BUSINESSEUROPE

POSITION PAPER

14 April 2023

Product Liability and AI Liability Directives

KEY MESSAGES

1. The expansion of scope of the PLD should be limited to embedded software. For instances of AI software overlapping with the PLD's strict liability regime an explicit clarification should be made that the strict liability regime of the PLD would only apply to High-Risk AI as defined under the AI Act.
2. Great care must be taken to ensure the revised PLD's new requirements will not upset existing national transposition or create new national procedures where no resourcing exists.
3. The PLD should maintain its focus on material damages only.
4. The PLD's newer notions on 'defect' must be narrowed down to prevent undue justification that can lead to a presumption of a defect and subsequent alleviation of the burden of proof.
5. The PLD and AILD must have stronger provisions to prevent the usage of irresponsible Third-Party Litigation Funding and take care against the malicious use of Mass Claims.
6. Appropriate safeguards under the PLD and AILD must be created to ensure evidence disclosures are proportionate, so that trade secrets and IP rights are protected. It is paramount that Europe does not introduce 'discovery clauses' or promote 'fishing expeditions' to the detriment of the defendant.
7. The PLD and AILD provisions on the burden of proof de facto establish a situation of 'guilty until proven innocent' despite the Commissions efforts to avoid this exact outcome. We do not see sufficient evidence to justify the proposed alleviations.
8. Ensure the AI Act is finalised before fully implementing the AI Liability Directive and ensure that AI systems are dealt with under a fault-based liability regime.

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Introductory Remarks

As outlined in our consultation response from 2016[1] and our 10 January 2022[2] comments, BusinessEurope believes the Product Liability Directive (PLD) was sufficient as-is and established a future-proof, technology neutral framework for product liability. The need for a full revision is therefore questionable in our view especially since the evidence for the revision justifying such substantial changes to well-established and nationally transposed liability is low.[3] We regard a strict liability system as established by the PLD as a deviation from the traditional ground rules of litigation where a claimant must provide proof and fault needs to be proven. One should only deviate from these ground rules, as the PLD does, if it is proven necessary. The revision of the PLD, with its expanded scope, definitions, alleviations of burden of proof, the introduction of mass consumer claims, etc; we deem has not been substantiated sufficiently to justify bringing into the PLD's strict liability regime. Such new expansions make the strict liability of the PLD even more imposing, and concerning, as the Commission found the original PLD is still effective.

Yet we recognise that the European Commission has put product liability as a pivotal component in its work to overhaul and regulate the digital space. From the AI Act to Medical Devices, EU regulation is seeking to answer the question of how to govern the interaction of tangible and intangible components.

The Commission deemed that current product safety legislation *'already supports an extended concept of safety protecting against all kinds of risks arising from the product according to its use' However 'provisions explicitly covering new risks presented by the emerging digital technologies could be introduced to provide more legal certainty.[4]'* Furthermore the European Parliament's Own Initiative Report on AI and Liability states that there is no need for a complete revision of the well-functioning liability regimes but due to the new technical complexities of AI, specific and coordinated adjustments to the regime are necessary.[5] We argue that for this necessity to be justified any such coordinated adjustment must be based on solid evidence demonstrating necessity, which we have serious reservations has been proven.

Faced with this logic a balance between maintaining the generally fit-for-purpose framework and addressing the legal gaps that new technologies are presenting will need to be struck.

[1] Liability for defective products – public consultation
[2] Adapting liability rules to the digital age and Artificial Intelligence
[3] PLD Evaluation 2018, data was collected during 2000-2016, indicating that in 40% of the total cases are dismissed (to consumers detriment) due to evidence challenges. The same study shows that evidence problems are mainly in the pharmaceutical/medical sector. Additionally the study shows that 60-70% of cases are solved in amicable settlement and no issues of evidence occur. The study concludes by saying the consumer's burden of proof does not affect the effectiveness of the PLD- and that while providing evidence may be a problem for technically complex products this should be considered in light of the fact that most cases are amicably settled, and evidence did not present an obstacle. Additional studies should be conducted to determine the need for evidentiary presumptions for the scope of the PLD.
[4] Commission White Paper on AI
[5] European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence.

This is especially present with the proposal on the fault-based AI Liability Directive (AILD) as opposed to the PLD's strict liability regime. As the AILD allows for alleviation of the burden of proof for all AI systems, if the PLD is to maintain its scope for AI systems, we suggest that only high-risk AI systems are kept under the strict liability regime of the PLD. Strict liability places a higher burden on producers[6] and this will be particularly relevant to developers of AI technologies. The EU cannot foster an innovative AI ecosystem if its own developers are unjustifiably hindered by a strict liability regime for all integrated AI products.

We do not dispute the fact that opacity/lack of transparency, explainability, and general 'black box' attributed characteristics of AI may pose issues for assigning Liability. But before proposing new liability regulations the necessity for such additional rules needs to be proven. However, we note that the broadening of the scope of the PLD as well as the AILD have been proposed based on a theoretical concern. As the Commission's notes in its Impact Assessment[7] no judicial cases have emerged yet which the AILD would address. Therefore, bringing non-tangible products (stand-alone software and Software as a service (SaaS)) within the scope of the PLD, as well as proposing a technology specific liability directive for AI systems, is merely meant to pre-empt such uncertain developments. Yet there is no hard evidence to prove legal procedure failure and a need for such legislation currently.

At the same time, we do see the risk of legal fragmentation occurring as pointed out in the AILD Impact Assessment. We must avoid having a scenario where companies operating the same AI system across the single market face different liability exposures depending on the interpretation of the Member State. Therefore, in principle we support the choice for a fault-based regime to apply to AI systems.

The AILD is of course closely linked to the AI Act, which is ongoing negotiations thus it seems natural a staged implementation will occur and would be better to have the AI Act finalised first. This will give the market time to react properly.

Furthermore, we note that both the Product Liability Directive and AI Liability Directive proposals will generate significant costs and expenses for pre-trial procedures when it comes to the disclosure of evidence. In addition, both provide a worrying possibility for the expansion of 'for-profit' litigation by profit-motivated third parties, which historically are non-EU. While the EU seeks to build up its strategic and geopolitical muscle in digital technologies, we would risk leaving the door open for our own legal system to be manipulated by non-EU actors seeking to profit for their own gain. The European Parliament recently adopted a legislative resolution calling on the EU to ensure litigation funding is done responsibly precisely to address risks of third-party litigation schemes/entities triggering abusive litigation waves in the future. Besides ensuring

[6] Report from the Commission on the Application of Directive 85/374 on Liability for Defective Products, COM(2000)893 (2001)

[7] 'However, AI systems with the specific characteristics challenging liability rules are mostly not yet on the market, among others because they are not yet approved. Therefore, there are no available judicial cases yet where the problems to be addressed by this initiative have materialised.' AILD Impact Assessment

procedural safeguards, the EU legislative production should ensure precise, clear and proportionate rules for fair and balanced justice.

As concluding remarks, we see the PLD revision as a missed opportunity to promote alternative dispute resolution mechanisms. The Commission itself states that these methods as an alternate to litigation mean that *'resolving consumer disputes are easier, faster, and less expensive than going to court.*'[8] As it stands the PLD will likely incentivise producers to spend more on protecting themselves from unnecessary litigation costs (insurance premiums, legal fees, etc) and creating defensive strategies rather than focusing on innovation. Thus, potentially leading to higher prices and affecting availability of products on the market or even reluctance on behalf of the producer to invest and innovate in new technologies due to the new risks of liability and financial burden.

As a Social Partner and a representative of 40 national industry associations across Europe, we would like to provide our comments on the proposals and look forward to having a constructive dialogue with all stakeholders.

Specific Comments- Product Liability Revision

Chapter I: General Provisions:

Article 2: Scope:

As a general rule the scope of the PLD should be limited to tangible products (including imbedded software) Keeping intangible products out of scope is furthermore in line with the revised General Product Safety Regulation and in our view, there is no proof that it is necessary to bring intangible elements within the scope of a strict liability regime. As a result, producers of standalone software and SaaS should not be in the scope of the PLD[9]. In addition, we still have practical questions about the implications of this expansion- such as how Software as a Service will be dealt with and if this leads to Cloud services being covered. Furthermore, clarification of how the PLD Revision will work with the Cyber Resiliency Act's definition of software as a product and subsequent exemption for Software as a Service will be needed.

We do appreciate recital 13's exemption for open-source software and would urge this is codified under a suitable Article in order to be legally sound.

Article 3: Level of Harmonisation:

[8] Alternative Dispute Resolution for Consumers- European Commission

[9] As noted by the PLD Expert Group (and many others) software and AI bring philosophical challenges to the notion of 'product.' Embedded and non-embedded software thus have different implications. Further compounding the problem if standalone software is considered a product would be in cases where updates or data feeds are provided from outside the EEA, a claimant would have difficulty finding legal recourse as there is not typically an intermediary imported located in the EEA for direct downloads.

A full harmonisation approach is necessary to ensure a level playing field and prevent legal fragmentation. Both are important to further strengthen and complete the single market. We are concerned that certain provisions such as Article 8 on the disclosure of evidence will risk promoting diverging national interpretations- contrary to the aims of harmonisation of the PLD. To ensure full harmonisation we advocate for, a single market clause as it was used in previous EU consumer law related directives.[10]

Article 4: Definitions:

Article 4.1- The Definition of 'Product' and Relationship to Software

The definition of 'product' to include software is worrisome as we have also indicated in previous positions on the General Product Safety Regulation: software and data should not be defined as a 'product.' However, we recognise the Commission's intention with this PLD revision and as such would urge that more focus is given on how to define embedded software's relationship to a product.

Our concern for this stems from the fact that applying strict liability in a general manner to incorporate stand-alone software is highly disproportional considering we do not have a legal gap.[11] A blanket scope of software neglects to factor the varying levels of risk and control that developers have. These varying risk-profiles themselves are even acknowledged under the Cyber Resiliency Act which introduces the notion of a 'product with digital elements' and differentiates four different classes of these types of products. The CRA will thus allow for functional/custom built software to become CE-marked according to its risk classification which will put software under the remit of the New Legislative Framework. Yet even the CRA does not scope in software as a service, whereas the PLD has the notion of *'related service'* which with its broad definition could lead to digital services or even digital content falling under the PLD's scope. We acknowledge the challenge this will pose for co-legislators to reconcile with the Commission' drafting logic[12] which focused on the functionality of a product. However, it will be critical to find a way to avoid the overextension of *'related services.'* Especially as the ECJ in its 'Krone[13]' ruling found that the provision of the same service in a non-digital form does not apply to the PLD.

Recital 12 of the PLD outlines the Commission's intention that *'software is a product for the purpose of applying no-fault liability irrespective of the mode of its supply or usage'* but that source code is not considered a product for the PLD as this is pure information. The reflection that pure information should not be a product is welcome as this is reflective again of the ECJ's 'Krone' Judgement.

[10] Directive on Unfair Commercial Practices; Directive on Consumer Rights

[11] Recourse for Software is available already under EU sectoral regulation such as GDPR or Medical Devices Regulation. Furthermore National and Tort liability at Member State level also provides sufficient recourse, even when services are involved, which can assist in addressing standalone software.

[12] The PLD Explanatory Memorandum states 'it was legally unclear how to apply the PLD's decades-old definitions and concepts to products in the modern digital economy and circular economy (e.g. software and products that need software or digital services to function, such as smart devices and autonomous vehicles)'

[13] ECJ Case C-65/20- 'Krone'

Therefore the definition of Product should be limited to tangible products, including embedded software.

As stated earlier, Recital 13's clarification that source code would not be considered a *'product'* is positive but we would ask to see the exemptions for open-source software and its use codified in an Article such as under Article 4.1 or 4.3. And for precise clarity on open-source software being provided outside of a *'commercial activity'* As the interpretations for commercial activity under the New Legislative Framework can be interpreted broadly and could defacto lead to all Open-source software being held liable.[14]

In all cases awareness and where possible consistency with the respective harmonisation legislation is needed as embedded software has been made explicit as in examples such as the Machinery Directive, Measuring Instruments Directive, or in Medical Devices. For example, under the Medical Devices Regulation while standalone software is classified as a product, this is done to reflect the specificity[15] of the Medical Sector and should not be taken as proof standalone software in all cases can be considered a product as the PLD would suggest.

Art 4.6: Definition of 'Damage' must be kept to material loss.
We support maintaining the definition of *'damage'* limited to material losses. This is crucial. However, it needs more clarification that the losses are limited to material damages such as compensation for the costs of recovering data from a backup or costs for manual re-entry of data.

Otherwise, we fear that *'medically recognised harm to psychological health'* can be widely (mis)interpreted. In addition, clarification is needed what medically recognised harm entails. Is it sufficient to show a bill of a recognised psychiatrist or psychotherapist? Or would the claimant need to show evidence of a recognised disease/disorder according to peer-reviewed medical literature? Furthermore, it is important to highlight that the Commission noted that '*medically recognised harm to psychological health'* does not include stress or anxiety.[16]

Regarding damages stemming from data loss, this leaves the possibility for limitless litigation due to defects or bugs. It also bears the question for scenarios where these

[14] For example: under the EU Blue Guide- 'Making Available on the Market' - A product is made available on the market when supplied for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge… Commercial activity is understood as providing goods in a business related context. Non-profit organisations may be considered as carrying out commercial activities if they operate in such a context. This can only be appreciated on a case-by-case basis taking into account the regularity of the supplies, the characteristics of the product, the intentions of the supplier, etc. In principle, occasional supplies by charities or hobbyists should not be considered as taking place in a business related context'

[15] Stand alone software must have a medical purpose to be qualified as a medical device as based on the intended purpose of the manufacturer, Stand alone software that does not meet this definition but is still intended to be an accessory falls under separate legislation (Commission Medical Devices Guidance document Qualification and Classification of Stand Alone Software, 2016)

[16] As recognised by the Impact Assessment Report under Annex 5, which states that: 'Medically diagnosed psychological damage is generally accepted as falling under the concept of 'personal injury', while just stress or anxiety is not.'

damages could lead to claims of invasion of privacy- which relate to intangible interests or dignitary concerns, both unsuited for strict liability. It is important to consider the Commission's findings on this issue as well.[17]

Overall, these key concepts require much more nuance to prevent legal uncertainty, with a high risk that Member States will interpret them in various ways leading to disproportionate outcomes and harms the level playing field in the Union.

Art 4.10 Align 'Putting into Service' with the NLF
The definition of 'Putting into service' should be aligned with the Commission's Blue Guide of 2022:[18] '*Putting into service takes place at the moment of first use within the Union by the end user for the purposes for which it was intended.*'

Chapter II Specific Provisions on Liability for Defective Products:

Article 5: Right to Compensation:

Article 5.2(b) is of high concern as we do not see sufficient safeguards being taken to address frivolous litigation as well as irresponsible third-party litigation funding. As a minimum the procedural safeguards foreseen in Directive (EU) 2020/1828 on representative actions regarding the entities able to file representative claims as well as funders of claims need to be established in this Article. The references in Recital 21 are insufficient. The expansion of the PLD beyond physical and property damage into data could add additional profit-motivated incentive for third party litigators to specifically aim for cases on data loss/corruption. The European Parliament recently called for legislative actions at EU level to ensure responsible private funding of claims. [19]

Article 6: Defectiveness:

Art 6.1- 'Entitled Expectation Test' and Subjectivity
Art 6.1 established an '*entitled expectation test'* that a product is defective when it *'does not provide the safety which the public at large is entitle to expect.*' While this is maintained from the original PLD proposal- which is positive, with this context in mind we have some doubts as to how this language could apply to AI and software as this introduces quite a subjective element into this entitled expectation test. We do however endorse the continued acknowledgement under Art 6.2 from the original PLD that a product is not considered defective merely because an improved version exists.

Art 6.1.B Alignment with the Blue Guide

[17] The 2018 PLD Evaluation found that between 2000-2016, for new technological developments only one case could be identified which invoked the PLD for damages being claimed for data loss but no material loss- the court found the claimant was unable to prove the occurrence of defect in this instance.
[18] Commission notice The 'Blue Guide' on the implementation of EU product rules 2022 (Text with EEA relevance) 2022/C 247/01
[19] As outlined in a joint statement on Responsible Private Funding of Litigation several majors business associations (including BusinessEurope) expressed concerns about the growing presence and actions of private litigation funding supporting EU action to ensure responsible funding of claims by profit-motivated third parties.

This should be aligned with the Blue Guide (and GDPR) and *'misuse'* should be removed. At the least it must be recognised that the manufacture cannot be held liable for the misuse of a product by a consumer especially when warnings and safeguards have been provided.

Article 6.1.C: Regulate AI under the AILD
A product would be considered defective with regards to its ability to continue learning after deployment. A simple presumption of defectiveness as set out in 6.C could be abused by regulators who do not have the necessary understanding of how an AI system operates, resulting in strict interpretations of *'defect'* when an AI system is deployed. As the notion of *'continuing to learn after deployment'* implies AI, for sake of legislative consistency issues of AI should be regulated strictly under the AI Act and AI Liability Proposal.

6.1.f: Cybersecurity Recourse
We believe the cybersecurity requirements for identifying a *'defect'* should be left out of scope and addressed via contractual relationships. Consumers can find recourse with the producer of the physical product who is then able to recover the cost further up in the supply chain using these contractual relationships.

6.1.G: Regulatory Intervention Should Not Mean a Product is Defective
We fear that this provision acts far too broadly in its intentions and conflates product liability with product safety. 6.1G in essence would allow for even minor technical infractions to allow for a presumption of a defect even if the authorities do not have any issue with the risk profile or the products still being available on the market. This would lead to conflicting outcomes and undermines the regulatory process and dialogue established under EU product safety rules. Under these rules it is common for producers to be in continual dialogue with authorities over product safety- such as in medicinal products. Due to this It can be possible that producers find themselves in a technical breach of an obligation such as being late with documentation submission. In which case the regulators do have the tools needed to ensure compliance and identify if a breach has occurred. We do not believe however that in such cases of a breach this should determine that a product is 'defective' as per the PLD.

Article 7: Economic Operators Liable for defective products:

We view the overall structure of Article 7 positively as this correctly identifies the person responsible in Europe. We would however call for clarity under 7.2 so that the liability of the importer when the manufacturer is established outside the EU is established by default.

We are highly supportive of Article 7.4 on substantial modification and urge that it be used consistently with other files such as Machinery Regulation, AI Act, and General Product Safety Regulation. We are encouraged by the fact the Commission took note of our calls for alignment in their Product Liability Impact Assessment Report.[20]

[20] Impact Assessment Report on the Product Liability Directive, SWD(2022) 316 final

But more clarity is needed for instances of repair or refurbishment as currently worded it is difficult to determine liability especially for the original manufacturer or the person who made the significant changes. It is essential that each actor is aware of the consequences that can result from conducting such modifications on a product. We see risk of conflicting interpretations and litigation emerging if the wording around modification that acknowledges *'Union rules or national rules'* remains. Adopting the Blue Guide Framework here with regards to 'substantial modification' is recommended especially as the ten-year term for liability will start running again upon substantial modification.

Regarding liability for Online Marketplaces and fulfilment service providers we support the creation of a level playing field between the EU and non-EU providers but stress that we must align with other relevant legislation such as General Product Safety Regulation, Digital Services Act, Market Surveillance Regulation, and Platform2Business Regulation, which all establish sufficient traceability and due diligence obligations.

Article 8: Disclosure of Evidence

The provisions on the disclosure of evidence are entirely unacceptable as there is a lack of sufficient safeguards. It is paramount that the rights of IP, trade secrets, and privacy are protected. We are strongly concerned that Article 8 as it stands would provide an easy basis for 'fishing expeditions' which allow for parties to demand access to broad amounts of material to determine potential claims even beyond product liability. Although it is understood that a company's collaboration in evidence gathering is essential for the substantiation of claims, it is important not to forget other fundamental rights at play such as due process, protection of commercially sensitive information and proportionality within legal procedures. It is essential that Europe does not import US style discovery rules which lead to great burdens on companies, are costly, and could lead to abuses by claimants.

More safeguards need to be established to prevent abuse of this provision. For example: currently we do not see anything that prevents a claimant from requesting and obtaining evidence then dropping the case.
Safeguards to prevent this should consider:

- A judge determines 'after conciliation' what the opposition party has access to
- Documents requested must be sufficiently specified and the applicant has a legitimate interest in their disclosure (not only a legitimate interest in starting a claim procedure).
- The amount of documentation being requested and disseminated, which prolongs the litigation period and increases costs on both parties.
- The involvement of third-party litigation funding is done transparently and by entities fulfilling future (necessary) EU requirements to operate.

We propose the following amendments to:

Article 8 PLD 'disclosure of evidence'

1. Member States shall ensure that national courts are empowered, upon request

of an injured person claiming compensation for damage caused by a defective product ('the claimant') who has presented facts and evidence sufficient to support the plausibility of the relevance of the **specific evidence within the context of the substantiated plausibility of the** claim for compensation, to order the defendant to disclose specific **relevant ~~evidence~~ document**s[21] that is **readily** at its disposal.

2. Member States shall ensure that national courts limit the disclosure of evidence to what is necessary and proportionate to support a claim referred to in paragraph 1.
3. When determining whether the disclosure is proportionate, national courts shall consider the legitimate interests of all parties, including third parties concerned, in particular in relation to the protection of **intellectual property**, confidential information and trade secrets within the meaning of Article 2, point 1, of Directive (EU) 2016/943.
4. Member States shall ensure that, where a defendant is ordered to disclose information that is a trade secret or an alleged trade secret, national courts are empowered, upon a duly reasoned request of a party or on their own initiative, to take the specific measures necessary to preserve the confidentiality of that information when it is used or referred to in the course of the legal proceedings.

Overall, a system where a judge can balance the interests of both parties and take specific context of the case into account is needed. To consider as well is that various Member States[22] have differing practices on evidence provisions. Some, such as the Netherlands, allow for a party to refuse information provision on grounds of 'compelling reasons' such as when it comes to medical, financial, or confidential business information.

These discrepancies in national practices and in combination with Article 8's insufficient safeguards can lead to a high risk of 'forum shopping' regarding cross-border requests in the context of Representative Actions. This could create vexatious Mass Claims (see our point on pg. 11) allowing for claimants to target Member States that have more favourable disclosure laws than the original jurisdiction of the claim.

Article 9: Burden of Proof:

We understand the PLD wishes to alleviate the burden of proof for consumers and make filing of claims easier, but this must be substantiated by evidence that existing laws and

[21] 'Documents' include- besides data on paper, data on data carriers other than paper such as film, photograph, CD-ROM, DVD, audio tapes, computer files, email, USB sticks.

[22] Other examples of varying practices are as follows: France and Spain both restrict disclosure to only those documents which are admissible at trial and the Judge supervises said disclosures and decides on relevance and admissibility. In Germany, a party only needs to produce documents that support its case- the documents must be verified as authentical and certified but the party seeking the disclosure must appeal to the Court first to obtain them, the appeal must be specific and with appropriate justification, including any agreement of a third-party if need be. In Belgium there is no discovery or pre-trial disclosure proceeding.

regulations are inadequate. Recital 3 of the PLD does admits consumers face challenges in evidence gathering and the Commission's own 2018 PLD Evaluation Report[23] acknowledges the burden of proof is '*the most difficult steppingstone for consumers to obtain compensation, However it is a requirement that cannot be set aside'* The Evaluation found that a *'reasonable balance'* is still to be considered under the original PLD between protecting victims and ensuring fair compensation[24]. But it does acknowledge guidance and clarifications are needed.

In this case though we are concerned that a rebuttable presumption de facto becomes a reversed burden of proof and the defendant will have to prove the defect did not cause damage, either by demonstrating the product defect could not cause the damage or that the damage was caused by other factors. This places European companies in a place of guilty until proven innocent which is disproportionate and contrary to the PLD's explanatory memorandum.[25]

Furthermore, as a general note, it is concerning to see the Commission cite AI as an example of where the reversal of proof may happen as this risk creating a strict liability regime for emerging AI Systems which would be counterintuitive to promoting innovation.

Art 9.2- Presumption of Defect

By having such a widened scope for the presumption of defect the Commission creates a recognition of potential product failure that in practice means manufacturers will be required to withdraw all products of the same type without the existence of a defect or a demonstrated causal link for the same batch. This is further compounded by Article 6.1g and recital 33 which could allow for minor technical infractions to be justified as proof a product is *'defective.'*

We are unsure of the benefits that the reversal of burden of proof brings under Art 9.2b as Article 6.1.f states that product safety requirements must be taken into account for establishing if a product is defective. We see no substantial evidence that demonstrating a product does not comply with product safety requirements leads to claimants not recovering damages already. Permitting for a reversed burden of proof in this instance is disproportionate.[26]

Art 9.2C Establishing a Clear Legal Test for 'Obvious Malfunction'

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[23] 2018 Report on the Application the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (85/374/EEC)

[24] The evaluation states that while there are specific difficulties for the burden of proof, in successful cases (60% of those mapped in the study) it did not represent an obstacle. Established ECJ case law has also helped to overcome difficulties in proving a defect and causal link.

[25] 'The burden of proof will be more fairly shared between injured persons and manufacturers in complex cases, increasing the chances of enforcing a successful compensation claim. However, there will be no reversal of the burden of proof, as this would expose manufacturers to significantly higher liability risks and could hamper innovation, leading also to potentially higher product prices and reduced access to innovative products.'

[26] The Commissions found the majority of cases are settled out of court, with only 32% going to court, Around 60% of claims were successful for the injured parties- indicating 'no particular difference in the level of success of injured parties if the case is settled in court rather than out of it'

The presumption of defectiveness being reliant on *'obvious malfunction'* is problematic as there is no guidance provided on this term. Clarity between the concept of *'obvious malfunction'* and *'defect'* are needed. Care must be taken that *'obvious malfunction'* does not set a lower threshold and supplants the legal requirement to establish a *'defect'* per Article 6. Thus, a clear legal test to establish what is an 'obvious malfunction' is needed.

Art 9.4 Outlining 'Technical Complexity'

Alleviating the burden of proof and broadening the disclosure of evidence should be limited to situations where and in so far this is truly necessary. This necessity needs to be clearly proven and the wording of such measures needs to be sufficiently specific to prevent legal uncertainty It should be noted that reversing the burden of proof combined with the disclosure of evidence are far-reaching measures that can have a large negative impact on innovation. If necessity has been proven than certain limits[27] for lifting the burden of proof in cases of technical or scientific complexity should factor to reduce the negative impact on innovation:

- In light of the function of the product the safety requirements consumers are entitled to expect are particularly high.
- Damage suffered was severe.
- The source of the technical or scientific complexity, and not just the product as a whole, as a likely cause of the damage.
- There is no traceability of contributing processes within the technology.

Additionally, clarity should be given to the defendant outlining the basis they can *'contest the existence of excessive difficulties or likelihood*' and what sort of legal test should be applied to a court to reject a reversal of burden of proof.

Addressing Mass-Claims

In the face of a growing business model of third parties funding mass claims, we see recital 31 as entirely underequipped to address the issue. These mass claims are particularly dangerous for small businesses as they are externally heavily funded. We must ensure a reference is made for procedural safeguards under the European Mass Claims Directive[28] on entities that can act as consumer advocates and on the financing of mass claims.

Article 10: Exemption from Liability:

We endorse the exceptions to liability contained in Article 10 of the PLD proposal and are pleased to see the continued catalogue of defences or circumstances for excluding liability under the original PLD be maintained. But it is unclear whether this provision is intended as an exhaustive list. In our view, the possibility of rebuttal should not be

27 Such limits would be consistent with ECJ case law. For example, it has only assumed defectiveness in limited circumstances where:
(1) in the light of the function of the product and the particularly vulnerable situation of the users, the safety requirements which they are entitled to expect are particularly high;
and (2) the product presents an 'abnormal potential for damage'
(Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt) Furthermore the Expert Group on Liability and New Technologies- New Technologies Formation conclusion 26 suggests additional balancing factors to be taken into account for alleviating the burden of proof.

28 Directive 2020/1828 on representative actions for the protection of the collective interest of consumers

restricted. We propose to amend the opening words of Article 10 as follows: *'An economic operator referred to in Article 7 shall not be liable for damage caused by a defective product if that economic operator proves it has not caused the damage or is otherwise not liable, including the following.'*

We also stress that Member States have been obliged to transpose many of these exemptions into national law already, any changes therefore to existing exemptions would have drastic effects on the national level. Furthermore, we remind policymakers that if a defect arises from a product complying with mandatory regulation, demonstrating compliance with voluntary standards does not provide a defence. Additionally, the Commission itself found *'little to no evidence'* that Art 10.d (Original PLD Art 7.d) poses major problems.

We see it vital that the Development Risk Clause or 'State of the Art Defence' under 10.1.e is maintained to continue ensuring a balance between consumer expectations for safety and promoting innovation. We note that under the original PLD a derogation for this which makes products liable has been adopted by various Member States and even this derogation is not equally transposed.

Chapter III General Provisions on Liability:

Article 13: Exclusion or limitation of liability:[29]

First, we question why the Commission does not see sufficient evidence for the 500 EUR threshold to be maintained. But we view the Commission's concerns[30] on this rather as a question of transposition and not a question of concept. Indeed, various Member States have interpreted the threshold differently- some see it as a deductible, others as a legitimate threshold that upon reaching triggers a claim. This can create varying degrees of protection.

Art 14: Limitation Periods:
We support the expansion of the limitation period to 15 years for the cases where symptoms are slow to emerge, but stress it is crucial that the 10-year period remains the norm for all other instances. A 10-year expiration period is sufficient in our view as this is longer than most guarantees, which last around two years.

Art 15: Transparency:
The proposal requires member states to publish court decisions on product liability. These rulings may be included in a public database to be set up by the Commission[31]. We support the aim to publish the majority of judgments, but it should be up to the judiciary to make the decision whether or not to publish judgments.

Article 17: Repeal and transitional provision: Implementation period:

[29] VNO respectfully is unable to comment on the position of the removal or maintaining of the threshold.
[30] The 2018 PLD Evaluation outlined two concerns: One of transposition, the other that in 4 out of 5 cases a compensation is not claimed as the damage is below the threshold.
[31] We note that in some Member States such as the Netherlands it is an independent judiciary that decides if a court ruling should be made public.

We would urge for a longer implementation period of at least two years, one year is insufficient for businesses to adapt to these changes, furthermore national legislation will require amending and re-design. A minimum of two years is necessary for the PLD revision to be properly implemented.

Specific Comments- AI Liability Directive

AI Liability Directive

Article 1: Subject and Scope:

The AILD being under fault-based liability regime is a positive feature. But we reiterate that without clear definitions on what constitutes 'AI' or 'High-Risk AI' or 'Prohibited AI' it is impossible to properly assess the impact of the AILD. The difference in an AI definition that is 'narrow' and focused on Machine Learning techniques versus a more expansive definition covering broader techniques has serious implications for how one reacts to the AI Liability proposal. It is irresponsible to legislate this issue without first having a solid foundation of definitions.

The goal of harmonisation is welcome, but already the trap of undermining this endeavour is set as Art 1.4 allows for Member states to adopt or maintain national rules. Recital 14 of the AILD states *'this will follow a minimum harmonisation approach'* which we understand the intention of but see as inconsistent with the full harmonisation clause under Art 3 of the PLD. Alignment between the two is necessary and Art 1.4 should be removed.

If the objective of the AILD is to prevent discrepancy in interpretation in Member State courts, such unalignment is not helpful. Additionally, in the AILD's Consultation[32] findings 77% of the consumer/NGO respondents supported full harmonisation whereas Business stakeholders of 70% opposed minimum harmonisation.

But it is positive to see the AILD attempting to lighten the burden of proof for AI users, we agree that Users should feel safe when using AI products and services- regardless of if they are businesses or consumers. But as always, a careful balance must be struck between users and producers' rights. As there is now a lightened burden of proof, an equivalent balance would be to safeguard producers against arbitrary compensation claims.

Article 2: Definitions:

Ensuring alignment with the AI Act is crucial therefore it is good to see the logical linking of terminology to the AI Act. But given the AI Act itself is still under negotiations, the new terminology would require adjustments in both pieces of legislation to be coherent.

Other definitions under the AILD would benefit from further refinement:

[32] AILD Impact Assessment Report, SWD(2022) 319 final

'Claim for Damages' is unclear what the intended scope of '*where such an output should have been produced'* is supposed to encompass. We suggest that it should be limited to *'output that the AI system was specifically designed to produce but did not'*.

'Potential Claimant' is a new concept that does not appear in other liability frameworks. It is crucial to define this properly as it is concerning that such a loose term would benefit from evidence disclosures and leaves a serious risk competitors would be able to take advantage of. Evidentiary disclosures should only apply to the actual claimants- or a potential claimant must be able to demonstrate they are connected to the AI system or the specified developer.

Article 3: Disclosure of Evidence and Rebuttable Presumption of Non-Compliance:

We broadly reiterate our concerns with Evidence Disclosure as well with the PLD- that safeguards and explicit protections for information are paramount. Otherwise, the risk of fishing expeditions or malicious abuse by competitors to obtain valuable information is too high.

Safeguards need to be properly created around this provision the requests need to be specific, with the claimant demonstrating reasonable interest and relevance of the requested evidence. We also suggest that for Art 3 and Recital 16 that *'relevant evidence'* is specified as *'documentation, information, and logging requirements required under the AI Act or where integrated into Union Harmonisation legislation listed in Section B under Annex II of the AI Act.'* As this would balance the proportionality and necessity of such disclosure requests. At the very least limits on what *'relevant evidence'* is considered are needed.

Further safeguards should consider the possibility for denial of the request based on reasonable grounds- and the usage of such a denial should not be held against the defendant. This denial should be allowed both during a legal process and at a pre-trial stage. Furthermore, protection of confidentiality of information is paramount and this should not be limited to just high-risk systems.

While Art 3.4 does make reference to *'procedural remedies'* and Member States allowing for *'specific measures'* to preserve confidentiality we must have clearer protections. For example, procedural mechanisms such as timeline and format of disclosure need elaboration.[33]

Article 3 however will be a significant burden on national legislations which do not have disclosure/discovery in their litigation (As in Belgium) Therefore the AILD would need to ensure proper support is given as the infrastructure to provide such information on a confidential basis likely does not exist.

[33] In such an example it is unclear even if the Defendant needs to turn over existing documents or would they also need to attend depositions.

Aside from the risk of fishing expeditions and competitors, these disclosures leave the door open for the development of the business model of third-party mass litigation funding that bundle consumer claims, which will increase costs on companies. Evidence disclosures are costly processes and especially for SMEs which will have to bear high administrative burdens. In many of these instances this puts SMEs in a comparable position to consumers due to the costs. The 2018 evaluation found that 1/3 of SMEs do not have liability insurance which would make businesses pay out of pocket for these claims.

Faced with these concerns and risks it is difficult for us to see Article 3 as being a proportionate measure and would likely increase costs on AI usage. It is wise to bear in mind that as the AI Act is developing, compliance costs for High-Risk systems could be roughly 17% of total AI investment costs, with another 13.5% of AI Investment Cost dedicated to Conformity Assessments.[34]

Article 4: Rebuttable Presumption of a causal link in the case of fault:

Article 4 presents a de facto reversal of burden of proof from claimant to defendant. This puts the defendant in a situation where if a decision is unexplained and the defendant did something non-compliant with the duty of care, this entails the defendant must rebut the presumption of their guilt. In other words, the defendant must 'prove a negative.' Such a system could lead to higher liability risks on the developers, deployers, and users of AI systems. Thus stricter conditions for this presumption are needed. For example:

- The presumption under Art 4.1 should apply only to high-risk systems, as these are riskier by definition.
- Failure to comply with the AI Act must be relevant to the damage in order for a rebuttable presumption to apply.

Article 4 also utilises the term *'influence'* and *'giving rise'* which do not have clear meaning and will likely lead to differing interpretations by national courts. It should also be specified if it is the claimant who must prove *'influence'* under Art 4.1b.

Article 4(1) would also benefit from the following clarification:

'Subject to the requirements laid down in this Article, national courts shall presume, for the purposes of applying liability rules to a claim for damages, the causal link between the fault of the defendant and the output produced by the AI system or the failure of the AI system to produce an output ***damage alleged in the claim for damages****, where all of the following conditions are met:*

(c) the claimant has demonstrated that the output produced by the AI system or the failure of the AI system to produce an output gave rise to the damage ***alleged in the claim for damages****.'*

Additionally we would suggest the following for legal certainty under the AILD's recital 15 *'There is* ***no need*** *to cover liability claims* ***when the damage is caused by a human***

[34] Study to support an impact assessment of regulatory requirements for Artificial Intelligence in Europe

assessment followed by a human act or omission, while the AI system only provided information or advice which was taken into account by the relevant human actor...*'*

It is also counterintuitive to the AI Act's risk-based approach that Article 4 scopes in damages arising from non-high-risk AI systems. Non-prohibited and non-high-risk systems have very limited obligations under the AIA. A vast majority of systems that could be held liable under the AILD would be in situations where such a presumption is inappropriate commiserate to the low obligations these systems have under the AI Act and the Commission estimates only about 5-15% of AI systems are high-risk[35].

However, we do view Article 4.4 as positive as this sufficiently limits the presumption when the defendant is able to demonstrate sufficient evidence and expertise is reasonably accessible for the claimant to prove causal link. For clarity though *'reasonably accessible'* would need to be defined.

Article 5: Evaluation and targeted review:

A staged approach as envisioned is welcome. We suggest that evaluation take place after three years and periodic evaluations to follow. Yet more examination may be needed regarding the issue of insurance coverage under Article 5.2

[35] AI Act Impact Assessment