

Adapting liability rules to the digital age and Artificial Intelligence

Fields marked with * are mandatory.

Introduction

This public consultation aims to:

- confirm the relevance of the issues identified by the 2018 evaluation of the Product Liability Directive (e.g. how to apply the Directive to products in the digital and circular economy), and gather information and views on how to improve the Directive (Section I);
- collect information on the need and possible ways to address issues related specifically to damage caused by Artificial Intelligence systems, which concerns both the Product Liability Directive and national civil liability rules (Section II).

You can respond to both sections or just to Section I. It is not possible to respond only to Section II.

About you

* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian

- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

* I am giving my contribution as

- Academic/research institution
- Business association
- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

* First name

Sara

* Surname

Roda

* Email (this won't be published)

sara.roda@cpme.eu

* Organisation name

255 character(s) maximum

CPME - Standing Committee of European Doctors

* Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

Transparency register number

255 character(s) maximum

Check if your organisation is on the [transparency register](#). It's a voluntary database for organisations seeking to influence EU decision-making.

9276943405-41

* Country of origin

Please add your country of origin, or that of your organisation.

- | | | | |
|---|--|--|--|
| <input type="radio"/> Afghanistan | <input type="radio"/> Djibouti | <input type="radio"/> Libya | <input type="radio"/> Saint Martin |
| <input type="radio"/> Åland Islands | <input type="radio"/> Dominica | <input type="radio"/> Liechtenstein | <input type="radio"/> Saint Pierre and Miquelon |
| <input type="radio"/> Albania | <input type="radio"/> Dominican Republic | <input type="radio"/> Lithuania | <input type="radio"/> Saint Vincent and the Grenadines |
| <input type="radio"/> Algeria | <input type="radio"/> Ecuador | <input type="radio"/> Luxembourg | <input type="radio"/> Samoa |
| <input type="radio"/> American Samoa | <input type="radio"/> Egypt | <input type="radio"/> Macau | <input type="radio"/> San Marino |
| <input type="radio"/> Andorra | <input type="radio"/> El Salvador | <input type="radio"/> Madagascar | <input type="radio"/> São Tomé and Príncipe |
| <input type="radio"/> Angola | <input type="radio"/> Equatorial Guinea | <input type="radio"/> Malawi | <input type="radio"/> Saudi Arabia |
| <input type="radio"/> Anguilla | <input type="radio"/> Eritrea | <input type="radio"/> Malaysia | <input type="radio"/> Senegal |
| <input type="radio"/> Antarctica | <input type="radio"/> Estonia | <input type="radio"/> Maldives | <input type="radio"/> Serbia |
| <input type="radio"/> Antigua and Barbuda | <input type="radio"/> Eswatini | <input type="radio"/> Mali | <input type="radio"/> Seychelles |
| <input type="radio"/> Argentina | <input type="radio"/> Ethiopia | <input type="radio"/> Malta | <input type="radio"/> Sierra Leone |
| <input type="radio"/> Armenia | <input type="radio"/> Falkland Islands | <input type="radio"/> Marshall Islands | <input type="radio"/> Singapore |
| <input type="radio"/> Aruba | <input type="radio"/> Faroe Islands | <input type="radio"/> Martinique | <input type="radio"/> Sint Maarten |

- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau

- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena
Ascension and
Tristan da Cunha
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States
Minor Outlying
Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia

- Democratic Republic of the Congo
- Lesotho
- Saint Kitts and Nevis
- Zimbabwe
- Denmark
- Liberia
- Saint Lucia

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, ‘business association’, ‘consumer association’, ‘EU citizen’) country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

* Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

Anonymous

Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

Public

Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

I agree with the [personal data protection provisions](#)

Section I – Product Liability Directive

This section of the consultation concerns Council Directive 85/374/EEC on liability for defective products (“Product Liability Directive”), which applies to any product marketed in the European Economic Area (27 EU countries plus Iceland, Liechtenstein and Norway). See also Section II for more in-depth questions about the Directive and AI.

According to the Directive, if a defective product causes damage to consumers, the producer must pay compensation. The injured party must prove the product was defective, as well as the causal link between the defect and the damage. But the injured party does not have to prove that the producer was at fault or negligent ('strict liability'). In certain circumstances, producers are exempted from liability if they prove, e.g. that the product's defect was not discoverable based on the best scientific knowledge at the time it was placed on the market.

Injured parties can claim compensation for death, personal injury as well as property damage if the property is intended for private use and the damage exceeds EUR 500. The injured party has 3 years to seek compensation. In addition, the producer is freed from liability 10 years after the date the product was put into circulation.

The [Evaluation of the Directive](#) in 2018 found that it was effective overall, but difficult to apply to products in the digital and circular economy because of its outdated concepts. The [Commission's 2020 Report on Safety and Liability for AI, Internet of things \(IoT\) and robotics](#) also confirmed this.

The Evaluation also found that consumers faced obstacles to making compensation claims, due to thresholds and time limits, and obstacles to getting compensation, especially for complex products, due to the burden of proof.

* How familiar are you with the Directive?

- I have detailed knowledge of the Directive, its objectives, rules and application
 - I am aware of the Directive and some of its contents
 - I am not familiar with the Directive
 - No opinion
-
-

Adapting the Directive to the digital age

Digital content such as software, algorithms and data are playing an increasingly crucial role in the safe functioning of many products, e.g. domestic appliances, vehicles, smart lawnmowers and surgical robots.

However, the Evaluation of the Directive found that the Directive was not easy to apply to digital technologies. Above all, it is not clear whether intangible items like digital content, software and data are covered, especially when supplied separately from a tangible product. Therefore, it is not clear whether consumers can get compensation under the Directive in the event that 'digital' defects lead to damage.

Do you agree or disagree that consumers should get compensation under the Directive if the following intangible items are defective and cause physical /property damage?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Software embedded in a tangible product at the moment the tangible product is placed on the market	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Software made available separately via download for use on a tangible product (e.g. domestic robot) that has already been placed on the market	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Software upgrades and updates (e.g. to deliver new functionalities or fix a security flaw)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Software that controls how a product operates (e.g. a car's engine control system, a robot's operating system)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Software that is used on a device but does not drive the device (e.g. a gaming app on a computer or other device)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bespoke software (e.g. software customised to control the production line in a factory)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Digital services that control how a product operates (e.g. cloud-based service for operating smart thermostat)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Data capable of influencing how a product operates (e.g. training data for an autonomous vehicle)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Data that comprises only information (e.g. a digital map, a menu)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Software that provides immediate decision-triggering information (e.g. blood glucose meter)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Software that provides only guidance or advice to an end user (e.g. software that interprets medical imaging and provides diagnoses)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
--	----------------------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

The Directive holds importers strictly liable for damage caused by defective products when the producer is based outside the EU. Nowadays online marketplaces enable consumers to buy products from outside the EU without there being an importer.

Online marketplaces intermediate the sale of products between traders, including those established outside the EU, and consumers. Typically, they are not in contact with the products they intermediate and they frequently intermediate trade between many sellers and consumers.

Under the current rules, online marketplaces are covered by a conditional liability exemption (Article 14 of the e-Commerce Directive). The new proposal for a Digital Services Act includes obligations for online marketplaces to tackle illegal products online, e.g. gathering information on the identity of traders using their services. Moreover, the new proposal for a General Product Safety Regulation includes provisions for online marketplaces to tackle the sale of dangerous products online.

Do you agree or disagree with the following statements?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
The proposals for a Digital Services Act and General Product Safety Regulation are sufficient to ensure consumer protection as regards products bought through online marketplaces where there is no EU-based producer or importer.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
The Product Liability Directive needs to be adapted to ensure consumer protection if damage is caused by defective products	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

bought through online marketplaces where there is no EU-based producer or importer.						
---	--	--	--	--	--	--

What do you think is the appropriate approach for consumers to claim compensation when damage is caused by a defective product bought through an online marketplace and there is no EU-based producer or importer?

2000 character(s) maximum

Everything that can be legally bought in the EU should comply with the EU rules, civil liability, such as with cars, medicines, etc.
 Please note that the examples given in the first question - on whether we agree that consumers should get compensation under the Directive if the following intangible items are defective and cause physical/property damage - are not exhaustive. There are many other situations where decision support is used in different fields.

Digital technologies may bring with them new risks and new kinds of damage.

- Regarding risks, it is not always clear whether cybersecurity vulnerabilities can be considered a defect under the Directive, particularly as cybersecurity risks evolve throughout a product’s lifetime.
- Regarding damage, the Directive harmonises the rights of consumers to claim compensation for physical injury and property damage, although it lets each Member State decide itself whether to compensate for non-material damage (e.g. privacy infringements, psychological harm). National rules on non-material damage differ widely. At EU level both material and non-material damage can be compensated under the General Data Protection Regulation (GDPR) when a data controller or processor infringes the GDPR, and the Environmental Liability Directive provides for the liability of companies for environmental damage.

Do you agree or disagree with the following statements?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Producers should potentially be held strictly liable for damages	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

caused as a result of failure to provide necessary security updates for smart products						
The Directive should harmonise the right of consumers to claim compensation from producers who are not simultaneously data controllers or processors, for privacy or data protection infringements (e.g. a leak of personal data caused by a defect)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The Directive should harmonise the right of consumers to claim compensation for damage to, or destruction of, data (e.g. data being wiped from a hard drive even if there is no tangible damage)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The Directive should harmonise the right of consumers to claim compensation for psychological harm (e.g. abusive robot in a care setting, home-schooling robot)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Some products, whether digital or not, could also cause environmental damage. The Directive should allow consumers to claim compensation for environmental damage (e.g. caused by chemical products)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Coverage of other types of harm	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please specify:

200 character(s) maximum

Societal / Group damage

Adapting the Directive to the circular economy

The Directive addresses defects present at the moment a product is placed on the market. However, changes to products after they are placed on the market are increasingly common, e.g. in the context of circular economy business models.

The Evaluation of the Directive found that it was not always clear who should be strictly liable when repaired, refurbished or remanufactured products were defective and caused damage. It is worth noting here that the Directive concerns the defectiveness of products and not the defectiveness of services. So, a third-party repair that was poorly carried out would not lead to the repairer being held liable under the Directive, although remedies may be available under national law.

Do you agree or disagree with the following statements?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Companies that remanufacture a product (e.g. restoring vehicle components to original as-new condition) and place it back on the market should be strictly liable for defects causing damage	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Companies that refurbish a product (e.g. restoring functionality of a used smartphone) and place it back on the market should be strictly liable for defects causing damage	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The manufacturer of a defective spare part added to a product (e.g. to a washing machine) during a repair should be strictly liable for damage caused by that spare part	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Policy approach and impacts of adapting the Directive to the digital and circular economy

Please rank the following options for adapting the Directive to the digital and circular economy from 1 (like best) to 3 (like least)

	1	2	3
* Option 1. No legislative change	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Option 2. Make explicit that strict liability rules apply to products incorporating digital content (e.g. software, data). Address defects resulting from changes to products after	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

they are put on the market (due to circular economy activities such as refurbishments, software upgrades, interactions with other products and services, or due to safety-related cybersecurity risks)			
* Option 3. Address defects resulting from changes to products as in Option 2 and extend strict liability to digital content itself (and producers of such digital content) when placed on the market separately from the tangible product	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

In addition to the policy options presented in the previous question, should the EU take the following additional measures to adapt the Directive to the digital and circular economy?

	Yes	No	I don't know /no opinion
* Harmonise right to claim for non-material damages under the Directive (e.g. privacy infringement, psychological harm, environmental damage)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Define liability rules where there is no EU importer	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Other measures	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Please specify all the relevant impacts that you think the option you ‘like best’ and additional measures that you selected will have on the following aspects, compared to Option 1 (no legislative change). Only select an answer for those impacts that you expect the option you ‘like best’ to have. Impacts left blank will be processed as a ‘No opinion’ reply.

	Large increase	Small increase	No/negligible impact	Small decrease	Large decrease	No opinion
Legal certainty	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Costs for your company	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumer protection	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumer uptake of products in the digital and circular economy	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Purchase price of products	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Incentives for companies to place innovative products on the market	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Competitiveness of micro, small- and medium-sized enterprises (SMEs)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability of producers to obtain product liability insurance	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other impacts (please specify):

200 character(s) maximum

Market adjustment to the new rules will necessarily occur.
It will decrease meaningless applications thus improve competitiveness of serious EU SMEs.

Please elaborate on your answers concerning impacts:

2000 character(s) maximum

If no legislative measure is taken, the market will grow with legal uncertainty creating risks to patients and doctors using medical devices with AI systems. There needs to be trust and clear definition of roles and responsibilities in relation to the products with self-learning capabilities. A doctor that uses an AI system according to the training provided and in adherence with the instructions and guidelines, he/she should be fully indemnified against adverse outcomes. He/she cannot be held liable for the default of the machine, otherwise the incentive for using new and innovative systems will perish. New rules are needed to address liability for self-learning algorithms and to clearly identify who is responsible for what.

Reducing obstacles to getting compensation

The Evaluation of the Directive found that in some cases consumers face significant difficulties in getting compensation for damage caused by defective products.

In particular it found that difficulties in proving the defectiveness of a product and proving that the product caused the damage accounted for 53% of rejected compensation claims. In particular, the technical complexity of certain products (e.g. pharmaceuticals and emerging digital technologies) could make it especially difficult and costly for consumers to actually prove they were defective and that they caused the damage.

To what extent do you think that the following types of product present difficulties in terms of proving defectiveness and causality in the event of damage? (See additional burden of proof question concerning AI in Section II)

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
All products	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Technically complex products	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmaceuticals	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

AI-enabled products	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
IoT (Internet of Things) products	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other types of product (please specify):

50 character(s) maximum

In an effort to promote innovation, the Directive exempts producers from liability when a product’s lack of safety was not discoverable based on the best scientific knowledge at the time it was placed on the market (‘development risk defence’, Art. 7(e)).

However, the Evaluation found that this defence might be inappropriate when dealing with emerging technologies due to the increasing rate of development and the ability of certain products to adapt while in operation. Furthermore, certain stakeholders considered the defence too advantageous to producers.

When should producers be able to use the ‘development risk defence’?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
The defence should remain available without any change	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
The defence should be removed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
The defence should not be available for products designed to be influenced by other interconnected products or services (e.g. complex IoT systems)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The defence should not be available for AI products that continue to learn and adapt while in operation	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The defence should not be available for any AI products	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please specify any other conditions you think should apply to the use of the development risk defence:

1000 character(s) maximum

The use of the 'development risk defence' could exist in structured regulatory environments, such as the 'regulatory sandboxes' foreseen in the AI Act.

Reducing obstacles to making claims

The Evaluation of the Directive found that in some cases consumers faced or could face significant difficulties in making compensation claims for damage caused by defective products. The current rules allow consumers to claim compensation for personal injury or property damage. Time limits apply to all compensation claims and several other limitations apply to compensation for property damage.

To what extent do the following features of the Directive create obstacles to consumers making compensation claims?

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
Producers are released from liability for death/personal injury 10 years after placing the product on the market	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Producers are released from liability for property damage 10 years after placing the product on the market	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumers have to start legal proceedings within 3 years of becoming aware of the damage	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumers can claim compensation only for damage to property worth more than EUR 500	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumers can claim compensation only for damage to property intended and used for private purposes	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Policy approach and impacts of reducing obstacles to getting compensation and making claims

Please rank the following options for adapting the Directive to the digital and circular economy from 1 (like best) to 4 (like least)

	1	2	3	4
* Option 1. No legislative change	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Option 2. Alleviate the burden of proof for technically complex products by: a) obliging the producer to disclose technical information (e.g. data from clinical trials or log data of a robot vacuum cleaner) to the injured party to better enable the latter to prove their claim; and b) allowing courts to infer that a product is defective or caused the damage under certain circumstances (e.g. when other products in the same production series have already been proven to be defective or the product clearly malfunctioned).	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Option 3. Reverse the burden of proof for technically complex products. In the event of damage, the producer would have to prove the product was not defective.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Option 4. In addition to option 2 or 3: a) adapt the notion of 'defect' and the alleviation/reversal of burden of proof to the specific case of AI; and b) remove the 'development risk defence' to ensure producers of products that continuously learn and adapt while in operation remain strictly liable for damage.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

In addition to the policy options presented in the previous question, should the EU take the following additional measures to adapt the Directive to reduce obstacles to making claims?

	Yes	No	I don't know /no opinion
* Harmonise right to claim for non-material damages under the Directive (e.g. privacy infringement, psychological harm, environmental damage)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Define liability rules where there is no EU importer	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Other measures	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Please specify all the relevant impacts that you think the option you ‘like best’ and additional measures that you selected will have on the following aspects, compared to Option 1 (no legislative change). Only select an answer for those impacts that you expect the option you ‘like best’ to have. Impacts left blank will be processed as a ‘No opinion’ reply.

at least 4 answered row(s)

	Large increase	Small increase	No/negligible impact	Small decrease	Large decrease	No opinion
Legal certainty	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Costs for your company	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumer protection	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Consumer uptake of products in the digital and circular economy	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Purchase price of products	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Incentives for companies to place innovative products on the market	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Competitiveness of micro, small- and medium-sized enterprises (SMEs)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ability of producers to obtain product liability insurance	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other impacts (please specify):

200 character(s) maximum

Market adjustments to the new rules will necessarily occur.

Please elaborate on your answers concerning impacts:

2000 character(s) maximum

In healthcare, the legal uncertainty can be a strong disincentive for doctors to use AI. Doctors would not be able to guarantee and properly protect patients' rights.

Artificial intelligence is facing a lot of challenges to build evidence. Reproducibility is almost impossible by nature of training a model, generalizability is limited or at the cost of specificity, explainability is by far not reached and will not be easy to understand, interpretability is improving but remains difficult to implement in complex models, thus trust has to be built using new paths. Accountability and liability are powerful mechanisms to improve trust, and thus to improve the market.

There should be clarity on to whom a Doctor should address in case of a defective product, wrong diagnosis or wrong treatment caused by AI.

End of Section I on Product Liability Directive

* In Section II of this consultation the problems linked to certain types of Artificial Intelligence – which make it difficult to identify the potentially liable person, to prove that person's fault or to prove the defect of a product and the causal link with the damage – are explored further.

Would you like to continue with Section II on Artificial Intelligence?

- Continue with Section II on Artificial Intelligence
- Close the questionnaire

Section II - Liability for AI

Introduction

As a crucial enabling technology, AI can drive both products and services. AI systems can either be provided with a physical product (e.g. an autonomous delivery vehicle) or placed separately on the market.

To facilitate trust in and the roll-out of AI technologies, the Commission is taking a staged approach. First, on 21 April 2021, it [proposed harmonised rules for development, placing on the market and use of certain AI systems \(AI Act\)](#). The AI Act contains obligations on providers and users of AI systems, e.g. on human oversight, transparency and information. In addition, the recent [proposal for a Regulation on Machinery Products](#) (published together with the AI act) also covers new risks originating from emerging technologies, including the integration of AI systems into machinery.

However, safety legislation minimises but cannot fully exclude accidents. The liability frameworks come into play where accidents happen and damage is caused. Therefore, as a next step to complement the recent initiatives aimed at improving the safety of products when they are placed on the EU market, the Commission is considering a revision of the liability framework.

In the [White Paper on AI](#) and the accompanying [2020 Report on Safety and Liability](#), the Commission identified potential problems with liability rules, stemming from the specific properties of certain AI systems. These properties could make it difficult for injured parties to get compensation based on the Product Liability Directive or national fault-based rules. This is because in certain situations, the lack of transparency (opacity) and explainability (complexity) as well as the high degree of autonomy of some AI systems could make it difficult for injured parties to prove a product is defective or to prove fault, and to prove the causal link with the damage.

It may also be uncertain whether and to what extent national strict liability regimes (e.g. for dangerous activities) will apply to the use of AI-enabled products or services. National laws may change, and courts may adapt their interpretation of the law, to address these potential challenges. Regarding national liability rules and their application to AI, these potential problems have been further explored in this recent [study](#).

With this staged approach to AI, the Commission aims to provide the legal certainty necessary for investment and, specifically with this initiative, to ensure that victims of damage caused by AI-enabled products and services have a similar level of protection to victims of technologies that operate without AI. Therefore, this part of the consultation is looking at all three pillars of the existing liability framework.

1. The **Product Liability Directive**, for consumer claims against producers of defective products. The injured party has to prove the product was defective and the causal link between that defect and the damage. As regards the Directive, the proposed questions build on the first section of the consultation.
2. **National fault-based liability rules**: The injured party has to prove the defendant’s fault (negligence or intent to harm) and a causal link between that fault and the damage.
3. **National strict liability regimes** set by each Member State for technologies or activities considered to pose an increased risk to society (e.g. cars or construction activities). Strict liability means that the relevant risk is assigned to someone irrespective of fault. This is usually justified by the fact that the strictly liable individual benefits from exposing the public to a risk.

In addition to this framework, the General Data Protection Regulation (GDPR) gives anyone who has suffered material or non-material damage due to an infringement of the Regulation the right to receive compensation from the controller or processor.

Problems – general

Do you agree or disagree with the following statements?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
There is uncertainty as to how the Product Liability Directive (i.						

e. liability for defective products) applies to damage caused by AI	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There is uncertainty as to whether and how liability rules under national law apply to damage caused by AI	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
When AI operates with a high degree of autonomy, it could be difficult to link the damage it caused to the actions or omissions of a human actor	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In the case of AI that lacks transparency (opacity) and explainability (complexity), it could be difficult for injured parties to prove that the conditions of liability (such as fault, a defect, or causation) are fulfilled	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Because of AI's specific characteristics, victims of damage caused by AI may in certain cases be less protected than victims of damage that didn't involve AI	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is uncertain how national courts will address possible difficulties of proof and liability gaps in relation to AI	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please elaborate on your answers or specify other grounds of legal uncertainty regarding liability for damage caused by AI:

2000 character(s) maximum

Do you agree or disagree with the following statements?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
The lack of adaptation of the current liability framework to AI may negatively affect trust in AI	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The lack of adaptation of the current liability framework to AI may negatively affect the uptake	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

of AI-enabled products and services						
-------------------------------------	--	--	--	--	--	--

Please elaborate on your answers. You may reflect in particular on the recently proposed AI Act and on the complementary roles played by liability rules and the other safety-related strands of the Commission’s AI policy in ensuring trust in AI and promoting the uptake of AI-enabled products and services:

2000 character(s) maximum

There is a need to address human oversight, human control over a medical device with an AI system and instructions for use.

If the current liability framework is not adapted, to what extent do you expect the following problems to occur in relation to the production, distribution or use of AI-enabled products or services, now or in the foreseeable future? This question is primarily aimed at businesses and business associations.

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
Companies will face additional costs (e.g. legal information costs, increased insurance costs)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Companies may defer or abandon certain investments in AI technologies	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Companies may refrain from using AI when automating certain processes	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Companies may limit their cross-border activities related to the production, distribution or use of AI-enabled products or services	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Higher prices of AI-enabled products and services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Insurers will increase risk-premiums due to a lack of predictability of liability exposures	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

It will not be possible to insure some products/services	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Negative impact on the roll-out of AI technologies in the internal market	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please elaborate on your answers, in particular on whether your assessment is different for AI-enabled products than for AI-enabled services

2000 character(s) maximum

In healthcare, companies have an interest to provide secure and user-friendly systems to attract more buyers. If there is no harmonisation, it is certain that some Member States will adapt their liability regimes to ensure the same level of protection between products or services with AI and without AI.

With the growing number of AI-enabled products and services on the market, Member States may adapt their respective liability regimes to the specific challenges of AI, which could lead to increasing differences between national liability rules. The Product Liability Directive could also be interpreted in different ways by national courts for damage caused by AI.

If Member States adapt liability rules for AI in a divergent way, or national courts follow diverging interpretations of existing liability rules, to what extent do you expect this to cause the following problems in the EU? This question is primarily aimed at businesses and business associations.

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
Additional costs for companies (e.g. legal information costs, increased insurance costs) when producing, distributing or using AI-equipped products or services	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Need for technological adaptations when providing AI-based cross-border services	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Need to adapt AI technologies, distribution models (e.g. sale versus service provision) and cost management models in light of diverging national liability rules	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Companies may limit their cross-border activities related to the production, distribution or use of AI-enabled products or services	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Higher prices of AI-enabled products and services	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Insurers will increase premiums due to more divergent liability exposures	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Negative impact on the roll-out of AI technologies	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please elaborate on your answers, in particular on whether your assessment is different for AI-enabled products than for AI-enabled services, as well as on other impacts of possible legal fragmentation

2000 character(s) maximum

Policy options

Due to their specific characteristics, in particular their lack of transparency and explainability ('black box effect') and their high degree of autonomy, certain types of AI systems could challenge existing liability rules.

The Commission is considering the policy measures, described in the following questions, to ensure that victims of damage caused by these specific types of AI systems are not left with less protection than victims of damage caused by technologies that operate without AI. Such measures would be based on existing approaches in national liability regimes (e.g. alleviating the burden of proof for the injured party or strict liability for the producer). They would also complement the Commission's other policy initiatives to ensure the safety of AI, such as the recently proposed AI Act, and provide a safety net in the event that an AI system causes damage.

Please note that the approaches to adapting the liability framework presented below relate only to civil liability, not to state or criminal liability. The proposed approaches focus on measures to ease the victim's burden of proof (see next question) as well as a possible targeted harmonisation of strict liability and insurance solutions (subsequent questions). They aim to help the victim recover

damage more easily.

Do you agree or disagree with the following approaches regarding the burden of proof? The answer options are not mutually exclusive. Regarding the Product Liability Directive, the following approaches build on the general options in the first part of this questionnaire.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
The defendant (e.g. producer, user, service provider, operator) should be obliged to disclose necessary technical information (e.g. log data) to the injured party to enable the latter to prove the conditions of the claim	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If the defendant refuses to disclose the information referred to in the previous answer option, courts should infer that the conditions to be proven by that information are fulfilled	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Specifically for claims under the Product Liability Directive: if an AI-enabled product clearly malfunctioned (e.g. driverless vehicle swerving off the road despite no obstacles), courts should infer that it was defective and caused the damage	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If the provider of an AI system failed to comply with their safety or other legal obligations to prevent harm (e.g. those proposed under the proposed AI Act), courts should infer that the damage was caused due to that person's fault or that, for claims under the Product Liability Directive, the AI system was defective	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If the user of an AI system failed to comply with their safety or other legal obligations to prevent harm (e.g. those proposed under	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

the proposed AI Act), courts should infer that the damage was caused by that person's fault						
If, in a given case, it is necessary to establish how a complex and /or opaque AI system (i.e. an AI system with limited transparency and explainability) operates in order to substantiate a claim, the burden of proof should be shifted from the victim to the defendant in that respect	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Specifically for claims under the Product Liability Directive: if a product integrating an AI system that continuously learns and adapts while in operation causes damage, the producer should be liable irrespective of defectiveness; the victim should have to prove only that the product caused the damage	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Certain types of opaque or highly autonomous AI systems should be defined for which the burden of proof regarding fault and causation should always be on the person responsible for that AI system (reversal of burden of proof)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
EU action to ease the victim's burden of proof is not necessary or justified	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Please elaborate on your answers and describe any other measures you may find appropriate:

2000 character(s) maximum

If the defendant involves different parties, from provider to user, as the victim cannot know a priori who is to blame, a user (the doctor) that has not developed the AI by conception, is not in a position to prove that the product was not defective. The doctor can only prove what is within the remit of his/her actions, that is that he /she followed the instructions for use and guidelines from the manufacturer in relation to AI, that patient's consent has been collected after being sufficiently informed and that he/she adheres to the standards of due care. (medical standard at the time of the treatment).

A straightforward system should be implemented so that proof can be retrieved easily for court purposes. In a hospital setting, the employer must be the entity responsible in case of AI product or services liability - not the doctor (direct user) who sees 20-30 patients per day carrying out medical examinations and treatment. Otherwise the exponential litigation impact on doctor's daily lives would be impractical. This would

also have a negative impact on the image of medicine and on the relationship of trust between a doctor and a patient, as well as restrict the conditions of practice of the profession.

Separately from the strict liability of producers under the Product Liability Directive, national laws provide for a wide range of different strict liability schemes for the owner/user/operator. Strict liability means that a certain risk of damage is assigned to a person irrespective of fault.

A possible policy option at EU level could be to harmonise strict liability (full or minimum), separately from the Product Liability Directive, for damage caused by the operation of certain AI-enabled products or the provision of certain AI-enabled services. This could notably be considered in cases where the use of AI (e.g. in autonomous vehicles and autonomous drones) exposes the public to the risk of damage to important values like life, health and property. Where strict liability rules already exist in a Member State, e.g. for cars, the EU harmonisation would not lead to an additional strict liability regime.

Do you agree or disagree with the following approaches regarding liability for operating AI-enabled products and providing AI-enabled services creating a serious injury risk (e.g. life, health, property) for the public?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Full harmonisation of strict liability for operating AI-enabled products and providing AI-enabled services, limited to cases where these activities pose serious injury risks to the public	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Harmonisation of strict liability for the cases mentioned in the previous option, but allowing Member States to maintain broader and/or more far-reaching national strict liability schemes applicable to other AI-enabled products and services	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Strict liability for operating AI-enabled products and providing of AI-enabled services should not be harmonised at EU level	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Please elaborate on your answer, describe any other approaches regarding strict liability you may find appropriate and/or indicate to which specific AI-enabled products and services strict liability should apply:

2000 character(s) maximum

The availability, uptake and economic effects of insurance policies covering liability for damage are important factors in assessing the impacts of the measures described in the previous questions. Therefore, this question explores the role of (voluntary or mandatory) insurance solutions in general terms.

The subsequent questions concern possible EU policy measures regarding insurance. **To what extent do you agree with the following statements?**

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Parties subject to possible harmonised strict liability rules as described in the previous question would likely be covered by (voluntary or mandatory) insurance	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In cases where possible facilitations of the burden of proof would apply (as described in the question on approaches to burden of proof), the potentially liable party would likely be covered by (voluntary or mandatory) liability insurance	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Insurance solutions (be they voluntary or mandatory) could limit the costs of potential damage for the liable person to the insurance premium	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Insurance solutions (be they voluntary or mandatory) could ensure that the injured person receives compensation	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please elaborate on your answers:

2000 character(s) maximum

Under many national strict liability schemes, the person liable is required by law to take out insurance. A similar solution could be chosen at EU level for damage caused by certain types of AI systems that pose serious injury risks (e.g. life, health, property) to the public.

Possible EU rules would ensure that existing insurance requirements are not duplicated: if the operation of a certain product, such as motor vehicles or drones, is already subject to mandatory insurance coverage, using AI in such a product or service would not entail additional insurance requirements.

Do you agree or disagree with the following approach on insurance for the use of AI systems that poses a serious risk of injury to the public?

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
A harmonised insurance obligation should be laid down at EU level, where it does not exist yet, for using AI products and providing AI-based services that pose a serious injury risk (e.g. life, health, property) to the public	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

In reply to the previous question you agreed with the harmonisation of mandatory insurance coverage for using certain AI products and providing of certain AI-based services. **Regarding your reasons for this opinion, to what extent do you agree or disagree with the following statements?**

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
Mandatory insurance coverage ensures that the injured party receives due compensation	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mandatory insurance makes potential liability costs more predictable by limiting them to the insurance premiums, which facilitates business planning and lowers market entry barriers, especially across borders	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Mandatory insurance coverage ultimately spreads the liability costs over everyone taking out insurance, avoiding very high and burdensome one-off costs for the liable party	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
--	-----------------------	----------------------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

Please specify any other reason:

500 character(s) maximum

Insurance should include mandatory "tail" cover.

Taking into account the description of various options presented in the previous questions, please rank the following options from 1 (like best) to 8 (like least)

	1	2	3	4	5	6	7	8
Option 1: (Aside from measures to ease the burden of proof considered in Section I) Amending the Product Liability Directive to ease the burden on victims when proving an AI-enabled product was defective and caused the damage	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Option 2: Targeted harmonisation of national rules on proof, e.g. by reversing the burden of proof under certain conditions, to ensure that it is not excessively difficult for victims to prove, as appropriate, fault and/or causation for damage caused by certain AI-enabled products and services	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Option 3: Harmonisation of liability irrespective of fault ('strict liability') for operators of AI technologies that pose a serious injury risk (e.g. life, health, property) to the public	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Option 4: option 3 + mandatory liability insurance for operators subject to strict liability	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Option 5: option 1 + option 2	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Option 6: option 1 + option 2 + option 3	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Option 7: option 1 + option 2 + option 4	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Option 8: No EU action. Outside the existing scope of the Product Liability Directive, each Member State would be free to adapt liability rules for AI if and as they see fit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Please elaborate on your answers, also taking into account the interplay with the other strands of the Commission’s AI policy (in particular the proposed AI Act).

Please also describe any other measures you may find appropriate:

2000 character(s) maximum

Strict liability rules should be used for high-risk AI (align with the AI Act concepts) or for products under Class II medical device (align with the Medical Devices Regulation).

Impacts of preferred policy option

To what extent do you expect the option you ‘like best’ to have the following impacts compared to no EU action?

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
Victims would be equally well protected when AI causes damage as in cases where AI is not involved	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Positive impact on trust in AI-enabled products and services	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Increased legal certainty regarding liability for AI	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Increased uptake of AI-driven products and services	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please elaborate on your answer and specify any other impacts you would expect:

1000 character(s) maximum

Only by offering the complete spectrum of protection, can victims feel trust in the systems and users (doctors) too.

To what extent do you expect the option you ‘like best’ to have the following further impacts compared to no EU action? This question is primarily aimed at businesses and business associations.

	To a very large extent	To a large extent	To a moderate extent	To a small extent	Not at all	Don't know /no answer
Reduced legal information costs	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Reduced insurance costs	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Economies of scale due to a reduced need for technological adaptations when providing AI-based products or services cross-border	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cost savings due to a reduced need to adapt business models in light of diverging national liability rules	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Companies may choose to bring forward or pursue certain cross-border business activities involving AI technologies that they would otherwise have reduced, deferred or abandoned	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Companies may extend across borders certain business activities involving AI that they would otherwise have limited to a single Member State or a smaller number of Member States	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Positive impact on the development, roll-out and uptake of AI technologies in the internal market	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Higher costs due to increased insurance premiums and compensation claims	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Companies will pass on to consumers /customers cost increases linked to liability	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Negative impact on the development, roll-out and uptake of AI technologies in the internal market	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Please elaborate on your answer and specify any other impacts you would expect:

1000 character(s) maximum

Types of compensable harm and admissibility of contractual liability waivers

Aside from bodily injury or damage to physical objects, the use of technology can cause other types of damage, such as immaterial harm (e.g. pain and suffering). This is true not only for AI but also for other potential sources of harm. Coverage for such damage differs widely in Member States.

Do you agree or disagree with harmonising compensation for the following types of harm (aside from bodily injury and property damage), specifically for cases where using AI leads to harm? Please note that this question does not concern the Product Liability Directive – a question on the types of harm for which consumers can claim compensation under this Directive can be found in Section I. The answer options are not mutually exclusive.

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
Pure economic loss (e.g. loss of profit)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of or damage to data (not covered by the GDPR) resulting in a verifiable economic loss	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Immaterial harm like pain and suffering, reputational damage or psychological harm	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Loss of or damage to data (not covered by the GDPR) not resulting in a verifiable economic loss	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
All the types of harm mentioned above	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please specify any other types of harm:

500 character(s) maximum

Sometimes the person who has suffered damage has a contract with the person responsible. That contract may exclude or limit the right to compensation. Some Member States consider it necessary to prohibit or restrict all or certain such clauses. The Product Liability Directive also does not let producers limit or exclude their liability towards the injured person by contract.

If the liability of operators/users for damage caused by AI is harmonised at EU level, do you agree or disagree with the following approaches regarding contractual clauses excluding or limiting in advance the victim’s right to compensation?

--	--	--	--

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	No opinion
The admissibility of contractual liability waivers should not be addressed at all	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Such contractual clauses should be prohibited vis-à-vis consumers	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Such contractual clauses should be prohibited vis-à-vis consumers and between businesses	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
The contractual exclusion or limitation of liability should be prohibited only for certain types of harm (e.g. to life, body or health) and/or for harm arising from gross negligence or intent	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please elaborate on your answer and specify if you would prefer a different approach, e.g. an approach differentiating by area of AI application:

2000 character(s) maximum

A differentiated approach in healthcare is needed. In a hospital setting, the employer should be the entity liable towards the patient (consumer). The choice of the medical device with AI is done by the employer, not the doctor. A legal waiver should exist between a doctor and the employer.

Additional information

Are there any other issues that should be considered?

3000 character(s) maximum

I - Mandatory insurance should not be the exclusive obligation of the medical practitioner, but rather should be an obligation of all involved in the design, development and application of all modalities of AI. This should equally involve mandatory "tail" cover insurance.

II - We bring to your attention to reports received of type of products (medical devices) that have caused damage: i) Pip implants - heap material used (industrial-grade silicone) not cleared for human use, causing long-term health effects; ii) Hip prothesis - poor metal designs decreasing patient mobility; type of material that poisons the tissue (e.g. microscopic amounts of chromium, cobalt or other metals into the body) causing damage (metallois) and other serious conditions. It can destroy also the bone and muscles; design was not durable. Victims were only able to seek compensation with lengthy (10-15 years) and costly legal proceedings, which lead to a double punishment for victims.

You can upload relevant quantitative data, reports/studies and position papers to support your views here:

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

Do you agree to the Commission contacting you for a possible follow-up?

Yes

No

Contact

Mark.BEAMISH@ec.europa.eu