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From: Secretary-General of the European Commission, signed by Ms Martine  
DEPREZ, Director

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To: General Secretariat of the Council

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Subject: COMMISSION STAFF WORKING DOCUMENT Subsidiarity Grid  
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) 315 final.

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Brussels, 28.9.2022  
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**COMMISSION STAFF WORKING DOCUMENT**

**Subsidiarity Grid**

*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) 316 final} -  
{SWD(2022) 317 final}

## Subsidiarity Grid

<b>1. Can the Union act? What is the legal basis and competence of the Unions' intended action?</b>
<b>1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?</b>
Article 114 TFEU, according to which the EU may adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the single market.
<b>1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?</b>
In the case of internal market legislation, the Union's competence is shared (Article 4 TFEU).
<i>Subsidiarity does not apply for policy areas where the Union has <b>exclusive</b> competence as defined in Article 3 TFEU<sup>1</sup>. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU<sup>2</sup> sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU<sup>3</sup> sets out the areas for which the Unions has competence only to support the actions of the Member States.</i>
<b>2. Subsidiarity Principle: Why should the EU act?</b>
<b>2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2<sup>4</sup>:</b>
<ul style="list-style-type: none"> <li>- Has there been a wide consultation before proposing the act?</li> <li>- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?</li> </ul>
<p>The Commission consulted a broad range of stakeholders, including EU and national consumer associations and civil society organisations, industry associations, businesses, insurance associations, legal firms, academic experts, members of the public, and national authorities. The consultation activities included an inception impact assessment<sup>5</sup>, a 12-week dedicated public consultation to which 291 responses were submitted, stakeholder workshops, a workshop with Member States, as well as a targeted consultation and interviews with stakeholders carried out by an independent consultant.</p> <p>The explanatory memorandum and the impact assessment (chapter 3) contain a section on the principle of subsidiarity – see question 2.2 below for more detail.</p>
<b>2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?</b>
The 2018 evaluation of the Product Liability Directive concluded that the added value of having EU product liability rules to complement EU product safety rules was uncontested <sup>6</sup> . Indeed rules on compensating people harmed by defective products reinforce EU product safety rules. Both

<sup>1</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN>

<sup>2</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN>

<sup>3</sup> <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML>

<sup>4</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN>

<sup>5</sup> [Civil liability – adapting liability rules to the digital age and artificial intelligence \(europa.eu\)](#).

<sup>6</sup> Evaluation of Product Liability Directive, [SWD\(2018\)157](#), p. 60.

sets of rules pursue the same policy goal of a functioning internal market for goods that ensures a high level of consumer protection and they both also require modernisation.

Without a uniform set of rules for compensating people harmed by defective products, manufacturers would be faced with 27 different sets of rules. This would lead to different levels of consumer protection and distorted competition among businesses from different Member States.

**2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?**

The current Product Liability Directive harmonised product liability rules in the EU to ensure a level playing field between businesses and a common level of consumer protection. The proposed action aims to ensure this uniform set of rules is adapted to products in the digital age and circular economy, and will provide legal certainty and support the internal market. If Member States acted alone, businesses would be faced with 27 different sets of rules.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

Products manufactured in one Member State can be placed on the market in any other Member State – the internal market in goods is by definition transnational. Without a uniform set of rules for compensating people harmed by defective products that is updated to reflect the nature and risks of products in the digital age and circular economy (e.g. taking into account AI-enabled products, cybersecurity risks and remanufactured products), manufacturers would be faced with 27 different sets of rules. This would create barriers, a lack of level playing field between businesses and divergent levels of consumer protection. It is not possible to quantify the cross-border aspects given that the Product Liability Directive covers potentially millions of different products.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty<sup>7</sup> or significantly damage the interests of other Member States?

National action or the absence of EU level action would create a significant gap in the internal market, meaning no level playing field between businesses and divergent levels of safety as further described under point (a) above.

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

Given that the Product Liability Directive harmonises product liability rules in the EU, Member States are not permitted to enact measures in this area. National courts' role is to interpret the Directive, but because of unclear provisions (e.g. the extent to which software is covered as a product under the Directive), these interpretations are divergent, undermining the internal market.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?

There is no particular variation across the national, regional and local levels of the EU.

<sup>7</sup> [https://europa.eu/european-union/about-eu/eu-in-brief\\_en](https://europa.eu/european-union/about-eu/eu-in-brief_en)

(e) Is the problem widespread across the EU or limited to a few Member States?
Products are manufactured and marketed in all Member States and the problems are not specific to one Member State or another.
(f) Are Member States overstretched in achieving the objectives of the planned measure?
As referred to under point (c) above, it is not possible for Member States to enact measures to achieve the proposal's objectives.
(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?
Neither the Product Liability Directive nor its proposed revision impacts regional or local authorities. In a workshop with Member States in early 2022, all Member States that expressed a view were in favour of adapting the Directive to the digital age and circular economy. Views on the appropriate level of consumer protection varied to some degree.
<b>2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?</b>
The Product Liability Directive is a longstanding EU law from 1985. It works well on the whole, but is not adapted to the digital age and circular economy. Without a uniform set of rules for compensating people harmed by defective digital products or products in the circular economy, manufacturers would be faced with 27 different sets of rules. This would lead to different levels of consumer protection and distorted competition among businesses from different Member States. The revision of the Product Liability Directive can only be done at EU level.
(a) Are there clear benefits from EU level action?
The evaluation of the Product Liability Directive in 2018, carried out as part of the Commission's regulatory fitness and performance (REFIT) programme, concluded that the Directive was, on the whole, an effective and relevant instrument. However, the Directive also had several shortcomings, which the proposal aims to address. The benefits are: ensuring liability rules reflect the nature and risks of products in the digital age and circular economy; ensuring it is possible to obtain compensation when products are bought directly from manufacturers outside the EU; ease the burden of proof in complex cases; and ensuring legal certainty by better aligning the Product Liability Directive with the new legislative framework created by Decision 768/2008/EC <sup>8</sup> and with product safety rules, and by codifying product liability case law.
(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?
There are economies of scale for businesses, since they will face the same product liability rules all over the EU.

<sup>8</sup> Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.08.2008, p. 82).

<p>(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?</p>
<p>The Product Liability Directive replaced different national rules in 1985. The benefits are a level playing field for businesses and a high and consistent level of consumer protection.</p>
<p>(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?</p>
<p>The Product Liability Directive leaves intact all other national rules concerning other types of liability, such as liability based on fault, warranty or contract.</p>
<p>(e) Will there be improved legal clarity for those having to implement the legislation?</p>
<p>One of the key objectives it to improve legal clarity, since the current Product Liability Directive was adopted nearly 40 years ago and does not provide clear liability rules for defective products in the digital age and circular economy.</p>
<p><b>3. Proportionality: How the EU should act</b></p>
<p><b>3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission’s proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?</b></p>
<p>Several policy options were considered in the preparation of the proposed action. The repeal of the Product Liability Directive or issuing only guidance would not have achieved the objectives of legal certainty and a level playing field between businesses. Converting the Directive into a regulation was considered disproportionate, given the close interaction of product liability rules with national legal systems. Equally, extending the scope of the regime to cover harm to fundamental rights was considered disproportionate. The revision of the Directive to clarify its scope, definitions and the way it operates for products in the digital age and circular economy was considered proportionate and not exceeding what was necessary to achieve the objectives.</p>
<p><b>3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?</b></p>
<p>The proposed action is limited to the essential aspects of the liability regime for defective products and the choice of instrument, a directive, will allow Member States the flexibility needed to embed the rules into their national legal systems. The costs of the proposed action are offset by the benefits and are commensurate with the objectives to be achieved.</p>
<p>(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?</p>
<p>The proposed action sets out the essential aspects of the liability regime, such as the types of product and damage covered, and which economic operators can be held liable. Other aspects, such as how to introduce a compensation claim, are left to Member States.</p>
<p>(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives</p>

<p>pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?</p>
<p>Given that the Product Liability Directive's liability rules interact closely with national civil codes and are deeply embedded into diverse national legal systems, the option of converting the current Product Liability Directive into a regulation was discarded as disproportionate. A directive achieves the policy objectives effectively and allows flexibility to seamlessly embed the rules into national systems.</p>
<p>(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)</p>
<p>In order to achieve the internal market objective and give businesses legal certainty, the Product Liability Directive is a maximum harmonisation instrument and does not allow Member States to adopt more, or less, stringent provisions at national level if those provisions are within the scope of the Directive. However, the proposed action leaves intact other routes to compensation that injured people have at national level (such as compensation on the basis of contract, warranty or fault).</p>
<p>(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?</p>
<p>The initiative does not create administrative costs. The initiative creates financial costs for certain economic operators (such as producers of software products or the authorised representatives of non-EU manufacturers), in the form of compensation pay-outs or liability insurance. But these costs would otherwise have been carried by other economic operators (such as producers of hardware products) or by citizens themselves (for example, if they failed to get compensation because the manufacturer was established outside the EU).</p> <p>The changes to the Product Liability Directive are the minimum necessary to achieve the objectives, and the costs are commensurate with those objectives.</p>
<p>(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?</p>
<p>No special circumstances apply to any individual Member State in the frame of this initiative have been identified.</p>