POSITION PAPER

Brussels, 7 March 2023

Orgalim comments on the Legislative Proposal for a Directive on liability for defective products

Executive summary

Orgalim believes that the 1985 Product Liability Directive (85/374/EEC) remains fit for purpose and sees no reason to revise it. We are concerned that the new *Legislative Proposal for a Directive on liability for defective products* ("Revised PLD") will bring significant legal uncertainty and increased legal costs for Europe's technology industries, ultimately undermining their competitiveness and stifling innovation. Orgalim wishes to stress the following:

- **Standalone software is inherently different from physical products,** therefore it should not be subject to strict liability. Orgalim believes that **standalone software should not fall under the scope of the Revised PLD**.
- Material losses from **psychological damage** and **personal data loss** are extremely difficult to define and quantify. These aspects should be **excluded from the definition of "damage"**.
- **A product should not be considered defective under the PLD on account of its cybersecurity vulnerability,** as no product can ever be fully cyber-secure. A product should be considered defective only if **it does not comply with mandatory cybersecurity requirements under EU or national law**.
- The definition of "manufacturer's control" should be more precise, to ensure that manufacturers **are only liable for specific versions of software or related services that they supply or directly authorise**.
- **Fulfilment service providers are placed** at a disadvantage when compared with distributors in the allocation of liability when manufacturers, importers or authorised representatives are based outside the EU or cannot be identified. We believe that **fulfilment service providers should be subject to the same liability regime as distributors.**
- The revised PLD includes **unprecedented provisions on disclosure of evidence** that do not belong to the civil law tradition of most EU Member States. It will be **extremely difficult for defendants to comply with such far-reaching requirements** and as a result they will be more inclined to pay out or settle claims, increasing the likelihood of **speculative and opportunistic claims aimed at obtaining compensation**. The requirements expose manufacturers to **serious risks of loss of confidential information and trade secrets**.
- The proposal will allow national courts to **presume key elements of a claim for damages** in a wide range of circumstances, leading to a ***de facto* reversal of the burden of proof** that will considerably upset the balance between the rights of claimants and defendants under the 1985 PLD.
- The proposal **removes the minimum and maximum compensation thresholds,** which were present in the 1985 PLD and have effectively prevented frivolous claims and allowed manufacturers to insure risks.

1. Introduction

Thanks to its technology-neutral provisions, the 1985 Product Liability Directive (85/374/EEC) (hereinafter "PLD"), has created legal certainty while enabling technological innovation over the past years. The PLD has maintained a fair balance between protecting the rights of consumers and manufacturers. For this reason, in its response to the public consultation on the revision of the PLD, Orgalim expressed the view that **the PLD was still fit for purpose and that there was no need to revise it at this stage**.

However, we take note of the European Commission decision to go ahead with a *Legislative Proposal for a Directive on liability for defective products* (hereinafter "Revised PLD") and we are concerned that many of the new provisions introduced in the Revised PLD will bring considerable legal uncertainty and unmanageable burdens for European technology manufacturers. Orgalim wishes to stress that maintaining a product liability regime that is fit for purpose is essential to allow Europe's technology industries to continue to innovate and drive the EU's twin green and digital transitions.

2. Detailed comments on the proposal

2.1. Harmonisation clause (Article 3)

Orgalim welcomes the inclusion of an harmonisation clause in Article 3 of the Revised PLD. Orgalim is aware of several differences in the way Member States have transposed key provisions of the PLD into national law to date. We believe that the harmonisation clause in Article 3 will address the current **regulatory fragmentation** across EU Member States, which will be to the advantage of both plaintiffs and defendants.

2.2. Definitions (Article 4)

2.2.1. Definition of "product"

Orgalim is concerned about the definition of "product" in Article 4(1), which explicitly includes standalone software in the scope of the Revised PLD. It should be noted that the PLD already covers software embedded in products at the time at which they are put on the market and consumers are already able to claim compensation for damages in this case. On the other hand, we are convinced that **standalone software should in principle not be included under the scope of the Revised PLD**.

Firstly, in most cases software can cause physical injury only when embedded into physical products, and those cases are already covered in the existing PLD. While it is possible to identify some cases in which standalone software might cause harm by itself, these are extremely rare and do not justify the inclusion of standalone software in the Revised PLD.

Secondly, software is inherently different from physical products and this makes **no-fault liability ill-suited for application to software**. In contrast to physical products, which are typically used for a specific and foreseeable range of purposes, software can often be deployed in an almost unlimited number of ways, across a wide range of products, and for many different purposes. In addition, the functioning of software and its ultimate deployment is often heavily dependent on the user of the software and the context in which it is used. Also, safety expectations for software, given the extremely variable range of its use, should be lower than those for physical products. For this reason, **strict liability appears ill-suited for standalone software** and will only discourage innovation at a time when this is needed for the EU's twin digital and green transitions.

Thirdly, EU consumers already have means available to claim compensation for damages caused by software under fault-based civil liability regimes in all EU Member States.

2.2.2. Definition of "damage"

In the revised PLD, the definition of "damage" has been broadened to include "medically recognised harm to psychological health". In this respect, Orgalim notes that there is currently no clear and broadly accepted definition of "medically recognised harm to psychological health", which could support a uniform implementation of this provision. Furthermore, it would be impossible for manufacturers to test their physical products for effects on mental health. There is no evidence to suggest/prove that mental health issues like depression can be caused by a physical product on its own. Such issues are always due to a complex combination of different elements, including social factors.

The definition of "damage" in the revised PLD also includes "loss or corruption of data", which is not clearly defined in the text. In general, it would be extremely difficult to define the threshold of data loss or corruption that makes the loss material, which will result in legal uncertainty for manufacturers and the industry at large.

Key request:

- **Amend Article 4(6)(a) to exclude medically recognised harm to psychological health.**
- **Delete Article 4(6)(c).**

2.3. Definition of "defectiveness" (Article 6)

The revised PLD introduces a broad and vague definition of defectiveness, which brings great legal uncertainty for product manufacturers. According to Article 6, "*A product shall be considered defective when it does not provide the safety which the public at large is entitled to expect, taking all circumstances into account*". The Article further details some of the circumstances that might be taken into account:

- Article 6(1)(b): "*the reasonably foreseeable use and misuse of the product*"
    - This paragraph leads to significant difficulties as it considerably extends the scope of liability of manufacturers, who could also be held liable for any misuse of a product, which is notably difficult to foresee.
- Article 6(1)(d): "*the effect on the product of other products that can reasonably be expected to be used together with the product*".
    - This paragraph introduces great legal uncertainty, especially given that the scope of the revised PLD includes standalone software as a product. It is impossible for manufacturers, at the time of placing a product onto the market, to foresee all the potential software that such a product could be used with, especially when such software is provided by third parties and installed by users. Therefore, it would be extremely difficult to determine when a given third party software could be "reasonably" expected to be installed by a user in a product.
- Article 6(1)(f): "*product safety requirements, including safety-relevant cybersecurity requirements*".
    - This paragraph is also highly problematic, especially if read in conjunction with Recital 23, which states that "*a product can also be found to be defective on account of its cybersecurity vulnerability*". Orgalim wishes to point out that no product can be 100% cyber-safe and cybersecurity is always a relative concept. A product should be considered defective only if it does not comply with relevant and specific cybersecurity requirements laid down in relevant EU or national legislation.

Key requests:

- **Amend paragraph (1)(b) under Article 6 by deleting "[…] and misuse of […]"**
- **Delete paragraph (1)(d) under Article 6**

- **Amend paragraph (1)(f) under Article 6 in conjunction with Recital 23 to clarify that a product can be considered defective on account of its cybersecurity vulnerability only if it does not comply with mandatory safety requirements under EU or national law, e.g. the future Cyber Resilience Act.**

2.4. Manufacturer's control and liability exemption (Article 10)

Article 10(2) of the revised PLD states that manufacturers cannot be exempted from liability when defectiveness is caused by:

(a) *A related service* (i.e. a digital service that is integrated into, or inter-connected with, a product in such a way that its absence would prevent the product from performing one or more of its functions, pursuant to Article 4(4))

(b) *Software, including software updates and upgrades*

(c) *The lack of software upgrades or updates, when necessary to maintain safety*

In order for the manufacturer to be liable, such elements must be within the manufacturer's control.

The concept of "manufacturer's control", in turn, is defined in Article 4(5): "'*manufacturer's control' means that the manufacturer of a product authorises a) the integration, inter-connection or supply by a third party of a component including software updates or upgrades, or b) the modification of the product*".

Orgalim believes that it is crucial to ensure that manufacturers – as well as other economic operators potentially liable under the revised PLD – are only held liable for things that are under their control. In the light of this principle, we find that Article 10(2)(c) is highly problematic for two reasons:

- Software updates/upgrades may be supplied by manufacturers (therefore under their control) but **installed by users**. This paragraph, as currently formulated, could make a manufacturer liable when a user fails to install a software update. It is therefore essential to **further clarify the liability of the different actors** (manufacturers, users, third-party software providers) in this case.
- It is not always possible for manufacturers and software providers to foresee and prevent all safety risks. This applies particularly to cybersecurity risks. As mentioned above, cybersecurity is a relative concept and no product could ever be considered fully cyber-secure. Therefore this provision, as currently formulated, could make manufacturers liable for the failure to provide software updates that would have prevented an **unforeseen cybersecurity threat**.

It should also be noted that, in practice, manufacturers never authorise the integration of "software" or "digital services" with their products without taking into account a **specific version** of such software or service. Manufacturers have to test each new version of a third party software or service in order to "authorise" their integration or interconnection with products. We believe that the revised PLD should make explicit reference to this point.

Therefore, Recitals 15 and 37, when read in conjunction with the definition of manufacturer's control, bring considerable legal uncertainty. Recitals 15 and 37 indeed state that software updates or upgrades could be considered within the manufacturer's control not only when the manufacturer supplies or authorises them, but also if the manufacturer "recommends" them or "otherwise influences their supply by a third party". Such language is inherently unclear, does not reflect the common practice of manufacturers, and could have far-reaching liability implications.

Orgalim believes that software, including software updates and the integration of digital services, should be considered under the manufacturer's control only when these are supplied by the manufacturer themselves or when the manufacturer explicitly authorises the integration or interconnection of a **specific version** of a software or service with products.

Key requests:

- **Delete paragraph (2)(c) under Article 10**
- **Amend Article 4(5), Recital 15 and Recital 37 to clarify that software (including software updates) and the integration of digital services shall be considered under the manufacturer's control only when (1) these are**

supplied by the manufacturer or (2) the manufacturer explicitly authorises the integration or interconnection of a specific version of a software or digital service with products.

2.5 Economic operators liable for defective products (Article 7)

Orgalim supports a fair and balanced allocation of liability among the different actors in the supply chain for a given product. According to Article 7(1), manufacturers shall be held liable for damage caused by defective products. When the manufacturer is established outside the EU, importers and authorised representatives shall be held liable instead (Article 7(2)).

We welcome the recognition that online marketplaces and distributors (retailers) should not be held liable for damages caused by defective products unless another economic operator (manufacturer, importer or authorised representative) can be identified within one month. This should also be the case for fulfilment service providers, who should not be placed at a disadvantage when compared with retailers.

By contrast, the revised PLD states that fulfilment service providers should be held liable if neither the manufacturer, nor the importer or the authorised representatives are established in the EU [Article 7(3)].

Key request:

- **Delete Article 7(3).**
- **Amend Article 7 to ensure that the conditions that apply to distributors also apply to fulfilment service providers.**

2.6. Disclosure of evidence (Article 8)

Article 8 of the Revised PLD is highly problematic as it would bring into effect in Europe discovery principles originating in jurisdictions such as the UK and the United States. Such far-reaching principles have evolved from history and are based on the specific features of common law legal systems. Therefore, they cannot be introduced in European civil law systems in isolation without serious consequences for defendants.

Member States already have provisions intended to help overcome information asymmetries. Most Member States in the EU have rules in place according to which courts can order the disclosure of specific documents to support claims for damages and rules on the appointment of technical experts that can investigate product defects on behalf of the claimants. However, Article 8(1) of the revised PLD will enable courts to order a defendant to disclose "relevant evidence at its disposal", which is a much broader and far-reaching requirement than anything currently existing in European civil law legal systems.

The introduction of such discovery principles will have significant consequences and represent a **considerable burden for European manufacturers** (as well as any defendant under the revised PLD), which will be subject to a huge number of requests to disclose relevant evidence at their disposal to support claims for damages. Their position as defendants will be weakened from the very beginning and result in longer and more expensive proceedings, which will ultimately damage the competitiveness of European manufacturers.

It will prove extremely difficult for any manufacturer, large or small, to comply with disclosure of evidence (DOE) requirements. Claims are very often vague and general and **it is difficult for a manufacturer to determine which documents are to be disclosed to support a claim for damages**. Given the way the article is currently formulated, "relevant evidence" is extremely broad and manufacturers could be expected not only to disclose existing documents, but also to produce new documents based on evidence at their disposal.

As a result of this burden, manufacturers will often find it more convenient to pay out or settle the claim rather than comply with DOE requirements. Opportunistic claimants will be incentivised to seek compensation on a speculative basis, using the threat and cost of DOE as a means to force manufacturers to settle.

Also, pursuant to Article 9(2)(a), when a manufacturer fails to comply with DOE requirements under Article 8(1), national courts shall presume the defectiveness of the product. While this provision is intended to alleviate the burden of proof for claimants, it will be extremely damaging for manufacturers. They could easily lose cases only because they did not comply with DOE requests that are inherently difficult to comply with. Therefore, Orgalim considers it disproportionate to use this as a basis to presume the defectiveness of the product.

The Revised PLD also states that it will be the sole responsibility of national courts to limit the disclosure to what is "necessary and proportionate" to support a claim for damages (Article 8(2)). In many cases, manufacturers can be requested to disclose information on an entire product or system when the damage is likely to have been caused by a single component of such a product/system. This in turn exposes manufacturers to the risk of leaks of confidential information, potentially ending up in the hands of competitors.

Key requests:

- **Delete Article 8**
- **Delete Article 9(2)(a)**

2.7. Burden of proof (Article 9)

Orgalim is concerned about the far-reaching implications of Article 9 of the revised PLD, which significantly upsets the balanced liability regime of the existing PLD, according to which the claimant shall be required to prove the damage, the defectiveness and the causal link between the defectiveness and the damage. According to the Commission's impact assessment, the proposal does not reverse the burden of proof, but we are concerned that the "rebuttable presumptions" provided for in Article 9(4) will amount to a *de facto* reversal of the burden of proof.

Article 9(4) indeed states that in a case where a national court judges that a claimant faces excessive difficulties (due to technical or scientific complexity) to prove the defectiveness of the product, the causal link between the defectiveness and the damage, or both, these can be presumed. The threshold for such presumption is significantly low, as the claimant only has to demonstrate, on the basis of sufficient relevant evidence, that (1) the product **contributed** to the damage and (2) it is **likely** that the product was defective or that its defectiveness is a likely cause of the damage, or both.

Due to their inherent technical complexity, most software and AI systems (as well as manufactured products with embedded software/AI) would automatically fall under Article 9(4) and therefore for these products, the revised PLD would foresee a ***de facto* reversal of the burden of proof**. As AI technologies become increasingly mainstream, this approach risks creating a huge range of cases in which the burden of proof will be reversed, leading to large increases in legal costs for manufacturers and to the risk of more frequent litigation. Eventually, this approach will be harmful to innovation.

Orgalim therefore believes that the rebuttable presumptions in Article 9 of the revised PLD should be **strictly limited to a specific range of cases** and not depend only on the "technical complexity" of the product. We therefore call for the introduction of a specific and limited list of circumstances in which the rebuttable presumptions could apply.

Furthermore, Article 9(2) introduces a set of conditions based on which the defectiveness of a product can be presumed. One of these (Article 9(2)(c)) is that *"the claimant establishes that the damage was caused by an **obvious malfunction** of the product during **normal use** or under ordinary circumstances."* This provision rests on vague terms such as "obvious malfunction" and "normal use", which should be more clearly defined in order to avoid excessive legal uncertainty. Orgalim in particular recommends replacing the term "normal use" with "intended use" and introducing a clear definition of "obvious malfunction".

Key requests:

- **Introduce a specific and more limited set of conditions according to which the rebuttable presumptions in Article 9 would apply.**

- **Replace "normal use" with "intended use" in Article 9(2)(c).**

- **Introduce a clear definition of "obvious malfunction" to avoid legal uncertainty.**

2.8. Limitation periods (Article 14)

Economic operators can be liable for up to 15 years due to the latency of a personal injury, according to Article 14(3). While this extension of the limitation period might be relevant for some products (e.g. food, pharmaceuticals, chemicals), it would be an unnecessary extension for a whole range of other manufacturing products that are not linked to potential latent injuries.

Key requests:

- **Provide a more specific range of cases in which the proposed extension of the limitation period would apply.**

2.9. Removal of thresholds

The combination of the removal of minimum (€500) and maximum (€70 million) thresholds with the new presumptions, types of damage and types of products (and therefore defects in these further product types) upsets the careful balance of the current Directive. This overall perspective needs to be addressed when weighing the individual extensions being proposed.

The reasoning for having such thresholds remains valid today; a minimum threshold prevents frivolous claims and maintains the backstop nature of the regime, while an upper maximum allows for insurable risks. For SMEs in particular, persuading retailers to carry their products is becoming increasingly difficult. These figures should be subject to maximum harmonisation to address issues the Commission identifies with the current divergence across Member States.

Key request:

- **Reintroduce in the revised PLD the minimum and maximum compensation thresholds that are present in the existing PLD.**

Orgalim aisbl
BluePoint Brussels
Boulevard A Reyers 80
B1030 | Brussels | Belgium

+32 2 206 68 83
secretariat@orgalim.eu
www.orgalim.eu
VAT BE 0414 341 438