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| From:            | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director  |
| date of receipt: | 29 September 2022  |
| To:              | General Secretariat of the Council   |
| No. Cion doc.:   | SWD(2022) 317 final  |
| Subject:         | COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Directive of the European Parliament and of the Council on liability for defective products |

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Delegations will find attached document SWD(2022) 317 final.

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Brussels, 28.9.2022  
SWD(2022) 317 final

**COMMISSION STAFF WORKING DOCUMENT**  
**EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT**

*Accompanying the document*

**Proposal for a Directive of the European Parliament and of the Council**  
**on liability for defective products**

{COM(2022) 495 final} - {SEC(2022) 343 final} - {SWD(2022) 315 final} -  
{SWD(2022) 316 final}

## Executive Summary Sheet

Impact assessment on the revision of Directive 85/374/EEC concerning liability for defective products (Product Liability Directive)

### A. Need for action

#### What is the problem and why is it a problem at EU level?

The Directive lays down common EU rules for the strict liability (i.e. liability irrespective of fault or negligence – no-fault liability) of producers for damage caused by defective products. It allows any person who has been injured by a defective product, whether they are the owner or a bystander, to claim financial compensation for death, personal injuries or damage to consumer property.

Building on the findings of the evaluation<sup>1</sup>, the impact assessment identifies two problems.

1. **Certain products, economic actors and damage in the digital and circular economy escape no-fault liability.** The Directive was conceived long before the digital revolution and it is unclear how its rules apply to products in the digital age, in particular software and products that need software or digital services in order to function, such as smart devices and autonomous vehicles. It is also unclear who should be liable when a product that has been modified by a refurbisher or remanufacturer is defective and causes harm. In addition, it is increasingly common for consumers to purchase products from non-EU countries without there being a producer or importer based in the EU. This means there is no one to seek compensation from under the Directive if a product is defective and causes harm.
2. **Consumers face obstacles to getting compensation.** Proving a product is defective and that the defect caused the damage can be very difficult for victims of harm in complex cases, such as certain cases involving artificial-intelligence-enabled products, smart products or pharmaceuticals. The Directive does not give victims a right to technical information they might need to prove liability, nor is there any explicit possibility to ease the burden of proof when victims face disproportionate difficulties. The Directive also places restrictions on making claims: claims for property damage worth less than EUR 500 are not allowed and producer liability ends after 10 years.

#### What should be achieved?

The revision of the Directive pursues two general objectives to address the problems identified, both of which build on those of the current Directive:

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

The initiative pursues five specific objectives: (i) ensure liability rules reflect nature and risks of products in the digital age; (ii) ensure liability rules reflect nature of products in the circular economy; (iii) ensure there is always an EU-based liable person for defective products bought from producers outside the EU; (iv) ease the burden of proof in the case of complex products and clarify liability for undiscoverable defects, while ensuring fair balance between producers and consumers; and (v) ease restrictions on making claims, while ensuring fair balance between producers and consumers.

#### What is the value added of action at the EU level (subsidiarity)?

Regulatory action at EU level would ensure consistent implementation of product liability rules. As the Directive fully harmonises the matters it covers, any changes must be made at EU level. It would provide legal certainty about: (i) what products, economic operators and types of harm fall within the Directive's scope; and (ii) the appropriate balance of interests between producers and consumers across the EU. In the absence of a uniform set of rules for compensating victims harmed by defective products, manufacturers would be faced with 27 different sets of rules, leading to different levels of protection for consumers and no level playing field among businesses from different Member States.

### B. Solutions

<sup>1</sup> Evaluation of Product Liability Directive, [SWD\(2018\)157](#).

**What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?**

Besides the baseline scenario of no action, the impact assessment identifies three options to address problem 1 relating to the digital age and circular economy, and two options to address problem 2 on obstacles to getting compensation.

Option 1a would ensure that manufacturers of products for which software or digital services are necessary for them to operate would be liable under the Directive. Just like for tangible components, the providers of those intangible digital elements would be jointly and severally liable with the manufacturer. Businesses that substantially modify a product and place it back on the market, such as remanufacturers, would also be liable under the Directive. The authorised representative of a non-EU manufacturer would also be liable when there is no importer in the EU.

Option 1b builds on option 1a and, in addition, would include all safety-relevant software as a product in its own right. This includes third-party software added to a product or standalone software that itself may cause harm (such as medical device software). Under this option it would also be possible to hold a fulfilment service provider liable under the Directive if there is no importer in the EU and no authorised representative was appointed by a non-EU manufacturer.

Option 1c would include the measures of option 1b and, in addition, would include any software with implications for fundamental rights. Damage resulting from fundamental rights infringements, such as data protection breaches, privacy infringements or discrimination (e.g. by artificial intelligence recruitment software) would be compensable.

Option 2a would ease the burden of proof on victims of harm by harmonising: (i) rules on when producers are obliged to disclose necessary technical information to the victim in court; and (ii) conditions for national courts to presume that a product was indeed defective or that the defect did indeed cause the damage, especially in complex cases where proving liability is excessively difficult. Option 2a would reduce restrictions on making claims (by removing the property-damage threshold and lengthening the period of liability).

Option 2b would reverse the burden of proof, so that if a product causes harm it would be the producer who must prove the product was not defective and did not cause the harm. The development risk defence, which exempts producers from liability when the defectiveness of a product was not discoverable according to state-of-the-art knowledge, would be removed. Option 2b would further reduce restrictions on making claims (thresholds and time limits).

The impact assessment identifies options 1b and 2a as the preferred combination of options.

**What are different stakeholders' views? Who supports which option?**

In relation to the options to address problem 1, 56% of respondents to the public consultation (excluding members of the public) were in favour of legislative change to adapt liability rules to the digital and circular economy. Among the public this was 75%. Consumer organisations, public authorities and NGOs were more in favour of greater intervention (option 1b or 1c) than businesses and business organisations. These business stakeholders were particularly sceptical of option 1c, because they considered that infringements of fundamental rights could be compensated under other laws like the General Data Protection Regulation, and that applying no-fault liability to producers would be disproportionate. While recognising the current lack of legal certainty, stakeholders representing larger businesses and the software industry were more in favour of addressing that issue through guidance than through legislative change. Stakeholders from more traditional sectors (engineering, component suppliers, domestic appliances) were in favour of cautious change (option 1a or 1b).

In relation to the options to address problem 2, consumer organisations and NGOs were more in favour of option 2b. They considered that option 2a did not go far enough to strike a fair balance between consumers and producers. Stakeholders representing business were more in favour of option 2a but overall they were sceptical about making any changes to the existing balance between consumers and producers.

**C. Impacts of the preferred option**

**What are the benefits of the preferred option (if any, otherwise main ones)?**

Option 1b would provide legal certainty on what products and producers are covered by no-fault liability and would encourage all producers, including non-EU producers, to place only safe products on the EU market to avoid incurring liability. This reinforces product safety. It would also ensure that consumers enjoy the same protection when they are harmed by defective products regardless of whether the defect concerned the product's digital or tangible components and when they are harmed by defective standalone software itself. By

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| <p>explicitly bringing software providers, businesses that substantially modify products, authorised representatives and fulfilment service providers into the scope of the Directive, victims of harm will have a better chance of getting compensation because they will not have to prove the fault of the producer (the Directive's no-fault liability principle). Annual compensation for injured persons is expected to increase by between EUR 0.15 million and 22.13 million compared to the baseline.</p> <p>Option 2a would create greater legal certainty and achieve more equal consumer protection across the EU. The burden of proof would be shared more fairly between injured parties and producers in more complex cases. This would increase the chances of enforcing a successful compensation claim in such cases. Disproportionate obstacles to making claims would be reduced. Annual compensation for injured persons is expected to increase by between EUR 0.20 million and 43.54 million compared to the baseline.</p> <p>By extending the application of no-fault liability, the policy options would lead to shorter legal proceedings because courts would not have to deal with questions of fault or negligence.</p>   |
| <p><b>What are the costs of the preferred option (if any, otherwise main ones)?</b></p>  |
| <p>The benefits of increased compensation for consumers is a cost to producers. For the 80% of producers that have liability insurance, this would lead to a small increase in the annual insurance premium. For option 1b, this is estimated to be between EUR 4.35 million and 8.69 million compared to the baseline. For option 2a, this is estimated to be between EUR 14.35 million and 28.71 million compared to the baseline. For the minority of producers that do not have liability insurance, they would face compensation pay-outs in relation to victims. However, in order to avoid double counting, this is taken on board in the benefits to consumers of increased compensation.</p> <p>Although legal proceedings would be shorter (see benefits), the number of proceedings would also increase due to the expanded scope of the Directive. Under option 1b, total annual legal costs are assessed to slightly increase between EUR 1.12 million and 2.75 million compared to the baseline. Similarly, under option 2a, total annual legal costs are estimated to slightly increase by between EUR 0.41 million and 1.02 million compared to the baseline.</p> <p>Authorised representatives and fulfilment service providers, who could be held liable when there is no EU-based importer, would pass on increased costs to non-EU producers. This could lead to small but unquantifiable price rises of products from non-EU countries. Any price rise is counterbalanced by increased product safety and consumer protection in the event of harm.</p> |
| <p><b>What are the impacts on small and medium-sized enterprises (SMEs) and competitiveness?</b></p>   |
| <p>Stakeholder feedback did not highlight any specific impacts on SMEs of the policy options. However, SMEs would greatly benefit from clearer liability rules, as they have fewer resources for legal advice. Increases in product liability insurance, even if expected to be small, might affect SMEs more than larger companies, as they have less ability to absorb costs.</p>  |
| <p><b>Will there be significant impacts on national budgets and administrations?</b></p>   |
| <p>There are no administrative costs generated by the Directive. No impact on national budgets was identified.</p>   |
| <p><b>Will there be other significant impacts?</b></p>   |
| <p>No other significant impacts have been identified.</p>  |
| <p><b>Proportionality?</b></p>   |
| <p>The proposed action addresses the objective of the initiative and does not go beyond what is necessary to bring the liability rules up to date with developments in the digital and circular economy and reduce obstacles for getting compensation.</p>   |
| <p style="text-align: center;"><b>D. Follow-up</b></p>   |
| <p><b>When will the policy be reviewed?</b></p>  |
| <p>The Commission will prepare a review of the revised Directive 6 years after its entry into force.</p>   |