer property unchanged[170] or removing it altogether[171], although one industry association asked for the option of lowering the threshold to be examined[172]. That option was discarded, because the same internal market objections would apply: any other fixed EU-wide threshold would impact consumers more significantly in Member States where consumer goods are cheaper (i.e. where more consumer property falls below the threshold).

Extending the 10-year limit to 20 years: Holding producers liable for up to 20 years after they put a product into circulation was considered. BEUC, the consumer

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[164] Evaluation of Product Liability Directive, SWD(2018)157, p. 69.
[165] Expert Group on Liability and New Technologies (2019), Report on Liability for artificial intelligence and other emerging digital technologies
[166] Response of France Assos Santé to the public consultation.
[167] Responses of The Future Society and of Irish Council for Civil Liberties to the public consultation.
[168] N-268.
[169] Bernhard A. Koch in Essays in honour of Helmut Koziol, Jan Sramek Verlag 2020, p. 82.
[170] Position papers of BVMed; EFPIA; Eurochambres; Siemens; ZDH; ZVEI in response to the public consultation.
[171] Responses of AEBS; Austrian Bundesarbeitskammer; German Federal Government; The future society to the public consultation.
[172] Comment made by Federation of the European Sporting Goods Industry (FESI) at the PLD Workshop of 14 December 2021.

organisation, called for this, while a French patient organisation called for the limit to be removed altogether[173]. However, industry stakeholders and insurers were opposed to any change. This longer extension was discarded in favour of a shorter extension with a view to striking a fair balance between all stakeholders.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

The following assessment provides a qualitative analysis of the impacts generated by each policy option, based on the evidence gathered from multiple sources. Whenever possible, it also provides a quantitative analysis of benefits and costs relating to the main economic and social impacts. The cost/benefits analysis, however, is not fully comprehensive due to significant data gaps and limitations. The quantification of costs and benefits is based on a number of assumptions coming from stakeholder feedback and expert knowledge of the contractor. The aim of this assessment is to provide ranges of the magnitude of potential impacts generated by each policy option, rather than exact monetisation[174].

Policy options mainly involve a re-attribution of costs between stakeholders, either from victims to the producers whose defective products caused the costs, or between economic operators by enlarging the notion of "producer"[175].

The **main measurable benefit** for consumers is the amount of compensation to be paid to injured parties. The analysis assesses the impacts of the policy options on the annual number of in-court cases (estimated between **209 and 452** across the EU27) and out–of-court cases (**1,255 and 3,165)** based on product liability rules In line with the 2018 PLD evaluation, the share of successful cases (for injured parties) over total cases is estimated to be 60%, for both in-court and out-of-court cases. The measures proposed by each policy option might affect the proportion of cases brought under the PLD and/or the success rate of claims. This increase, multiplied by the average compensation pay-outs, will provide ranges for the estimates on the benefits for consumers.

The **main indirect costs** generated by the PLD are liability insurance costs attributable to strict liability under the PLD as well as legal costs that producers and consumers have to bear in the case of a product liability claim, whether in-court or out-of-court.

The large majority of economic operators that faces any additional claims as a result of a policy option would not face increased compensation costs vis-à-vis victims, but would rather face a marginal increase in their insurance premiums[176]. The minority of economic operators without product liability insurance and that face any additional claims would, on the other hand, face increased compensation costs vis-à-vis victims. In the analysis, the cost of liability insurance is assessed and quantified as a cost for producers, whereas compensation costs are assessed as a benefit for victims. Compensation costs are not assessed as costs for producers, because adding them to the increased cost of liability insurance premiums would have led to double counting and no data was available to make estimates about which producers have insurance and which do not. To assume that

[173] BEUC (2020). Product Liability 2.0 - How to make EU rules fit for consumers in the digital age. BEUC-X-2020-024 - 07/05/2020; Response to inception impact assessment of Réseau D.E.S. (Victimes du Valproate de sodium).
[174] More details on data gaps and limitation are presented in Annex 4.
[175] Baseline scenario presented in section 2.1. Annex 4 provides details over assumptions as well as the estimation methodology used to assess the impacts of policy options.
[176] Evaluation of Product Liability Directive, SWD(2018)157: 79% of producers.

the 21% of producers without insurance are spread across all manufacturing sectors would entail a high risk of overestimating costs for producers, since interviews with the insurance industry suggest that the 21% represents mainly producers of lower-risk products that are rarely subject to compensation claims. In contrast, producers of the sorts of products covered by options 1a, 1b and 1c (e.g. autonomous vehicles, robots) or for which the burden of proof is currently challenging (e.g. complex products like pharmaceuticals or Internet of Things devices) are more likely to have liability insurance at present, since there is a higher risk of those products being subject to compensation claims. It is acknowledged that not assessing compensation costs as a cost for producers may lead to a small underestimation of costs.

There are no relevant administrative costs under the PLD in contrast to much product safety legislation, as there are no specific obligations or information requirements for economic operators. There will be one-off **familiarisation costs** for economic operators not previously covered as producers under the PLD, which are minimal.

The estimates were developed on the basis of interviews with experts. They were validated during the Stakeholder workshop in December 2021.

6.1. Policy option 1a – Adaptations for products with digital elements and circular economy

Economic impacts

a. Impacts on economic operators

Under PO1a, the liability exposure of manufacturers of products with digital elements would increase. Explicitly making providers of software, updates and digital services "producers" would also slightly increase their liability exposure, although victims are likely to seek compensation from the manufacturer of the overall product[177]. Because PO1a could create an incentive to provide security updates to avoid liability, this could indirectly generate software development costs. Stakeholders most impacted are manufacturers of IoT or AI-enabled products, such as robots, connected and autonomous vehicles, machinery and domestic appliances.

78% (122 out of 155) of respondents to the public consultation, excluding citizens, agreed or strongly agreed that software controlling how a product works should be included in the scope of the PLD. Another 66% (102 out of 154) agreed or strongly agreed that software upgrades and updates should be included.[178] EU and non-EU citizens showed even stronger agreement, with over 90% (117 out of 122) replying that consumers should get compensation if damaged is caused by defective software or digital services that control how a product works and software upgrades/updates. See annex 2 for details.

Explicitly clarifying that economic operators who make substantial modifications to a product and place it back on the market are also "producers" would slightly increase their liability exposure. Sectors likely to be impacted are electrical and electronic as well as

[177] Very few cases are brought against component manufacturers (average of 3 court cases per year, see Evaluation, p. 14), so only a minor impact is expected under PO1a on insurance premiums for software producers.

[178] Further disaggregation shows that consumers' associations were fully in favour of including software controlling how a product works in the scope of the PLD (87% strongly agreed and 13% agreed), compared to the industry/business (where 22% strongly agreed and 46% agreed).

medical equipment and machinery sectors. As is the case today, if a victim sought compensation from the original manufacturer, the latter would be able to escape liability by proving the defect emerged after he put the product into circulation. Equally, if a remanufacturer or refurbisher were held liable, but the original manufacturer were ultimately responsible for the defect, they could make a recourse claim against the original manufacturer[179] to recoup the costs of compensating the victim.

Business associations, including representatives from the refurbishment and remanufacturing industries, supported extending liability only to cases where a "substantial modification" was undertaken[180]. This would be in line with recent legislation and legislative proposals[181], according to which an economic operator making the modification places a new product on the market, and therefore assumes responsibility for the safety of the product or part of a product.

Finally, under PO1a, "authorised representatives"[182] would be exposed to product liability in cases where there is no EU-based importer.

In terms of indirect costs, annual product liability insurance costs are assumed to increase[183] by 3% for producers of products with digital elements, producers of digital elements themselves as well as for refurbishers and remanufacturers[184].

Authorised representatives would have an incentive to take out product liability insurance, in case they do not already, to cover their liability exposure[185]. Product liability insurance costs are assumed to increase by 15%. As is the case for importers, it is expected that this cost would be passed on to the non-EU producers they represent, as part of the cost of their service[186].

Taking all this into account, under PO1a the total **annual product liability insurance costs** are assessed to increase incrementally compared to the baseline, with an increase ranging between 1.21 and 2.41 EUR million. These increases in product liability insurance costs are extra revenues for the insurance companies.

b. Impacts on SMEs

The views of SMEs expressed in the course of consultation activities[187] did not particularly diverge from the overall views of business respondents. The impact assessment study did, however, conclude that clearer liability rules, particularly regarding

[179] Article 5 of Directive 85/374/EEC, N.B. rules on recourse are governed by national law.
[180] Responses of Business Europe, France Assureurs and the French Business Confederation (Medef) to the public consultation, and comments of Conseil Européen de Remanufacture at Stakeholder Workshop of 13 December 2021.
[181] Concept of full and partial refurbishment is included in the Medical Devices Regulation 2017 and the concept of a substantial modification is included in proposed AI Act, GPSR and Machinery Regulation, as well as in the Commission's Blue Guide on the implementation of product safety legislation, 2016/C 272/01, 26.7.2016, p. 15 to 17.
[182] See footnote in section 5.2.1.
[183] Insurance firms are expected to pass on the increased risk of litigation through higher insurance costs.
[184] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.
[185] As for other economic operators already concerned by the PLD, it is assumed that 80% have liability insurance already.
[186] Confirmed in interview with authorised representative in the context of the impact assessment study.
[187] 13 SMEs (businesses) and two SME associations (European Digital SME Alliance and Allied for Startups) responded to the public consultation.

software and refurbished products, would particularly benefit SMEs, which have fewer resources than larger companies to devote to understanding unclear rules[188].

On the other hand, the 2018 evaluation found that 31% of small enterprises do not have liability insurance, whereas among medium and large firms the figure is only 15%. Thus, SMEs could be more exposed than larger firms to compensation pay-outs not covered by insurance. Also, higher product liability insurance costs might affect SMEs more than larger companies, as SMEs have less ability to absorb the costs and might have less favourable insurance conditions.

c. Impacts on the internal market and competitiveness

PO1a would increase regulatory clarity and close liability gaps by making explicit that software and digital services necessary for a tangible product to operate are included in the scope of the PLD as component parts of those tangible products. It would create a more level playing field among market operators, because not only producers of tangible parts but also producers of intangible parts would be potentially liable. Ensuring no-fault liability applies to updates and failure to update would, thanks to the deterrent effect of no-fault liability, also incentivise final producers and software developers to place safer software on the market and to invest in safety-relevant cybersecurity beyond the moment a product is put into circulation.

By clarifying that remanufacturers and refurbishers may be liable, but only for substantial modifications, PO1a would reduce liability gaps, create legal certainty and contribute to the broader EU policy objectives of the Circular Economy Action Plan[189].

PO1a would also promote a more level playing field between EU and non-EU producers by making the latter's authorised representative liable, who are then expected to pass the costs on to the non-EU producer in their service fees. It should be noted that one authorised representative interviewed raised the prospect that non-EU producers might in turn raise the price of their products and that some might be unwilling to pay higher authorised representative fees to cover the liability cost, and decide not to offer their product on the internal market at all[190]. On the other hand, PO1a would ensure that the deterrent effect of no-fault liability, which encourages producers to place only safe products on the market, indirectly reaches non-EU producers too, which would reinforce ongoing efforts to improve the safety of products imported directly online[191].

d. Impacts on the judicial system and legal costs

Whereas, based on the current text of the PLD, courts may have applied fault-based liability rules to software updates and digital services, PO1a would make clear that the PLD's no-fault regime applies. There should only a very small increase in overall cases (either in-court or out-of-court) for producers of products with digital elements, producers of digital elements (assumed 1% increase, reflecting future-proofing as

[188] CSES with Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive, section 2.3.1.
[189] https://ec.europa.eu/environment/strategy/circular-economy-action-plan_en.
[190] It is not possible to quantify these risks, as they would vary considerably depending on the type of product.
[191] See impact assessment on the proposed GPSR, SWD(2021)168, p. 15.

software-related cases are likely to increase)[192]. However, it is foreseen that a greater proportion of cases would be now brought under the PLD. Those court cases should be shorter, because the victim only has to prove the product's defectiveness and not the producer's fault. Thus, a 2%[193] legal cost reduction is assumed for software producers and related victims of harm[194].

On the other hand, making authorised representatives liable would potentially lead to an increase of 1% in the annual number of in-court and out-of-court cases. Victims who could not have claimed compensation under the current PLD, and who may well not have had any enforceable claim against any wrongdoer under national rules, would be entitled to make a claim under PO1a.

Taking all this into account, under PO1a the total **annual legal costs** are assessed to slightly increase incrementally compared to the baseline, with an increase ranging between 0.41 to 1.02 EUR million.

Social impacts

a. Impacts on consumers

PO1a would benefit consumers and indeed any person harmed by a defective product, as they would have a clear route to compensation without having to prove fault: i) where defects relating to software or digital services emerged after the product was put into circulation[195], ii) in the case of defective refurbished or remanufactured products; iii) in the case of defective products purchased directly from third-country producers. In line with the impacts on the judicial system described above, the greater proportion of cases brought under the PLD would mean greater chances of getting compensation thanks to not having to prove fault. The deterrent effect of no-fault liability can be expected to have a positive impact on product safety and therefore consumer protection – this is further reflected under 'impacts on internal market and competitiveness' above[196]. PO1a would not affect the average compensation pay-outs to victims.

Taking all this into account, under PO1a the total **annual compensation paid to victims** is assessed to increase incrementally compared to the baseline, with an increase ranging between 0.07 to 14.47 EUR million[197].

b. Impacts on employment and fundamental rights

No impacts on employment or fundamental rights were identified under PO1a.

Environmental impacts

[192] It is generally accepted that software either embedded or crucial to the operation of a product is already included within scope; that software developers are already liable under other grounds of liability and that software rarely causes physical damage except in certain circumstances.
[193] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.
[194] Legal costs that producers and claimants have to bear in case of a product liability claim (whether in court or out-of-court).
[195] BEUC, the consumer organisation, considered it essential to widen the notion of product to ensure that consumers can get compensation under the PLD when software or a digital service renders a product defective. Product Liability 2.0 - How to make EU rules fit for consumers in the digital age. BEUC-X-2020-024-07/05/2020, p. 13).
[196] See that section also for further impacts on consumer protection of making authorised representatives potentially liable.
[197] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.

Measures relating to the circular economy are expected to have a positive environmental impact, since clearer liability rules should help promote circular business models which would in turn improve product sustainability and reduce waste. Firstly, clarifying that economic operators who substantially modify products are producers under the PLD would address original equipment manufacturers' fear of being held liable for changes outside of their control and would therefore help promote the independent refurbishing sector[198]. Secondly, from the consumer's perspective a refurbisher/remanufacturer is the same as the producer of a new product, as both are expected to have been in control of the safety features of the product before distributing it. Giving consumers the same protection should promote trust in such products. These benefits to the sector and the knock-on benefits for the environment are expected to outweigh the small increase in annual liability insurance premiums associated with no-fault liability. This increase will be small, because refurbishers/remanufacturers are already liable for fault or negligence under national rules, and would qualify as producers under the PLD only if the modification they make is substantial enough to warrant treating it like a new product, in line with product safety rules. The measures are consistent with the Union's climate-neutral objectives set out in the European Climate Law[199]. Environmental impacts are the same in PO1b and PO1c too.

6.2. Policy option 1b – Inclusion of safety-relevant software in its own right and adaptations for circular economy

Economic impacts

a. Impacts on economic operators

PO1b would have the same impacts in respect of circular economy aspects and products with digital elements as PO1a. But under PO1b software producers would be more exposed to liability because of the inclusion in scope of add-on software that is not necessary for a tangible product to operate, and where the manufacturer of the overall tangible product may be able to use the later-defect defence, and of safety-relevant standalone software.

In terms of the sector affected, the number of software companies in Europe producing either component or standalone software is over one million[200]. While most "standalone" software will rarely cause physical injury[201], defective medical device software could do so, and defective apps could cause potentially damage the device on which they are downloaded.

Representatives of the medical device sector considered that since medical device software is regulated as a product, PO1b would be in line with the Medical Devices Regulation[202], and therefore provide more legal certainty. Representatives of the software

[198] Impact assessment study on the revision of Product Liability Directive, p. 46.
[199] Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law'), OJ L 243, 9.7.2021, p.1.
[200] Source: Bold data; Note that providers of open-source software would be unaffected as the PLD applies only to products put into circulation for economic purposes in the course of business activity (Art. 7(c) of PLD).
[201] Pointed out, inter alia, by Siemens in their position paper in response to the public consultation, Civil liability – adapting liability rules to the digital age and artificial intelligence.
[202] Position papers of Bundesverband Medizintechnologie in response to the public consultation, p. 2; Regulation (EU) 2017/745 on medical devices.

industry itself were hesitant about treating software as a product in its own right, partly for fear of over-inclusion of software that does not cause physical harm or where the service element is more important than the software, for example a facial-recognition systems used in a bank or an AI-system used to generate consumer credit ratings[203]. However, these would not be covered under PO1b as they are not relevant to safety. They were nevertheless open to treating software that has the potential to cause harm as a product, even if some stakeholders believed this was possible to achieve by guidelines[204]. As discussed in section 5.3 and annex 6, however, guidelines would not provide legal certainty.

Clarifying that material loss resulting from damage to digital property is also compensable as property damage would impact producers of electronic devices, in particular data storage devices and hard drives, and software producers. Although damage to such digital property may currently be covered by liability insurance[205], it usually requires physical damage of the data storage device first in order to be recoverable. In the public consultation, 60% of respondents agreed or strongly agreed that producers should be liable for "damage to data" (87% among consumer representatives and citizens; only 18% among industry representatives)[206].

Finally, under PO1b, fulfilment service providers[207] would be potentially liable under the PLD in cases where there is no EU-based producer, importer or authorised representative. These cases are expected to be less common, as in a majority of cases an authorised representative will be appointed, although it is not possible to quantify this given that the Market Surveillance Regulation started to apply only in July 2021. Fulfilment service providers are often the fulfilment branch of an online marketplace (e.g. Amazon has over 40 fulfilment centres in Europe), or have contracts with producers directly[208]. In Europe, the market size of warehousing and storage businesses, two activities that fulfilment service provider may carry out, is estimated to be EUR 54 billion[209]. Analogously with authorised representatives under PO1a, third-country producers could expect to face an increase in the cost of fulfilment services to cover this exposure liability.

In terms of indirect costs, PO1b builds on PO1a but the annual product liability insurance costs for software producers would increase by 10%,[210] to cover the wider scope of the measures (inclusion of add-on software, standalone software with safety relevance). Effects on as well as for refurbishers and remanufacturers would remain as in PO1a. The annual product liability insurance costs are assumed to increase by 1-2% for manufacturers of electronic devices (including PCs, laptops, IoT products and external data storage devices) to cover digital property in the notion of property damage.

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[203] Response of Microsoft to inception impact assessment, p. 3.
[204] Response of Google to inception impact assessment, p. 3.
[205] Position paper of Insurance Europe in response to public consultation, p. 2.
[206] N.B. The question was phrased broadly and may have been understood as including loss of personal data or of digital assets more generally. The option considered in this impact assessment is more narrowly defined and concerns the treatment of digital content as property.
[207] The contractors of the support study were unable to interview any fulfilment service providers, despite repeated attempts.
[208] CSES with Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive, section 4.3.3.3.
[209] Companies holding the largest market share in Europe include Deutsche Post AG, XPO Logistics, Inc., Kuehne + Nagel International AG and A.P. Moller – Maersk A/S. Source: IbisWorld.
[210] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.

Compared to PO1a, fulfilment service providers would also have an incentive to take out product liability insurance, if they do not do so already[211]. Product liability insurance costs for these economic operators are assumed to increase by 5%.

Taking all this into account, under PO1b the total **annual product liability insurance costs** are assessed to increase incrementally compared to the baseline, with an increase estimated in the range between 4.35 and 8.69 EUR million[212].

b. Impacts on SMEs

Same as PO1a.

c. Impacts on the internal market and competitiveness

PO1b would, in comparison to PO1a, further incentivise the placing of safer software on the market, by covering 3rd-party software that influences but is not necessary for a tangible product, and safety-relevant standalone software. This broader scope would be better in line with existing and proposed product safety legislation (see section 2.2.1.1). PO1b would also provide regulatory certainty about the availability of compensation for damage to digital property and could incentivise producers to improve the reliability of hard drives and other data storage devices. Increasing regulatory clarity and closing liability gaps will benefit innovation.

PO1b would ensure that the deterrent effect of no-fault liability, which encourages producers to place only safe products on the market, reaches non-EU producers also in cases where no authorised representative has been appointed. Including fulfilment service providers as liable persons in such cases is expected to reinforce the impacts of PO1a, with costs similarly passed on to non-EU producers in service fees.

d. Impacts on the judicial system and legal costs

PO1b would have additional impacts compared to PO1a.

For software producers and related victims of harm, PO1b would reduce the annual legal costs by 4%[213], due to the broader application of no-fault liability, meaning shorter proceedings, while increasing the number of in-court and out-of-court cases by around 2%.This small increase in cases is expected to largely cancel out the small decrease in legal costs.

PO1b would also lead to an increase of around 6% in the number of in-court and out-of-court cases related to manufacturers of electronic devices. Finally, fulfilment service providers liable would potentially lead to an increase of 1% in the annual number of in-court and out-of-court cases.

Taking all this into account, under PO1b the total **annual legal costs** are assessed to slightly increase incrementally compared to the baseline, with an increase between 1.12 and 2.75 EUR million.

[211] As for other economic operators already concerned by the PLD, it is assumed that 80% have liability insurance already.
[212] As for PO1a, these increases in product liability insurance costs are extra revenues for the insurance companies.
[213] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.

Social impacts

a. Impacts on consumers

Consumer benefits would be greater under PO1b than PO1a. BEUC, the consumer organisation, has stressed that recognising software as a product in its own right is essential, since software can be purchased separately from producers beyond the control of hardware producers[214]. Consumers would also benefit from the possibility of compensation for material losses resulting from damage to digital property (digital content on a data-storage device).

Finally, consumers would benefit from the greater possibility to get compensation when defective 3rd-country products cause harm, due to fulfilment service providers becoming potentially liable when an authorised representative has not been appointed. It should be noted that several stakeholders[215] called for providers of online marketplaces, which merely intermediate sales between non-EU sellers and EU consumers, to shoulder no-fault liability rather than authorised representatives or fulfilment service providers. But this would be inconsistent with the conditional liability exemption of online marketplaces under the eCommerce Directive and proposed Digital Services Act (see annex 5).

In line with the impacts on the judicial system described above, PO1b would increase the annual number of in-court and out-of-court cases under the PLD in the EU27, and the increase in cases brought under the PLD would mean greater chances of getting compensation thanks to not having to prove fault. As for PO1a, the measure would not affect the average compensation pay-outs to victims.

Taking all this into account, under PO1b the total **annual compensation paid to victims** is assessed to increase incrementally compared to the baseline, with an increase between 0.15 and 22.13 EUR million[216].

b. Impacts on employment and fundamental rights

No impacts on employment or fundamental rights were identified under PO1b.

6.3. Policy option 1c – Inclusion of software in its own right, new types of damage and adaptations for circular economy

Economic impacts

a. Impacts on economic operators

PO1c would build on option 1b and significantly expand the types of compensable damage to **include material and non-material damage** flowing from fundamental rights infringements (data protection breaches, privacy infringements or discrimination) rather than only safety-related harm (personal injury, property damage). This would principally impact producers of IoT products in respect of privacy and AI systems in respect of discrimination. In the public consultation 87% of consumer associations and NGOs were in favour of compensating losses flowing from breaches of data protection

[214] BEUC (2020), Product Liability 2.0 - How to make EU rules fit for consumers in the digital age. BEUC-X-2020-024 - 07/05/2020, p. 13.
[215] Response of BEUC and Toy Industries of Europe to the public consultation.
[216] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.

requirements. BEUC, the consumer organisation, supported it as a way of encouraging compliance with the GPDR's privacy-by-design rules[217]. Business associations and companies, however, were opposed (57% against; 18% in favour. In position papers the vast majority[218] of business associations expressed strong opposition to compensating such harm under the PLD, arguing that such harm could already be compensated under the GDPR itself and that imposing no-fault liability for harm that is difficult to define and quantify was disproportionate.

No specific question on discrimination was asked in the public consultation, but several stakeholders raised it in position papers. Legal academics recognised that discrimination risks in the context of AI are real but that such risks would be more coherently addressed under non-discrimination law than product liability law[219]. Consumer organisations also did not advocate for the inclusion of compensation for discrimination under the PLD.

On the broader question of whether non-material damage should be compensated under the PLD if it did not arise as a result of personal injury, consumer organisations and an NGO were in favour[220], arguing that this would improve access to justice. However, most industry respondents and insurers considered that this would expose producers to liability costs that were difficult to predict, and therefore difficult to insure, because of the subjective nature of non-material damage like emotional harm[221].

Annual product liability insurance costs are assessed to increase for software producers by 15%[222]. Effects on as well as for refurbishers and remanufacturers would remain as in PO1a and PO1b.Annual product liability costs are assumed to increase by 2-3% for producers of IoT products, including providers of AI systems, due to inclusion of damage flowing from fundamental rights infringements. Assumptions for refurbishers and remanufacturers as well as authorised representatives and fulfilment service providers are as in PO1b.

Under PO1c, total **annual product liability insurance costs** are assessed to increase incrementally compared to the baseline, with an increase between 6.55 and 13.10 EUR million EUR million[223].

b. Impacts on SMEs

Same as PO1a.

c. Impacts on the internal market and competitiveness

Extending the PLD to include immaterial damage such as emotional harm may lead to positive harmonisation effects in the internal market, as national authorities currently compensate immaterial damage across the EU in different ways. However, compensating

[217] BEUC (2020), Product Liability 2.0 - How to make EU rules fit for consumers in the digital age, p. 13; the comment also encompasses "data protection by design" rules.
[218] Austrian Federal Economic Chamber; Business Europe; BVMed (German Medical Technology Association); EFPIA (European Federation of Pharmaceutical Industries and Associations); EUROCHAMBRES; French Business Confederation; Google; GSMA; Siemens; Siemens Healthineers; ZVEI (German Electro and Digital Industry Association).
[219] Responses of European Law Institute and Irish Council for Civil Liberties to the public consultation.
[220] ADAPTA; BEUC; The Future Society; Verbraucherzentrale Bundesverband.
[221] For example, responses of EUROCHAMBRES, Business Europe and Insurance Europe to the public consultation.
[222] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.
[223] As for PO1a and PO1b, these increases in product liability insurance costs are extra revenues for the insurance companies.

damages for personal data breaches under the PLD would create overlap with the GDPR. Also, industry stakeholders (especially representatives in the digital, tech and software industries) expressed their concerns that liability for the harms considered under PO1c could harm innovation and the competitiveness of the tech and software industry.

d. Impacts on the judicial system and legal costs

For software producers and related victims of harm, PO1c would reduce the annual legal costs by 6%[224] due to the even broader application of no-fault liability compared to PO1a and PO1b, meaning shorter proceedings. On the other hand, however, PO1c would increase the number of in-court and out-of-court cases of around 3.5%.

Similarly, PO1c would also increase by 16% the number of in-court and out-of-court cases due to inclusion of damage flowing from fundamental rights infringements, relevant for producers of IoT products and providers of AI systems. Effects derived from making authorised representatives and fulfilment service providers liable would be the same as in PO1b.

Taking all this into account, under PO1c the total **annual legal costs** are assessed to increase incrementally compared to the baseline, with an increase between 1.83 and 4.50 EUR million.

Social impacts

a. Impacts on consumers

PO1c would enhance consumer protection as they could get compensation for immaterial damages, such as emotional harm, and for losses caused by discrimination and privacy breaches. In the apparently limited cases of data protection infringements in which the GDPR does not apply (see section 2.2.1.1), the PLD could provide compensation. Consumers could also stand to get compensation for losses caused by discriminatory AI systems, such as recruitment or credit-rating software. However, a negative impact on innovation, as referred to under Economic Impacts above, would also have negative consequences for consumers in terms of potentially higher prices and reduced access to innovative products.

In line with the impacts on the judicial system described above, PO1c would increase the annual number of in-court and out-of-court cases under the PLD in the EU27[225]. The measure would not affect the average compensation pay-outs to victims.

Taking all this into account, under PO1c the total **annual compensations paid to victims** are assessed to increase incrementally compared to the baseline, with an increase between 0.17 and 47.70 EUR million[226].

b. Impacts on employment and fundamental rights

Adequate provisions against discrimination and privacy breaches within the PLD may contribute to protecting human dignity and personal data protection across the EU, but it

[224] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.
[225] New harms introduced under PO1c would be included in the PLD as a new category of harm alongside personal injury and property damage.
[226] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.

is not possible to quantify this. There are no foreseen impacts to employment under PO1c.

6.4. Policy option 2.a – Easing the burden of proof and reducing disproportionate restrictions to make claims

Economic impacts

a. Impacts on producers

The obligation on producers to disclose necessary technical information to injured persons in court will have a limited impact, given that nearly all Member States already have disclosure rules (see section 2.2.2.1). Industry stakeholders were generally open to having more uniform, pan-European rules on information disclosures for this reason, so long as a claimant's request was justified and intellectual property rights were adequately protected[227].

Easing the burden of proof in a harmonised way by setting conditions for defectiveness/causality to be presumed would have a limited impact on producers, because national courts already have tools at their disposal to ease the burden of proof where it is too heavy. Indeed industry stakeholders do not dispute the role of presumptions to ease the burden of proof in complex cases, they just believe it should be left to national systems[228]. Making the rules explicit in the text of the PLD could, however, potentially give consumers greater confidence to make compensation claims in more complex cases, in which the producer would have to play a more active role to demonstrate the product was safe.

The adaptation of the development risk defence under PO2a would be the logical corollary of the change to the later-defect defence under PO1a, under which producers of products like robots or autonomous vehicles continue to be liable for defects that emerge after the product was put into circulation owing to their ongoing control over the product. There would therefore be no additional impact compared to PO1a.

The removal of the EUR 500 threshold could potentially concern any producer of a product capable of causing property damage. The threshold was introduced to avoid excessive litigation, but litigation, including for property damage, has remained altogether low under the PLD. Nevertheless, the removal could lead to more compensation pay-outs, and therefore a slight increase in annual insurance premiums, as producers would prefer to settle small claims rather than dispute them in a costly court case[229].

Industry stakeholders did not expect any significant impacts but rather saw the threshold as one element of the balance of producer-consumer interests that they did not want to change.

[227] Responses of Siemens Healthineers, Bundesverband Medizintechnologie, Confederation of European Security Services, to the public consultation.
[228] E.g. responses of Business Europe, of European Federation of Pharmaceutical Industries and Associations, of Insurance Europe, and of Google to the public consultation.
[229] Both consumers and industry prefer out-of-court settlements for smaller claims, given the high cost of court cases; confirmed inter alia by European Justice Forum (2021), Input to EU Commission on Review of PLD.

The extension of the 10-year liability period to 15 years concerns only producers of products capable of causing latent personal injury, in particular products that can affect the human body internally, such as pharmaceuticals, chemicals and construction materials like asbestos[230]. Nevertheless, for concerned producers, the extended exposure to liability could potentially mean a very small increase in the volume of legal cases and therefore a small increase in insurance premiums.

Annual product liability insurance costs are assumed to increase by 4%[231] for producers of more complex products such as pharmaceuticals, IoT and AI-enabled products, due to information requirements and more uniform conditions for easing the burden of proof.

Moreover, total product liability insurance costs are assumed to increase by 3-4% due to the insurers' exposure to risk increases with the extension of the liability period and damage threshold[232].

Under PO2a, total **annual product liability insurance costs** are assessed to increase incrementally compared to the baseline, with an increase ranging between 14.35 and 28.71 EUR million[233].

b. Impacts on the internal market and competitiveness

Setting out explicitly obligations for producers to disclose information and the conditions for easing the burden of proof through presumptions would create greater legal certainty and achieve a more equal level of consumer protection across the EU. The burden of proof would be more fairly shared between injured parties and producers in cases involving more complex products. Removing the EUR 500 threshold would promote more uniform consumer protection in the internal market, given the unequal impact the threshold has in light of the wide disparities in price levels between Member States of consumer property, while still preserving innovation that could be hampered by more far-reaching measures, especially in innovative sectors like pharmaceuticals and AI, and undermine the uptake of new technologies.

c. Impacts on the judicial system and legal costs

Since disclosure rules and alleviations of the burden of proof are familiar to almost all Member States, there should be no particular impact on the justice system. The use of presumptions is expected to make court cases shorter, as more onus would be placed on the party with greater understanding of the product: the producer.

PO2a would reduce the annual legal costs by 10%[234] for more complex products such as pharmaceutical, IoT and AI-enabled products, due to shorter proceedings as a result of better access to information for claimants and presumptions while increasing the number of proceedings, both in court and out of court, by 5%, due to changes in the burden of proof. Moreover, PO2a would also increase the overall number of cases by 2%, due to the reduced restrictions in making claims.

[230] See section 2.1.2.2.
[231] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.
[232] Furthermore, producers of digital products and elements would be affected by the adaptation of the development risk defence. But because the adaptation is linked to PO1a, no additional increase is expected.
[233] As for previous policy options, these increases in product liability insurance costs are extra revenues for the insurance companies.
[234] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.

The increase in relation to the removal of the EUR 500 threshold is expected to concern only out-of-court rather than in-court proceedings. However, class actions[235] would theoretically become possible after removing the threshold, but these are expected to remain a very rare occurrence in relation to property damage (class actions would be more common in relation to personal injuries).

Under PO2a, total **annual legal costs** are assessed to slightly increase incrementally compared to the baseline, with an increase between 0.41 and 1.02 EUR million.

Social impacts

a. Consumer protection and access to justice

Harmonised disclosure of necessary information and harmonised application of presumptions would ensure a **more uniform level of consumer protection**. As products become more and more complex, guaranteed access to information would help to lessen the asymmetry of information, particularly in the area of digital technologies, such as AI, where digitally logged information could help reveal how a product (e.g. a robot) caused the harm.

The policy option would be in line with principles the ECJ has already endorsed, recognising the need to ease the burden of proof in complex cases. The greater visibility of the possibility to ease the burden of proof could improve consumer confidence and trust in more complex products.

The removal of the EUR 500 threshold would mean that the PLD protects consumers no matter what the value of property damage caused by a defective product. Even though there are unlikely to be additional court cases for lower-value claims, the removal may incentivise producers to settle smaller claims by negotiation or out-of-court settlement.

The extension of the 10-year liability period to 15 years would improve the prospects of victims of latent personal injury getting compensation when the harm takes longer to manifest itself. Although it will benefit few victims, given the rarity of latent personal injury, it will help those victims considerably.

PO2a would slightly increase the overall annual number of in-court and out-of-court cases under the PLD in the EU27 by 2%[236] due to reducing restrictions on making claims, but, more significantly, would increase by 7% the number of claims for more complex products, such as pharmaceuticals, IoT and AI-enabled products, that successfully lead to compensation due to information disclosures and the more uniform use of presumptions. The measure would not affect the average compensation pay-outs to victims.

Under PO2a, the total **annual compensations paid to victims** are assessed to increase incrementally compared to the baseline, with an increase ranging between 0.20 and 43.54 EUR million.

b. Impacts on employment and fundamental rights

[235] e.g. under Directive (EU) 2020/1828 on representative actions for the protection of the collective interests of consumers.
[236] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.

Reducing restrictions on making claims and easing the burden of proof in the case of complex products would strengthen the right to an effective remedy, a right guaranteed under Article 47 of the EU Charter of fundamental rights. PO2a should not have any impact on employment.

6.5. Policy option 2b – Reversing the burden of proof

Economic impacts

a. Impacts on producers

Reversing the burden of proof, therefore requiring the producer to prove the product in question was not defective and did not cause the harm suffered, would go significantly beyond option 2a and beyond what national courts are currently allowed to do under the PLD. This option would in principle affect all producers.

In the public consultation, a full reversal of the burden of proof for technically complex products was only first-ranked by 5% of respondents and second-ranked by 32%[237], considerably less than for option 2a. BEUC, the consumer organisation, has argued that a reversal of the burden of proof, especially needed for complex products, is needed to remove the difficulties consumers face in proving defectiveness and the causal link between defect and damage[238]. Only 22% of business and industry associations ranked this option first or second.[239] Industry position papers indicated strong opposition to a reversal of the burden of proof, on the grounds that the burden of proof is rightly borne by the claimant as a counterbalance to no-fault liability being imposed on producers, and that it could expose companies to unnecessary, frivolous and even abusive litigation[240].

Removing the development risk defence would in principle impact all producers, but in particular those operating in highly innovative sectors where undiscoverable risks might emerge after a product is put into circulation, such as in the pharmaceuticals or AI sectors. 57% of consumer associations, NGOs and citizens were in favour of removing the defence, whereas 87% of industry associations were in favour of keeping it.[241] Insurance Europe argued that removing the defence would deter technological innovation and hinder economic development, while EFPIA insisted it would place excessive burdens on producers[242].

The impacts of removing the EUR 500 threshold would be the same as under PO2a, but extending the 10-year liability period to 15 years in all cases of personal injury and lengthening the 3-year period for starting legal proceedings to 5 years would increase all producers' liability exposure.

Annual product liability insurance costs are assumed to increase by 6-8%[243] for all producers due to the reversal of the burden of proof and by 5-6% due to the removal of the development risk defence and due to the incremental changes to the liability period and time limit.

[237] 9 out of 168, and 53 out of 168 respectively.
[238] Response of BEUC to public consultation.
[239] 24 out of 110
[240] Response of EFPIA, pharmaceutical association, to public consultation.
[241] 15 out of 26, and 57 out of 65 respectively
[242] Response of EFPIA, pharmaceutical association, to public consultation.
[243] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.

Under PO2b, total **annual product liability insurance costs** are assessed to increase incrementally compared to the baseline, with an increase between 41.73 and 83.46 EUR million[244].

b. Impacts on the internal market and competitiveness

Industry stakeholders argued that reversing the burden of proof and removing the development risk defence would be disproportionate, hampering innovation, especially in innovative sectors like pharmaceuticals and AI, and undermine the uptake of new technologies[245].

c. Impacts on the judicial system and legal costs

PO2b would increase the number of proceedings, both in court and out of court, by 10%[246], due to the reversal of the burden of proof and by 5% due to the reduced restrictions in making claims.

Under PO2b, total **annual legal costs** are assessed to slightly increase incrementally compared to the baseline, with an increase between 6.90 and 16.96 EUR million.

Social impacts

a. Consumer protection and access to justice

Reversing the burden of proof would facilitate the position of the consumer significantly, as they would only have to prove a product caused damage and then the burden of proof would pass to the producer. Consumers would be reassured that in case of a product causing harm, it would be up to the producer to demonstrate that their product was not defective and had not caused damage. On the other hand, any hampering of innovation, identified under Economic Impacts above, would have negative consequences for consumers in terms of potentially higher prices and reduced access to innovative products. The position of consumers would also be improved by extending producers' liability to 15 years for any personal injury claim and by giving victims of harm 5 years to start legal proceedings.

PO2a would increase the overall annual number of in-court and out-of-court cases under the PLD in the EU27 by 5%[247] due to reducing restrictions on making claims, but, more significantly, would increase by 12% the number of claims that successfully lead to compensation due to the reversal of the burden of proof. The measure would not affect the average compensation pay-outs to victims.

Under PO2b, the total **annual compensations paid to victims** are assessed to increase incrementally compared to the baseline, with an increase ranging between 0.99 and 217.70 EUR million.

b. Impacts on employment and fundamental rights

PO2b should not have any impact on employment or fundamental rights.

[244] As for previous policy options, these increases in product liability insurance costs are extra revenues for the insurance companies.
[245] For example response of Business Europe to public consultation, p. 4.
[246] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.
[247] Annex 4 provides details on the assumptions and analytical methodology used for these estimations.

Environmental impacts

A reversal of the burden of proof could potentially facilitate the development of safer complex products that are less likely to malfunction, and therefore to be replaced.

7. HOW DO THE OPTIONS COMPARE?

7.1. Effectiveness of the proposed policy options

The following tables present the effectiveness of the proposed options against the relevant specific objectives.

Table 3: Effectiveness of policy options to adapt the PLD to the digital age and circular economy

	Objective 1: Adapt PLD to reflect nature and risks of products in the digital age	Objective 2: Adapt the PLD to reflect the nature of products in the circular economy	Objective 3: Ensure there is always an EU-based liable person for defective products bought in the EU	Net effect
Baseline	0			
PO1a	++	++	++	++
PO1b	+++	++	+++	+++
PO1c	++	++	+++	++

Legend: - not effective; + limited effectiveness; ++ effective; +++ very effective

PO1b would, in comparison to PO1a, further incentivise the placing of safer software on the market, by covering 3rd-party software that influences but is not necessary for a tangible product, and safety-relevant standalone software. PO1b would also provide regulatory certainty about the availability of compensation for damage to digital property and could incentivise producers to improve the reliability of hard drives and other data storage devices. Increasing regulatory clarity and closing liability gaps will benefit innovation. PO1b would ensure that the deterrent effect of no-fault liability, which encourages producers to place only safe products on the market, reaches non-EU producers also in cases where no authorised representative has been appointed.

By extending the PLD to include immaterial damage, option 1c may lead to positive harmonisation effects in the internal market, as national authorities currently compensate immaterial damage across the EU in different ways. However, compensating damages for personal data breaches and discrimination under the PLD would create overlap with the GDPR and non-discrimination law. Also, industry stakeholders (especially representatives in the digital, tech and software industries) expressed their concerns that liability for the harms considered under PO1c could harm innovation and the competitiveness of the tech and software industry.

Table 4: Effectiveness of policy options to reduce disproportionate obstacles to getting compensation

	Ease the burden of proof in the case of complex products and clarify liability for undiscoverable defects, while ensuring fair balance between producers and consumers	Ease restrictions on making claims, while ensuring fair balance between producers and consumers	Net effect
Baseline	0		
PO2a	+++	+++	+++
PO2b	++	++	++

Legend: - not effective; + limited effectiveness; ++ effective; +++ very effective

By reversing the burden of proof, Option 2b would alleviate the difficulties that consumers face. However, especially if taken together with the removal of the development risk defence, this measure would overly favour consumers, thus undermining a fair balance of interests between consumers and producers. Reversing the burden of proof and removing the development risk defence would also have negative impact on innovation.

By easing the burden of proof in the case of complex products, option 2a would achieve a fairer balance of interests between injured parties and producers. Option 2a would create greater legal certainty and achieve a more equal level of consumer protection across the EU, while still preserving innovation that could be hampered by further-reaching measures, especially in innovative sectors like pharmaceuticals and AI, and could undermine the uptake of new technologies.

7.2. Impacts of policy options

The following table summarises the costs and benefits, for each policy option, quantified and presented in section 6.

Table 5: Costs & Benefits summary table (EUR million annual)

	Incremental benefits compared to baseline		**Incremental costs compared to baseline**			
	Incremental annual compensation paid to victims(*)		Incremental annual product liability insurance costs		Incremental annual legal costs	
	Low end	High end	Low end	High end	Low end	High end
PO1a	0.07	14.47	1.21	2.41	0.41	1.02
PO1b	0.15	22.13	4.35	8.69	1.12	2.75
PO1c	0.17	47.70	6.55	13.10	1.83	4.50
PO2a	0.20	43.54	14.35	28.71	0.41	1.02
PO2b	0.99	217.70	41.73	83.46	6.90	16.96

Summary of incremental costs per policy options. See annex 4 for details.
(*) In most cases covered by insurance

As explained in section 6, the cost/benefits analysis is not fully comprehensive due to significant data gaps and limitations. The aim of the assessment is to provide ranges of the magnitude of potential impacts generated by each policy option, rather than exact monetisation. The following table summarises the quantitative and qualitative assessments, presented in section 6, on the potential effects of policy options to producers, consumers, internal market, and competitiveness as well as on the environment.

Table 6: Summary of Economic, social and environmental impacts

	Economic impact	**Social impact**	**Environmental impact**
PO1a	++	++	++
PO1b	+++	++	++
PO1c	-	+++	++
PO2a	+-	++	NA
PO2b	--	+++	NA

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ significant positive impact; - minor negative impact; -- negative impact; --- significant negative impact, NA – not applicable

The scale of the negative economic impacts will increase with the level of intervention. In contrast, however, the policy options with high levels of intervention are anticipated to have potentially significant positive social impacts on consumer protection.

Options 1a and 1b would have slight negative impacts on the insurance costs counterbalanced by strong positive impacts in terms of internal market, competitiveness and innovation as well as positive impacts in the functioning of the circular economy. They would also have strong positive impacts on consumer protection. Option 1c would enhance consumer protection due to greater harmonised coverage but with a risk of hindering innovation by including non-material damage into the compensable damages.

Option 2a would have some implications for the internal market (e.g. greater uniformity in use of presumptions and in information disclosures) and only minor impacts on competitiveness and innovation. However, it would have strong positive impacts on consumer protection.

Under policy option 2b, a notable negative economic impact is to be expected, with a potential increase in costs for producers due to various reasons (e.g. higher legal costs for defendants if the burden of proof were to be reversed, higher numbers of claims and compensation pay-outs). Option 2b would have a significant positive impact on consumer protection.

Policy options face greater opposition from industry as the level of intervention increases, while receiving greater support from consumers.

Table 7: Stakeholder support

	Stakeholder support		
	MS	Industry	Consumers
PO1a	++	++	+
PO1b	++	++	++
PO1c	+	+-	+++
PO2a	++	+	++
PO2b	+	+-	+++

Legend: +- no support; + limited support; ++ support; +++ strong support

In particular, industry stakeholders voiced strong opposition to the reversal of the burden of proof in policy option 2b (in the interview programme, targeted and public consultations). The main concern was that the delicate balance between consumer protection and producers accepting the principle of no-fault liability whilst maintaining innovation and competitiveness would be undermined if the burden of proof were reversed. Balanced against this, there was less industry opposition to policy option 2a in respect of clarifying the circumstances in which presumptions can be used and making necessary technical information available to injured parties. Member States expressed clear support for revising the PLD in the dedicated Member State workshop held in February 2022 and in the responses to the public consultation, but only several Member States expressed clear views on specific policy options[248].

[248] See annex 2 for details.

7.3. Summary of policy options assessment

The table below summarises the assessment presented so far, providing an overview of the effectiveness, efficiency and coherence with the EU law for each of the policy option analysed.

Table 8: Summary table

	Effectiveness	Efficiency	Coherence with EU law
PO1a	++	++	+++
PO1b	+++	++	+++
PO1c	++	+	++
PO2a	+++	+	+++
PO2b	++	+-	+++

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ significant positive impact; - minor negative impact; -- negative impact; --- significant negative impact

The proposed measures are considered to generally be coherent with wider EU policy and regulatory developments, with the exception of 1c, which would risk duplicating Art. 82 of the GDPR in respect of data protection and privacy infringements, and risk overlapping with non-discrimination law.

8. PREFERRED OPTION

Based on the comparative assessment of policy options above, the preferred combination of policy options consists of PO1b to address problem 1 and PO2a to address problem 2. They scored well across a range of criteria (positive economic, social and environmental impacts, effectiveness, efficiency and coherence).

As regards the policy options to adapt the PLD to the digital and circular economy, while PO1a would make the PLD work better for products with digital elements, it is less effective as it would not fully adapt the PLD to the digital age, because it would not address liability for safety-relevant software supplied separately from a tangible product nor deliver legal certainty with regard to compensation for digital property. Consumers should not enjoy less protection in such cases, and an economic operator's liability should not depend on the tangibility of what they put into circulation if it causes harm. Option PO1b also scored well with regard to economic, social and environmental impacts. PO1c, on the other hand scores lower because, while it would afford consumers greater protection, it would go too far by opening producers up to no-fault liability for new harms (privacy, discrimination, emotional harm) that could be more appropriately addressed under other legal frameworks not based on no-fault liability. PO1b strikes the right balance in adapting the PLD to the digital age, it achieves the objective of reflecting the nature of products in the circular economy, and it would ensure the liability of an EU-based responsible person for defective products, in line with market surveillance rules.

As regards the policy options to reduce disproportionate obstacles to getting compensation, PO2b's reversal of the burden of proof would expose producers to significantly higher liability risks, by requiring them to prove their products were safe. This and removing the development risk defence could hinder innovation, to the detriment of both industry (in particular SMEs, which would less easily absorb additional costs) and consumers. PO2a scores more highly than PO2b in terms of effectiveness and efficiency. Information disclosures and more uniform use of presumptions should help consumers prove liability where complex products are involved, but in a way that seeks

to restore the balance between producer and consumer interests. PO2a also seeks balance by reducing restrictions on making claims in a focussed and proportionate way, by ensuring victims are not worse off just because the value of property damage suffered was below a threshold or because personal injuries emerged after a long period of time.

Although PO1b and PO2a each address a distinct problem, they have synergistic impacts. The objective of adapting liability rules to the digital age in PO1b is reinforced by ensuring under PO2a that consumers are able to get compensation for harm caused by complex digital products, among others. Similarly, the fair balance between producer and consumer interests, which is at the heart of PO2a, is reinforced by the choice of PO1b, in that that option does not over-burden producers with liability for privacy infringements, discrimination and non-material harm. The costs and benefits as assessed will be cumulative. The preferred option will contribute to SDG 3 due to its positive social impacts on victims' health and well-being, to SDG 9 by providing legal certainty for businesses to innovate and to SDG 12 by enhancing product safety when substantial modifications are made.

In terms of net impacts on different stakeholder groups:

- **Producers** with liability insurance may face an increase in liability insurance premiums. If they are found liable for harm caused by a defective product, the liability insurance would cover the compensation and legal costs. Producers without a liability insurance would face direct compensation costs to victims (costs not considered in the analysis, see section 6), and legal costs if the case goes to court.
- **Insurance companies** may have to bear higher compensation costs, but they would off-set that cost by marginally raising insurance premiums, leading to higher revenues. Their net income is therefore assumed to remain stable over time.
- **People who suffer damage** will receive compensation pay-outs if they prove liability. They are assumed to bear legal costs if they do not win the case.

Table 9: Costs & Benefits of preferred option (EUR million annual)

	Incremental benefits compared to baseline		**Incremental costs compared to baseline**			
	Incremental annual compensation paid to victims(*)		Incremental annual product liability insurance costs		Incremental annual legal costs	
	Low end	High end	Low end	High end	Low end	High end
PO1b + PO2a	0.15	22.13	4.35	8.69	1.12	2.75

Summary of incremental costs per policy options. See annex 4 for details.
(*) In most cases covered by insurance

The preferred option is coherent with, although independent of, the preferred option under the AI liability impact assessment. The revised PLD will continue to provide a system for compensating harm caused by any defective product, but will do so more effectively for digital and complex products than is currently the case, including for all AI-enabled products. The measures envisaged in the AI impact assessment (such as alleviating the burden of proof in fault-based claims) concern only high-risk or highly

autonomous/opaque AI systems, and products/services that use them, and those measures will apply only to national fault-based claims and not to claims brought under the PLD. A more effective PLD will provide victims with a straightforward route to compensation without having to prove fault, which should reduce the number of cases brought under national fault-based rules. However, when victims *do* use national fault-based rules, the measures envisaged in the AI impact assessment will help them. Victims will do this mainly when they seek compensation from persons other than the producer – in particular *users* of AI systems (e.g. companies providing cleaning or security services using AI-enabled robots) – or when seeking compensation from the producer but for damage not covered by the PLD, like non-material damage or discrimination (e.g., discrimination damages for biased recruitment software).

The impacts of both preferred options are therefore consistent, since they will help victims with different claims for different types of damage against different liable persons. The preferred options use similar tools (access to information, adaptations of the burden of proof). With respect to AI systems, the preferred options should, in their combination, ensure that victims of damage caused by AI-systems have the same level of protection compared to damage caused by traditional products, no matter which route to compensation is taken.

8.1. REFIT (simplification and improved efficiency)

The evaluation of the PLD found the current administrative burden to be very low, as it consists only in a one-off obligation on Member States to inform the Commission in the event that they wish to derogate from the development risk defence in Article 7(e). The evaluation of the PLD concluded there was no scope for simplification[249]. As the PLD does not result in any direct compliance costs or administrative costs for economic operators or consumers, no quantifiable efficiency gains could be identified. Economic operators would, however, benefit from more legal certainty and more coherent interpretation of liability rules in the internal market. Consumers would benefit from more equal level of consumer protection.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

The Commission will monitor the implementation and application of, and compliance with, the revised provisions of the PLD according to the preferred option. This will be done consistently with the monitoring of any legislative instrument resulting from the impact assessment on AI liability. A Commission Expert Group would be set up with all relevant stakeholders and Member States to analyse the implementation of the revised PLD in all Member States. The Commission would prepare an implementation report 3 years after transposition of the revised PLD, and conduct an evaluation after 5 years.

While it is challenging to isolate the impacts of the PLD on the functioning of the internal market and the level of consumer protection, due to its very broad scope, its synergistic effects with product safety rules, the availability of other routes to compensation and the lack of robust data on its use, indicators for monitoring the impacts of the preferred option have been identified They are not based on hard data but rather

[249] European Commission (2018). Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products, p.39.

the reported cases of use of the PLD and perception of affected stakeholders – see annex 9.

Annex 1: Procedural information

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

Lead DG: DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)

Directorate: Directorate G – Ecosystems II: Tourism & Proximity

This impact assessment is part of the initiative with the *Decide* reference PLAN 2020/9848, entitled "Adapting liability rules to the digital age and Artificial Intelligence".

2. ORGANISATION AND TIMING

The inception impact assessment consultation period ran from 30 June to 28 July 2021.

The public consultation period ran from 18 October 2021 to 10 January 2022.

An inter-service steering group was convened and chaired by the Secretariat-General and the last meeting on the final draft impact assessment report was held on 18 February 2022. The following Directorates-General participated: SG, LS, JUST, GROW, CNECT, JRC, SANTE, EMPL, COMP, FISMA, AGRI, ECFIN, ENV, TRADE.

3. CONSULTATION OF THE RSB

The RSB was consulted in an upstream meeting on 2 June 2021. This impact assessment was submitted to the RSB on 4 March 2022. The meeting with the RSB took place on 6 April 2022.

The RSB issued its opinion on 8 April 2022, following which this impact assessment was revised as follows:

RSB recommendations	Revision made
1) The report should better explain the scope of the problem, in particular why it does not cover repaired products. It should clarify why the product/service overlap with the parallel initiative on artificial intelligence liability is not problematic.	- Clarification in section 2.2.1.2 that repairers are not producers within the meaning of the PLD. - Clarification that there is no problematic overlap with AI liability in section 1.2.5 and section 8
2) The report should clarify the baseline assumptions. It should explain better to what extent the reduction of number of liability cases resulting from the expected product safety improvements are included in the baseline and be clear how this affects the size of the remaining problem. Given the significance of the expected reduction of product-related accidents, further efforts should be undertaken to produce a more realistic assessment and description of the dynamic baseline.	Better explanation in 5.1 of impacts of product safety improvements, in particular that: - Improvements seek both to reduce product-related harm in real terms but also to avoid a future rise in harm from novel risks. - The range of case numbers takes this into account, even if it is not directly quantifiable. - Annex 4 provides further explanation on the baseline assumptions.

3) The report should be clear on the uncertainties related to the baseline estimates. It should explain how representative and robust the baseline figures extrapolated from a limited data source (one Member State) are. It should explain better to what extent the legal database from the Netherlands can serve as a realistic reference basis for extrapolation to all EU-27 Member States	- The baseline estimates on the number of cases have been reviewed. The baseline figures are based on databases from 5 Member States instead of only one. - The limitations of the database and extrapolation are explained in Annex 4. - The estimates of costs and benefits have been recalculated using the revised baseline figures.
4) The report should show that the selected options contain all relevant combinations of measures. It should not discard measures based on the views of only one stakeholder group.	- The introduction to section 5.2 explains the development of the combinations and the descriptions of options explain better the rationale behind the combinations. - The introduction to section 5.2 also explains that for greater transparency on the impact of different elements within each option, the costs and benefits (increase of insurance premiums and compensations for victims) related to each measure are shown separately in section 6 of the impact assessment - Clarification that discarded measures were based not on one stakeholder group but on the need for a fair balance among different groups.
5) The report should clarify what the costs to businesses include and how the quantitative estimates were calculated. Given that the direct compensation costs borne by businesses having no liability insurance coverage are not quantified due to data limitations, it should acknowledge the risk that the presented estimates result in a likely underestimation of the costs.	- Clearer justification of the approach to assessing direct compensation costs added in the introduction to section 6. - Clarification of the costs for businesses and the methodology for estimates added in Annex 4.
6) The report should present the overall net impact of the preferred option taking into account all transfers between different stakeholder groups. In addition, it should clarify and complete the distributional analysis of the impacts on the different stakeholder groups. In particular, it should analyse the impacts on producers (both with and without liability insurance) and on insurance companies. Given the high SME relevance of the initiative, the report should further develop the analysis of the effects on SMEs, including the extent to which they might be faced with direct compensation costs, due to a lack of (adequate) insurance coverage.	- Better explanation of the impacts of the preferred option per stakeholder group in section 8 and Annex 3. - SME relevance reflected in section 6 (SME impacts of PO 1a), in Annex 2 (1st section), section 8 on the preferred option. All evidence is presented together in the SME test in new Annex 10.
7) The report should better justify why the transfer of product liability from the original manufacturer to refurbishers and remanufacturers would not negatively affect the development of the circular economy.	Better justification give in section 6.2 under Environmental Impacts.
8) The report should be clear to what extent the analytical assumptions and results (in both the baseline and impact analyses) have been validated by experts and stakeholders. More generally, the report should deal better with uncertainty, for instance by considering sensitivity analysis when assessing the scale of the (remaining) problem and comparing the options in terms of costs and benefits.	Annex 4 includes detailed explanation of the methodology and how different results have been validated by experts and stakeholders. The clarification concerning the validation of options and estimates by stakeholders also added in introductions to sections 5 and 6. Baseline assumptions have been reviewed (see point 3) and are based on ranges, providing different scenarios depending on the assumptions on the number of PLD cases and on the average compensations paid out to victims. Net impacts of different options have been more clearly

	explained for the relevant stakeholder groups.

4. EVIDENCE, SOURCES AND QUALITY

The Evaluation[250] of the Product Liability Directive identified the key areas for the revision. It was supported by a study by an external contractor[251].

This impact assessment is also supported by a study undertaken by another external contractor[252], who carried out dozens of interviews, analysed data from public and targeted consultations and complemented this through desk research and case studies.

The impact assessment provides qualitative information regarding the positive and negative impacts generated by each PO, reporting the main information on the sectors and economic operators mostly affected by the proposed changed. This qualitative analysis is based on the evidence gathered through interviews and desk research.

Whenever possible, economic, social and environmental impacts were assessed quantitatively. Because of the wide scope of the PLD, the costs and benefits generated by this Directive are also extremely vast, we outline approximate quantitative estimates for the main quantifiable benefits (compensation pay-outs to victims) and main costs (namely, product liability insurance costs; and legal costs).

Data needed for the analysis has been obtained from multiple sources, chosen as reliable as possible[253]. Relevant limitations of data generated important challenges in the quantification of costs and benefits. Challenges encountered:

- Insufficient information and data are currently available on likely future trends for all product groups to translate these into a full quantitative analysis.
- A general lack of granular information on the economic and social impacts of the PLD as it currently stands.
- Uncertainty as to whether technological innovation and digitalisation will increase the number of product liability legal cases.
- Data on the number of affected economic operators in the value chain is difficult to generate.
- The costs of strict product liability insurance premium borne by economic operators can vary significantly.

Thus, it was not feasible to conduct a comprehensive quantification of costs and benefits for both the baseline scenario and different policy options.

[250] Evaluation of Product Liability Directive, SWD(2018)157.
[251] EY, Technopolis, VVA (2018), Study accompanying Evaluation of Product Liability Directive.
[252] CSES with Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive.
[253] See Annex 4

Annex 2: Stakeholder consultation

1. CONSULTATION STRATEGY

The objectives of the consultation were to collect evidence and views from a broad range of stakeholders, on the identified problems and the potential solutions concerning the PLD. The activities included a 12-week dedicated public consultation concluded in January 2022, two Stakeholder Workshops held on 23 June and 13 December 2021, a workshop with Member States held in 1 February 2022 and feedback collected in response of the Commission's inception impact assessment. Also, as part of the impact assessment study, an external contractor organised interviews with 80 relevant stakeholders and an online targeted consultation between July and November 2021. Consulted stakeholders included EU and national consumer associations and civil society organisations; industry associations; economic operators; insurance associations; legal firms; academic experts; citizens; and national authorities. The only stakeholder category it was not possible to reach was fulfilment service providers. Feedback from SMEs was also fairly limited, despite disseminating the targeted and public consultations to the EU SME associations network and through the Enterprise Europe Network[254], but the feedback did not diverge particularly from the views of business respondents overall.

2. INCEPTION IMPACT ASSESSMENT (IIA)

The Inception Impact Assessment for this initiative was launched in 2021, with a feedback period running from 30 June to 28 July 2021. There were a total of 34 responses, of which 11 from business associations, 11 from company/business organisations, 6 from non-governmental organisations, 2 from EU citizens, 2 from consumer organisations, and 1 each from academic/research institution and public authority. Responses from industry revealed different interpretations of the scope of the PLD, particularly in respect of the coverage of software within the definition of product. It was widely acknowledged that some such notions required careful clarification, but industry respondents were skeptical of any fundamental revision, urging limited revision or guidelines. Industries also stressed that refurbishers should be considered as producers given the fact that they alter existing products making them de facto new products. In addition, there was almost unanimous opposition among industry groups to harmonising the entitlement to compensation for non-material damages under the PLD.

3. STAKEHOLDER WORKSHOPS

- The Stakeholder Workshop on 23 June 2021 brought together approximately 60 representatives of EU-level consumer, patient, business and industry organisations, legal practitioners, legal academics and Member State authorities. The objective of the workshop was to present the state of play on the impact assessment work and to discuss ways to adapt the PLD to the digital age and circular economy and to address obstacles to obtaining compensation under the PLD. Consumer and patient groups considered the identified problems to be significant and a revision of the PLD needed. Specific concerns were, for instance, raised on the 10-year time limit, considered as too short for some pharmaceutical harm, since adverse effects might manifest

[254] 13 SMEs (businesses) and two SME associations (European Digital SME Alliance and Allied for Startups) responded to the public consultation.

themselves many years after treatment. Conversely, business stakeholders that took the floor tended to be more skeptical of the need for legislative change, and called for legal uncertainty to be addressed through guidelines. Experts' views, for instance, differed on whether the problem could be addressed with a flexible horizontal solution or whether some products should be subject to differentiated rules (e.g. pharmaceuticals, AI or IoT).

- The Stakeholder Workshop on 13 December 2021 brought together mostly the same stakeholders. The purpose of the workshop was to inform stakeholders of the impact assessment work and get feedback on the policy options under consideration. In December, similar reflections to the previous June's session were highlighted. Consumer and patient representatives further stressed that harmonising the use of presumptions would not be adequate to assist consumers and that a reversal of the burden of proof was required, particularly for complex products. One French association representing victims of pharmaceutical harm called for the requirement to prove a defect to be dropped in cases of pharmaceutical harm and noted that presumptions would not help reduce the cost of technical expertise.

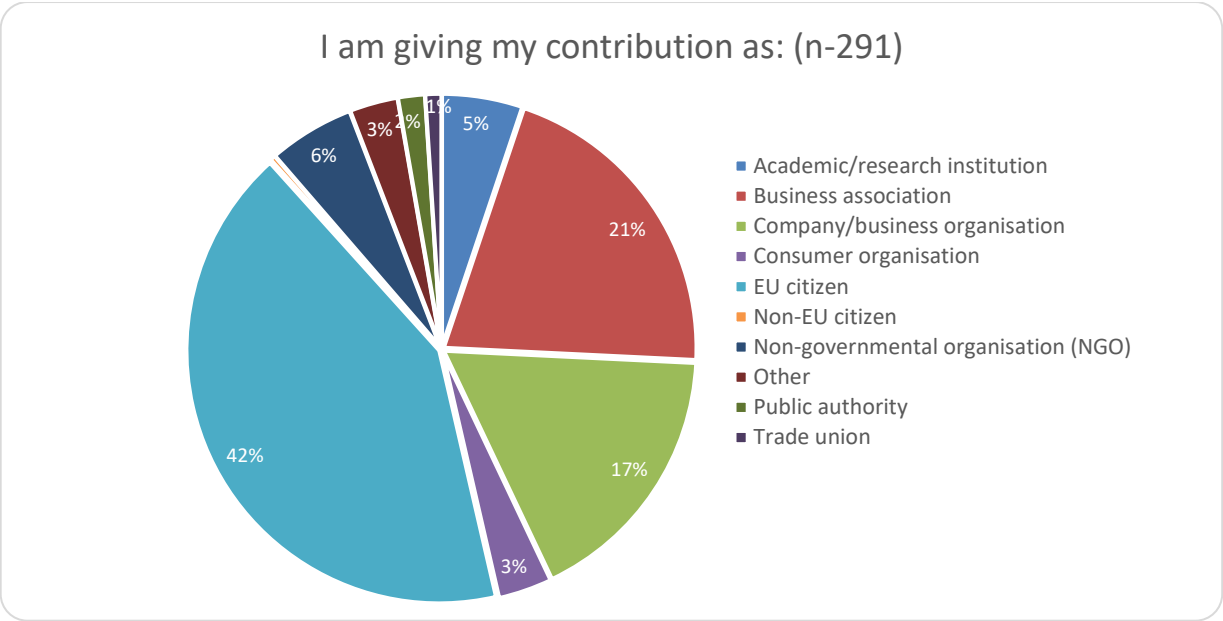
- The Member State Workshop on 1 February 2022 brought together Member State ministries responsible for the PLD. Only seven Member States expressed views. All were in favour of bringing software within the scope of the PLD, although views were not precise on what types of software to include. There was general agreement that fundamental rights risks should not be addressed in the PLD, that those who substantially modify products should be treated as producers and that any changes to make authorised representatives or fulfilment service providers liable for defect products should take into account the Market Surveillance Regulation and the ongoing negotiations on the General Product Safety Regulation. Views were mixed on the options to reduce obstacles to getting compensation: two large Member States urged for caution when considering the burden of proof, whereas two small Member States called for a reversal of the burden of proof in some cases. More Member States favoured removing the EUR 500 threshold and extending the 10-year liability period than keeping them as they are. The Commission also presented the initial results of the public consultation launched between October 2021 and January 2022.

4. PUBLIC CONSULTATION

The consultation was open during 12 weeks between 18 October 2021 and 10 January 2022, via the EU Survey online system in 24 EU languages, and received 291 answers. A total of 65 position papers were attached by stakeholders to the consultation. An additional seven position papers were received by email.

4.1. Respondents by Stakeholder category

A total of 291 individuals and organisations from all over the EU Member States and non-EU countries took part in the consultation.



The most common type of respondent was individual EU citizens, which accounted for 41.9% of responses (122). This was followed in second and third place by business and industry associations (60 responses) and individual companies/businesses respectively (50 responses). The next most frequent type of respondent were Non-Governmental Organisations (NGOs), including victims' associations, 16; Academics/research institutions, 15; and Consumer Organisations, 10. In addition, 9 of respondents declared listed 'Other' as their category, while other respondents included public authorities (5 responses) and trade unions (3 responses). Only one Non-EU citizen gave his/her contribution to the consultation.

The combined response from industry and business associations and from individual enterprises meant that industry accounted for 110 of the total 291 responses (37.8%). However, considering the organisational responses, whereas industry and business associations accounted for 60 responses, those representing the interests of consumers and injured parties, i.e. NGOs (which included access to justice and victims' rights associations) and consumer associations accounted for 26 responses.

4.2. Respondents by country of origin

Approximately 93.5% of all responses came from EU Member States, which is equal to 272 respondents. The largest group of respondents came from Germany which accounted for more than a third of all responses (108, or 37.1%), with respondents from Belgium and France in second and third place, with 46 (or 15,8%) and 36 (or 12,4%) respondents, respectively. Other Member States that provided a reasonable share of respondents were Italy (14 or 4.8% of the total), followed by Austria (12 or 4.1%), Netherlands (9, or 3.1%), Finland (8 or 2.7%), Poland (8 or 2.7%) and Spain (7 or 2.4%). 19 respondents (or 6.5%) came from non-EU countries, which included 8 respondents from the US (2.7%), 4 from the UK (1.4%) and 2 from Canada (0.7%).

4.3. The Directive and the problems this initiative aims to address

As regards questions 1 to 7 of Section I of the questionnaire, 128 out 291 respondents (thus 44%) replied to have detailed knowledge of the Directive, its objectives, rules and application.

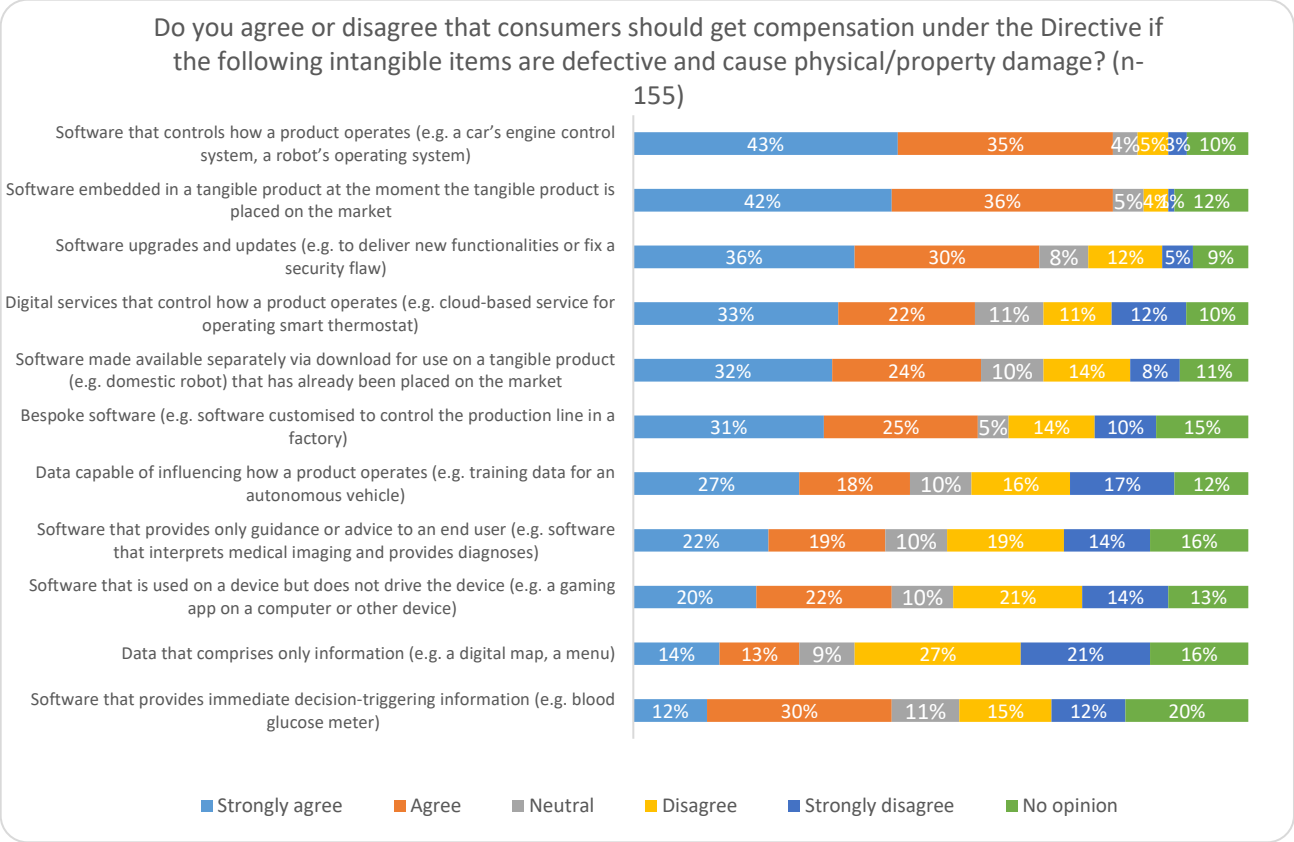
Among individual members of the public, 50 out of 133 replied to have suffered damage due to a defective product, of which 44% (or 22) reporting to have suffered personal injury or death and another 42% (or 21) property damage. In particular, 62% of respondents who suffered damaged reported defection related to "Vehicles; Machinery and mechanical appliances or parts thereof; Electrical equipment; Digital consumer products", while the remaining 38% report to have suffered a damage because of Pharmaceutical products (16 out of 19 of these replies concerned one specific pharmaceutical product in one specific country). Out of the 50 respondents, 15 replied that they had sought compensation.

4.4. Adapting the Directive to the digital age and circular economy

- **Intangible items: software and digital services**

This section of the consultation focused on the need to adapt the Directive to the digital age and, in particular, on the role that digital content such as software, algorithms and data should play in the safe functioning of many products. Respondents were asked to agree or disagree with a list of statements, proposing simplified answer options for individual members of the public.

Replies by **all respondents except members** of the public:



All respondents (excluding members of the public), mainly agree that consumers should get compensation under the Directive when intangible products are defective and cause physical/property damage. In particular in the case of: software that controls how a product works (78% or 122 out of 155)[255]; software upgrades and updates (66% or 102 out of 154)[256]; software supplied separately to use on a product (56% or 87 out of 155) [257]; digital services that controls how a product work (55% or 85 out of 154)[258]. Fewer than half were in favour of including data or information per se.

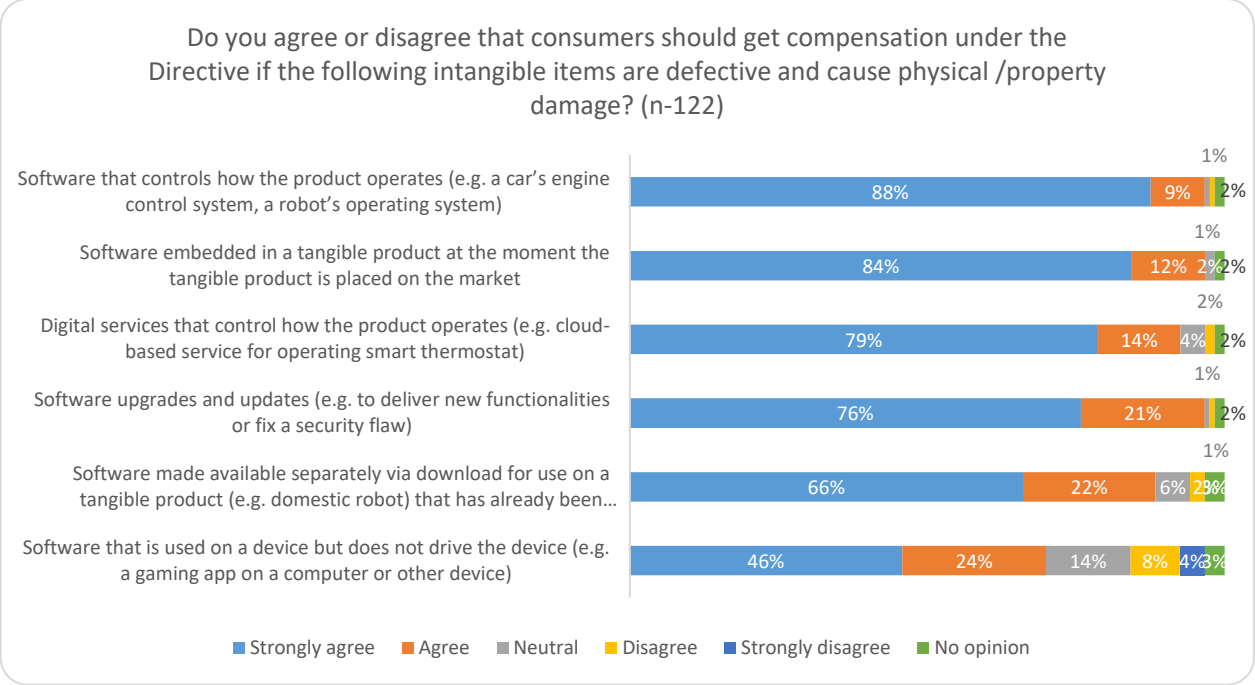
The analysis of the position papers showed that, when responding whether software and other intangible items should be included in the scope of the Directive, chambers of commerce, big software companies, and industry representatives mostly supported the position of keeping digital content out of the scope of the PLD. Some stakeholders insisted that such inclusion would fail to take into account the specific characteristics of software and AI systems[259]; some that it would harm innovation and prevent development[260]; some that any possible damage would not in any case undermine people's health or property[261].

On the contrary, consumer and labour organizations, academic institutions, and some business associations[262] were more inclined to prefer a revision of the Directive that would also encompass intangible items in its scope.

Also, big digital industries[263] and some actors mostly representing the interests of producers or industries[264] were skeptical of the need for a legislative revision of the Directive, preferring to leave the subject unchanged. Among those companies and business associations, some expressed a preference to develop guidelines at the European level for interpreting the current rules. Furthermore, some stakeholders[265] stressed how the general product safety and liability rules should remain technologically neutral. Case-law can adequately address the identified challenges, such as complexity or opacity, and it is only in individual cases that special rules for specific products or uses in particularly dangerous areas may be necessary[266].

Replies by **members of the public**:

[255] Out of 78%, 57% (or 70) were business organisations while 44% (or 52) were non-business respondents.
[256] Out of 66%, 25% (or 39) were business respondents and 75% (or 115) were non-business respondents.
[257] Out of 56%, 43% (or 37) were business respondents while 57% (or 50) were non-business respondents.
[258] Out of 55%, 39% (or 33) were business respondents and 61% (or 52) were non-business respondents.
[259] Avast Software and American Chamber of Commerce in Europe.
[260] Software & Information Industry Association (SIIA).
[261] Siemens.
[262] German Medical Technology Association; European Association of Automotive suppliers; European Federation of Pharmaceutical Industries and Associations; EuroSmart.
[263] Bitkom; Bosch; BVMed; Google; Siemens; Siemens Healthineers.
[264] American Chamber of Commerce; CCIA Europe; Czech Confederation of Industry; GSMA.
[265] American Chamber of Commerce; Austrian Federal Economic Chamber; Google; ZVEI (Electrical Industry)
[266] ZVEI (Electrical Industry).



Members of the public show even stronger agreement, with 90% replying that consumers should get compensation if damaged by defective software or digital services that control how a product works and software upgrades/updates.

➢ **Online marketplaces and products coming from outside the EU**

Nowadays, online marketplaces enable consumers to buy products from outside the EU without there being an importer. Around 64% of all respondents (or 179 out of 280) agree or strongly agree that the Directive needs to ensure consumer protection if defective products cause damage bought through online marketplaces where there is no EU-based producer or importer.[267] While non-business respondents accounted for 83% (or 148 out of 179), business respondents represented only 17% (or 31).

In contrast, there was greater disagreement among respondents (45% (or 126 out of 280) either disagreed or disagreed strongly) on whether the PLD needs to be adapted to ensure consumer protection if damage is caused by defective products bought through online marketplaces where there is no EU-based producer or importer, while only 29% (or 81) were favourable.

➢ **New risks and new kinds of damage**

Respondents were asked to agree or disagree with a set of statements to better understand their position concerning new risks and kinds of damages that the digital technologies might bring.

- 70% of respondents (or 196 out of 280) agree or strongly agree that producers should be liable for **failing to provide security updates**. At a disaggregated level, notable differences were noticed between the positions of business and consumers. While only 31% of business associations and industries agreed or

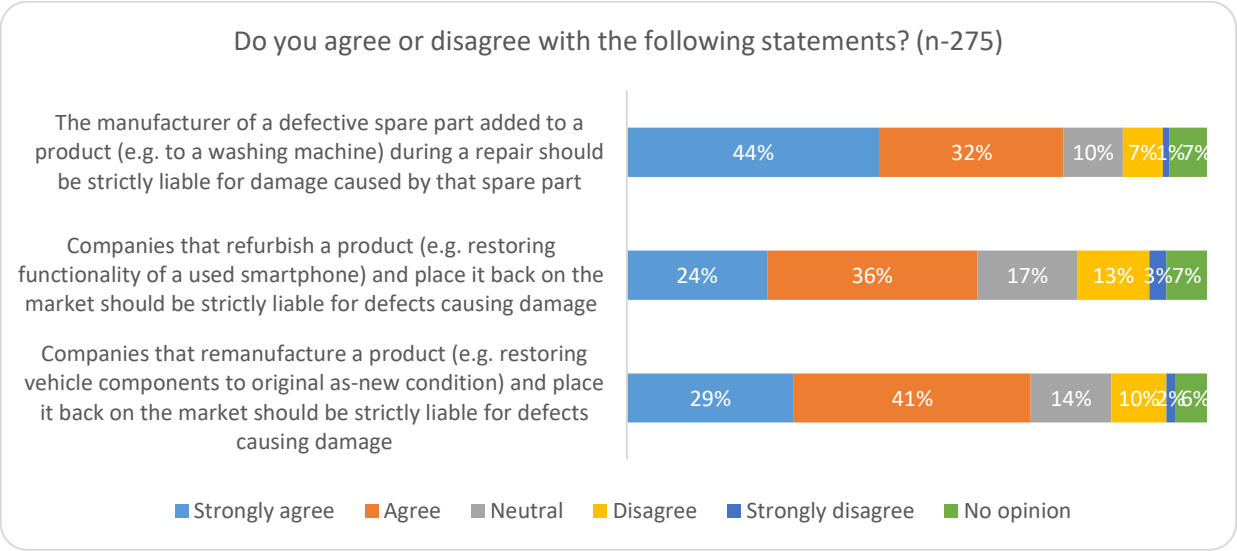
[267] Ahead of the question, we provided some information on the current legislative framework plus on the new proposal for a Digital Services Act. However, because of the complexity of the issue, there is the possibility that replied where not fully informed and can thus be biased.

strongly agreed with the statement, 93% of consumer associations, NGOs and citizens agreed or strongly agreed.

- 60% (or 168) agree or strongly agree that producers should be liable for **damage to data**. There were significant variations in the perspectives of businesses and consumers, with only 18% of business and industry-focused stakeholders agreeing or strongly agreeing, compared to 87% of consumer representative associations and citizens.
- 59% (or 165) that producers should be liable for **data protection infringements**. There was a significant difference in viewpoints between business and consumers. Whereas only 18% of businesses (individual producers and industry associations) agreed or strongly agreed, 86% of consumer stakeholders and individuals agreed or strongly agreed.
- Only around 50% of respondents agree or strongly agree that the Directive should **cover new risks and kinds of damages** that the digital technologies might bring.

➢ **Adapting the Directive to the circular economy**

In the context of circular economy business models, changes to products after they are placed on the market are increasingly common. Respondents were asked to agree or disagree on a set of statements to better understand who should be strictly liable when repaired, refurbished or remanufactured products were defective and caused damage.



Over 60% of all respondents (or 164 out of 273) agree or strongly agree that the Directive should also cover defective refurbished or remanufactured products and defective spare parts that cause damage.

When asked if companies that refurbish a product and place it back on the market should be strictly liable for defects causing damage, individual citizens and consumer association were more inclined to strongly agree with strict liability being applied to refurbishers, remanufacturers and the producers of defective spare parts being added to a product during repairs. In contrast, businesses were significantly more likely to either disagreeing or having no opinion on this.

It can be concluded that there was wide support overall for making changes to update the PLD with respect to the circular economy, and to integrate economic operators such as repairers, refurbishers and remanufacture, but with variations in the extent of support between different types of stakeholders with businesses being tendentially more sceptical.

Business Europe, France Assureurs and the French Business Confederation (Medef), in their position papers, supported the concept of "substantial modification," in which case the economic operator making the modification assumes responsibility for the safety of the product or part of a product as new risks may arise. These stakeholders also emphasized the importance of better defining "substantial modification" in the Directive. Business Europe further noted the importance of ensuring that such definition would comply with the Machinery Regulation, the Artificial Intelligence Act, and the General Product Safety Regulation.

More generally, regarding the issues of extending the definition of a producer, some industry stakeholders in the stakeholder consultations were against the possibility of extending it with respect to economic actors relevant to the circular economy (e.g. refurbishers, remanufacturers), on the basis that they perceived the existing Directive as generally working well as it stands (e.g. ORGALIM). However, other industry associations (industry associations representing refurbishers and remanufacturers, and CLEPA, the association representing automotive components suppliers) supported the principle that all economic operators who derive an economic benefit from production should assume their fair share of responsibility, liability and risks, on a proportionate basis.

Circular economy associations and individual producers were in favour of updating the PLD to reflect the important role played by circular economy economic operators in some industry sectors (e.g. medical devices). Moreover, it was pointed out that in the case of circular products, when damage is incurred due to refurbished medical devices, the framework already sets provisions stipulating that manufacturer's responsibilities are to be assumed by a person in charge of reprocessing a device, liability being one of those responsibilities under the MDR/IVDR. This allows for the identification of a responsible party and seek redress in case of damage (e.g. mentioned by COCIC medical devices industry association and individual producers such as Siemens Healthineers). The need to ensure alignment in the PLD as a horizontal supporting piece of legislation was emphasised.

- **Policy options for adapting the Directive to the digital and circular economy**

Regarding the legislative change, respondents have opposite views, with academic/research institutions, consumer organisations, NGOs and four out of five government ministries supporting it while business associations and company/business organisation opposing it. Among the government ministries, Austria, Estonia, Finland and Czech Republic support the legislative change, while Bulgaria is against it.

Overall, 56% (or 94 out of 168) of respondents (excluding EU and Non-EU citizens) are in favour of legislative change. Out of this:

- 62% (or 58) are in favour of treating digital content/software as a product in its own right;

- 38% (or 36) are in favour of only covering digital content as a component of a tangible product.

Among private respondents, 75% (or 93 out of 123) replied that the EU should revise the Directive to address the challenges posed by the digital and circular economy.

4.5. Reducing obstacles to making claims and getting compensation

The Evaluation of the Directive found that in some cases consumers faced or could face significant difficulties in claiming and getting compensation for damage caused by defective products.

- **Reducing obstacles to getting compensation**

Respondents point to difficulties in proving defectiveness and causality in the event of damage due to the technical complexity of certain products. In particular, they pointed to moderate, large and very large difficulties in case of: AI-enabled products (77% or 206 out of 268), technically complex products (77% or 206 out of 268), IoT products (72% or 193 out of 268) and pharmaceuticals (65% or 175 out of 270). Consumer organizations, non-governmental organizations, and citizens were all in agreement when it came to emphasizing such challenges, with 95%, on average, pointing to moderate, large, or very large difficulties for each of these items. Business organizations and industries, on the other hand, were less likely to identify such a problem, with 38%, on average, acknowledging such challenges in demonstrating defectiveness and causality in the event of damage caused by the aforementioned products.

The digital security industry (Eurosmart) has argued, in its position paper, that the Directive should be aligned with new form of damages such as loss of data, while software developers, given their role in terms of security and safety, should be considered as producers. According to the game developer federation (EGDF), potential loss or damages compensated by a price decrease should be only limited to any economic loss.

The vast majority[268] of digital industries and business associations representing industry interests, who contributed position papers, expressed strong opposition to harmonising compensation also in the case the use of technology cause an immaterial damage. On the contrary, an American digital company (ACM) and other actors representing an academic institution and consumer associations[269] advocated for the inclusion of immaterial harm among the damages covered by the revised Directive. The Austrian Chamber of Labour further stated that all enterprises participating in the value chain should be held jointly and severally liable, and suggested that affected people be assigned to a "single point of contact".

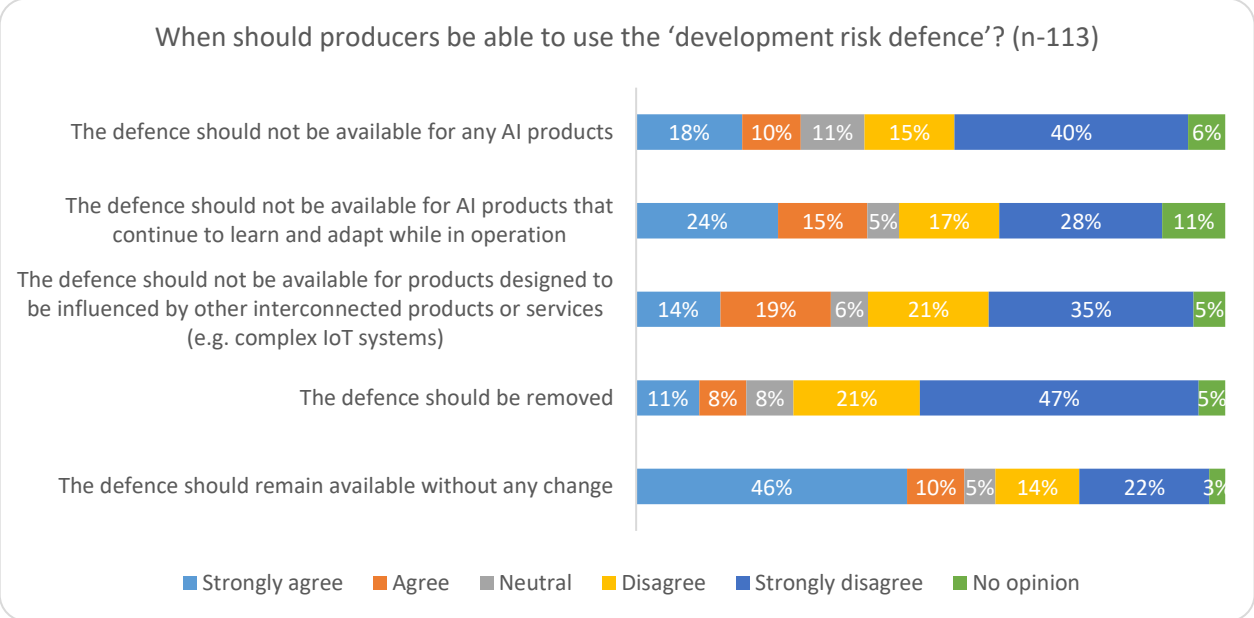
The German Federal Government argued that immaterial damage should be left to Member States, while it would be important, when revising the Directive, to consider damage to digital property, such as loss of data that results in economic loss. BVMed, on the other hand, supports the argument that data breaches or loss are already sufficiently

[268] Austrian Federal Economic Chamber; Business Europe; BVMed (German Medical Technology Association); EFPIA (European Federation of Pharmaceutical Industries and Associations); EUROCHAMBRES; French Business Confederation; Google; GSMA (interest of the mobile operators worldwide); Siemens; Siemens Healthineers; ZVEI (German Electro and Digital Industry Association). And also, the European Law Institute.
[269] ADAPTA; BEUC; The Future Society; Verbraucherzentrale Bundesverband.

covered by Article 82 of the General Data Protection Regulation (GDPR) and that environmental damages is be governed by special environmental laws.

- **The development risk defence (DRD)**

Respondents with detailed knowledge of the PLD (excluding members of the public) were consulted on the possibility for producers to use the development risk defence with the following results:



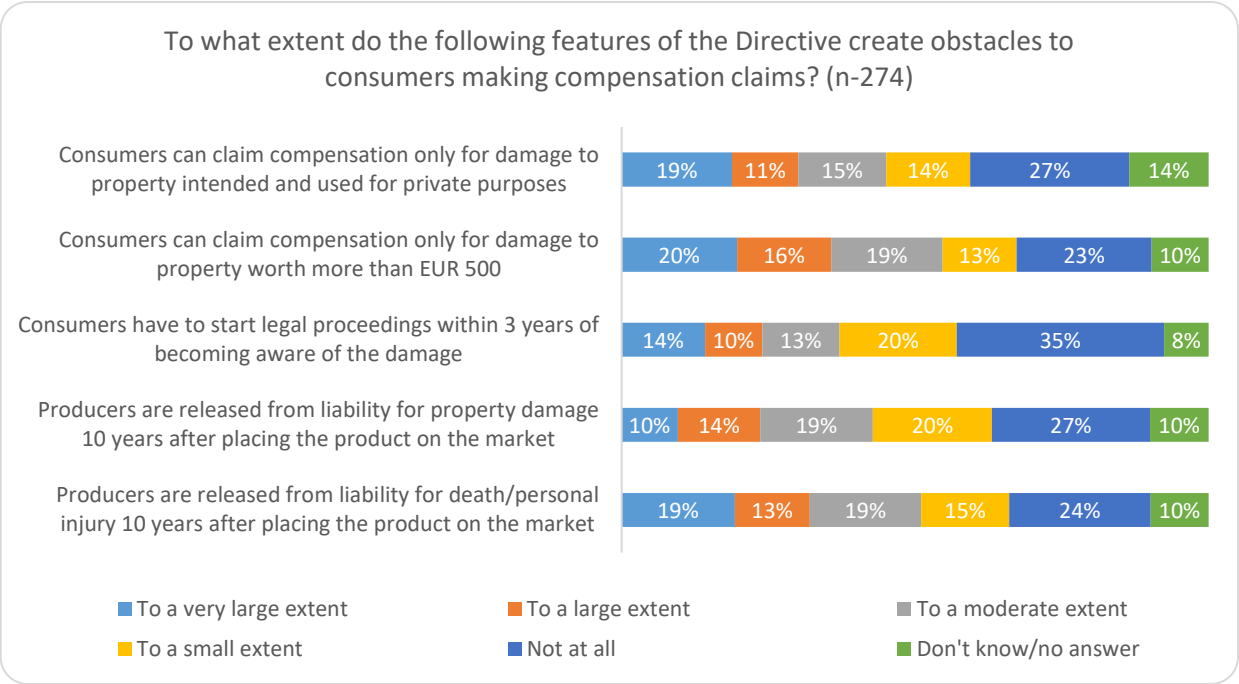
On the possibility of removing DRD from the Directive, overall 51% (or 57 out of 112) of respondents disagreed or strongly disagreed and among those, the vast majority were business and industries. The position papers revealed why industry was generally in favor of maintaining the development risk defence. For example, Insurance Europe argued that removing existing defence mechanisms would deter technological innovation and hinder economic development, as they are needed to help EU producers remain competitive in the international market. Similarly, the European Pharmaceutical Industry Association (EFPIA) determined that development risk defence is critical in ensuring that producers are not penalized for factors beyond their control, especially in fast-paced technological changes and innovation markets with accelerated renewal cycles and frequent product upgrades. Removing the development risk defence would "put unreasonable obligations on producers to constantly inspect, validate, and approve future product versions."

Regarding the possibility of keeping the DRD unchanged, this was supported by industry but not by consumers or their representative associations. Overall, 56% (or 63 out of 113) of respondents expressed there should be no change. Out of this 56%, the vast majority of respondents were business or industries while consumer associations, NGOs and citizens strongly favoured the revision of the DRD.

Of the possible changes suggested in the questionnaire, the one that received most support (39% of respondents (or 44 out of 112) agreed or strongly agreed) was denying the defence for AI products that continue to learn and adapt while in operation. However, it is important to flag that this question was only asked to respondents with a detailed knowledge of the PLD, 58% of which were from business associations and/or company/business organisations.

- **Making claims**

Finally, respondents were asked for their opinion on whether the following features of the Directive create obstacles to consumers making compensation claims:



Overall, 55% (or 147 out of 269) of respondents indicated that the EUR 500 thresholds for damage to property creates obstacles to consumers making compensation claims to either a moderate, large or very large extent. While non-business respondents accounted for 89% (or 131), business stakeholders represented the remaining 11% (or 19). Furthermore, 51% (or 140 out of 274) of respondents indicated that the 10 years-time limit for death/personal injury creates obstacles to consumers making compensation claims to either a moderate, large or very large extent. Out of this 51%, 89% (or 125) were non-business respondents, while 11% (or 15) were business respondents.

Concerning the possibility of removing the EUR 500 threshold, industry feedback as evidenced by some of the position papers, was mostly negative. One example included the view of the EFPIA association, which found there was still a need to maintain the €500 minimum threshold for damage to launch a claim, in order to avoid litigation in an excessive number of cases. However, BEUC in its position paper argued the threshold to be inadequate because firstly, it excludes a large range of immaterial damages such as data destruction, and second, because the threshold is arbitrary.

Concerning the potential impediment that producers are released from liability for property damage 10 years after placing a product on the market, this was not among the POs considered. While there are some items where personal injury may occur as a result of damage that is only identified later (e.g., latent health injuries), this is not the case for property damage where the harm is discovered within the current maximum time requirement of 10 years. Only 10% (or 27 out of 274) believed this was a major impediment, 14% (or 38) thought it was a major impediment, and 19% (or 53) thought it was a moderate impediment. This compared to 20% (or 55) who stated only to a limited extent and 27% (or 74) who stated not at all. The remaining 10% (or 27) stated that they do not know.

Finally, when it came to the potential impediment that producers are relieved from liability 10 years after placing a product on the market, only 10% (or 26 out of 271) thought it was an impediment to a very large extent, 14% % (or 38) thought it was an impediment to a large extent, and 19% (or 52) thought it was a moderate impediment.[270] This compares to 20% (or 55) who said only to a limited extent and 27% (or 73) who said not at all. The pharmaceutical industry EFPIA, in its position paper, was against to any extension of the 10-year timeframe noting that it might lead to concerns with data processing and retention methods. The Austrian Chamber of Commerce, on the other hand, concluded that such an expansion would be required to respond to technological growth, since the negative implications of some digital applications would only get more severe.

- **Policy Options for reducing obstacles to making claims and getting compensation**

Respondents showed opposite views regarding their support to a legislative change for reducing obstacles to making claims and getting compensation. On one side, business associations, company/business organisations as well as the Bulgarian Ministry for the Economy against a legislative change, while academic/research institutions, consumer organisations, NGOs as well as four government ministries (Austria, Estonia, Finland and Czech Republic), supporting the legislative change.

Overall, 53% (or 89 out of 168) of all respondents (except members of the public) were in favour of legislative change. 75% (or 67) of respondents (except members of the public) agreed with alleviating the burden of proof for technically complex products by obliging the producer to disclose technical information and by allowing courts to infer that a product is defective or caused the damage under certain circumstances (they indicated it as being either their preferred option or second best option).

Among members of the public, 78% (96 out of 123) replied that the EU should revise the Directive to address obstacles to making claims and getting compensation under the Directive.

5. TARGETED CONSULTATION

The online consultation was launched by the external consultant on 30 July 2021 and closed on 8 November 2021, and received 93 responses. However, among those 93, only 36 participants completed the survey fully, while other 57 partially finalised the questionnaire, only answering selected questions.

Out of the total 93 responses, 42 were from industry association (45%). Among the additional stakeholder groups contributing to the responses (both fully complete and incomplete), 14 were Consumer/Victims' organisations (15%), 14 were Insurance firms (15%), 7 were legal firms (8%), 6 were academic and legal researchers (6%), 6 considered themselves as other (6%), 3 were economic operators (3%) and one was national/notifying authority.

[270] Out of those who answered that it was an impediment to a very large, large and moderate extend business respondent accounted respectively only for 4% (or 1 out of 26), 5% (or 2 out of 38) and 19% (or 10 out of 52).On the other hand, business respondents accounted for 24% (or 13 out of 55) and 81% (or 59 out of 73) among those who said only to a limited extent and not at all.

The proposed questionnaire was consistent with the questions presented as part of the European Commission's public consultation. Overall, despite the low rate of participation to this consultation, the examination of the findings revealed a high degree of agreement with the outcome of the public consultation.

6. INTERVIEWS CONDUCTED BY EXTERNAL CONTRACTOR

80 stakeholders were interviewed in the **interview programme**, considerably exceeding the target of 30-50 interviews. Interviews were carried out with relevant stakeholders e.g., industry associations (representing large firms and SMEs), producers, consumer associations and / victims' associations, product liability lawyers (working with both victims / complainants and producers) legal academics, and product liability insurance specialists.

Additional interviews were carried out to ensure that additional stakeholder categories were consulted (e.g. online marketplaces, authorised representatives). This also compensated for the somewhat disappointing response to the targeted survey. However, despite making contact, it was not possible to interview Fulfilment Service Providers (FSPs).

Annex 3: Who is affected and how?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

The preferred policy package would lead to policy objectives relating to strengthening regulatory certainty and enhancing consumer protection. The PLD's legislative revision would also contribute towards the achievement of other EU policy objectives in strategic areas for the future of the EU economy, such as the digital, circular and green economies.

Impacts on producers

The preferred POs will strengthen regulatory certainty for producers by extending strict liability to software and digital services necessary to make a product work and to safety-relevant software, and to products and actors in the circular economy, as well as by including digital property within the concept of property damage.

Producers in all sectors would be affected by a more common approach to disclosure rules and presumptions across the EU-27. However, this would be mitigated by the fact that the great majority of MS already have disclosure rules and mechanisms to ease the burden of proof in one form or another.

In terms of costs, producers with liability insurance may face an increase in liability insurance premiums. If they are found liable for harm caused by a defective product, the liability insurance would cover the compensation and legal costs. Producers without a liability insurance would face direct compensation costs to victims (costs not considered in the analysis, see annex 4 for more details), and legal costs if the case goes to court.

Impacts on insurance companies

Insurance companies may have to bear higher compensation costs, but they would off-set that cost by marginally raising insurance premiums, leading to higher revenues. Their net income is therefore assumed to remain stable over time.

Impacts on consumers

The main impact on consumers is that individuals who suffer harm will receive compensation pay-outs if they prove liability. They are assumed to bear legal costs if they do not win the case. In particular, the preferred POs will strengthen consumer protection in cases where products with digital elements or software in its own right causes harm, and it will contribute to cybersecurity protection by creating incentives for producers to provide security updates to keep products safe. It will ensure that damage or destruction of consumers' digital property can also be compensated within the notion of property damage. Similarly, they will strengthen consumer protection in cases where substantially modified products cause harm due to defects. The preferred POs will also broaden the pool of liable persons from whom to seek compensation, in particular in the case of third-country products.

The preferred POs will strengthened access to justice for consumers experiencing property damage and latent health injuries, reducing at the same time information asymmetries for consumers in respect of complex products.

The preferred POs will finally ease of the burden of proof for consumers if there are clearly grounds to infer that a product was defective.

National authorities and judiciaries

National authorities in each MS responsible for the PLD would need to ensure timely transposition of the revised PLD following its adoption at EU level. National authorities would also need to

- Review national tort laws and procedural laws setting out disclosures rules in product liability (civil) cases to ensure that there are not too many obstacles to injured parties making requests for technical information disclosures (with a particular emphasis on complex products, but in some MS, the rules are generally problematic and outdated).
- Review national legal rules on presumptions and ensure that these are clear in the transposition of the revised PLD into national implementing legislation. Also in parallel review evidentiary requirements at national level in relation to the burden of proof in order to ensure that clarifications regarding the circumstances in which presumptions can be used under the PLD are reflected in national legislation (e.g. civil law codes, national tort laws in which the PLD has been transposed).

Regarding national courts and judiciaries:

- Ensure that national courts are well-informed and trained in relation to the specific circumstances in which the burden of proof may be alleviated (such as technically and technologically complex products), given that for most product defects, the burden of proof will continue to lie with the injured party).
- This would overcome a seeming reluctance and cautiousness by national courts that already allow presumptions to actually make use of them.

2. SUMMARY OF COSTS AND BENEFITS

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Improved well-being (Protection of injured persons)	Total amount not quantifiable but benefits generated by measures affecting the digital and circular economy, compensable damage, burden of proof, restrictions on making claims, as well as by ensuring the presence of an EU-based liable person.	Consumers
Harmonisation of rules for injured persons and businesses	Total amount not quantifiable but benefits generated by measures affecting the digital and circular economy, compensable damage, burden of proof, as well as by ensuring the presence of an EU-based liable person.	Producers and consumers
Higher liability insurance premiums	Total amount not quantifiable but benefits to insurance companies generated by the different measures proposed in the policy options.	Insurance companies
Indirect benefits		
Support to competitiveness in the single market (market efficiency)	Total amount not quantifiable but benefits generated by measures affecting the digital and circular economy, compensable damage, as well	Producers

	as by ensuring the presence of an EU-based liable person.	

(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action (a)	Benefit: Consumer protection (compensation pay-outs to consumers/victims)	Not relevant	*[pay-outs to consumers/victims 0.34 – 65.67 EUR million annually]*	Not relevant	Not relevant	Not relevant	Not relevant
	Indirect cost related to liability insurance	Not relevant	Not relevant	Not relevant	18.70 – 37.40 EUR million annually	Not relevant	Not relevant
	Legal costs	Not relevant	0.61 – 1.51 EUR million annually *[assuming consumers will pay 40% of legal costs]*	Not relevant	0.92 – 2.26 EUR million annually *[assuming producers will pay 60% of legal costs]*	Not relevant	Increased litigation leading to higher costs of justice administration
	Other costs	No other incremental costs for consumers would be generated by the preferred option, compared to the baseline scenario.		Costs of familiarisation with new provisions	Not relevant	Not relevant	
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	Given the low administrative costs, the 'one in, one out' approach is not applicable to this initiative					
	Indirect adjustment costs						
	Administrative costs (for offsetting)						

(1) Estimates (gross values) to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified.

3. RELEVANT SUSTAINABLE DEVELOPMENT GOALS

III. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG no. 3 – healthy lives and well being	Promote safe products and compensate victims of harm, it will have positive social impacts on victims' health and well-being	
SDG no. 9 – foster innovation	Provide legal certainty for businesses to innovate	
SDG no. 12 – responsible consumption and production	Make people responsible for product safety when they make substantial modifications	

Annex 4: Analytical methods

1. DATA GAPS AND LIMITATIONS

There is a lack of data on the number of injuries and deaths caused by defective products in Europe and no common injury database with meaningful information to support product safety work is in force in the EU[271]. In the literature, it has been noted that while the amount of information available and potentially of use for product safety is considerable in some EU countries, its usability at EU level is difficult due to high fragmentation of the data sources, the diversity of data collection methods and increasing data protection concerns[272]. This was confirmed through contacts with relevant stakeholders, who stated that the collection of data about unsafe products and defective products in future could be useful for product safety policy, market surveillance and enforcement purposes, but as such, no such data is currently being collected.

Data is instead collected on the number of injuries and deaths generally through the European Injury Database (EU-IDB). Whilst this database includes some data on injuries that involved products, this covers all types of accidents, and not product defects (i.e. injuries caused by falling off a ladder, but not whether any injuries have been caused by the ladder proving to be a defective product as defined under the PLD).

The evaluation of the General Product Safety Directive[273] conducted on behalf of the European Commission in 2021, making use of EuroSafe data, estimated product-related injuries related to a sub-set of product groups (not coinciding with the overall PLD scope) to be about 11 million injuries each year on average. In addition, based on WHO data from the WHO Mortality Database[274], the study estimates 8,632 fatalities per year. A significant limitation of this database is the impossibility of determining how many of these are due to defective products, which are the fatalities that should be looked at when assessing costs and benefits related to the PLD. Counting all product-related injuries would result in a major overestimation of impacts. On the other hand, these figures do not include, among others, pharmaceutical products or medical devices, which according to the 2018 PLD evaluation are among the most relevant products in terms of liability claims, nor food and beverages, sectors also covered under the Directive. The EU-IDB data is thus useful in demonstrating that the problem of injuries and accidents (including those relating to products) is significant in the EU but cannot be used in this specific analysis.

Finally, there is no data available concerning damages to property caused by defective products.

<u>Challenges in the quantification of costs and benefits</u>

- Relating to the general problem of reliable baseline data, which is either absent altogether or based on survey data from the 2018 evaluation, but not actual data

[271] Geiss, O. et al. (2016), Injury and accident data collection efforts in Europe in support of consumer product safety policy.
[272] Radovnikovic, A. et al. (2020), Assessment of the opportunities for increasing the availability of EU data on consumer product related injuries.
[273] Civic Consulting (2021), Study to support the preparation of an evaluation of the General Product Safety Directive as well as of an impact assessment on its potential revision.
[274] https://www.who.int/data/data-collection-tools/who-mortality-database

(e.g. number of injuries and deaths due to defective products, number of out-of-court cases falling under the PLD, % of firms with product liability insurance).

- Insufficient information and data are currently available on likely future trends in market size and structure for all product groups to translate these into a full quantitative analysis.
- A general lack of granular information on the economic and social impacts of the PLD as it currently stands. Uncertainty as to whether technological innovation and digitalisation will increase the number of product liability legal cases, as there have been very low numbers of legal cases to date relating to new technologies, software and digital elements.
- Uncertainty about the impact of the ongoing revision of product safety rules on reducing the incidence of defective products and therefore reducing the number of product liability cases.
- Uncertainty about the impact of the PLD's deterrent effect (which encourages producers to place only safe products on the market) on reducing the incidence of defective products and therefore reducing the number of product liability cases.
- Data on the number of affected economic operators in the value chain is difficult to generate, as the PLD covers all sectors and all product groups (although some policy packages and measures within these will impact some sectors more than others).
- The costs for strict liability for defective products borne by economic operators can vary significantly, as the number of compensation claims, the type of damage and the amount of compensation costs vary between sectors and different product types[275].

Thus, it was not feasible to conduct a comprehensive quantification of costs and benefits for the baseline scenario and different policy options. The aim of the assessment is to provide ranges of the magnitude of potential impacts generated by each policy option, rather than exact monetisation.

The quantifications of costs and benefits are based on a number of assumptions made in the study supporting this IA coming from stakeholder feedback and evidence gathered through interviews and desk research. The underlying assumptions were also presented to, and discussed with, a wider group of stakeholders during the study-validation workshop and were not challenged.

The following sections will present the main assumptions of the analysis. Further details and comprehensive explanations and justifications can be found in the study accompanying this IA[276].

[275] For instance, whereas damage leading to personal injury caused by pharmaceuticals and medical devices could cause damage running into hundreds of thousands (or even millions) of EUR, given the longer-term impact on human health, ability to work etc. other products may cause minor injury and the claims be relatively small.
[276] CSES, Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive

2. GROSS VALUE ADDED OF INDUSTRIES UNDER THE SCOPE OF THE PLD

To approximate the size of the market covered within the scope of the PLD, data on the Gross Value Added (GVA) of a selection of industries has been extracted from Eurostat. Seventeen industries (based on the statistical classification of economic activities in the European Community – NACE Rev. 2) have been included in the query[277].

This approximation of the market size of the industries under the PLD scope covers almost the entire manufacturing sector as defined in the NACE classification (with the single exclusion of C33 – Repair and installation of machinery and equipment). Based on this approximation, the total GVA of the industries under the PLD scope amounted to over 2,250 billion EUR in 2019. With GVA of 356 billion EUR, Computer programming, consultancy, and information service activities represent the industry with the largest gross value added (16% of the total)[278] in the PLD scope, followed by the manufacture of food products, beverages and tobacco products (C10-C12), with 251 billion EUR (11%). Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21) accounts for 4%. Sometimes the NACE code classification does not correspond wholly to PLD scope, for instance, software falls within the NACE on computer programming, but consultancy and information services is outside the PLD's scope.

3. NUMBER OF LEGAL CASES AND COMPENSATION CLAIMS

According to the 2018 evaluation study, in the reporting period (2000-2016), there were only 798 court cases based on product liability rules in EU27, with 50-60 cases per year. Around 60 claims based on product liability rules per years in EU27 as a whole, covering deaths, personal injuries and property damages. The evaluation study acknowledged that this was likely an underestimate[279].

Data from selected Member States concerning the number of judgments on EU product liability law published in recent years confirm that the figure of product liability cases in the EU27 per year is considerably higher than was reported in the evaluation study. Considering only Austria, France, Germany, the Netherlands and Spain, the number of cases per year between 2018 and 2021 has a range of between 28 and 47[280]. Moreover, only the legal database from the Netherlands and Spain can be considered to be sufficiently comprehensive, as they also include many cases from both low-instance courts and high-instance courts, while legal databases from France, Germany and Austria

[277] Manufacture of food products; beverages and tobacco products (C10-C12); Manufacture of textiles, wearing apparel, leather and related products (C13-C15); Manufacture of wood, paper, printing and reproduction (C16-C18); Manufacture of coke and refined petroleum products (C19); Manufacture of chemicals and chemical products (C20); Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21); Manufacture of rubber and plastic products (C22); Manufacture of other non-metallic mineral products (C23); Manufacture of basic metals (C24); Manufacture of fabricated metal products, except machinery and equipment (C25); Manufacture of computer, electronic and optical products (C26); Manufacture of electrical equipment (C27); Manufacture of machinery and equipment n.e.c. (C28); Manufacture of motor vehicles, trailers and semi-trailers (C29); Manufacture of other transport equipment (C30); Manufacture of furniture; other manufacturing (C31-C32); Computer programming, consultancy, and information service activities (J62-J63).

[278] Consultancy and information service activities are included in sectors J62-J63. They cannot be disaggregated from value added of the total sector.

[279] Evaluation of Product Liability Directive, SWD(2018)157, p. 23.

[280] CSES, Wavestone, CSIL (2022).

tend to reflect only higher-level court judgements[281]. To make use of data from these three Member States, the results of the respective database extractions have been scaled up to estimate a total number of both low-instance and high-instance court cases[282].

To scale up the number of cases to the EU27 level, the population size has been used as a proxy. While it is recognised that there are also other relevant factors that influence the number of cases in each country (such as differences in national legal systems, the national transposition of the Directive, and the availability of alternative routes to compensation in national tort law[283]), population size is a variable that has an indirect influence on the number of cases. Moreover, cross-checking the data provided in the 2018 evaluation reveals that, in aggregated terms, population size is a relatively reliable proxy.

The corresponding **annual number of court cases at EU27 level can then be estimated in the range between 209 and 452**[284]. Despite the considerable differences in legal and dispute culture and court systems across EU27 Member States, this range seems consistent with the upwards trend observed in the 2018 evaluation.

For the purpose of cost quantification, independent experts considered 20% of annual legal cases under the PLD to be related to deaths; 40% related to personal injuries; 40% related to property damage. Whilst it was not possible to obtain disaggregated data based on the 2018 evaluation, this has been estimated based on desk research and interview feedback[285].

The evaluation study also found that, for the 2000-2016 period, most liability claims were settled out of court, with 46% settled in direct negotiation, 32% in court, 15% through alternative dispute settlement mechanisms and a residual 7% solved through other means, such as the insurance of the responsible party[286]. In other words, court cases were assumed to represent only one third of the total compensation claims based on product liability rules.

The IA study checked this assumption with industry associations and product liability lawyers, however, and found that there may be as many as 6-7 times the number of cases settled out-of-court compared with cases that actually go to court.[287] This is because it is very costly to go through a court case, and from a producer perspective, as the PLD is based on strict liability, there is a high risk they could lose the case given they are liable regardless of fault. The number of compensation claims ending up in a court case depends on national legal systems and the existence of alternative mechanisms to reach a settlement, namely through direct contact between producers and claimants and the role of Alternative Dispute Resolution (ADR). For instance, in France, there are more than 80 ADRs nationally (only some of which may deal with defective products), and it is common to resolve claims through ADRs. In Ireland, there were many claims for

[281] The Austrian database is very selective, listing mainly cases from the Supreme Court; the German database is rather selective, with mostly cases from higher courts; the French database is very selective, with mainly cases from the Cour de Cassation (the highest court) or courts of appeal.
[282] Independent experts considered that high instance court cases in France, Germany and Austria likely represent around 10% of the total number of court cases (CSES, Wavestone, CSIL (2022).
[283] For example, in Germany it is more common not to use the PLD but to rely on tort law.
[284] Extrapolation based on the number of inhabitants per country.
[285] CSES, Wavestone, CSIL (2022).
[286] Evaluation of Product Liability Directive, SWD(2018)157, p. 13.
[287] CSES, Wavestone, CSIL (2022).

compensation involving hip replacement defects and an ADR was specifically set up to address these.

Moreover, it is difficult to get any information on cases resolved directly between producers' lawyers and claimants and/ or their legal representatives as the agreements are confidential, subject to non-disclosure agreements and the producer wants to avoid any reputational damage.

Assuming that out-of-court proceedings overall account for six to seven times as many claims cases as in-court proceedings, it is estimated a range between **1,255 and 3,165 for cases settled out of court per year across the EU-27**.

The number of cases based on product liability rules will likely be impacted by the ongoing product safety-related legislative proposals, even though it is not possible to accurately quantify these impacts. Ongoing product safety-related legislative proposals will in part suppress a future rise in accidents caused by novel risks, but might also, to a small extent, reduce accidents in real terms by improving the safety of products, inter alia, by addressing products from outside the EU, reinforcing market surveillance and reducing exposure to, say, chemicals in toys etc.

The expected modest reduction in product-related harm as a result of ongoing product safety-related legislative proposals has been factored into the baseline scenario, in particular by making conservative assumptions for the lower range of both in-court and out-of-court cases.

Finally, the 2018 evaluation study found that 60% (476 out of 798) of claims for defective products were successful for injured parties from 2000 to 2016 and that there was no particular difference in the level of success of injured parties if the case was settled in court rather than out of court. The other cases were decided in favour of producers. The analysis considered a success rate of 60% for the baseline scenario, differently affected by the policy options analysed (as further explained in section 4.1 of this annex).

4. COST AND BENEFIT ANALYSIS

The cost-benefit assessment follows the guidance for the categorisation of costs in the Better Regulation guidelines, which identify direct, indirect, enforcement/legal costs.

There are no relevant administrative costs under the PLD in contrast to much product safety legislation, as there are no specific obligations or information requirements for economic operators. There will be one-off **familiarisation costs** for economic operators not previously covered as producers under the PLD, which are minimal.

Policy options mainly involve a re-attribution of costs between stakeholders, either from victims to the producers whose defective products caused the costs, or between economic operators by enlarging the notion of "producer".

The cost-benefit analysis mainly considers the effects of the proposed policy options on the following actors:

- The main impact on consumers is that individuals who suffer harm will receive compensation pay-outs if they prove liability. They are assumed to bear legal costs if they do not win the case.

- In terms of costs, producers with liability insurance may face an increase in liability insurance premiums. If they are found liable for harm caused by a defective product, the liability insurance would cover the compensation and legal costs. Producers without a liability insurance would face direct compensation costs to victims (costs not considered in the analysis), and legal costs if the case goes to court.

- Insurance companies may have to bear higher compensation costs, but they would off-set that cost by marginally raising insurance premiums, leading to higher revenues. Their net income is therefore assumed to remain stable over time.

4.1. ASSESSMENT OF THE BENEFITS ATTRIBUTABLE TO STRICT LIABILITY UNDER THE PLD

The **main measurable benefit** for consumers is the compensation they receive if they successfully prove the liability of the producer. Regardless the number of claims, only successful cases are considered for the assessment of victims' compensation. This success rate is assumed to be 60% for in-court and out-of-court cases based on the findings of the Evaluation.

The **number of successful cases**, multiplied by the **average compensation pay-outs**, will provide ranges for the estimates on the economic benefits for consumers.

The measures proposed by each policy option might affect the number of successful cases, i.e. cases for which consumers are recognised as victims and receive compensation pay-outs for the damage suffered, by affecting:

- the actual number of cases brought under the PLD. All the policy options considered are assumed to increase that number compared to the baseline scenario[288].

- the success rate of claims. Only policy options 2a and 2b are assumed to increase the success rate of claims compared to the baseline scenario[289].

The independent experts considered that the measures of the different policy options would have no effects on the average compensation pay-outs, since the ranges used for the baseline scenario were already extremely wide:

- The limited data available from selected countries suggests a range between 20,000 and 1,500,000 EUR for compensation paid for **deaths.**

[288] Any change in the number of cases brought under the PLD will affect both the calculations for the economic pay-outs for victims, as well as the legal costs faced by the party losing the case.
[289] The success rate will only affect the calculation of the victims' pay-outs with no effects on the calculation of the total legal costs: for a given number of cases, the success rate indicates the likelihood of success for victims to win the case

- The compensation paid for **personal injuries** varies from 1,500 to 700,000 EUR[290].
- Finally, **property damage** is estimated in a range between 5,000-25,000 EUR.

Evidence collected[291] through stakeholder consultation for the IA study 2021-22 confirms the 2018 evaluation's finding that the financial size of compensation pay-outs varies widely depending on the Member State, the product and sector, the nature and extent of the damage, as well as on the circumstances of individual cases.

The table below summarises the assumptions used to calculate the impacts for each policy option. In particular, for each policy options, the table shows the estimated **increase in the number of successful legal cases** (in court and out of court) for the three types of damage covered under the PLD: death, personal injury, property damage[292].

Table 9: Changes in variables for the calculation of the benefit under the different policy options, compared to baseline

	Number of legal cases under the PLD in the EU27 per year, related to deaths	Number of legal cases under the PLD in the EU27 per year, related to personal injuries	Number of legal cases under the PLD in the EU27 per year, related to damages to property (>500 EUR)
PO1a	• 1% increase for software developers, i.e. 10% of industry under PLD scope • 1.5% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 1% increase for expanding liability to Authorised Representatives	• 1% increase for software developers, i.e. 10% of industry under PLD scope • 1.5% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 1% increase for expanding liability to Authorised Representatives	• 1% increase for software developers, i.e. 10% of industry under PLD scope • 1.5% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 1% increase for expanding liability to Authorised Representatives
PO1b	• 1% increase for software developers, i.e. 10% of industry under PLD scope • 1.5% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 1.5% increase for expanding liability to Authorised Representatives and Fulfilment Service Providers	• 2% for software developers, i.e. 10% of industry under PLD scope • 1.5% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 1.5% increase for expanding liability to Authorised Representatives and Fulfilment Service Providers	• 2% increase for software developers, i.e. 10% of industry under PLD scope • 1.5% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 15% increase for manufacturers of electronic devices, i.e. 16% of industry under PLD scope • 2% increase for expanding liability to Authorised Representatives and Fulfilment Service Providers
PO1c	• 1% increase for software developers, i.e. 10% of industry under PLD scope	• 4% increase for software developers, i.e. 10% of industry under PLD scope	• 4% increase for software developers, i.e. 10% of industry under PLD scope

[290] This very wide range reflects the fact that the nature of the injury varies widely, whether this causes a temporary physical injury or more long-lasting damage leading to permanent disability.
[291] Data was collected from Germany, Greece and Baltic States. Fort further details, please refer to: CSES, Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive for justifications over the assumptions used to calculate compensation costs, product liability costs and legal costs.
[292] For justifications on the assumptions summarised in the table, please refer to CSES, Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive.

	• 1.5% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 1.5% increase for expanding liability to Authorised Representatives and Fulfilment Service Providers	• 1.5% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 15% increase for manufacturers of electronic devices, i.e. 16% of industry under PLD scope • 1.5% increase for expanding liability to Authorised Representatives and Fulfilment Service Providers	• 1.5% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 25% increase for manufacturers of electronic devices, i.e. 16% of industry under PLD scope • 2% increase for expanding liability to Authorised Representatives and Fulfilment Service Providers
PO2a	• 7% increase for easing the burden of proof for complex products, i.e. manufacturers of electronic devices counting for 16% of industry under PLD scope + pharmaceutical products and pharmaceutical preparations counting for 4% of industry under PLD scope • 2% increase for reducing restrictions in making claims	• 7% increase for easing the burden of proof for complex products, i.e. manufacturers of electronic devices counting for 16% of industry under PLD scope + pharmaceutical products and pharmaceutical preparations counting for 4% of industry under PLD scope • 2% increase for reducing restrictions in making claims	• 7% increase for easing the burden of proof for complex products, i.e. manufacturers of electronic devices counting for 16% of industry under PLD scope + pharmaceutical products and pharmaceutical preparations counting for 4% of industry under PLD scope • 2% increase for reducing restrictions in making claims
PO2b	• 12% increase for reversing the burden of proof for all products • 5% increase for further reducing restrictions in making claims	• 12% increase for reversing the burden of proof for all products • 5% increase for further reducing restrictions in making claims	• 12% increase for reversing the burden of proof for all products • 5% increase for further reducing restrictions in making claims

Source: CSES, Wavestone, CSIL (2022)

The increase number of successful cases multiplied by the average compensation pay-outs provide the incremental benefits, i.e. increase in the compensation pay-outs to victims, compared to the baseline scenario. Results are shown in the following table[293].

Table 10: Annual benefit of consumers' protection (increased compensation) under the different policy packages (EUR million)

	Incremental benefit compared to baseline (low)	Incremental benefit compared to baseline (high)
PO1a	0.07	14.47
PO1b	0.15	22.13
PO1c	0.17	47.70
PO2a	0.20	43.54
PO2b	0.99	217.70

Compensation paid to victims, thus benefits for consumers, increases with the increase of the level of intervention of the policy options.

[293] Since the baseline scenario is defined using ranges for the annual number of court cases at EU27 level, the table below also presents the incremental benefits using low and high values.

4.2. ASSESSMENT OF THE COSTS ATTRIBUTABLE TO STRICT LIABILITY UNDER THE PLD

The main quantified **indirect costs** generated by the PLD are liability insurance costs attributable to strict liability under the PLD as well as legal costs that producers and consumers have to bear in the case of a product liability claim, whether in-court or out-of-court.

Compensation costs are not assessed as costs for producers, because adding them to the increased cost of liability insurance premiums would have led to double counting.

The large majority of economic operators are covered by liability insurance[294] and would therefore not bear direct compensation costs vis-à-vis victims in the event of a product liability claim, whether in-court or out-of-court, since this would be covered by their insurers. They could, however, face a marginal increase in their insurance premiums. That is why direct compensations costs for companies are not included in the cost estimates, while insurance premium increases are included.

Economic operators without a liability insurance would, on the other hand, face direct compensation costs, which could be included in the cost calculations. However, there is no information or data to make robust estimates on which economic operators have insurance and which do not. The 2018 evaluation stated that around 80% of producers in the entire manufacturing sector have product liability insurance, but provides no further information or breakdowns on the remaining 20%.

Assuming this 20% to be equally spread across all manufacturing sectors would entail a high risk of overestimating costs: interviews with the insurance industry suggest that this 20% represents mainly producers of lower-risk products: products, in other words, that are not usually the subject of compensation claims (e.g. clothing, for which only 11 cases were reported between 2000 and 2016).

In contrast, the producers of the sorts of products for which the scope is being extended (e.g. autonomous vehicles, robots) or for which the burden of proof is currently challenging (e.g. complex products like pharmaceuticals or Internet of Things devices) are more likely to have liability insurance at present, since there is a higher risk of those products being subject to compensation claims. Thus adding direct compensation pay-outs to liability insurance premiums could generate double counting.

It is acknowledged that not assessing compensation costs as a cost for producers may lead to a small underestimation of costs.

4.2.1. PRODUCT LIABILITY INSURANCE COSTS

The liability insurance costs are defined as insurance premiums related specifically to strict liability. Usually economic operators have general product liability insurance policies, covering a number of different types of liability, not only strictly liability (e.g. contractual, extra-contractual, including fault-based liability where national rules exist).

[294] Evaluation of Product Liability Directive, SWD(2018)157: 79% of producers.

Therefore, only a percentage of total product liability insurance costs (estimated at 1-2%[295]) relates to strict liability.

The total amount of liability insurance costs in the EU27 in 2021 was in the range between 333 million EUR – 667 million EUR. Thus, applying the 1-2%, it was estimated that the direct premiums of general product liability insurance in the EU27 in 2021 was to be 37.94 billion USD, or 33.38 billion EUR (adopting a conversion rate of 1 USD = 0.88 EUR)[296].

The measures proposed in the policy options will affect the direct premiums of general product liability insurance in the EU27 in 2021, depending on the magnitude of the measure and the market share of the economic operators potentially affected. The table below summarises the assumptions used to calculate these impacts[297], providing the percentage increase in the direct premiums of general product liability insurance for the relevant producers.

Table 11: Estimated changes in variables for the calculation of the insurance cost under the different policy packages, compared to baseline

PO1A	PO1B	PO1C	PO2A	PO2B
• 3% increase for software developers, i.e. 10% of industry under PLD scope • 3% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 15% increase for Authorised Representatives, i.e. 0.01% of industry under PLD scope	• 10% increase for software developers, i.e. 10% of industry under PLD scope • 3% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 1.5% increase for manufacturers of electronic devices, i.e. 16% of industry under PLD scope • 15% increase for Authorised Representatives, i.e. 0.01% of industry under PLD scope • 5% increase for Fulfilment Service Providers, i.e. 0.01% of industry under PLD scope	• 15% increase for software developers, i.e. 10% of industry under PLD scope • 3% increase for remanufacturers and refurbishers, i.e. 2% of industry under PLD scope • 2.5% increase for manufacturers of electronic devices, i.e. 16% of industry under PLD scope • 15% increase for Authorised Representatives, i.e. 0.01% of industry under PLD scope 5% increase for Fulfilment Service Providers, i.e. 0.01% of industry under PLD scope	• 4% increase for reversing the burden of proof for complex products producers, i.e. manufacturers of electronic devices counting for 16% of industry under PLD scope + pharmaceutical products and pharmaceutical preparations counting for 4% of industry under PLD scope • 3.5% increase for total insurance costs for reducing restrictions in making claims	• 7% increase for total insurance costs for reversing the burden of proof for all products • 5% increase for total insurance costs for further reducing restrictions in making claims

[295] Desk research based on data collection from EU and national insurance associations. Moreover, in the 2018 evaluation and in some of the earlier PLD application reports between 1995 and 2018, various commentary and percentage estimates as to the increase in product liability insurance costs since the Directive was adopted have been provided. See: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52000DC0893&from=GA

[296] Desk research based on data from SwissRe on general product liability insurance policies.

[297] For justifications on the assumptions summarised in the table, please refer to CSES, Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive.

Source: CSES, Wavestone, CSIL (2022)

Thus, direct premiums of general product liability insurance in the EU27 will be affected by the different measures proposed by each policy option. The table below summarises the incremental changes compared to the baseline scenario, providing the incremental costs using low and high values.

Table 12: Annual insurance cost under the different policy packages (EUR million)

	Incremental costs compared to baseline (low)	Incremental costs compared to baseline (high)
PO1a	1.21	2.41
PO1b	4.35	8.69
PO1c	6.55	13.10
PO2a	14.35	28.71
PO2b	41.73	83.46

4.2.2. LEGAL COSTS

The legal cost relates to the costs that producers and consumers have to bear in case of a product liability claim (whether out-of-court or through a judicial proceeding). In principle, in case of in-court settlement, the total legal cost consists of all costs related to judicial proceedings (lawyers' fees, bailiffs' fees, court fees). In case of out-of-court settlement, it consists of lawyers', mediators' and arbitrators' fees. However, due to a lack of data and the fact that legal costs are reported to be the main cost among legal costs, the analysis focuses on legal fees only[298].

To estimate this cost in case of in-court settlement, the sum of judicial proceedings and out-of-court settlements is multiplied by the average lawyers' fees.

There is considerable variance in the **legal costs** involving compensation claims falling under the PLD, depending on: (1) the product and its complexity[299] (2) the circumstances of the case and (3) the Member State concerned and the prevailing differences in legal costs (e.g. legal fees in central and Eastern Europe tend to be considerably below those in Western Europe).

The data and information collected about legal costs for court proceeding shows a very wide range of costs from 500 to 40,000 EUR. The legal cost per out-of-court proceeding across Europe is estimated in the range of 500 to 25,000 EUR[300].

The number of proceedings and lawyers' fees are subject respectively to the following two impacts generated by the policy options: i) a shift from other grounds of liability

[298] Experts' fees are not included under legal costs, as they have been conceptualised under the cost linked to the burden of proof, not quantified.
[299] The application reports under the PLD illustrated that the costs for legal cases for pharmaceutical products and medical devices are highly complex and cost many times more than for most other products.
[300] CSES, Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive for justifications over the assumptions used to calculate compensation costs, product liability costs and legal costs.

(e.g. national fault-based liability) to the PLD; ii) less expensive cases (e.g. strict liability cases are expected to be shorter and cheaper, as fault does not have to be proven; also, presuming defectiveness in very complex cases is expected to speed up the procedure by putting the onus on the better informed party).

It may also be noted that some policy options are expected to lead to an increase in the number of legal cases, both in court and out of court (e.g. through the inclusion of immaterial harm under the PLD coverage, or through reduced restrictions).

The table below summarises the assumptions used to calculate these impacts[301].

Table 13: Changes generated by Policy Options in relation to legal cost

	Changes generated by Policy Option in relation to legal cost	
	Less expensive cases	**Increase in the number of cases under the PLD**
PO1a	• -2% cost reduction for software developers and related consumers, i.e. 10% of industry under PLD scope	• 1% increase in the number of legal cases for software developers and related consumers, i.e. 10% of industry under PLD scope • 1% increase in the number of legal cases for expanding liability to Authorised Representatives
PO1b	• -4% cost reduction for software developers and related consumers, i.e. 10% of industry under PLD scope	• 1.8% increase in the number of legal cases for software developers and related consumers, i.e. 10% of industry under PLD scope • 6% increase in the number of legal cases for manufacturers of electronic devices, i.e. 16% of industry under PLD scope • 2% increase in the number of legal cases for expanding liability to Authorised Representatives and Fulfilment Service Providers
PO1c	• -6% cost reduction for software developers and related consumers, i.e. 10% of industry under PLD scope	• 3.4% increase in the number of legal cases for software developers and related consumers, i.e. 10% of industry under PLD scope • 16% increase in the number of legal cases for manufacturers of electronic devices, i.e. 16% of industry under PLD scope • 2% increase in the number of legal cases for expanding liability to Authorised Representatives and Fulfilment Service Providers
PO2a	• -10% cost reduction for easing the burden of proof for complex products producers, i.e. manufacturers of electronic	• 5% increase in the number of legal cases for easing the burden of proof for complex products producers, i.e. manufacturers of electronic devices

[301] For justifications on the assumptions summarised in the table, please refer to CSES, Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive.

	Changes generated by Policy Option in relation to legal cost	
	Less expensive cases	**Increase in the number of cases under the PLD**
	devices counting for 16% of industry under PLD scope + pharmaceutical products and pharmaceutical preparations counting for 4% of industry under PLD scope	counting for 16% of industry under PLD scope + pharmaceutical products and pharmaceutical preparations counting for 4% of industry under PLD scope • 2% increase in the number of legal cases for all products for reducing restriction in making claims
PO2b		• 10 % increase in the number of legal cases for easing the burden of proof for all products • 5% increase in the number of legal cases for all products for reducing restriction in making claims

Source: CSES, Wavestone, CSIL (2022)

Total legal costs under the PLD differ according to the proposed measures in each of the policy section. The table below summarises the incremental changes compared to the baseline scenario, providing the incremental costs using low and high values.

Table 14: Annual legal costs compensation under the different policy packages (EUR million)

	Incremental cost compared to baseline (low estimate)	Incremental cost compared to baseline (high estimate)
PO1a	0.41	1.02
PO1b	1.12	2.75
PO1c	1.83	4.50
PO2a	0.41	1.02
PO2b	6.90	16.96

The following summarised the quantified benefits and costs of the different policy options.

These values should not be seen as a comprehensive quantification of the costs and benefits for each of the policy option analysed but rather they aim at providing the magnitude of the potential impacts generated by each policy option.

Table 15: Costs & Benefits summary table (EUR million annual)

	Incremental benefits compared to baseline		Incremental costs compared to baseline			
	Incremental annual compensation paid to victims(*)		Incremental annual product liability insurance costs		Incremental annual legal costs	
	Low end	High end	Low end	High end	Low end	High end
PO1a	0.07	14.47	1.21	2.41	0.41	1.02
PO1b	0.15	22.13	4.35	8.69	1.12	2.75
PO1c	0.17	47.70	6.55	13.10	1.83	4.50

	Incremental benefits compared to baseline		Incremental costs compared to baseline			
	Incremental annual compensation paid to victims(*)		Incremental annual product liability insurance costs		Incremental annual legal costs	
	Low end	High end	Low end	High end	Low end	High end
PO2a	0.20	43.54	14.35	28.71	0.41	1.02
PO2b	0.99	217.70	41.73	83.46	6.90	16.96

Annex 5 – Matters to be clarified in the context of revising the Product Liability Directive

There are a number of matters that call for clarification in the context of revising the PLD, **but which do not form part of the problem definition in the main report**.

Compensable damage: psychological damage as personal injury

Section 2.2.1.1 "Liability rules not adapted for products in the digital age" includes discussion of what types of compensable damage should be covered by the PLD. In this context, there is evidence that new digital technologies can have a psychological impact on users, such as anxiety and loss of sleep[302]. Medically diagnosed psychological damage is generally accepted as falling under the concept of "personal injury", while just stress or anxiety is not[303], and this should be clarified in the revision.

Compensable damage: damage to property intended or used for professional purposes

The PLD provides for compensation for damage to property intended for and actually used for private purposes. In the public consultation conducted for the 2018 evaluation, 83% of respondents stated that it was sometimes difficult to distinguish between private and professional use of property[304]. This is all the more so in the context of modern working practices where goods like home office equipment or computers may be used both for private and professional purposes. This distinction should be clarified in the revision.

Liability of providers of online marketplaces depending on role in supply chain

Section 2.2.1.3 "No liable person under the PLD when consumer purchases product from a 3rd country directly" concerns situations in which there is no EU-based producer or importer from whom to seek compensation for harm caused by a defective product. Such products are typically bought via an online marketplace, the provider of which intermediates the sale between the non-EU trader and the EU-consumer.

Providers of online marketplaces are subject to a conditional liability exemption under the eCommerce Directive and proposal for a Digital Services Act[305], by virtue of being a provider of an online platform, which is a type of information society service. Providers of online marketplaces are therefore not liable for the products or services whose sale they intermediate. Nonetheless, the provider cannot rely on the exemption from liability

[302] Dresp-Langley B. Children's Health in the Digital Age. Int J Environ Res Public Health. 2020 May 6;17(9):3240. doi: 10.3390/ijerph17093240. PMID: 32384728; PMCID: PMC7246471.
[303] Duncan Fairgrieve, Product Liability, 3rd edition, p. 267; Christiane Wendehorst, Study on Safety and Liability Related Aspects of Software, p. 80; Interview with Pan-European Organisation of Personal Injury Lawyers.
[304] EY, Technopolis, VVA (2018), Study accompanying Evaluation of Product Liability Directive, p. 33.
[305] Article 14(1) of Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce') and Article 5(1) of Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC

if it was aware of facts or circumstances on the basis of which it should have realised that the products or services for sale in question were unlawful and, in the event of it being so aware, failed to act expeditiously in accordance with Article 14(1)(b) of Directive 2000/31 and Article 5(1)(b) of the proposal for a Digital Services Act.

In addition to the well-established liability exemptions, the proposal for a Digital Services Act includes clarifications to the liability regime for consumer protection:

- the liability exemption does not apply when the content uploader acts under the authority or control of the service provider (Article 5(2));

- online marketplaces do not benefit from the liability exemption when they present products to consumers in a way that confuses them as to whether it is the marketplace or a third-party seller offering the products (Article 5(3)).

These clarifications allow to enhance consumer protection, while stimulating innovation, and ensuring continuity with the existing case law[306], which has given the sector legal certainty and predictability.

Since liability under the PLD is triggered by harm caused by the inherent defectiveness of a product and not by the actions or omissions of an economic operator (since liability is irrespective of fault), it is under national fault-based rules that consumers could seek compensation in cases where the liability exemption of providers of online marketplaces does not apply.

However, it should be clarified in the revision of the PLD that a provider of an online marketplace may also provide services other than intermediation services and may thereby play a role in the supply chain for a given product that *would* attract liability under the PLD:

- If a provider of an online marketplace manufacturers a product or attaches its trademark to it, it is the producer and can be liable as such under the PLD;
- If a provider of an online marketplace imports a product, it is the importer and can be liable as such under the PLD;
- If a provider of an online marketplace itself sells the product, it is (in the language of the PLD) the “supplier”, and could be held liable unless it identifies the producer.

[306] C-324/09, L’Oréal SA and Others v eBay International AG and Others.

Annex 6: Viability of non-binding guidance

Issuing non-binding guidance was discarded as a policy option (see section 5.3). This annex assesses in more detail the extent to which non-binding guidance would be capable of achieving the specific objectives set for the revision of the PLD.

- **SO 1: Adapt PLD to reflect nature and risks of products in the digital age**

Discussions in the Expert Group on liability and new technologies (PLD formation) about how the current text of the PLD should be interpreted in the context of digital technologies were inconclusive. Members of the Expert Group argued variously that only software physically embedded at the time the tangible product was put into circulation was covered, but not any subsequently downloaded software (e.g. updates/upgrades); some insisted that software, even if provided separately from a tangible product, was already covered; some insisted software developers themselves currently qualified as producers; some argued the opposite. Since guidance would require broad consensus by stakeholders, it would only be possible to adopt a narrow interpretation:

- Guidance could confirm that product manufacturers are liable for the software they embed in their product before putting it into circulation. However, this would not address the problem driver identified: that software can also be added to products after they are put into circulation, either as updates/upgrades to existing software or as new software, and may be added outside of the control of the product manufacturer. It would also mean that software manufacturers themselves would escape no-fault liability. Victims of harm caused by defective software other than software embedded at the time a product was put into circulation would have to prove the fault of the product or software manufacturer in order to get compensation. These unaddressed problems might eventually be resolved by an ECJ preliminary ruling, if a relevant case were referred to it.

- Guidance could confirm that a cybersecurity vulnerability present at the time a product is put into circulation is capable of being classed as a defect. However, this would not address the problem driver identified: that cybersecurity vulnerabilities are dynamic in nature and can emerge after a product was put into circulation.

- Guidance would not be able to extend the types of compensable damages under the PLD.

- **SO 2: Adapt PLD to reflect nature of products in the circular economy**

The measures envisaged in this impact assessment in respect of the circular economy are limited. Guidance could provide some clarity by drawing an analogy with the concept of "substantial modification" in the area of product safety legislation. The Commission's

"Blue Guide" on the implementation of EU product safety legislation says that an economic operator who makes important changes to or who overhauls a product should be seen as putting a new product into circulation and should be responsible for safety compliance[307]. This concept of "substantial modification" has been integrated into legislation and legislative proposals in recent years[308] and the Medical Devices Regulation explicitly includes economic operators who fully refurbish devices in its definition of manufacturer[309]. There was no consensus in the Expert Group, however, on drawing this analogy, since the text of the PLD itself is silent on the notion of substantial modification. Revision of the PLD itself in this regard would provide more legal certainty.

- **SO 3: Ensure there is always an EU-based liable person for defective products bought in the EU**

Guidance would be suitable for clarifying that online marketplaces are to be treated as producers, importers or suppliers when they fulfil that particular role in respect of the product in question. Guidance could also confirm that providers of online marketplaces cannot be liable under the PLD when they play a mere intermediary role.

Since the PLD only considers producers, importers and suppliers as potentially liable persons, guidance would not be sufficient to make new economic actors (authorised representatives, fulfilment service providers) liable.

- **SO 4: Ease the burden of proof in the case of complex products and clarify liability for undiscoverable defects, while ensuring fair balance between producers and consumers**

Guidance could provide a useful summary of ECJ rulings concerning the burden of proof, which could help ensure a more coherent approach to the issue among national courts. However, guidance would not be able to guarantee access to information in court that the claimant needs to prove liability, nor would it provide clarity on the conditions and limits of easing the burden of proof in the case of complex products.

- **SO 5: Ease restrictions on making claims, while ensuring fair balance between producers and consumers**

It would not be possible to make changes to the EUR 500 threshold or time limits through non-binding guidance. The problem would remain unresolved.

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[307] Commission Notice— 'The 'Blue Guide' on the implementation of EU products rules 2016', **2016/C 272/01**, 26.7.2016, p. 15 to 17.

[308] Proposal for a Regulation of the European Parliament and of the Council on machinery products, COM(2021) 202 final, https://ec.europa.eu/docsroom/documents/45508; proposal for a Regulation on General Product Safety (GPSR), https://ec.europa.eu/info/sites/default/files/proposal_for_a_regulation_on_general_product_safety.pdf.

[309] Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, Art. 2(1)(30).

Annex 7: Further details of legal context

Interplay of PLD with other liability regimes

The interplay of the PLD with national fault-based liability rules is fully explained in the main body of the impact assessment. Here are additional details concerning other liability rules:

Contractual liability: The Sale of Goods Act[310] makes sellers liable to the consumer for lack of conformity. The Digital Content and Services Directive[311] gives consumers the right to remedy, i.e. replacement, repair or reimbursement, when digital content or a digital service does not work properly. The PLD concerns extra-contractual liability of producers for injuries/damage caused by a lack of safety – a complementary tool to ensure consumer protection. However, these Directives have already been modernised to protect consumers' contractual rights in the context of digital goods, which the PLD has not.

Liability for infringements of data protection law: The General Data Protection Regulation (GDPR)[312] aims to give people more control over their personal data and makes controllers and processors liable for damage caused by data processing which infringes the GDPR. Any person who has suffered material or non-material damage as a direct result of an infringement of the GDPR has a right to compensation under the GDPR. Product manufacturers may be liable under the GDPR if they act as controllers (i.e. if they determine the purposes and means of the processing of personal data) or processors (i.e. if they process personal data on behalf of the controller). The GDPR is complementary with the current PLD, which provides compensation only for death, personal injury and damage to consumer property.

Liability for environmental damage: The Environmental Liability Directive[313] establishes a framework to prevent and remedy environmental damage based on the polluter pays principle. It deals with pure ecological damage such as damage to protected species and natural habitats as distinct from damage to privately owned property, which is covered by the PLD.

1.1.1. Interplay of PLD with other EU legislation

Product safety framework

EU product safety legislation aims to ensure that only safe products are placed on the internal market. Manufacturers (producers) are responsible for the safety of their product. All products placed on the internal market are subject to safety rules, set under either:

[310] Directive (EU) 2019/771 on certain aspects concerning contracts for the sale of goods.
[311] Directive (EU) 2019/770 on certain aspects concerning contracts for the supply of digital content and digital services.
[312] Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR).
[313] Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage.

- Sectoral safety legislation, which sets EU-wide essential health and safety requirements that the products need to meet. This covers, for example, machinery, pharmaceutical products, toys, electrical and electronic goods, radio equipment, cosmetics, chemicals, medical devices, food and feed.
- The *General Product Safety Directive* (GPSD)[314], which requires all consumer products that do not fall under sectoral legislation to be safe, and which the Commission has proposed to replace with a regulation[315].

Safety rules are enforced by market surveillance established under the Market Surveillance Regulation[316] and the General Product Safety Directive, which ensure consumer protection by stopping non-compliant products circulating or by bringing them into compliance. Product safety legislation does not contain specific provisions on liability of manufacturers, but make reference to the fact that the PLD applies when a defective product causes damage. Product safety and product liability are therefore complementary mechanisms for achieving a functioning single market for goods that ensures high levels of safety. The 2018 Evaluation concluded that the PLD was fully coherent with the product safety framework, but that ongoing coherence needed to be assessed in light of plans to update safety legislation to meet the challenges of digital technologies[317] - see section 1.2.4.

Safety and Health at work: a series of Directives[318] establish rules to ensure the safety and health of workers in the context of using work equipment[319], as well as against chemical agents, physical hazards, biological agents, as well as other risks. These Directives concern obligations of employers to ensure safety but are without prejudice to the PLD, which concerns the liability of producers for defects inherent to the products themselves.

Cybersecurity: The **Cybersecurity Act[320]** establishes a voluntary, EU-wide certification framework for digital products, services and processes, intended to mitigate cybersecurity risks. In addition, the recently adopted delegated act[321] under the Radio Equipment Directive[322] will oblige manufacturers of IoT products to make their devices cybersecure by including features to guarantee the protection of personal data and privacy. This legislation is relevant to the safety and security of products, but does not regulate the liability of producers. In addition, the Commission is preparing a Cyber-

[314] Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council
[315] Proposal for a Regulation of the European Parliament and of the Council on General Product Safety (GPSR), COM(2021)346 final.
[316] Regulation (EU) 2019/1020 on market surveillance
[317] European Commission. (2018). Evaluation of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective, p. 49.
[318] European directives on safety and health at work | Safety and health at work EU-OSHA (europa.eu) European Framework Directive on Safety and Health at Work (Directive 89/391 EEC).
[319] Directive 2009/104/EC of the European Parliament and of the Council of 16 September 2009 concerning the minimum safety and health requirements for the use of work equipment by workers at work.
[320] Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (Text with EEA relevance), OJ L 151, 7.6.2019, pp. 15-69.
[321] Commission Delegated Regulation (EU) 2022/30 of 29 October 2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive
[322] Radio Equipment Directive 2014/53/EU, Article 3(3)(e) and Article 3(3)(f).

resilience Act[323], which would build on existing rules to encourage manufacturers and software developers to mitigate cybersecurity risks, but does not envisage rules on liability. Under the current PLD a product that causes harm due to a cybersecurity vulnerability can be found defective, but only if the vulnerability was present at the moment it was placed on the market.

1.1.2. Interplay with ongoing initiatives

The proposed Machinery Regulation[324] and proposed General Product Safety Regulation[325] (GPSR) aim, in their respective fields, to address the risks of digitalisation in the area of product safety. This includes safety risks posed by software updates and downloads, interconnected products and the evolving functionalities of products enabled with AI and other digital technologies. The concern that the PLD will become out of step with modernised product safety rules is addressed in the problem section.

The proposed Digital Services Act[326] (DSA) sets out rules for online intermediary services, including online marketplaces. The DSA imposes obligations on online marketplaces to tackle illegal products online, such as collecting information on the identity of traders using their services. The proposal for a GPSR also imposes obligations on them to tackle the sale of unsafe products online. While online marketplaces are relevant for product safety, they are covered by a conditional liability exemption under the e-commerce Directive[327] and the DSA when they play a mere intermediary role. When a provider of an online marketplace does not provide intermediary services, but plays another role in the supply chain, such as producer or importer of a product, they can in principle be held liable under the PLD if the product is defective and causes harm.

Circular economy action plan/Sustainable Products policy framework: The Circular Economy Action Plan 2020[328] announced a sustainable products policy framework intended to provide high-quality, functional and safe products, which are efficient and affordable, last longer and are designed for reuse, repair, remanufacturing and high-quality recycling. The Action Plan does not contemplate measures on liability for defective products.

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[323] How a European Cyber Resilience Act will help protect Europe | European Commission (europa.eu).
[324] Proposal for a Regulation of the European Parliament and of the Council on machinery products, COM(2021) 202 final.
[325] Proposal for a Regulation of the European Parliament and of the Council on General Product Safety (GPSR), COM(2021)346 final.
[326] Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC, COM(2020) 825 final.
[327] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce').
[328] Circular economy action plan, March 2020.
https://ec.europa.eu/environment/strategy/circular-economy-action-plan_en.

Annex 8: Products that may carry risks but are not defective

The PLD provides a single set of rules for all types of products and regulates the liability of producers for products that do not provide the level of safety the general public are *entitled to expect* (i.e. that are defective). Because the notion of defectiveness is linked to entitled expectations, it is very difficult to get compensation in cases where a victim of harm was informed of the risks involved in using a product beforehand – in such a case it is difficult to prove that a person is entitled to expect those risks not to materialise. This situation particularly arises in the context of health products, like pharmaceuticals and medical devices, which work as specified on the information leaflet, but nevertheless entail a risk of adverse reactions.

Two French patient associations[329] have argued that the concept of defect is fundamentally unsuitable for pharmaceuticals, and that producers should be subject to no-fault liability whenever their products cause harm, irrespective of defectiveness. The support study for this impact assessment, however, did not find further support for this viewpoint among stakeholders, although pharmaceuticals were certainly identified as a product whose defectiveness can be difficult to prove due to complexity – this issue is addressed in policy options 2a and 2b in the main report. The pharmaceutical industry has argued that unbalanced liability rules would hamper innovation, considering the significant investment needed to bring a new pharmaceutical product to market[330]. They also pointed to the existing obligations on pharmaceutical companies to ensure, report and monitor product safety, including the authorisation requirement of those products before they are placed on the market.

Indeed, the EU has a robust legislative framework in place to ensure the safety of pharmaceutical products, which includes stringent requirements before a product can be placed on the market and stringent rules on monitoring the ongoing safety of products once on the market. EU law requires each marketing authorisation holder, national competent authority and the European Medicines Agency (EMA) to operate a pharmacovigilance system. The overall EU pharmacovigilance system operates through cooperation between the EU Member States, EMA and the European Commission. In this context, marketing authorisation holders have to justify market withdrawals and indicate whether they are based on safety grounds or not. Medicines regulators have the tools to withdraw medicinal products from the market in case the benefit/risk is no longer positive. Furthermore, the EU legislation on pharmaceuticals sets requirements on information to patients and healthcare professionals.

The Pharmaceutical Strategy 2020[331] announced a review of pharmaceuticals legislation[332] to ensure the quality and safety of medicines, while boosting the sector's

[329] Responses to public consultation and to inception impact assessment of France Assos Santé and Réseau D.E.S. (Victimes du Valproate de sodium).
[330] On average USD 2,56 billion and 12-13 years: response to public consultation of EFPIA, European Federation of Pharmaceutical Industries and Associations.
[331] A pharmaceutical strategy for Europe (europa.eu).
[332] Revision of the EU general pharmaceuticals legislation (europa.eu).

global competitiveness. It also emphasised the need to stimulate innovation in areas of unmet medical needs (e.g. neurodegenerative and rare diseases and paediatric cancers).

It is important to note that when it comes to harm suffered due to pharmaceuticals that are not defective, all Member States cover basic losses through national health systems or social security schemes. To cover further losses, some Member States have created insurance schemes for pharmaceuticals, in particular in Sweden, Finland and Norway[333], under which victims of harm may get compensation if the pharmaceutical product caused the harm, without any need to prove fault or defectiveness. Almost half of Member States have also created compensation funds for harm caused specifically by vaccines, including COVID-19 vaccines, which have the particular characteristic of having very high benefits for society, despite also causing grave harm to some individuals[334].

Since the PLD constitutes a liability regime based on product defects and not an insurance scheme or compensation fund, these national measures fall outside of its scope of the PLD and are therefore compatible with it.

[333] Duncan Fairgrieve, Product Liability, 3rd edition, p. 274.
[334] E. Rajneri, J-S. Borghetti, D. Fairgrieve, P. Rott, Remedies for Damages Caused by Vaccines: A Comparative Study of Four European Legal Systems, European Review of Private Law 1-2018 [57-96].

Annex 9 – Indicators for monitoring impacts of preferred option

The following table supplements section 9 of the main report by identifying indicators for evaluating the impacts of the preferred option, ordered according to the specific objectives set out in this impact assessment.

Objectives	Indicators	Sources of information
Continue to ensure the functioning of the internal market, free movement of goods and undistorted competition between market operators	Uniformity of transposition of the PLD in the Member States Perceived increased legal certainty and reduced legal fragmentation Changes in level of liability insurance premiums attributable to PLD	Transposition checks Study/ consultation of stakeholders
Adapt PLD to reflect nature and risks of products in the digital age	Number of court cases[335] concerning digital products based on the PLD in particular claims against software producers Number of reported safety problems with products due to the lack of security updates of software	Study/ desk research/ MS reporting
Adapt the PLD to reflect the nature of products in the circular economy	Perceived increase in legal certainty among stakeholders	Study/ desk research/ MS reporting
Ensure there is always an EU-based liable person for defective products bought in the EU	Ability of consumers to get compensation from authorised representatives/fulfilment service providers (number of cases) Number of claims rejected due to the lack of liable person for 3rd country products	Study/ desk research/ / MS reporting
Ease the burden of proof in the case of complex products and clarify liability for undiscoverable defects, while ensuring fair balance between producers and consumers	- ability of claimants to obtain necessary information in court -frequency of use by courts of presumptions provided for in PLD - reduction in perceived difficulties for victims claiming compensation - perceived balance between producers and consumers interests	Study/ MS reporting /consultation of stakeholders
Ease restrictions on making claims, while ensuring fair balance between producers and consumers	- number of claims for damages below 500 EUR - number of claims in the period between 10 15 years after putting the product in circulation (for latent personal injury)	Study/ MS reporting

[335] It should be noted that while the existence of court cases would give an indication that the PLD can be successfully applied to products in the digital age, the deterrent function of product liability actually aims to increase safety and so reduce product harm and therefore reduce the number of claims and court cases.

Annex 10 – SME Test – summary of results

(1) Preliminary assessment of businesses likely to be affected	
SMEs are among the businesses that are affected by the Directive and its revision. That may be in their role as manufacturers or as importers, authorised representatives and, to a lesser extent, as fulfilment service providers or distributors. By way of example, 95% of medical equipment manufacturers and 99% of toy manufacturers are SMEs.	(See sections 6 and 8, as well as Annex 2 and 3 and the supporting impact assessment study)
(2) Consultation with SMEs representatives	
The targeted and public consultations were disseminated through the EU SME associations network and through the Enterprise Europe Network. 13 SMEs (businesses) and two SME associations (European Digital SME Alliance and Allied for Startups) responded to the public consultation, but none to the targeted consultation.	(See section 6.1.a and Annex 2)
(3) Measurement of the impact on SMEs	
The views of SMEs expressed in the course of consultation activities did not particularly diverge from the overall views of business respondents. The impact assessment study did, however, conclude that clearer liability rules, particularly regarding software and refurbished products, would particularly benefit SMEs, which have fewer resources than larger companies to devote to understanding unclear rules[336]. On the other hand, the 2018 evaluation found that 31% of small enterprises do not have liability insurance, whereas among medium and large firms the figure is only 15%. Thus, SMEs could be more exposed than larger firms to compensation pay-outs not covered by insurance. Also, higher product liability insurance costs might affect SMEs more than larger companies, as SMEs have less ability to	(See sections 6.1.b)

[336] CSES with Wavestone, CSIL (2022), Impact assessment study on the revision of Product Liability Directive, section 2.3.1.

absorb the costs and might have less favourable insurance conditions.	
4) Assess alternative options and mitigating measures	
The preferred policy option was selected with a view to achieving a fair balance of interests between industry and consumers, in particular avoiding measures that could make it difficult for SMEs to innovate or could create additional costs that might be more difficult for SMEs to absorb. Specific mitigation measures for SMEs as part of the revised PLD would not be appropriate, because proper compensation for persons injured by defective products cannot be made dependent on the size of the liable company. Consumers do not know when purchasing a product whether it was manufactured by a large company or an SME. It would also distort competition between market players if companies selling similar products faced different liability rules.	(See section 8)