U.S. Chamber of Commerce
Institute for Legal Reform

Providing a Fairer and More Effective Apportionment of Risk: Implementation Notes for Member States on the New EU Product Liability Directive

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The U.S. Chamber Institute for Legal Reform (ILR) is pleased to submit these implementation notes for Member States on the Directive of the European Parliament and of the Council on liability for defective products and repealing Council Directive 85/374/EEC (Directive).[1]

ILR is a not-for-profit public advocacy organisation affiliated with the U.S. Chamber of Commerce, the world's largest business federation, representing the interests of more than three million businesses of all sizes and sectors, as well as state and local chambers and industry associations. ILR's mission is to champion a fair legal system that promotes economic growth and opportunity. Since ILR's founding in 1998, it has worked diligently with law makers around the world on legal reform efforts, in particular in relation to collective redress systems and safeguarding against litigation abuse.

[1] https://www.europarl.europa.eu/doceo/document/TA-9-2024-0132_EN.html

I. Introduction

The original Product Liability Directive forms the foundation of the EU product liability regime. The Directive was adopted nearly 40 years ago and during that time has provided a largely effective compensation mechanism for those who suffer damage caused by defective products in the EU.

Maintaining a fair balance of interests between consumers and producers has been viewed as the main objective of the EU product liability regime since the day of its adoption. However, the new Directive introduces substantial – and unjustified – changes to the previous regime that have the potential to create a radical imbalance between the rights of claimants and defendants, conferring significant evidential advantages on claimants and upending longstanding safeguards for economic operators.

The changes under the Directive will likely affect broad swathes of consumers and economic operators. Its application extends well beyond "traditional" consumer products to software, pharmaceuticals, medical devices and more. The Directive also creates opportunities to pursue wide categories of potential damages, covering diverse causes of action that include, for example, psychological harm caused by the loss or corruption of data.

The full scope of the Directive's impact is difficult to predict as the Directive is likely to interconnect with various pending EU legislative acts that are in themselves expected to significantly reshape potential liability risks for economic operators. A key example is the revised pharmaceutical package proposed by the Commission in April 2023, under which claimants will likely have recourse under the Directive.

The Directive also now requires that product liability actions can be pursued using the collective action mechanisms described in the Representative Actions Directive (RAD). This significantly increases liability risks for economic operators, and it is likely to embolden opportunistic claimants and third-party litigation funders who, tempted by the potential rewards for themselves, may test and exploit the Directive by bringing speculative claims. It is crucial that the Directive is implemented thoughtfully by Member States to mitigate the risk of vexatious and predatory litigation.

This paper identifies key areas where Member States have margins of discretion in how they implement the Directive in their national laws. In doing so Member States should strive to achieve the goals of the Directive while maintaining the right balance between the interests of consumers and industry and seek to preserve legal certainty to the benefit of all.

II. Recommended Safeguards to Ensure a Fair and Effective Apportionment of Risk

A. Who has a right to compensation?

The Directive ensures that any natural person who suffers damage caused by a defective product is entitled to compensation. However, the right to compensation also extends to a

"*person that succeeded or was subrogated to the right of the injured person*" or "*a person acting on behalf of one or more injured persons.*"

Issue

Depending on how national law is adapted to this provision, the number of people who can potentially bring a claim despite not having been injured themselves may increase dramatically. National law may determine the extent to which the right to compensation extends both to "injured persons" but also to others who have suffered no damage whatsoever but who "succeed" or act on behalf of injured persons. The possibility under national laws for injuries to be assigned or sold for exploitation as an asset class by professional intermediaries creates incentives that have little to do with the delivery of justice.

The Directive has been brought under the scope of the RAD, which enables representative or collective actions to be brought on behalf of one or more injured persons. This will significantly increase liability risks for all economic operators who place products on the EU market. The provisions of the Directive combined with new EU representative action laws are likely to embolden opportunistic litigants and litigation funders to support representative actions arising from injury, property damage or loss of data claims.

Recommendation

In implementing the Directive and the RAD or other collective redress mechanisms, Member States should bear in mind that these instruments may be taken advantage of to pursue abusive product liability claims.

It will be important for Member States to ensure that the category of persons indirectly impacted and who are eligible to claim compensation is tightly defined to include only those individuals who have been genuinely affected by a defect. Those who had only a minimal or tangential exposure or are seeking compensation for minor or speculative damages that are remotely connected to the defect in a product should not be eligible. Otherwise, the system may become vulnerable to exploitation through unfounded claims and vexatious litigation.

In review of their collective redress and succession/subrogation laws, Member States should seek to find an appropriate balance between facilitating legitimate actions and safeguarding against opportunism and abusive litigation.

B. Types of damage that may be compensated, including non-material losses

An injured person's right to compensation under the Directive extends to material losses from death or personal injury (including medically recognized damage to psychological health), damage to or destruction of property, and the destruction or corruption of data.

The right to compensation also covers non-material losses resulting from this damage to the extent such losses can be compensated under national law. The rules on calculating compensation are to be laid down by Member States.

Issue

Broad, undefined or large differences in the definitions of the non-material loss that may be claimed in different Member States risks introducing a high degree of uncertainty for economic operators and their insurers as to the frequency and quantum of claims for non-material losses across the EU market.

Psychological harm is particularly difficult to define and assess, with legal uncertainty arising from there being no harmonized definition at EU level. The criteria for what constitutes significant psychological harm can be vague and open to interpretation, making it susceptible to claims that may go beyond the intended scope of the Directive. Opportunist claimants may exploit these vulnerabilities for financial gain rather than legitimate redress.

As regards the loss or corruption of data, such infringements are already covered at the EU level by the GDPR. Since the GDPR already provides the opportunity for redress, it is difficult to see why further options should be available under the Directive. To have multiple overlapping consumer protection regimes gives rise to the risk of conflicting calculations, which undermines legal certainty and adds additional complexity and cost for economic operators.

Recommendation

Member States should define carefully what may constitute psychological harm and seek to align their definitions as far as possible. This could be achieved, for instance, by using the World Health Organization's International Classification of Diseases, or by ensuring that compensation is only paid for specific types of verified psychological harm.

Member States should also provide definitions regarding the loss or corruption of data such that the risk of conflict with the GDPR is removed.

Member States should carefully define national laws regarding which (if any) non-material losses may give rise to compensation in order to increase certainty for both consumers and economic operators. A lack of definition will give rise to speculative claims to test the boundaries of compensation availability, clogging courts with unnecessary litigation, pressuring economic operators into undue settlements simply to avoid outcome uncertainty, and causing upward pressure on insurance premiums.

C. When is a product defective?

Under the Directive, a product shall be considered defective if it does not provide the safety that a person is entitled to expect or that is required under EU or national law.

In assessing the defectiveness of a product, all circumstances shall be considered, including the non-exhaustive list of factors contained in Article 7(2) of the Directive.

Whether a product is defective can be defined in part by the safety standards set out in national law.

Issue

Under EU and national consumer law, manufacturers already need to comply with a whole suite of regulatory and safety requirements. The Directive adds to these rules, creating the risk of parallel and overlapping regimes, which may lead to overlapping and contradictory obligations in areas such as financial services, healthcare, transportation and data protection, rather than legitimate redress of harm.

Recommendation

The concept of defect is already complex. Member States should anticipate potential conflicts between the definition of defectiveness in the Directive, and any parallel or overlapping definitions under pre-existing national law.

Furthermore, Member States should require that "*all circumstances*" are considered in identifying defectiveness, not just those identified in Article 7(2)(a) – (i). This should include, among other things, labelling and the fact that the product may already meet extensive safety requirements under EU or national law. Indeed, compliance with rigorous safety standards must presumptively allow the conclusion that a product is not defective.

D. Disclosure of evidence

Due to the complexity of certain products and the obstacles that there may be to a claimant proving defectiveness or causation, the Directive provides for enhanced disclosure obligations on defendants.

Where a claimant has presented facts and evidence sufficient to support "*the plausibility of the claim*" for compensation, the defendant will be required to disclose "*relevant evidence*" at the defendant's disposal. Member States retain discretion to provide guidance on the interpretation and these terms.

The disclosure of evidence is only made in accordance with national law, and it is limited to what is necessary and proportionate.

Issue

There could be a great deal of disruption to the normal legal process if claimants are able to go on fishing expeditions for wide-ranging disclosure based on thinly described claims. The burden upon economic operators of all sizes is likely to be too great if they are required to disclose a large number of documents in response to claims that have not been fully articulated.

Recommendation

Member States are encouraged to follow a common sense understanding of the terms used in the Directive. For instance, "*plausibility*" should be interpreted to mean something being reasonable or probable rather than merely possible. Equally, the disclosure of "*relevant evidence*" must be limited to what is necessary and proportionate. These restrictions should be read in light of EU law so as to mean that the disclosure required does not go beyond what is reasonably necessary in order for the claimant to have access to sufficient evidence in order to be able to prove its case. It should not be interpreted as giving a right to claimants to receive *any* evidence which could set it on a train of inquiry that may or may not lead to relevant evidence, as such disclosure would not be necessary or proportionate.

E. Burden of proof

A national court shall presume the defectiveness of the product or the causal link between the defectiveness and the damage where the claimant demonstrates that it faces "*excessive difficulties, in particular due to technical or scientific complexity*" in proving the defectiveness of the product, or where the claimant demonstrates that it is "*likely that the product is defective or that there is a causal link*".

Member States retain discretion to provide guidance on the meaning and interpretation of key terms such as (i) "*excessive difficulties*", (ii) "*technical or scientific complexity*" and (iii) what is *"likely".*

Issue

These terms give rise to significant legal uncertainty and may allow defectiveness to be presumed whenever a claimant finds it difficult or complex to provide proof (which might be argued anytime a case is weak). Such uncertainty tips the balance towards presuming defectiveness where none can be shown to exist, or at least is likely to lead to costly legal proceedings. The increased threat of frivolous, excessive or expensive litigation will ultimately reduce consumer choice by frustrating efforts to foster innovation (as the more technically or scientifically complex a product is, the more likely it is to be presumed defective).

Recommendation

Member States are encouraged to define carefully what amounts to "*excessive difficulties*" or "*technical or scientific complexity.*" A definition of "excessive difficulties" should indicate a level of difficulty that surpasses normal expectations, and which suggests that the complexity or obscurity of proving the defect is unusually high and requires exceptionally specific, technical or scarce evidence that is not readily available or easy to interpret without specialised expertise. In other words, "*excessive difficulties*" means a requirement for highly specialized technical analysis or expert knowledge that goes beyond common expertise and does not thwart the innovation of scientifically novel or complex products. Additionally, Member States may consider setting down explicit evidential standards for a claimant to demonstrate the existence of excessive difficulties arising from technical or scientific complexity.

Similarly, to establish that a defect or causal link is "*likely,*" the claimant should have to refer to objective criteria, and "*likely*" should be interpreted in accordance with its natural and ordinary meaning to mean more than merely possible.

F. Development risk defence

By default, the Directive provides that an economic operator will not be held liable for damage caused by a defective product if it shows that the objective state of scientific and technical knowledge at the time the product was placed on the market was not such that the defectiveness could be discovered (the "development risk defence"). The development risk defence provides a crucial safeguard to allow economic operators to continue to innovate without fear that hindsight alone will imply liability.

The Directive introduces a derogation mechanism whereby Member States may introduce or maintain in their legal systems measures that provide for economic operators to nonetheless be liable based on hindsight, even where the objective state of scientific and technical knowledge at the time the product was placed on the market was not such that the defect could be discovered.

Issue

Economic operators are at risk of being held liable for defects that they could not reasonably have been aware of or foreseen at the time the products were placed on the market.

Recommendation

Member States are encouraged *not* to make use of the derogation from the development risk defence, or to do so only in the most extreme or narrow circumstances. To use this derogation would create too great a level of uncertainty for economic operators – no manufacturer (or lawmaker) can know what knowledge will be acquired in the future. Manufacturers must of course behave responsibly based on what is currently known.

G. Liability and rights of recourse, including establishing a national sectoral compensation scheme

The Directive provides that Member States may set up a national sectoral compensation scheme to compensate claimants *where no economic operator can be held liable*. The Directive also provides for an economic operator to seek contributions from other economic operators if they are also liable for the same damage. Member States retain discretion over factors affecting how successful claimants may be compensated and which economic operators may be responsible for paying any damages awarded. Member States can achieve greater certainty for both claimants and the industry by focusing their efforts on clarifying that liability rests with those at fault.

Issue

The Directive already constitutes a radical extension of the scope of liability compared to its predecessor, and it provides for a substantial broadening of the list of potential defendants going far beyond the entities found in a traditional supply chain.

The concept of a national compensation scheme appears to imply that liability would be imposed on operators who are, by definition, not liable, and that responsibility for harm caused would become a shared responsibility simply by virtue of being present in the sector in which harm arose. Thus, all food manufacturers pay compensation because one food manufacturer allowed a contamination, or all sellers of electronics products must pay compensation because one sells a defective product. The attribution of liability in cases where an operator has no responsibility, and could have done nothing to prevent the harm, up-ends concepts of fairness and individual responsibility.

Recommendation

Economic operators must not be forced to pay for harm caused by others. If Member States decide to establish any national sectoral compensation scheme, these should be extremely narrowly defined and should be an extension of the public enforcement role, and therefore funded from the public purse. It would suppress competition and innovation to require economic operators to carry the cost of their competitors' failures. The availability of a public compensation fund could also create undesirable incentives and increase the risk of frivolous litigation, as such a fund may be targeted instead of claimants doing the work of proving their case against an economic operator motivated to defend themselves.

III. Conclusion

Member States have only been given a narrow discretion in their implementation of the Directive. However, where their discretion is preserved, they are strongly encouraged to adopt national law that seeks to establish an appropriate balance between the rights of consumers and economic operators rather than further tilt proceedings to the advantage of claimants, be they bona fide consumers deserving of compensation or opportunistic litigants seeking to exploit a favourable legal framework to hold economic operators to ransom.

During the implementation process, it is essential for Member States to focus in particular on how consumers can be allowed to benefit from this redress system and – critically – how entrepreneurial funders or litigants will seek to test and exploit every feature for opportunities for gain. Without appropriate implementation, those opportunities will be found, and consumers, defendants and the justice system will bear the consequences.

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