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Evaluation of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

Accompanying the document

Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (85/374/EEC)

{COM(2018) 246 final} - {SWD(2018) 158 final}

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1. INTRODUCTION

1.1. Evaluation of Product Liability Directive: Purpose and scope

Directive 85/374/EEC concerning the liability for defective products[1] (hereinafter 'the Directive) lays down common rules for strict liability (i.e. "liability without fault") of producers for damage caused by defective products at European Union level. It allows parties that have been injured by defective products to claim financial compensation for death, personal injuries or for damage caused to an item of property intended for private use with a threshold of 500 EUR. The Directive provides the injured person with an extra-contractual regime of liability[2]. It does not cover contractual liability, which is imposed on an entity by the terms of a contract.

The strict liability regime put in place by the Directive implies that liability is imposed on the producer regardless of any fault on his part (such as negligence or intention).

The purpose of this evaluation is to assess the functioning and the performance of the Directive for the period 2000-2016, as it was never evaluated. It covers the EU-28 Member States.

According to the Better Regulation principles, this evaluation assesses the effectiveness, efficiency, coherence, relevance and EU added value of the Directive. In fact, the evaluation assesses retrospectively the functioning and performance of the Directive. However, the evaluation also investigates whether the Directive remains fit-for-purpose vis-à-vis emerging digital technologies such as the Internet of Things and autonomous systems. For this purpose, the evaluation examines to what extent it has been used in Member States when it comes to damage caused by advanced robots, autonomous systems, Internet of Things, defective apps or other non-embedded software. In this context, this evaluation also assesses whether the objectives and requirements of the Directive are still fit for purpose in light of these technologies.

The results of this evaluation will inform the Commission's further approach to product liability by clarifying whether the Directive is functioning well, whether guidance on and clarification of certain concepts are necessary, or to see whether certain adaptations of the Directive may be of value to ensure the Directive's continued value to the EU legal framework.

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1 Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, as modified by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 (OJ L 210, 7.8.1985, p.29 and JO L 141 4.6.1999, p. 20)

2 Extra-contractual liability is set outside of a contract, for example directly in imposed pieces of legislation or through common law as types of :
a) Liability arising from an offense: The person who committed the offense will be liable in front of the injured party or responsible for the damage he/she caused to the party without any contractual agreement between them. An offense can be an intentional act or negligence;
b) Liability in the absence of an offense: In liability without an offense, a person may be liable notwithstanding that the damage caused was unforeseeable. For example, the occupier of a building shall be liable for any damage caused by objects falling from it. Sometimes, not only one party should be held liable. For example, where two motor vehicles have a collision and each of the vehicles shall be deemed to have contributed equally to the accident, the owner of each vehicle shall bear half of the total amount of the damage resulting from the accident.
c) Liability for the action of others: if a person is liable for another person by law he/she is bound to compensate the injured party (e.g. a parent is liable under law if his child incurs liability).

1.2. Background for the evaluation

The Directive was adopted in 1985 and since then the European Commission has regularly reported to the Council and Parliament on the main issues related to its application pursuant to Article 21 of the Directive[3]. This Article obliges the Commission to report every five years to the European Parliament and to the Council on the application of the Directive and, if necessary, to submit appropriate proposals. This evaluation accompanies the fifth report[4].

In the fourth report (covering the period 2006-2010), the Commission highlighted the contribution of the Directive in maintaining the balance of interests between producers and consumers regarding the liability for defective products. The Commission pinpointed that national experts and stakeholders had underlined the importance of having balanced liability instruments governing the relationship between companies and consumers. However, the parties concerned had expressed differing opinions on the effectiveness of specific provisions, notably about the burden of proof, the defence of regulatory compliance, the development of risk defence and the EUR 500 threshold for property damage.

Organisations representing consumers, for instance, claimed to be unfairly disadvantaged by the burden of proof in product liability claims and stressed the difficulties to investigate claims properly or to gain access to essential information especially in case of technical products. Moreover, consumer organisations asked for more protection at a lower cost, which would imply removing the threshold of EUR 500. On the side of the producers and insurers, however, the arguments raised focused on the risk that any relaxation of the rules on the burden of proof or on the threshold for property damages would lead to more claims for minor damages.

Facing the challenges of digital transformation and in particular to facilitate the investment into and the development of the digital economy, questions arose concerning

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[3] The Directive does not foresee the presentation to the Commission of national reports.
To face the lack of information on the implementation of the Directive when preparing the Commission's report, Commission's services used to submit a questionnaire to the national authorities and to the different categories of stakeholders concerned by the Directive. The questionnaire raised points related to its application during the concerned period and about the problems encountered. It was addressed to the representatives of the two experts groups of the Commission, one composed of national authorities, the other of stakeholders (such as producers, consumers, insurers). It facilitated the task of gathering information and its comparison.
The lack of information on the application of the Directive available to the Commission was the main reason to launch the study for the evaluation. Therefore, the data and information contained in this SWD comes mainly from the Study for the evaluation (see footnote 8 for further information).

[4] Earlier reports: First report on the application of the Council Directive on the approximation of laws, regulations and administrative provisions of Member States concerning liability for defective products, COM (95) 617 final of 13 December 1995;
Green Paper of the Commission "Liability for defective products". COM(1999) 396 final of 28 July 1999
Second report on the application of the Council Directive on the approximation of laws, regulations and administrative provisions of Member States concerning liability for defective products, COM (2000) 893final of 31 January 2001
Third report on the application of the Council Directive on the approximation of laws, regulations and administrative provisions of Member States concerning liability for defective products, COM (2006) 496final of 14 September 2006
Fourth report on the application of the Council Directive on the approximation of laws, regulations and administrative provisions of Member States concerning liability for defective products. COM (2011) 547 final of 8 September 2011.

the clarity of the legal framework, in particular the scope of the Directive to deal with liability issues for IoT devices and complex autonomous systems.

In its Digitising Industry Communication[5], the Commission indicated that it would examine in greater detail the emerging issues of data ownership, access and re-use as well as the legal conditions of safety and liability related to the specificities of the Internet of Things, robotics and automated systems (such as robots, highly automated cars, distribution intelligence as part of the smart grids). The uptake of the Internet of Things may create challenges with respect to liability for damages of the economic players. In this context, interested parties also raised questions about the allocation of liability in the Internet of Things[6].

This evaluation was launched in June 2016. It takes into account the European Parliament's Resolution with recommendations on Civil Law Rules on Robotics of February 2017[7].

This evaluation builds on a study carried out by an external contractor[8]. The final report of the Study for the evaluation of Directive 85/374/EEC has been approved by the Commission's services in February 2018.

2. BACKGROUND TO THE INTERVENTION

2.1. Baseline and points of comparison

When the Commission proposed the Directive, it considered that a legal approximation of Member States' laws was necessary to protect consumers against damages caused to health and property by defective products. Before the Directive, a consumer was protected by damages caused by defective products according to the legal conditions of the individual Member States. These provided different degrees of protection. The Commission further considered that an equal and adequate protection of the consumer could be achieved only through the introduction of liability irrespective of fault on the part of the producer of the defective product that caused the damage. Any other type of liability would have created almost insurmountable difficulties of proof to the injured party or might not have covered the most important causes of damage.

By striking a fair balance of risk between consumers and producers, the Directive aims at reconciling consumers' interests with the interests of producers' in line with the Single Market policies, notably for the free circulation of goods and a fair competition. It seeks

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5 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - *Digitising European Industry Reaping the full benefits of a Digital Single Market* (COM(2016) 180 final) of 19 April 2016.

6 Commission Staff Working Document- *Advancing the Internet of Things in Europe*, accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions " *Digitising European Industry- Reaping the full benefits of a Digital Single Market* (SWD(2016) 110/2) of 19 April 2016.

7 European Parliament Resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL). http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bTA%2bP8-TA-2017-0051%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN

8 A specific contract was signed by the Commission with Technopolis Consulting Group Belgium in the context of the Framework contract N° ENTR/172/PP/2012/F LOT 4 (evaluations) on 19 December 2016. An amendment of the contract related to the duration was agreed on 14 July 2017. The Final report of the Study for the evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of Member States concerning liability for defective products was approved by the Commission's services in February 2018.

to ensure that injured persons are compensated for damages suffered due to a defective product.

Therefore, the Commission considered that liability on the part of the producer irrespective of fault would ensure an appropriate solution to this problem in an age of increasing technicality. The producer could indeed include the expenditure incurred to cover this liability in production costs when calculating the price of the product.

2.1.1. What is the current legal framework?

The Directive was adopted on the basis of Article 100 of the EEC Treaty (today Article 114 TFEU).

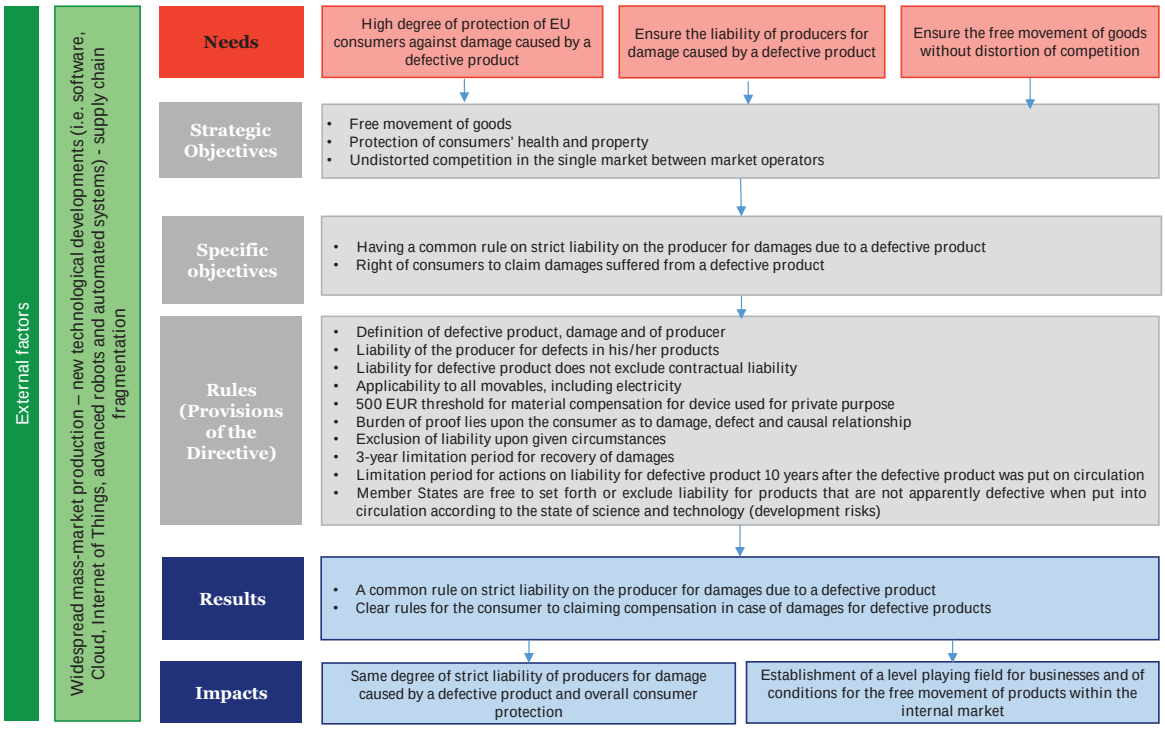
The Directive is considered to create an exhaustive harmonisation for the matters that it explicitly covers[9]. Several matters are however left to national law, as for instance the ceilings for damages resulting in death or personal injury by identical items (Article 16 (1)), the development risk defence (Article 15.1 (b)) or the rules related to non-material damages (Article 9).

The intervention logic of the Directive is summarised in the figure below. Three main needs or drivers led to the definition of three strategic objectives, namely the free movement of goods, the protection of consumer's health and property, and an undistorted competition among market operators in the single market.

These three strategic objectives are translated into two specific objectives (common rules on strict liability for producers and the right for consumers to claim damages), representing the operational orientations of the Directive. These strategic and specific objectives are achieved through a set of rules that were hence expected to produce several key results and eventually trigger a set of impacts. To fully understand how the interaction among the above factors works and delivers the promised changes over time, the intervention logic also considers external factors which may influence the performance of the Directive.

[9] For instance, CJEU Judgment of 25 April 2002, *Case C-52/00*. Commission of the European Communities v French Republic

Figure 1: Intervention logic of the Directive



Source: Study for the evaluation of the Directive

Since this is the first comprehensive evaluation of the Directive, this evaluation pays specific attention to the impacts of some relevant provisions of the Directive, for instance the definition of 'product' or 'defectiveness' or the allocation of the burden of proof on the injured person for obtaining compensation. The objective is to assess whether these definitions and provisions are still fit for purpose, especially in the context of the technological developments (i.e. software, Cloud, Internet of Things, advanced robots, automated and autonomous systems).

The fundamental elements of the Directive are the following (more information can be found in Annex 6):

- "**Strict liability**"(Article 1) means that producers are liable for damages caused by a defect in their product independently of whether the defect is due to negligence or ill-intent. Producers are liable without fault on their part.
- '**Product**' (Article 2) means any movable, even though incorporated into another movable or into an immovable, including electricity.

  The Court of Justice indicated that the Directive applies to products used while providing any service (*Case C-203/99*)[10] but that the liability of a service provider does not fall within the scope of the Directive (*Case C-495/10*)[11] However, the Directive does not prevent Member States from applying national rules under which a service provider using a defective product is liable for damage thus caused.

10 CJEU. Judgment of 10 May 2001. *Case C-203/99*.Henning Veedfald v Århus Amtskommune.

11 CJEU, Judgement of 21 December 2011, *Case C-495/11*, Dutrueux and Caisse primaire d'assurance maladie du Jura.

- A product is '**defective**' (Article 6) when it does not provide the safety a person is entitled to expect, taking all circumstances into account, including the presentation of the product, the reasonably expected use and the time when the product was put into circulation.[12] This provision also points out that a product may not be considered defective for the sole reason that a better product is subsequently put into circulation.

  The main concept of the product liability regime is the defectiveness of the product which is, in turn, related to the expected safety of the product[13]. It is irrelevant whether the product is fit for purpose or fit for use. This question of fitness for use belongs to the rules related to the sale of goods, outside of the scope of the Directive.

- '**Producer**' (Article 3) means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer, as well as any person who imports into the European Union a product for sale, hire, leasing or any form of distribution in the course of his business. The producer defined as such shall be liable for damage caused to consumers by a defect in his product.

  The term "producer" is deliberately broad so that an injured person easily can find a liable person. In case of an anonymous product, the supplier will be held liable unless he discloses the identity of the producer.

  The Directive foresees that where two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse (Article 5). Pursuant to Article 12, the liability of the producer may not, in relation to the injured person, be limited or excluded by a provision of national law limiting his liability or exempting him from liability.

- **Exemptions of liability** (Article 7): the Directive establishes a catalogue of defences or circumstances that could exclude liability.

  In particular, the producer shall not be liable if he proves some circumstances, including:

  a) that he did not put the product into circulation; or
  b) that, having regard to circumstances, it is probable that the defect which causes the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or

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12 Distinction is to be made between product "liability" and product "safety". Directive 85/374/EEC seeks to compensate ex-post for damages suffered by consumers due to a defective product. However, there are other pieces of European Union legislation that prevent damages ex-ante, by ensuring that products placed on the EU market are safe (for instance, the General Product Safety Directive or other sector-specific legislation such as the directives related to machinery, electrical equipment, radio equipment, medical devices, cosmetics, pharmaceutical products or toys). To the extent that safety legislation ensures the safety of products on the market, it will reduce the need for consumers to seek for compensation under product liability rules.

13 However, this definition does not always fit with all product categories, for example for products such as pharmaceuticals, which by their very nature may be considered as high-risk products. For those products the (unexpected) harmfulness becomes more relevant than the defectiveness of the products as such.

c) that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business; or
d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or
e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered (the so-called Development Risk Clause); or
f) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

Member States are obliged to include in their transposition laws the circumstances listed in Article 7 releasing a producer from strict liability. However, according to Article 15(1)(b), each Member State may provide that the producer shall be liable even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered.

In the context of defect due to compliance with mandatory regulations, it should be noted that compliance with voluntary standards would not provide a defence.

- '**Burden of proof**' (Article 4): the injured person is required to prove the damage, the defect and the causal relationship between defect and damage for the purpose of compensation.

  The Court of Justice stated, in *Case C-621/15*[14], that this proof could be facilitated by accepting national evidentiary rules according to which certain factual evidence may constitute serious, specific and consistent evidence, even if there is no conclusive scientific evidence to the matter.

- '**Damage**' (Article 9) for the purpose of the Directive means:

  a) any damage caused by death or by personal injuries, and
  b) any damage to, or destruction of, any item of property other than the defective product itself, provided that it was intended and used for private use and consumption with a lower threshold of EUR 500.

  By subjecting the compensation of damages to property to a minimum threshold of a fixed amount (EUR 500), the Directive aims to avoid litigation in an excessive number of cases. The Directive limits the compensation for damage to property for goods for private use or consumption (as opposed to business property, for instance, damage caused to a company car would be excluded).

- **Time-limits** (Articles 10, 11 and 16)

  According to Article 10, a limitation period of three years shall apply to proceedings for the recovery of damages and the rights conferred upon the injured person pursuant to this Directive expire after ten years from the date on which the producer put the defective product into circulation (Article 11).

  These time-limits aim at creating a balance between the interests of producers and those of injured parties. They are there to give legal certainty and reduce financial burdens for producers.

[14] CJEU. Judgment of 21 June 2017. *Case C-621/15*. N. W and Others v Sanofi Pasteur

Any Member State may provide that a producer's total liability for damage resulting from death or personal injury and caused by identical items with the same defect shall be limited to an amount which may not be less than 70 million EUR (Article 16).

- **Other liabilities**:

The Directive does not affect any rights an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive was notified (Article 13).

While the Court clarified that Member States may not maintain a general system of product liability different from that provided for in the Directive *(Case C-52/00)*[15], it does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault or a warranty in respect to latent defects (*Case C-183/00 and C-310/13)*[16].

3. IMPLEMENTATION / STATE OF PLAY

3.1. Description of the implementation

According to the analysis carried out by the Commission's services on the national measures transposing the Directive, all Member States transposed the Directive, including the amendments brought by Directive 1999/34/EC[17].

Five Member States (Finland, France, Hungary, Luxembourg and Spain) adopted the derogation for "Development risk clause" under Article 15(1) (b), thus providing that the producer shall be liable even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered. However, the derogation has not been transposed uniformly across those Member States. Two Member States having adopted the derogation without limitations, thus applying to all categories of producers and products (Luxembourg and Finland)[18], while the others only exclude some categories of producers and products: in Hungary the derogation does not apply to pharmaceutical products; in Spain it does not apply to medicinal products, foodstuffs or food products

15 CJEU. Judgment of 25 April 2002. Case C-52/00. Commission of the European Communities v French Republic.

16 CJEU- Judgement of 25 April 2002. Case C-183/00 María Victoria González Sánchez v Medicina Asturiana SA. and Judgement of 20 November 2014, Case C-310/13, Novo Nordisk Pharma GmbH

17 http://eur-lex.europa.eu/search.html?DB_NATURAL_DIRECTIVE=1985,374&qid=1519146702874&DTS_DOM=NATIONAL_LAW&type=advanced&lang=en&SUBDOM_INIT=MNE&DTS_SUBDOM=MNE
http://eur-lex.europa.eu/search.html?DB_NATURAL_DIRECTIVE=1999,34&qid=1519146793581&DTS_DOM=NATIONAL_LAW&type=advanced&lang=en&SUBDOM_INIT=MNE&DTS_SUBDOM=MNE

18 In Luxembourg, the legislator does not make any distinction; therefore the producer can invoke the development risk clause for any products, regardless of their nature. In Finland, according to the Government proposal regarding the enactment of the Product Liability Act and the implementation of the Directive, the extent of the derogation has not been explicitly defined yet, so it should be interpreted to apply to all products according to the Directive.

intended for human consumption. In France the derogation only applies to products derived from the human body[19].

Some Member States have introduced provisions to elaborate some concepts of the Directive:

- Austria, Belgium, Cyprus and Czech Republic have introduced a criterion to determine when a product is "put into circulation",
- Spain, Hungary, Italy, Poland, Portugal and Sweden have set the "reasonable time" by which the supplier of the product must inform the injured person of the identity of the producer or of the person who supplied him with the product where the producer of the product cannot be identified, so as not to be treated as its producer;
- Some Member States have added other complementary provisions. Germany, for instance, specified the nature of damages that can be indemnified, while the Netherlands specified the term for recourse against the producer held liable for a defect.

The Commission monitored the transposition of Member States. In this context, infringement proceedings were launched during the reporting period for incorrect transposition of the Directive. One was based on the grounds of a national provision providing that the supplier were liable under the same conditions than the producer *(Case C-327/05*), other on the fact that the thresholds for material damages was lower than EUR 500 (*Case C-52/00*).

In the majority of Member States, the national provisions implementing the Directive were generally applied alongside other regulations on contractual, non-contractual or other types of liability. The coexistence of different product liability rules, which is permitted under Article 13 of the Directive, makes consumer protection more comprehensive as it will explicitly extend to aspects not covered by the Directive.

3.2. Products about which claims are made

According to the information collected by the Study for the evaluation of the Directive, in the reporting period (2000-2016)[20], the Directive was more frequently applied to raw materials, pharmaceutical products and vehicles. 52% of cases relate to one of these categories. As it appears in the table below, raw materials represent 21% of products at stake, followed by pharmaceutical products (16%), motor vehicles (15%) and machinery (12%). The cases submitted to the CJEU concern pharmaceutical products and medical devices (67%), followed by electrical machinery (17%), food and beverages (8%) and vehicles (8%).

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19 For further detail, the Hungarian Civil Code states that the producer of any pharmaceutical products is liable even if the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable detection of the existence of the defect. Along the same line, the Spanish Royal Legislative Decree 1/2007 of 16 November 2007 states that producers of medicinal products, foods or foodstuffs intended for human consumption cannot invoke the exemption provided under Article 15 §1(b) of the Directive. In France, the Law n° 98-389 of 19 May 1998 modifying Art. 1386-12 of the Civil Code states that the producer cannot invoke the exemption when the damage has been caused by an element of the human body or by products derived from it.

20 Evaluation of Council Directive 85/374/EEC. Final report, p. 19f.

Each of the other product categories did not exceed 8% of total cases. Also, due to the heterogeneity of the raw materials and machinery categories, the products in question varied substantially.

Concerning new technological developments, the study could only identify one case in Bulgaria invoking the Directive where the claimed damage concerned specifically data but no material damage[21]. The case was about a storage unit, a product in which software and apps from different sources can be installed after purchase. The damage claimed was the loss of stored information, due to defects in the external hard disk. The claimant, who claimed for a compensation of around €800 (1,600 BGN), was not able to prove that the information had been stored on the external disk prior to the occurrence of the defect and also to prove the damages caused to him by the loss of the information.

Table 1: Recurrence of product categories subject of claims over 2000-2016

Product categories	Total	%
Raw materials	116	21%
Pharmaceutical products	88	16%
Vehicles	83	15%
Nuclear reactors, boilers, machinery and mechanical appliances; parts thereof	68	12%
Miscellaneous manufactured articles	44	8%
Chemicals	40	7%
Agricultural goods	38	7%
Electrical machinery and equipment and others	33	6%
Foods & beverages	16	3%
Clothing and accessories	11	2%
Cosmetics	10	2%
Total	**547**	**100%**

Source: Study for the evaluation of Directive 85/374/EEC

According to the available information, no recurrent types of defects have been reported in the mentioned categories of products.

3.3. How are injured parties making use of the Directive?

The Directive does not contain specific provisions in respect of access to the courts for injured parties. Injured parties can settle claims for damages following the procedural rules based on private law in the different legal systems of the Member States, such as litigation in court but also through direct negotiation or other mechanisms as, for instance, arbitration or mediation. The information collected by the Commission for the application reports and for the evaluation shows that, in general, the parties settle product liability related claims through direct negotiation in 46% of cases, whereas 32% are resolved in court and 15% through mechanisms for alternative dispute resolution[22]. Only a small share (7%) of claims under the Directive is decided through other means, such as settlements with the insurer of the responsible entity.

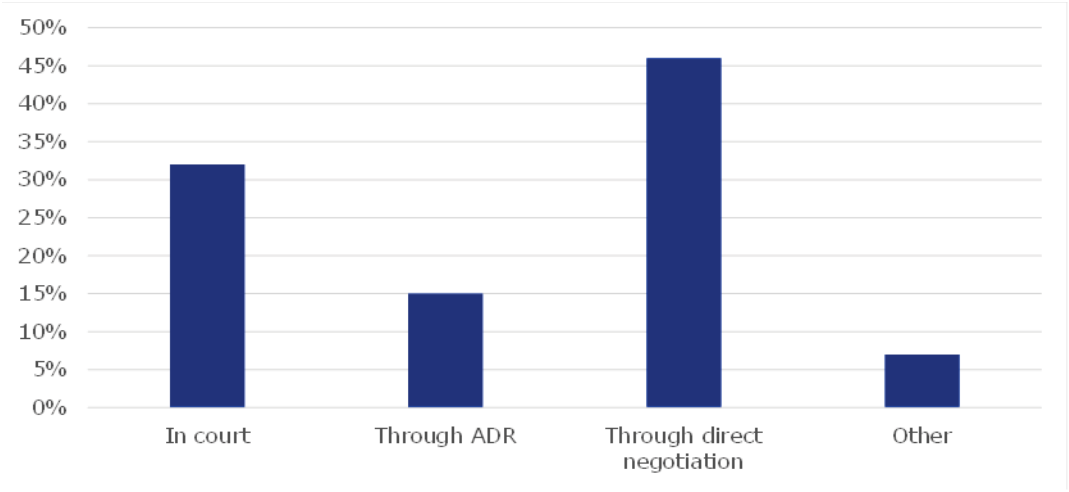
According to the desk research performed by the contractor, the majority of claims are settled:

[21] Bulgarian case no. 20942/2012

[22] Directive 2013/11/EU on alternative dispute resolution for consumer does not apply to litigation under the Product Liability Directive.

- By direct negotiation between interested parties in Cyprus, Czech Republic, Croatia, Hungary, Italy, Portugal and Sweden,
- Litigation in a national court in Estonia, Finland, France, Poland and Romania,
- Through a dispute resolution mechanism in Bulgaria, Greece and Lithuania.

Figure 2: Systems used to settle the claims, EU28, average percentage



Source: Study for the evaluation of Directive 85/374/EEC

This desk research performed by the contractor is confirmed by data gathered from consumers and producers responding to the open public consultation related to the evaluation of the Directive. All categories of stakeholders[23] indicate how extrajudicial arrangements represent a common way to settle cases, and that most cases are settled out of court. No significant differences appear when firms are broken down by size.

Most producers have a general insurance contract covering different risks, including the cost of compensation in case of defective products. Only a small share has a specific insurance contract covering the risks related to the Directive.

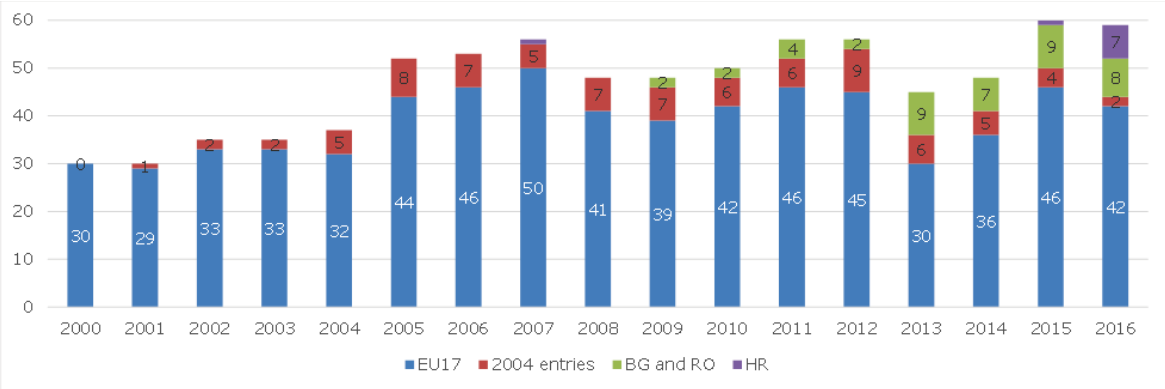
According to the findings of the Study for the evaluation of the Directive, 798 claims based on product liability rules were brought to national courts in the Member States during the period of 2000 to 2016[24].

The graphic below shows that the number of claims brought to court each year has nearly doubled over the period: while it was equal to 30 in 2000, in 2016 it reached 59.

[23] Around 60% of consumers providing a response to the specific questions in the OPC replied that they were not involved in a judicial proceeding to claim compensation for a damage caused by a defective product, whilst the remaining 40% were involved in a judicial proceeding. 66.7% of producers providing a response answered that they have received claims for compensation regarding damages caused by defective products and that the claimant obtained compensation though an extrajudicial arrangement. In addition, it was also indicated by the 71,4% of other participants that injured parties have been compensated "rarely" or "never" through a judicial decision.

[24] Information on national case law was gathered by the external contractor through desk research at national level. The information is likely not complete and thus not entirely representative as databases and information available varied from Member State to Member State.

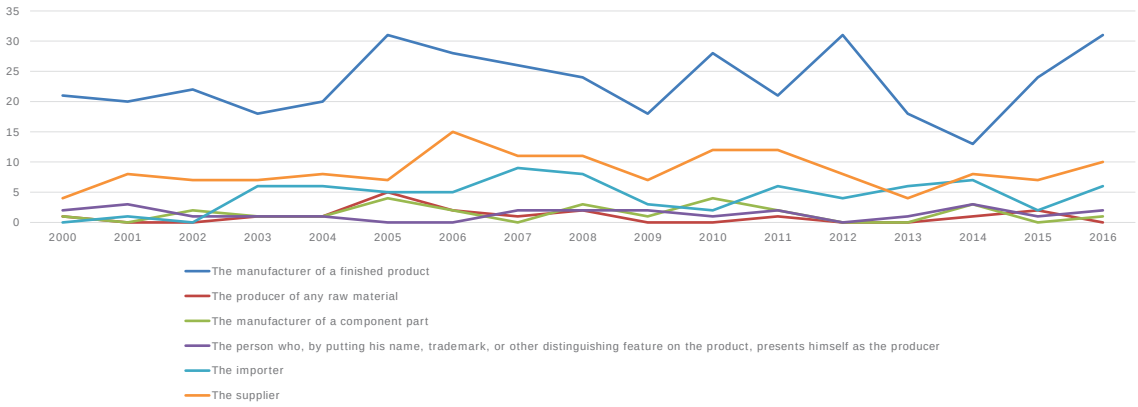
Figure 3: Number of claims per year, adjusted per new Member State entries



Source: Study for the evaluation of Directive 85/374/EEC

In the majority of cases, the producer sued was the manufacturer of a finished product. A significant role has been played also by suppliers and importers: as shown in the figure below, they have been brought to court almost half as many times as the manufacturers of finished products.

Figure 4: Number of times when producers have been brought to court from 2000-2016



Source: Study for the evaluation of Directive 85/374/EEC

According to the Study, claimants quite often invoke the national law implementing the Directive, but tort or contract law is also used to decide on compensations for defective products. The legislation invoked by the injured persons to raise a claim was, on average, contract law in 68% of cases, general tort law in 21% of cases, similar legislation to that implementing the Directive in 7% of cases, specific legislation in 3% of cases, and another legislation in 1% of cases[25].

Around 60% (476 out of 798) of claims for defective products were successful for injured parties from 2000 to 2016. The other cases were decided in favour of producers. It seems that there is no particular difference in the level of success of injured parties if the case is settled in court rather than out of it.

25 This occurred in the 14 Member States for which information was available, but particularly prevalent is in France, Germany and Greece.

4. METHOD

4.1. Short description of methodology

The evaluation was carried out according to the Commission's evaluation techniques and triangulation methods to ensure robustness of the information obtained. As much as possible, conclusions are based on results of the consultation activities, official statistics and studies.

The evaluation followed several steps to collect both qualitative and quantitative data from the relevant stakeholders, and national authorities.

The following criteria and corresponding questions were identified by the Commission.

Effectiveness:

- To what extent does the Directive meet its objective of guaranteeing at EU level the liability of the producer for damage caused by a defective product and in turn, contributes to an effectively operating internal market for goods and to the protection of the consumer?
- In this case, which are the main elements that have contributed to meeting these objectives?
- Are there any aspects/provisions/definitions that have rendered certain aspects of the Directive more or less effective than others, and if there are, what lessons can be drawn?
- How many cases have been brought to courts on the applicability of the Directive? Which was the issue in question and the ruling?
- Has technical and technological progress and, in particular the development of connected objects, affected the effectiveness of the Directive?
- What are, if any, the consequences or effects (either positive or negative) that were not originally planned?

Efficiency:

- What are the regulatory (including administrative) costs for relevant stakeholders stemming from the Directive and how do they compare to the benefits? Are the benefits achieved at reasonable costs (with focus on SMEs)?
- Are the benefits achieved at reasonable cost for consumers? Does the Directive strike the right balance between the strict liability of the producer and the burden of proof placed on consumers?
- What factors influenced the efficiency of reaching the achievements which the Directive sets out?

Coherence:

- To what extent are there complementarities between the Directive and any other Union action, in particular initiatives in the context of DSM? To what extent are they coherent?
- To what extent is the Directive coherent with wider EU policy, such as the free movement of goods and/or the protection of the consumers, including EU product safety legislation?

- To what extent is the intervention consistent and coherent with the EU rules on consumer protection in the area of contractual liability (including new Commission initiatives in the digital context[26])?

Relevance:

- To what extent do the initial objectives correspond to the current needs, including new needs created by innovative products?
- To what extent is there a need to clarify or modify the concept of product, producer, defective, damage or the category of exemptions in the Directive?
- How well is the term "defective" in the Directive adapted to new technological or scientific advances such as apps and non-embedded software, advanced robots and autonomous/intelligent systems?
- How well adapted is the intervention to the changing market environment: often blurred distinction between private and professional use of products and the servitisation of products when products and services are often sold and consumed together?
- How has the strict liability been allocated in case of damage caused by a product which is interconnected with other products or services in the IoT? Why?
- How has the strict liability been allocated when the damage comes from the unintended behaviour of an autonomous system or an advanced robot? Why?

EU added value:

- What is the added value of the Directive for stakeholders (manufacturers, including software developers and economic operators in the DSM, and consumers*)?*
- To what extent does the issue of strict liability addressed by the Directive continue to require action at EU level?
- What would be the most likely consequences of reducing the scope of the existing EU intervention?

The study for the evaluation of Directive 85/374/EEC was carried out by an external consultant[27].

4.2. External study for the evaluation

An external supportive study on the Directive aimed to assess its functioning and performance and to identify potential shortcomings and whether improvements should be envisaged was launched. It covered the time period of 2000-2016 and the Directive's application in the 28 Member States. A specific focus lay on its application with regards to new technological developments, such as the Internet of Things and autonomous systems. The assessment was done according to five criteria: effectiveness, efficiency, coherence, relevance and EU added value.

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26 http://ec.europa.eu/justice/contract/digital-contract-rules/index_en.htm

27 The initial duration of the contract was of 30 weeks. The deadline was extended to 43 weeks by an amendment to the contract, agreed by the parties on 14 July 2017. The final list of evaluation questions considered for that Study, addressing the questions identified by the Commission, can be found in Annex 3.

During the preparation of the study and the evaluation, the consultant encountered difficulties in obtaining all the relevant data from the national courts and from the economic operators on its implementation. Despite the big effort and the mitigation measures to gather more feedback from stakeholders, the rate of responses remained low for the Open Public Consultation and the online targeted survey. In particular, the conclusions related to the effectiveness and the efficiency parts, are based on qualitative rather than quantitative analysis. This was mitigated by the computer assisted telephone interviews, which were addressed to 457 stakeholders, and the face or telephone interviews which provided an additional feedback from stakeholders. These, together with the desk research including studies or literature, were used to validate the collected data and results[28].

The most important tools used the for data collection were:

4.2.1. Desk research and literature review

Desk research was mainly conducted by the consultant focused on[29]:

- Judgements of the Court of Justice and national case law related to the Directive;
- The national legislation transposing the Directive in the 28 EU Member States;
- European Union legislation most relevant to product liability (in particular, product safety and consumer protection legislation);
- Literature relevant to the Directive, its policy context and the main issues related to its implementation. Mostly, this comprised academic literature.

The information gathered in preparation of the reports on the application of the Directive also served to identify and compare recurrent issues in in the application of the Directive since its entry into force.

Furthermore, the Lowels report of 2003 on the Directive[30] as well as the reflections provided by the Study on the emerging issues of data ownership, interoperability, re-usability and access to data, and liability[31] were taken into consideration. The latter specifically contemplates matters related to the liability of the Internet of Things, robots and autonomous systems. Based on legal analysis, it highlights possible problems, their causes and effects and possible ways of dealing with liability in the near future.

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28 More information on the difficulties and mitigation measures can be found in section 4.4 Limitations and robustness of findings.

29 Please refer to the Bibliography (Annex 10) of the Final report for the Study for the evaluation of Directive 85/374/EEC for a complete overview of the sources used during the desk research.

30 Among this, the Lowels Report:, *Product Liability in the European Union*, 2003. A Study carried out on behalf the European Commission in order to analyse and compare the practical effects of different systems applicable in Member States of the European Union regarding procedural aspects of claims for defective products.
Fondazione Rosselli Report: *Analysis of the Economic Impact of the Development Risk Clause as provided by Directive 85/374/EEC on Liability for Defective Products*, 2004. A Study carried out of behalf of the European Commission with a view to analyse the economic impact of the development risk clause provided in Article 7 e) of the Directive.

31 Study on emerging issues of data ownership, interoperability, (re-)usability and access to data, and liability. https://ec.europa.eu/digital-single-market/en/news/study-emerging-issues-data-ownership-interoperability-re-usability-and-access-data-and

4.2.2. Stakeholders consultation[32]

The stakeholders' consultation followed the consultation strategy adopted for the evaluation[33]. The consultant performed the following actions:

- **An Open Public Consultation** (10 January 2017 to 26 April 2017) addressed to any interested stakeholders. The consultation ran 12 weeks on the Commission web-site Your-Voice in Europe and consisted of three different questionnaires for producers/insurers; consumers; and national authorities, civil society and academia. All three questionnaires were prepared by the Commission's services and were available in all official languages.

  The Commission received 113 online replies and 14 position papers that were analysed by the consultant.

- **An online targeted survey** (3 April 2017 to end May 2017) aimed at collecting stakeholders' specific feedback on the application and performance of the Directive by means of five different questionnaires for producers, suppliers and related industry associations; consumer associations; insurers and related associations; public authorities; civil society and technical experts working in judicial matters. More than 400 stakeholders were consulted but only 26 complete replies were submitted.

- **A computer-assisted telephone interviewing (CATI**) (29 May to 14 June 2017), consisting of one questionnaire with closed questions targeted to business aimed at collecting feedback on producers', importers' and suppliers' experience with the Directive. 457 stakeholders responded.

- **61 telephone or face interviews** (3 May to end July 2017) with representatives from Industry and SMEs across all sectors, consumers, insurers, academia, think-tanks, consultants, public national administrations and also EU officials from the European Parliament and from the Commission.

For the purpose of collecting data**,** the consultant set up a network of correspondents in the Member States with the aim to gather information on the Product Liability Directive for each Member State.

The Commission organised a **Conference on the Evaluation of the Product Liability Directive** that took place on 20 October 2017 in Brussels (Belgium). The Conference was addressed to Member States and different categories of interested stakeholders, in particular to those that participated in the public consultation. The purpose of the Conference was to have an exchange of views on the preliminary results of the external Study.

In addition to the data collection tools foreseen in the consultation strategy for the evaluation of the Product Liability Directive, further information was gathered through the activities launched in the context of the **Building a European Data Economy Communication**[34]**.** They provided supplementary information from stakeholders and

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32 For more detail, see the Synopsis report of the consultation activities in Annex 2 of this document.

33 http://ec.europa.eu/DocsRoom/documents/18843

34 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. *Building the European Data Economy*. COM(2017) 9 final, 10 January 2017.
Commission Staff Working Document *on the free flow of data and emerging issues of the European data economy*, accompanying the Communication Building a European data economy. SWD(2017) 2 final.

Member States on their views on the adequacy of the Directive for the new technological developments. Among those:

- Liability part of the Open public consultation "*Building a European Data Economy"* (10 January to 26 April 2016).
- Workshop with the Member States on the emerging issues of the data economy follow-up to the Communication *'Building a European Data Economy'*, 31 May 2017, Brussels, Belgium.
- Workshop on "*Liability in the area of Autonomous Systems and Advanced Robots/Internet of Things-Systems*", 13 July 2017, Brussels, Belgium.
- Meeting of the Internal Market Advisory Committee (IMAC), on 23 October 2017, Brussels, Belgium on *Data Economy* (session Liability). The preliminary results of the evaluation study were discussed with member States at this occasion.

In addition, the Commission's services participated in the following events:

- Seminar "*Reviewing the Product Liability Directive*" organised by the British Institute of International and Comparative Law of the University of London (Product Liability Forum), 14 June 2017, London, United Kingdom.
- OECD Conference on *Artificial Intelligence- AI: Intelligent Machines, Smart Policies*, 26-27 October, Paris, France[35].

4.3. Data analysis

To assess the functioning and performance of the Directive and to evaluate whether it achieves its objectives and is able to deal with new technological developments, a number of Evaluation Questions (EQs)[36] addressing those identified by the Commission have been used to guide the analysis of the contractor:

- **Effectiveness:** whether and to what extent the Directive's objectives in terms of protection of consumers, undistorted competition and free movement of goods have been achieved so far at both national and EU levels (EQs 1-3).
- **Efficiency**: whether the Directive has proportionally delivered its results in terms of resources used, cost and benefits for stakeholders (EQs 4-8).
- **Coherence**: whether the Directive is consistent with other relevant EU legislation and to what extent the divergences (if any) prevent the achievements of its objectives (EQs 9-10).
- **Relevance**: whether the objectives of the Directive still correspond to current problems, needs and challenges. In particular, the study assessed to what extent the scope and mechanisms of the Directive allowed addressing the main issues arising from new technological developments (EQs 11-15).
- **EU Added value**: to what extent the results of the EU action are additional to the value that would have resulted from action at Member State level (EQs 16-20).

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https://ec.europa.eu/digital-single-market/en/news/synopsis-report-public-consultation-building-european-data-economy

35 http://www.oecd.org/going-digital/ai-intelligent-machines-smart-policies/conference-agenda

36 According to the Terms of Reference for the contract, the final report of the Study for the evaluation of Directive 85/374/EEC answers to 37 EQs, 11 of them are descriptive and related to the implementation of the Directive.

4.4. Limitations and robustness of findings

Several limitations were encountered for the evaluation of the Directive. First of all, it was impossible to compare the current situation with the situation before the entry into application of the Directive as the overall economic and legal environment of the EU has fundamentally changed since the 1980s and as no data is available from this time.

It was also difficult to obtain comprehensive data on the use of the Directive in court and in out of court settlements in the 28 Member States during the period concerned by the evaluation (2000-2016). In particular, the absence of monitoring at national level and the special features of each Member States (for instance, only some of them have public databases or registers) rendered the research and collection of information at national level very difficult. Therefore, the collected data may be incomplete and not fully reliable.

Especially the number of cases resolved in court cited in the study was retrieved from the information found by the network of lawyers collecting data for the purposes of the desk research conducted in the Study. This number therefore needs to be treated with caution, as the information collected depended on specific features of each Member State and of the public databases available. For instance, the French cases were found through the main public legal databases that do not list first instance decisions. Therefore, the analysis for France was limited to the decisions of the courts of appeal and the Supreme Court between 1 January 2000 and 31 December 2016. For other Member States, the cases were retrieved from commercial and public databases that do not necessarily report all cases. The assumption is therefore that this number is not fully representative and underestimates the real dimension of claims based on product liability rules in the European Union.

Out-of-court settlements, including arbitration awards, mediations and direct negotiations were either confidential or not listed in official databases. The evaluation therefore bases itself on the data available for each Member State which is not likely to provide a complete picture of the out-of-court settlements for the reasons mentioned.

The consultation strategy originally foresaw a balanced feedback from different categories of stakeholders, including a geographical balance and a broad spectrum of products. However, while this has not been possible to achieve across the board and the data collected should therefore not be regarded as statistically representative, the targeted interviews have mitigated this to the extent possible.

To complement the data collected, the Commission also participated e.g. in the Product Liability Seminar organised by the Product Liability Forum and organised the Product Liability Conference to discuss and verify the preliminary results of the external evaluation study.

Finally, the poor response on the targeted survey hampered the quantification of the costs and benefits. These costs and benefits were qualitatively evaluated. The Product Liability Directive's provisions were mapped and discussions developed on whether, compared to the situation previous to its entry into force (i.e. in the absence of it), these provisions entail a cost rather than a benefit for the relevant stakeholders. All elements provided by stakeholders were used for the quantification of costs and benefits, where possible. Moreover, three cases were analysed to provide quantitative examples of the costs placed on producers and consumers due to the Product Liability Directive. However, the limited amount of information provided on this aspect did not allow a proper and reliable quantification of costs and benefits to be made.

Despite these shortcomings, a picture of the functioning and performance of the Product Liability Directive emerged. For new technological developments (apps and software, Internet of Things connected objects or autonomous systems) on the other hand, there was limited information available at this stage so that no sufficiently robust conclusions can be drawn and further investigation and analysis are needed.

5. ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

5.1. Effectiveness: Evaluating to what extent the Product Liability Directive achieved its objectives

EQ. To what extent does the Directive meet its objective of guaranteeing at EU level the liability of the producer for damage caused by a defective product and in turn, contribute to an effectively operating internal market for goods and to the protection of the consumer?

EQ. What are, if any, the consequences or effects (either positive or negative) that were not originally planned?

The Directive is expected to ensure the right of consumers to claim damages suffered from defective products, and to create a common and harmonised set of rules on strict liability. This should enhance the protection of consumers' health and property, the free movement of goods, and undistorted competition among market operators in the Single Market, thus producing a harmonised level-playing field across Member States. While the allocation of the burden of proof foreseen by the Directive appears to have rendered claims particularly difficult for consumers, in particular for complex products, no other unintended consequences or effects have been identified.

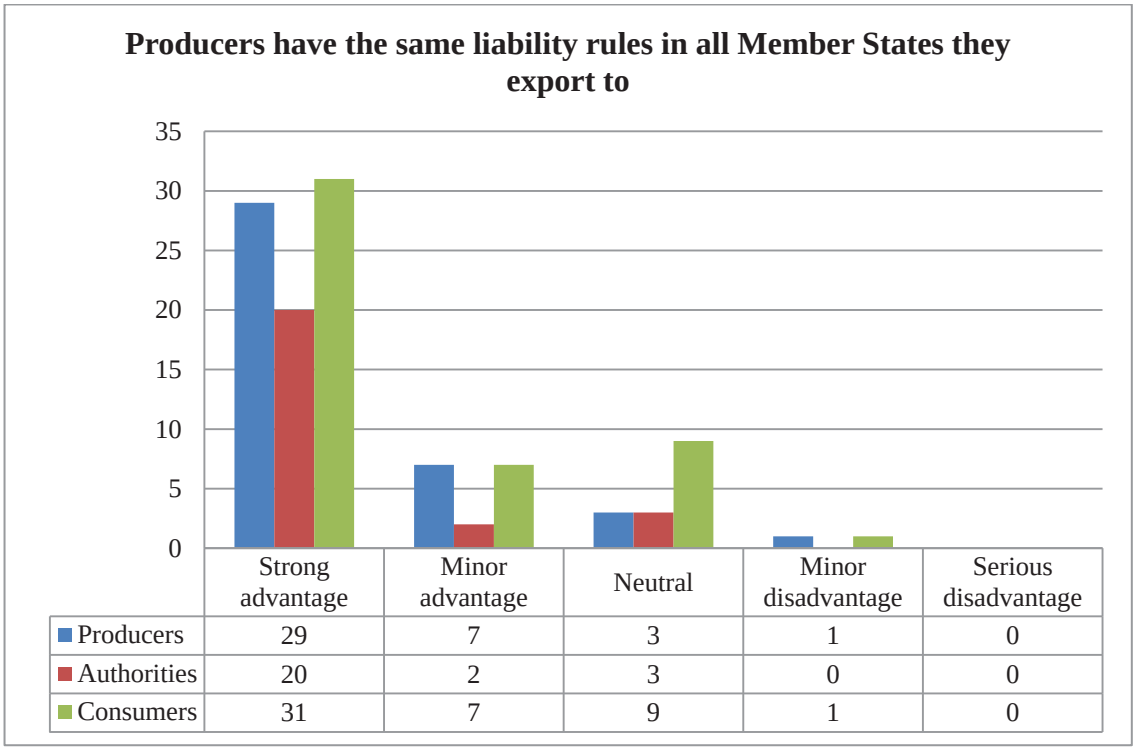
5.1.1. Effectiveness towards harmonisation of strict liability rules and an effectively operating internal market

The analysis of national legislation transposing the Directive carried out by Commission's services shows that the Directive has been uniformly transposed in Member States. Therefore, compensation for damages caused by defective products on the basis of strict liability is uniformly available to injured parties across the EU.

According to the reviewed literature in the Study[37], the harmonisation of the rules and the judgments of the CJEU contributed to a harmonised environment for businesses by preventing distorted competition in the internal market. Stakeholders have shared this view. In the context of the consultation activities for the evaluation[38], most stakeholders deem the Directive effective in providing a level playing field across the European Union, by defining the same liability rules in all Member States they export to, which is deemed to be a strong advantage.

[37] See section 5.1.3 of the Study.

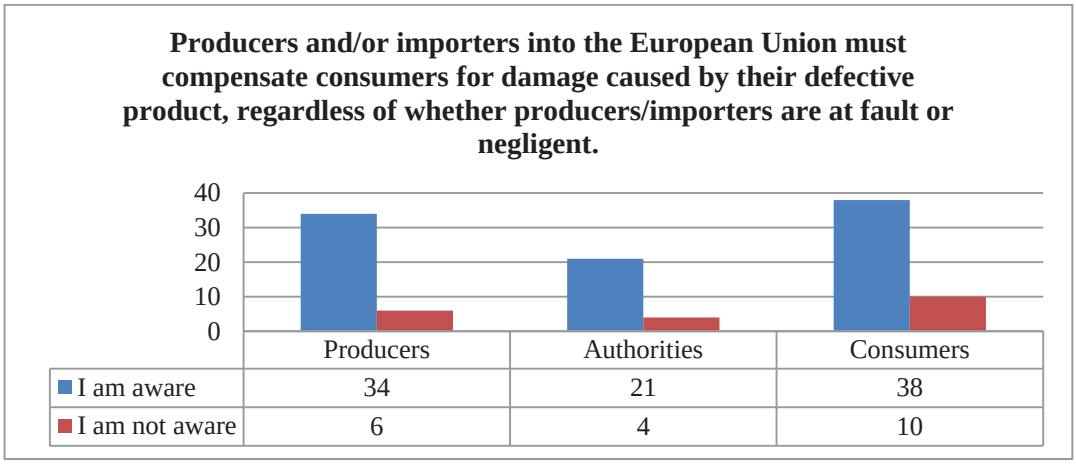
[38] See Synopsis report on the stakeholders consultation, Annex 2 of this document



	Strong advantage	Minor advantage	Neutral	Minor disadvantage	Serious disadvantage
Producers	29	7	3	1	0
Authorities	20	2	3	0	0
Consumers	31	7	9	1	0

Source: Open public consultation

The majority of stakeholders were aware of injured parties' right to compensation for damage caused by defective products.



	Producers	Authorities	Consumers
I am aware	34	21	38
I am not aware	6	4	10

Source: Open public consultation

EQ. How many cases have been brought to courts on the applicability of the Directive?

According to the Study, 798 claims based on product liability rules were brought to national courts in the Member States during the period 2000 to 2016[39]. In the very large majority of cases identified, the product at stake had been produced in the same Member State where the claim was brought and the defendant was in most cases the manufacturer of a finished product (on average, 81% of claims for defective products); only 3% the cases on average concerned products originating from another Member State, with 0% involving products from third countries. While the Directive is considered to level the playing field in the EU, the study could only identify 21 cross-border cases (i.e. 3% of the total). No definite reasons were identified for this in the Study. Lack of knowledge of procedural rules as well as difficulties relating to possible language barriers were identified as possible reasons that could discourage consumers from bringing a claim against a defendant in the jurisdiction of another Member State.

5.1.1.1. Role of specific rules in contributing to the effectiveness of the Directive

EQ Are there any aspects/provisions/definitions that have rendered certain aspects of the Directive more or less effective than others, and if there are, what lessons can be drawn?

The Directive pursues its objectives through its main provisions. These therefore need to be assessed in terms of how and to what extent they affect the effectiveness of the Directive.

According to the analysis of the provisions implementing the Directive, the results of the consultation activities in the context of the evaluation[40], mainly the open public consultation, as well as other desk research carried out for the Study, it appears the following.

- *Product*

  The Directive applies to a broad range of heterogeneous products; from agricultural products to highly sophisticated and complex industrial products. This broad notion was considered to render the Directive future proof by the open public consultation's respondents. As such, the Directive has stood through more than 30 years of technological evolution. The products that could be found in the European market in 1985 where the Directive was adopted may not present the same technical complexity or characteristics as they do today, but they continue to be covered by the notion of product set out in the Directive. However, with the increasing overlap between products and services, it has been highlighted e.g. by the Study on emerging issues[41] that the distinction between products and services

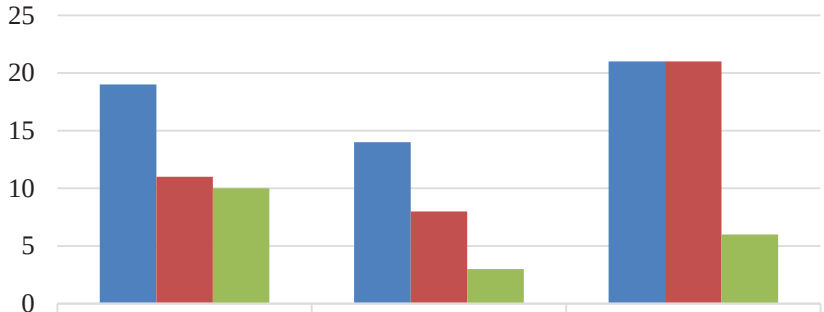
[39] Information on national case law was gathered by the external contractor through desk research at national level. The information is likely not complete and thus not entirely representative as databases and information available varied from Member State to Member State.

[40] See also Synopsis report of the stakeholders consultation, Annex 2 of this document

[41] Study on emerging issues of data ownership, interoperability, (re-)usability and access to data, and liability. https://ec.europa.eu/digital-single-market/en/news/study-emerging-issues-data-ownership-interoperability-re-usability-and-access-data-and

for the purpose of the Directive may become difficult in the future[42]. A clarification of the concept "product", e.g. with regards to software, may therefore contribute to improving effectiveness. This needs further assessment.

The Directive applies to very heterogeneous products (e.g. to damages caused by malfunctioning pacemakers or by defective staplers)



	Producers	Authorities	Consumers
Future-proof	19	14	21
Needs to be adapted	11	8	21
No opinion	10	3	6

Source: Open public consultation

- *Damages*[43]

The Directive applies to damages caused by death or personal injuries and to private property. A threshold of EUR 500 applies. The Directive does not prejudice compensation for pain and suffering and other non-material damages under the benefit of national provisions.

The CJEU has stated that a Member State may not restrict the types of material damage for which claims can be brought forward (*Case C-203/99*) and this does not seem to be under discussion in Member States.

Claimants more often seek compensation in court for damages to physical well-being. Even if there is no clear evidence to explain this pattern, one may conclude that damages to physical well-being have a bigger impact on injured persons and such claims are not subject to a financial threshold – and most likely concern larger sums anyhow.

With regard to material damages and, in particular to the distinction between private and professional use, evidence gathered by the evaluation suggests that the claims have been brought at the national level irrespectively of the type of use: the number of successful claims even if the item was subject to professional use is higher (150 cases) [44] than the number of claims rejected because the injured party

42 See Synopsis Report.

43 See Section 5.1.1.2 of the Study. For more information, see Annex 6.

44 Member States that did not report claims in which the damages where suffered in the context of a professional activity were Czech Republic, Estonia, Ireland, Latvia, Malta, Romania, Slovak Republic, Slovenia, Sweden and United Kingdom.

did not use the item of property for his own private use or consumption (23 cases)[45].

Nevertheless, concerning material damages, the effectiveness of the condition on the EUR 500 threshold seems to be questionable:

Firstly, there are concerns as regards its national interpretation. Some Member States transposed Article 9 of the Directive interpreting the EUR 500 threshold as a threshold which, when reached, would allow for pursuing compensation for the entirety of the damage suffered, whereas others (e.g. France, Germany, Netherland and Spain) transposed it as a deductible, i.e. as a sum to be deducted from the compensation owed without regard to the scale of the damage. This divergence in the interpretation may create a different degree of protection of the injured party across Member States.

Secondly, according to the information obtained, in four out of five cases a compensation is not claimed as the damage is below the threshold. This could explain why this is rarely cited as a reason for rejecting a claim in court and why most cases relate to physical well-being.

Therefore, despite the fact that the Directive seems to be effective and particularly for damages to well-being, the EUR 500 threshold represent, according to consumer representatives, an obstacle for the full effectiveness of the Directive to cover claims for compensation in many cases of material damage since claims for lower material damages cannot be introduced.

- *Defect and burden of proof*

  Issues related to the burden of proof raise significant concerns mostly among consumers[46]. Claimants find it particularly difficult to prove the defect and the link between defect and damage in court.

  The burden of proof is the central component of the Directive that triggers the right for compensation.

  According to the Study for the evaluation, the most frequent reasons to reject claims relate to the proof of the defect and its link with the damage, which together account for 53% of the cases of rejection. Difficulties in applying the definition of defective product and subsequently in proving the link between damage and defect seem to be particularly relevant in cases of complex products, such as pharmaceuticals. For those products, the injured party need to gather expertise to be able to prove the lack of safety of the product and the link to the damage suffered. It is therefore probably not surprising that all the CJEU preliminary rulings concerned these types of products and many dealt with the burden of proof in recent years.

  According to victims of medicines (*Stevens-Johnson Syndrome, Valproate or Distilben)* the definition of "defect" is not suitable for pharmaceutical products because the leaflet's information about the risk of serious adverse effects

45 Claims rejected because the damaged item of property was subject to professional use occurred in the following Member States: -Austria, Belgium, Germany, Hungary, Italy, Lithuania, Luxembourg, Netherland and Portugal.

46 More than half of the consumer representatives responding to the open public consultation for the evaluation declared to agree on the fact that it is difficult to prove the defect of a product to obtain compensation.

exonerates the producer for these effects[47]. Therefore, it is extremely difficult for such an injured party to demonstrate the causality and the defect of a medicine in connection with the damage. Either the adverse effect of the medicine is unknown and it is therefore hard to provide sufficient scientific elements to establish the link (causality) and the development risk clause may be invoked, or it is known and was therefore published in the leaflet, which means that the medicine was not defective. Injured persons potentially find themselves in a Catch-22 situation where they have to bear the full cost of damages without access to compensation.

In this respect, while the definition of defect, damage and their link seem to be effective for tangible products in general, the distinction between a known risk and an unexpected risk – particularly for pharmaceutical products – may be less clear.

Exceptions of the producer

According to the Study, most respondents to the public consultation find the exemptions from liability (such as compliance of a product with mandatory rules or the state of scientific and technical knowledge when the product was marketed) too advantageous for the producer. However, their effect in practice appears to be rather limited.

There was little to no evidence found by the study on the evaluation that compliance of the product with mandatory regulations issued by public authorities posed major problems. The development risk clause is much more contested

Nonetheless, there are arguments that the development risk clause has played an important role in ensuring the balance between consumer expectations about product safety and fostering innovation in Europe, well beyond its limited use in courts[48]. Furthermore, the development risk clause could represent a factor in determining the relative stability of product liability insurance costs for European industry and keeping litigation at a reasonable level. On the other hand, the evaluation study did not reveal remarkable differences between Member States that derogated from this clause and those who did not.

All in all, despite some difficulties expressed by stakeholders, there is no clear evidence on the fact that exceptions represent an obstacle to an effectively internal market, neither to consumer protection.

- *Limitation and expiry period*

  During the consultation activities, the three-year period to lodge a claim has been challenged by stakeholders: on average, 41% of the businesses and around a third of the stakeholders declared this limitation should be updated in light of recent technical developments. Moreover, the majority of stakeholders expressed difficulties in observing the three-year period for making a claim to recover damages in case of complex products, such as pharmaceutical products, that need expertise and research to find the defect and the link to the damage.

  As for the 10-year period, the Study for the evaluation has identified issues mainly related to its relation with the concept of "put into circulation" which has been

47 The perception of risk and acknowledged risk could be different in case of pharmaceutical products. For pharmaceutical products, it is a constituent element to highlight the risk which are known to patients

48 Study Fondazione Roselli (2004) already mentioned.

addressed in three CJEU judgments[49]. Besides the clarifications brought by these judgments, some Member States (Austria, Belgium, Cyprus and Czech Republic) have determined when a product is "put into circulation".

The 10-year period starts from the moment a producer puts the product into circulation. For products that remain in the distribution chain for a long time or deploy their effects over a long time span, the protection of the consumer may be reduced in comparison with his or her possible expectations: this is particularly the case of pharmaceutical products.

During the Product Liability Conference of 20 October 2017, representatives of victims of medicines (*Stevens-Johnson Syndrome, Valproate or Distilben)* raised the issue of the unsuitability of the 3- and 10-year limitation periods. The asymmetry of information between patients and firms regarding adverse effects means that victims may take more than three years after the onset of a serious adverse effect to prove that the product was defective and that it is related to their damage. Moreover, victims of long-term adverse effects (e.g. Distilben affects subsequent generations) cannot be compensated within the 10-year limitation period following the entry of the drug onto the market.

However, the number of claims rejected because of the expiry of the limitation period appears to be residual. This suggests that, in general, the limitation periods do not hamper the effectiveness of the Directive, except for certain pharmaceutical products for which some doubts can be raised on the basis of the elements mentioned above as highlighted in the Product Liability Conference of 20 October 2017.

- *Most important difficulties to obtain compensation*

  According to the information collected for the previous Commission's reports on the application of the Directive, it appeared that the main difficulty for the injured party to obtain compensation was the burden of proof, that is, to prove the defect in the product and the link between the defect and the damage.

  The desk research undertaken in the context of the Study showed that the most frequent reasons for rejecting a claim for a defective product are related to the burden of proof, and specifically to: i) prove the defect (32% of cases) and ii) prove the link between the defect and the damage (21% of cases). These two concern 53% of the cases of rejection.

  The causes of rejection connected to liability exemptions for the producer appear to be the least frequent (overall equal to 10% of cases). Among these, the most recurring liability exemption is the Development Risk Clause of Article 7 (e) (4% of cases)[50].

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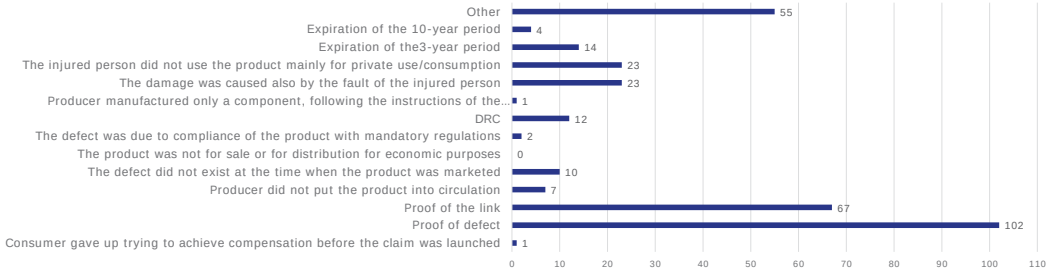
49 The CJEU stated that a medical device is deemed to be "put into circulation" when it is used to provide the relevant medical service, and the damage caused results from that service (*Case C-203/99*). In a second case concerning vaccines, the Court stated that a product is considered as "put into circulation" when it is taken out of the manufacturing process and enters a marketing process through which it is offered to the public to be used and consumed (Case C-127/2004). In a third case, the Court stated that the expiration term of 10 years starts from the moment when the product has been put into circulation by the producer and not by the retailer (*Case C-45/13).*

50 The Development Risk Clause (DCR) was used as a cause of rejection of claims more frequently in Italy, France, Hungary and Belgium. It should be said that the more cases pass the burden of proof test in favour of victims the more this exemption may become relevant, especially for complex products.

Other reasons for rejection are the expiration of the three-year limitation period (4%), the fact that the injured person did not use the product mainly for private use/consumption, and that the damage was caused also by the fault of the injured person (each equal to 7%). The following figure shows the total number of cases rejected and the related reasons.

Figure 5: Reasons for rejection of a claim, EU28



Source: Study for the evaluation of Directive 85/374/EEC

This is confirmed by the information collected from the open public consultation, which indicates that the main obstacle for consumers to succeed in their claim is the burden of proof of the defect of the product and the link with the damage. In addition, many consumers find it difficult to observe the three-year period for making a claim to recover damages, to exceed the threshold of EUR 500 for property damages or to distinguish between private and professional use of a product.

The burden of proof appears to be particularly problematic in the pharmaceutical sector as the claimant must use scientific evidence showing that the risk is known and because the producer can dismiss liability by indicating the risk in the product leaflet. Accordingly, the associations of victims of medicines consider that the three-year and ten years expiry period are too short for a patient to collect all the relevant information and documentation to prove the link between product and damage. In addition, the adverse effects of medicines may only become evident a long time after consumption.

The Court of Justice has played an important role in minimising these difficulties without a reversal of the burden of proof established by the Directive: Where a product belongs to the same group or forms part of the same production series (such as pacemakers and implantable cardioverter defibrillators) having a potential defect, they may be classified as defective without any need to establish the defect of the individual product. The cost of the operation that is necessary to remove such a potentially defective product is considered damage within the meaning of the Directive (*Cases C-503/13 and C-504/13*).

Similarly, the Court ruled that national rules granting consumers the right to require the manufacturer of a product to provide them with information on the adverse effects of that product can be accepted as they fall outside the scope of the Directive (*Case C-310/13*). Such rules make it easier for the injured person to establish the liability of the producer. Also, the Court accepted national evidentiary rules whereby certain factual evidence may be considered by the national court to constitute serious, specific and consistent evidence of a defect of

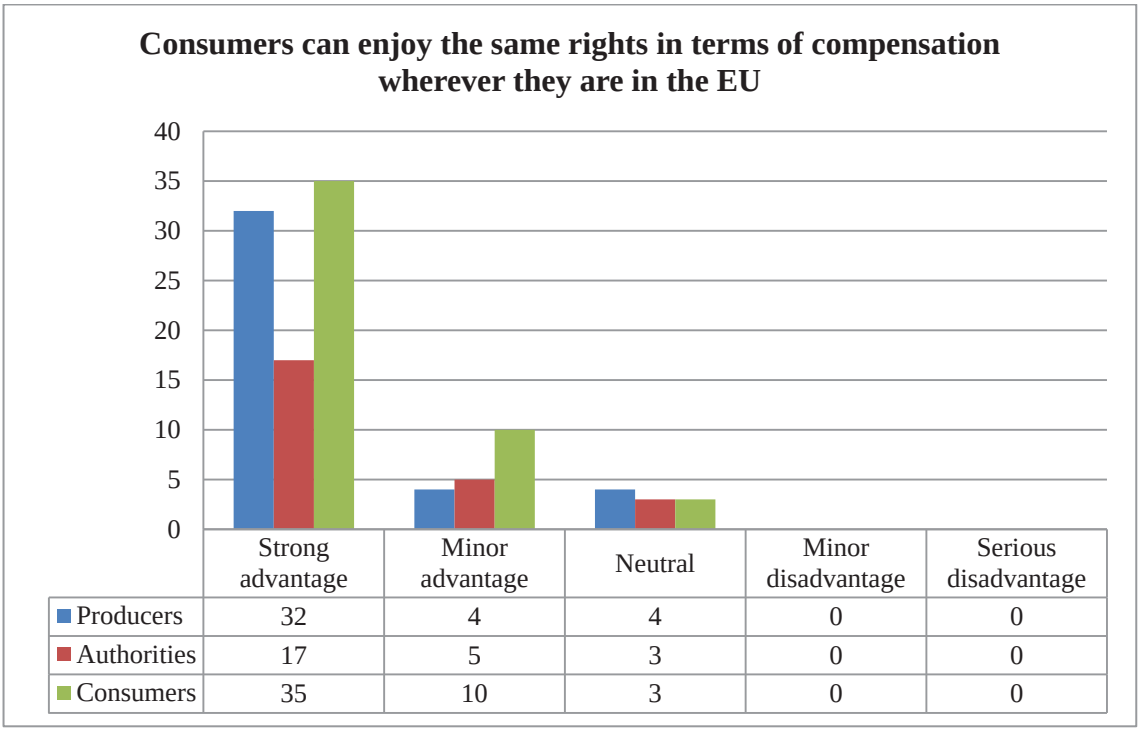
a product and the causal link with the damage, even if there is no conclusive scientific evidence to the matter. This method should not nevertheless result in a reversal of the burden of proof *(Case C-621/15)* but should be recognised as being an essential element, especially with respect to adverse effects of pharmaceutical products, where evidence often is inconclusive, this may facilitate matters for injured persons.

A further issue which proved to be difficult to interpret relates to the precise identification of the time when a product is "put into circulation". This was the subject of three rulings of the Court of Justice and appears to be particularly relevant for the pharmaceutical sector or for medical devices. In this regard, it is relevant to recall that four Member States (i.e. Austria, Belgium, Cyprus and Czech Republic) have introduced provisions to define when a product is put into circulation.

The CJEU stated that a medical device is deemed to be "put into circulation" when it is used to provide the relevant medical service, and the damage caused results from that service (*Case C-203/99*). In a second case concerning vaccines, the CJEU ruled that a product is considered to be put into circulation when it is taken out of the manufacturing process and enters a marketing process through which it is offered to the public to be used and consumed (C*ase C-127/2004*). In a third case, the CJEU clarified that the expiration term of 10 years starts from the moment when the product has been put into circulation by the producer and not by the retailer (C*ase C-45/13*).

5.1.2. Effectiveness towards the right for consumers to claim damages and consumer protection

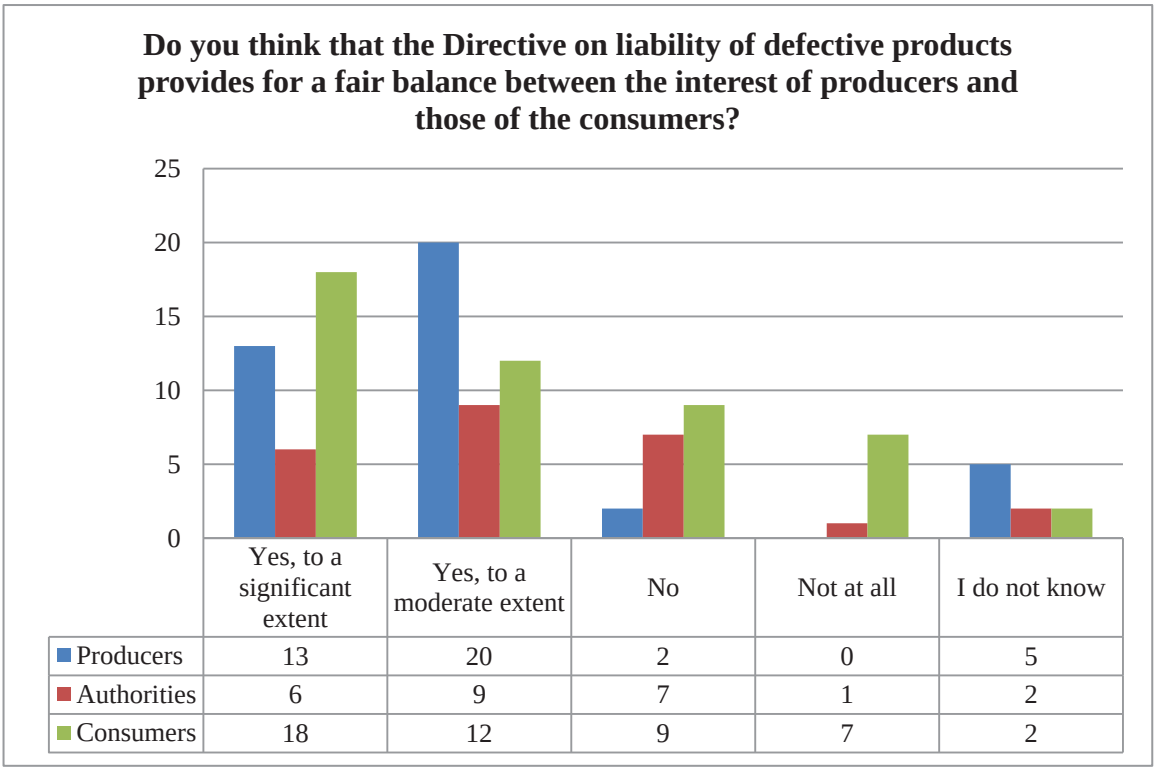
According to the results of the open public consultation, more than 85% of the respondents consider that the Directive is advantageous for consumers and producers because consumers can enjoy the same rights wherever they are in the European Union and the product liability rules covered by the Directive are the same in all the Member States.



	Strong advantage	Minor advantage	Neutral	Minor disadvantage	Serious disadvantage
Producers	32	4	4	0	0
Authorities	17	5	3	0	0
Consumers	35	10	3	0	0

Source: Open public consultation

In addition, 68% of respondents to the open consultation believe that the Directive strikes a fair balance between the interests of producers and those of the consumers. This last view, relating to the fair balance between the interests of producers and those of the consumers, is also expressly stated in most of the position papers[51].



	Yes, to a significant extent	Yes, to a moderate extent	No	Not at all	I do not know
Producers	13	20	2	0	5
Authorities	6	9	7	1	2
Consumers	18	12	9	7	2

[51] See Brief factual summary on the results of the public consultation on the rules of producer liability for damage caused by a defective product. http://ec.europa.eu/growth/content/public-consultation-rules-liability-producer-damage-caused-defective-product-0_en

However, when contrasting this information with targeted surveys and interviews, different stakeholders expressed specific views which painted a more differentiated picture.

With a view to justify their position, stakeholders refer to different provisions of the Directive to support their views. These views are not new; they have been expressed by the stakeholders in the context of the preparation of the three last Commission's reports on the application of the Directive. Overall, given that the Directive represents a trade-off that balances different interests, one can identify opposing views between consumers and producers when it comes to the effectiveness of certain concepts.

For most consumer associations, the Directive is not fully effective, as they consider producer's interests to be better protected than those of consumers.[52]

Similarly, consumers believe that the Directive is not always effective in protecting consumers mainly because:

- claimants have to prove the defect, the damage and their link, which can be burdensome in some fields, as for instance pharmaceutical or complex products, (these arguments have also been raised with regards to new technological developments),
- the EUR 500 threshold aims to avoiding litigation for small claims,
- compensation of the damage only if the item of property was intended and used for private purpose and not when the defective product was used for professional purposes;
- the time limit of 3 and 10 years to obtain compensation is too short in cases of complex products that require more expertise;
- the exceptions to liability in favour of the producers are too advantageous (such as the development risk clause).

Conversely, producers deem the Directive as effective in protecting consumers because:

- claimants may request compensation without need to prove the fault or negligence of the producer,
- clear identification of the operator(s) to be held liable.

These different views also manifest themselves in academic literature[53]. Some suggest that the Directive contributes to consumer protection through the right to claim damages suffered by defective products. Other scholars, on the other hand, consider the Directive's protection less effective as producers are rarely required to compensate victims -especially in the field of pharmaceuticals[54].

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52 See Synopsis report on the consultation of stakeholders, Annex 2 of this document

53 See Final report of the Study for the evaluation, in Annex 10 Bibliography.

54 More specifically, some stakeholders such as the European Federation of Pharmaceutical Industries and Associations have indicated that pharmaceuticals should be outside of the scope of the Directive and should have a specific liability regime. See section 5.3.

Based on the data available for the Study for the evaluation, it appears that the question related to the burden of proof (defect, damage and their link) as well as the EUR 500 threshold do indeed have an effect in terms of consumer protection, while the impact of other factors is less important. Courts have been accepting claims concerning products that were not intended for private use. The ratio of liability claims per person in those Member States that have derogated from the development risk clause is only marginally higher than in those Member States that have not. Rejections of claims based on the time limitations appear to be residual, even though clarification concerning the notion of "putting into circulation" may prove useful and avoid conflict.

In fact, most claims brought to court, appear to be successful for the injured party, while in general claims are rather settled out of court. An interpretation of this is that producers "fear" the Directive and prefer to settle out of court, rather than facing trial.

Overall, there appears to be agreement that the Directive is effective to some extent in contributing to consumer protection and a level playing field across the EU. However, certain provisions notably the burden of proof and the EUR 500 threshold may create difficulties to an effective application of the Directive.

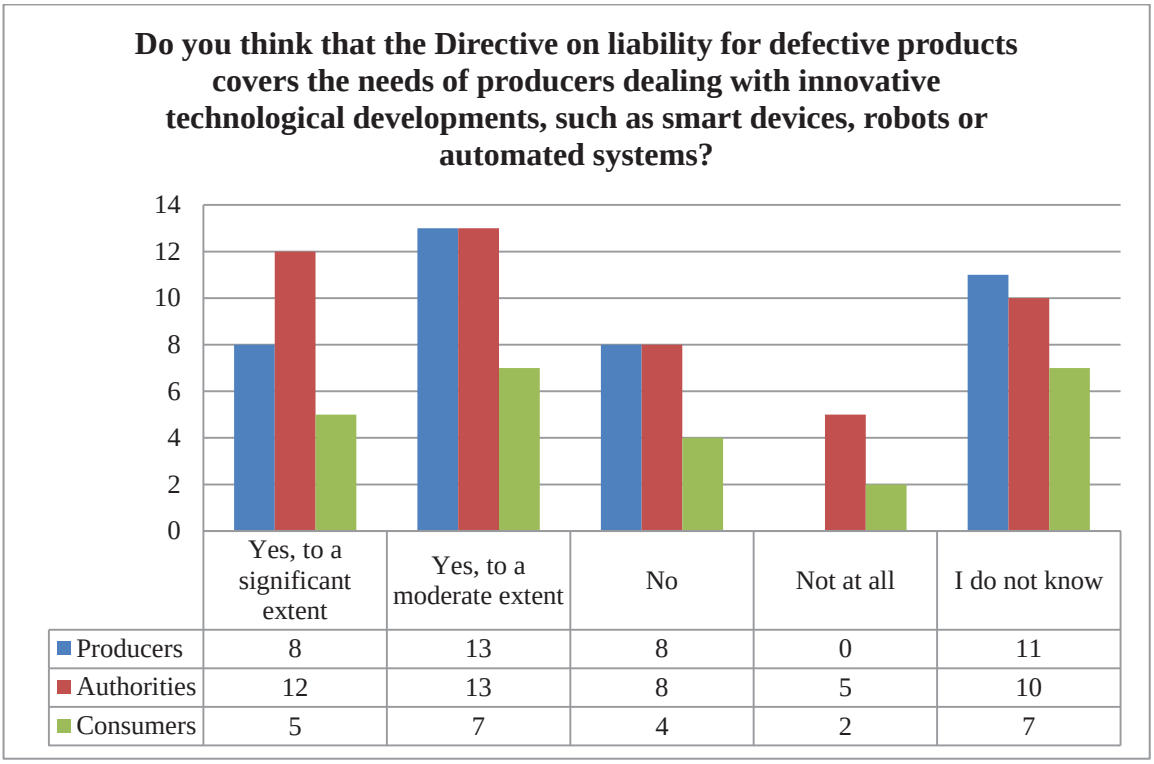
5.1.3. Effectiveness vis-à-vis new technological developments

EQ. Has the technological progress and, in particular the development of connected objects, affected the effectiveness of the Directive?

The acceleration of interconnectedness and autonomy of technology raises questions on whether the Directive will continue to be effective in a scenario where these technologies will become more widespread and advanced.

In the open public consultation around 50% of producers and consumers stated that the Directive is adequate to cover their own needs when dealing with innovative technological developments. This opinion was also expressed in the context of the consultation activities launched in the context of the initiative "Building a European Data Economy". [55]

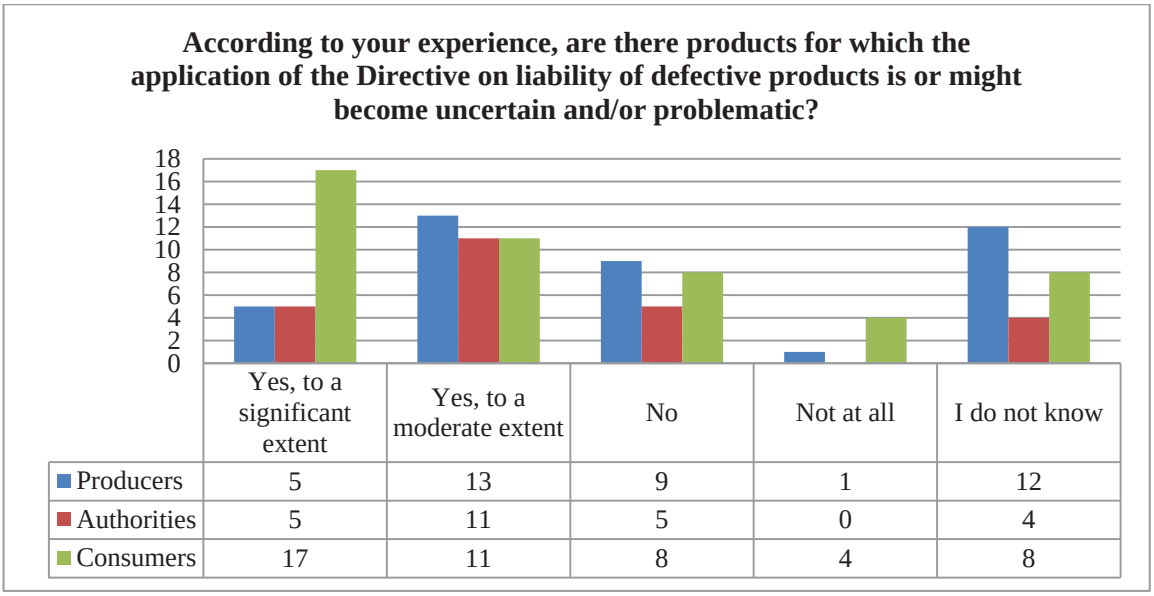
[55] See Synopsis report at https://ec.europa.eu/digital-single-market/en/news/synopsis-report-public-consultation-building-european-data-economy



	Yes, to a significant extent	Yes, to a moderate extent	No	Not at all	I do not know
Producers	8	13	8	0	11
Authorities	12	13	8	5	10
Consumers	5	7	4	2	7

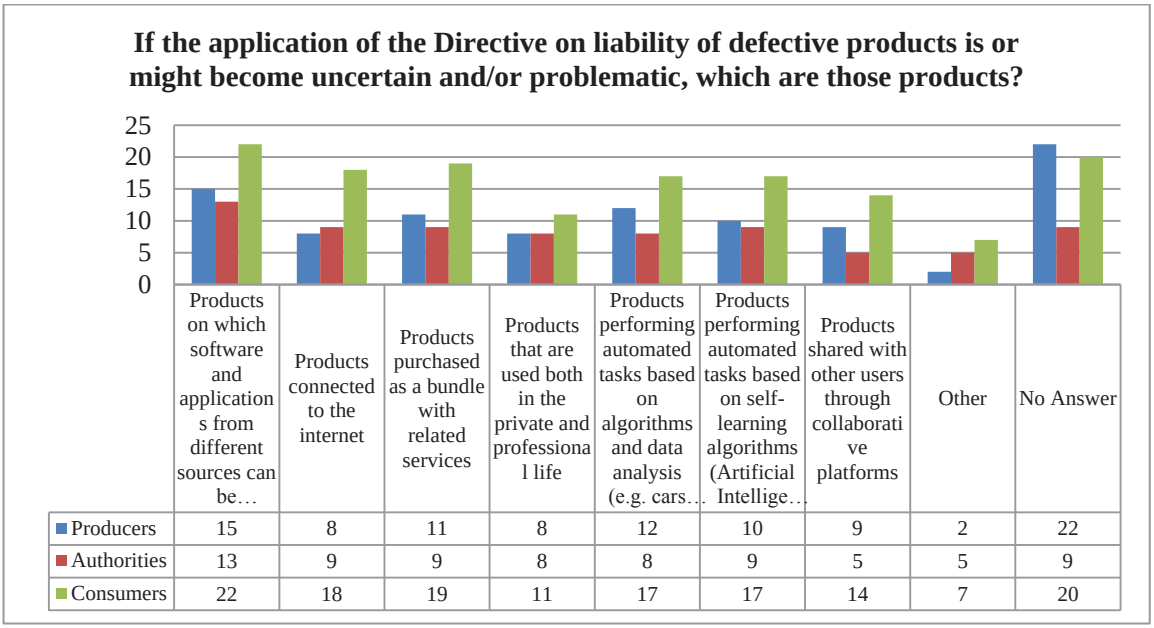
Source: Open public consultation

However, 45% of producers, 58% of consumers and 44% of the other respondents (including public authorities and civil society) consider that for some products (e.g. products where software and applications from different sources can be installed after purchase, products performing automated tasks based on algorithms, data analytics, self-learning algorithms or products purchased as a bundle with related services) the application of the Directive might be problematic or uncertain in particular due to their complexity and degree of automation.



	Yes, to a significant extent	Yes, to a moderate extent	No	Not at all	I do not know
Producers	5	13	9	1	12
Authorities	5	11	5	0	4
Consumers	17	11	8	4	8

Source: Open public consultation



	Products on which software and applications from different sources can be…	Products connected to the internet	Products purchased as a bundle with related services	Products that are used both in the private and professional life	Products performing automated tasks based on algorithms and data analysis (e.g. cars…	Products performing automated tasks based on self-learning algorithms (Artificial Intellige…	Products shared with other users through collaborative platforms	Other	No Answer
Producers	15	8	11	8	12	10	9	2	22
Authorities	13	9	9	8	8	9	5	5	9
Consumers	22	18	19	11	17	17	14	7	20

Source: Open public consultation

Feedback from stakeholders shows that a large majority, mostly producers and insurers, believe there is no need to update the Directive vis-à-vis new technological developments. Businesses consider contractual relations to be appropriate to deal with business to business liability questions. For business to consumer relations, they do acknowledge that difficulties may arise in the future, e.g. on 3D Printing or autonomous systems[56]. On the other hand, the majority of consumers believe that the current rules are not fit for new technological developments.

At the Conference on Product Liability, business associations reiterated that complex value chains and automatisation are nothing new and that the Directive is in fact technology-neutral. Only completely autonomous systems, such as self-driving cars might eventually require regulatory changes. They cautioned against premature regulation without concrete evidence of real life problems. It was for example highlighted that in terms of liability effects there is no difference between using a 3D printer to produce product parts or finished products, and using other more traditional machinery or manufacturing methods. Therefore, businesses considered that, at this stage, the directive is fit for purpose and that any changes would be premature as some technologies such as fully autonomous systems are not even marketed yet.

Representatives of insurers agreed that the directive is suitable, but that research on what safety is with regards to emerging digital technologies is needed. Consumer organisations were in favour of a revision of the Directive.

Also, most Member States have expressed caution against precipitated legislative action on several occasions; for instance, during the meeting of the Internal Market Advisory Committee (IMAC) of 23 October 2017 or at the Workshop with the Member States on emerging issues of the data economy of 31 May 2017. Member States indicated that they

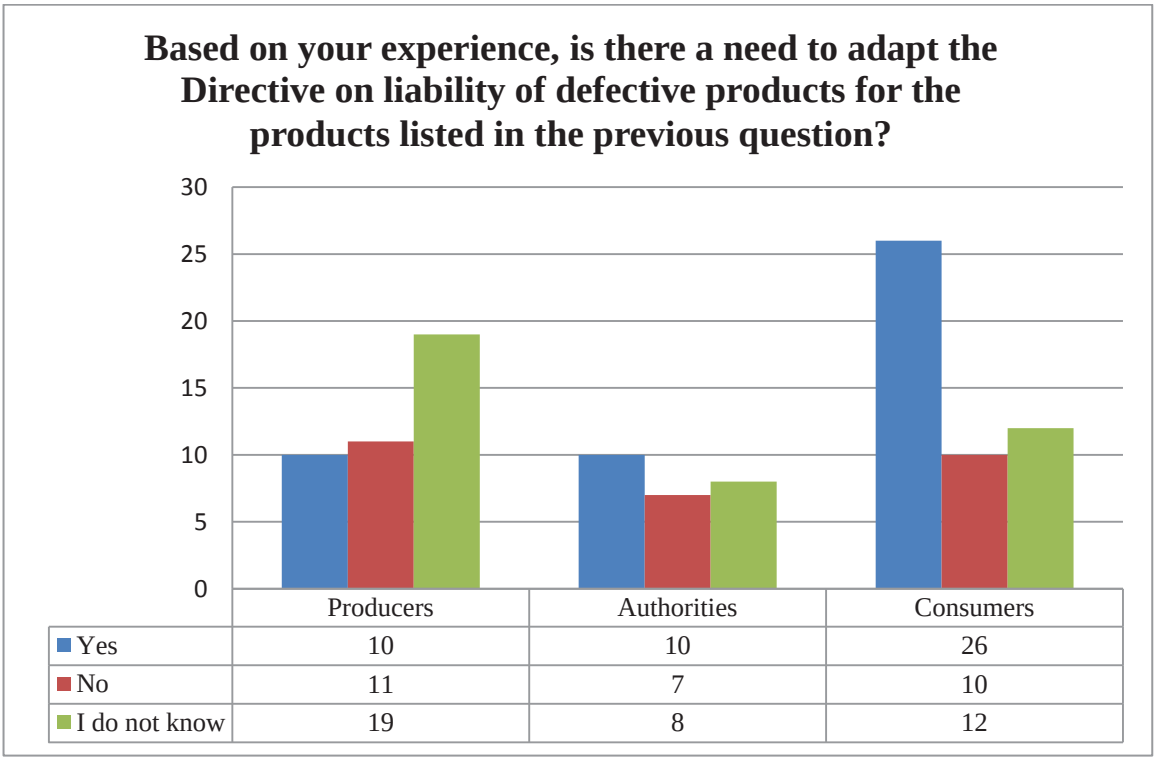
56 As regard autonomous vehicles, see *GEAR 2030 - High Level Group on the Competitiveness and Sustainable Growth of the Automotive Industry in the European Union-Final report* . https://ec.europa.eu/docsroom/documents/26081/

prefer collecting robust evidence of shortcomings before amending the current legal framework.

It appears that there is a need to ensure legal certainty for consumers and producers to support innovative businesses in this area.

The Study on emerging issues identifies a set of several main specificities of new technologies that challenge the product liability framework. These refer notably to changing complexities over the lifetime of a product that are no longer controlled by the producer (this can be autonomous, self-learning behaviour or added software applications). These technologies can also become increasingly intangible.

For the Directive, this raises mostly questions in terms of whether its current concepts are still relevant to grapple these types of situations.



	Producers	Authorities	Consumers
Yes	10	10	26
No	11	7	10
I do not know	19	8	12

Source: Open public consultation

In summary, due to the lack of concrete cases and experience with damages caused by new technological developments, the Directive's effectiveness remains a highly contested subject. Any assessment has to be purely abstract and further evidence gathering and reflection would be necessary to arrive at a sound conclusion on the Directive's (in)effectiveness in this respect.

5.1.4. Main drivers to the objectives achieved

EQ Which are the elements that have contributed to meeting the Directive's objectives?

The main drivers to the effectiveness of the Directive are related to the level of uniformity in its implementation, its role as "safety net" within a broader legislative

framework to protect consumers, the level of generality of some provisions that allow for flexibility and wide coverage, and the high level of awareness of stakeholders.

Firstly, the principle of strict liability on the producer in case of damages caused by a defective product is applied in all Member States with a reasonable uniformity in its implementation. Also the number of cases in comparison to the population of each Member State does not vary so much that one might suspect that in some Member States there are interpretations materially more favourable to the injured persons than in others

Secondly, the Directive is fully integrated into the wider EU legislative framework. Even if the number of case law examples identified in the European Union from 2000 to 2016 can be seen as low, these data need to be interpreted in light of the fact that the Directive acts as a "safety net" in the framework of European legislation. Indeed, there are several layers of protection which coexist and contribute to reducing the need to invoke the Directive: first, the safety legislation, both general and sectorial, guaranteeing the marketing of safe products in the internal market; second, the system of market surveillance; third, the contractual obligations and the guarantee available to the consumer.

In addition, the Directive does not exclude any other compensation claim based on contractual or other extra-contractual liability.

Thirdly, some provisions of the Directive are general enough to cover a wide variety of situations:

- Stakeholders' awareness of the right to seek compensation for damage caused by a defective product increases the Directive's effectiveness.
- The Directive does not provide indications on the systems to settle claims. Consumers are free to choose the most effective system (either direct negotiation with the person or entity held liable, alternative dispute resolution methods such as mediation and arbitration, or litigation in court. This is one of the strengths of the Directive, allowing for adaptation to national contexts (including their judicial systems) and specific circumstances.
- The concepts of product and defect cover a vast range of sectors and situations. The case law shows that almost any kind of movable can be the subject of product liability. All in all, evidence suggests there are no difficulties in interpreting what a product is, even though this may become less evident if there are services that affect the functioning of the product with resulting damage. In addition, a clarification of the concepts of damage, in particular of economic damages, and defect may nevertheless render the Directive more effective in practice.
- The methods for compensation are not defined in the Directive; producers are free to use the most useful way of covering their liability. In fact, most producers have a general insurance contract covering different risks, including the cost of compensation in case of defective products.

5.1.5. Conclusion on effectiveness

The Product Liability Directive appears overall to have met its objectives of guaranteeing the producer's liability for damages caused by a defective product, and, in turn, the protection of consumers, while ensuring an effectively operating internal market for goods. Overall, the Directive has reached a reasonable uniformity in its implementation and the set of its rules makes it effective.

However, certain concepts of the Directive, would benefit from clarification to ensure legal certainty. This relates, as highlighted above, to the concept of product in the context of new technological developments with regards to the increasing overlap between products and services as well as with regards to software, the concept of damage or the concept of defect in particular in relation to complex products such as pharmaceuticals. In addition, with regard to emerging digital technologies further evidence is necessary.

5.2. Efficiency

EQ. What are the regulatory (including administrative) costs for relevant stakeholders stemming from the Directive and how do they compare to the benefits?

As pointed out, the data collected for the purpose of the evaluation should not be regarded as complete. This section is therefore rather based on qualitative than quantitative analysis[57].

5.2.1. Analysis of costs

The relevant stakeholder groups affected by the Directive and its related obligations are producers, consumers, and Member States authorities.

The main costs entailed by the Directive are mapped in table below, explained more in detail in the following paragraphs.

Table 2: Mapping of costs due to the Directive

Types of cost	Provision	Stakeholder affected
Enforcement costs (e.g. court fees, lawyers' and experts' fees)	Given that the Directive is a private law instrument, it leaves to the parties (and specifically to consumers) the burden to "enforce" its rules, i.e. to raise a claim in case of damage caused by a defective product.	Consumers, producers. Member States affected only in case of in-court settlement
Substantive compliance costs (e.g. the amount of compensation to be paid)	Strict liability of producer (Art. 1)	Producers
	Burden of proof (Art. 4)	Consumers
	Joint liability of producers (Art. 5)	Producers
	EUR 500 threshold (Art. 9)	Consumers
	three-year limitation period (Art. 10)	Consumers

[57] To help to a better comprehension, the Study for the evaluation presents the costs related to three cases three cases studies.

Types of cost	Provision	Stakeholder affected
	10-year limitation period (Art. 11)	Consumers
Administrative burden[58]	Communicate to the Commission the derogation to Art. 7(e) (Art. 15(2))	Member States
Indirect costs[59] (e.g. specific liability insurance, reputational costs)	Not required by any Directive provision	Producers

Source: Study for the Evaluation of the Directive 85/374/EEC

Enforcement costs

The Directive does not provide specific details and procedures on how to settle claims for damages caused by defective products, and most of the settlements occur out of court, with negotiations between the parties. Therefore, the enforcement costs related to the Directive can be of two types, based on whether the claim is settled in court or out-of-court.

If the claim is settled in court, the enforcement costs are comprised of, for instance, lawyers', bailiffs' and experts' fees, court fees, taxes, and all costs related to judicial proceedings. These costs vary considerably across Member States, and depend, among other factors, on the type of litigation, the overall length of the proceeding, the compensation amount, the court and the final decision. For instance, civil proceeding fees can range from less than EUR 200 (e.g. in Belgium, Estonia and Sweden), to over EUR 1,000 (e.g. in Hungary and Slovakia).[60]

By way of example, these costs vary on the basis of the final decision as usually fees are reimbursed (wholly or in part) if the claimant is successful. Enforcement costs of this type primarily weigh on consumers, on producers or on the insurance company (if the producer has a specific insurance), and partly on national budgets, as courts are public institutions and not all court costs may be fully covered by court fees.

In case that the claim is settled out of court, the enforcement costs are related to lawyers' and experts' fees, and may also include mediation or arbitrators' fees. This type of enforcement costs weighs on consumers and producers (or insurance companies).

A general quantification of enforcement costs is not possible due to data limitations and to the fact that they are determined on a case-by-case basis based on specific systems of

58 Administrative burdens are costs borne by businesses, citizens, civil society organisations and public authorities as a result of administrative activities performed to comply with information obligations included in legal rules.

59 These costs are experienced by consumers, government agencies or other stakeholders that are not directly targeted by the Directive.

60 For instance, in a case between a producer and a buyer involving EUR 20,000 worth goods, the majority of Member States present fees between EUR 400 and EUR 800. The calculation of fees depends on several factors, and largely varies across Member States. In Finland, for instance, proceeding fees depend on the stage of the proceedings. Some Member States (e.g. France, Luxembourg or Sweden) may not have fees at the appeal stage; in some countries (e.g. Czech Republic, Poland or Slovak Republic) fees for the appeal are the same as those due for the first degree proceeding. See Study for the evaluation of the Directive.

each Member State jurisdiction. However, these costs (including procedural, court, experts and lawyers' fees) mainly are determined by national praxis and judicial systems – not the Directive.

Substantive compliance costs

The Directive attempts to strike a balance between consumers' and producers' interests. Its costs are a trade-off: the benefit of one is the other's cost. Compliance costs related to the Directive are detailed below per category of stakeholder:

Producers**:**

- *Strict liability* (Article 1): introduces a cost that –if the claim is successful- will be equal to the amount of compensation to be paid. This cost is case-dependent.

Consumers:

- The *burden of proof (*Article *4):* This provision is the stepping stone to compensation for damage but also appears to be the most burdensome to consumers. The costs related to the burden of proof varies from sector to sector. Particular difficulties were highlighted for pharmaceuticals. One of the major problems appears to be related to the demonstration of the link between the damage and the defect[61];
- The EUR 500 threshold (Article 9) represents a cost for consumers (and a benefit for the producer) inasmuch as it prevents any claims (and related possible compensation) under EUR 500 from being raised, which is often the case.
- The three-year limitation period (Article 10) for the recovery of damages entails a cost for consumers (and a potential benefit for the producer) in terms of missed compensation.
- The 10-year limitation period (Article 11) to make a claim from the date on which the producer put into circulation the product which caused the damage potentially entails a cost in terms of missed compensation. This provision is particularly costly in the case of damages caused by defective pharmaceutical products that are amongst the products most frequently subject of claims.

Administrative burden

The Directive foresees an information obligation in Article 15(2), requiring Member States to inform the Commission in case they derogate to the development risk clause (i.e. to Article 7(e)). This cost is deemed to be residual. It only requires a simple transmission of information.

The Commission received no comments on the administrative burden related to the implementation of the Directive. Given that the implementation costs of the Directive are residual, one can conclude that there is no simplification potential.

[61] This was recognised by the consumers, public authorities and civil society responding to the open public consultation and to the targeted survey.

Indirect costs

Indirect costs are not introduced by the Directive, but are its direct consequence. These costs affect producers and mainly relate to the payment of insurance premiums related specifically to strict liability.

Responses to the consultation show that these costs are basically unchanged from 2000, also considering sectors characterised by new technological developments. The coverage offered by strict liability insurances varies from one case to another. For instance, in Denmark and France, product liability insurance usually covers damages resulting from the defective product, the costs of the technical analyses made by the expert and the proceeding costs. Therefore, the producer is fully covered and does not need to bear any additional expenses. In Germany, insurance offers seem to be more differentiated and the product liability insurance may, for instance, cover damage compensation until a certain limit, and cover in addition the extra costs (expert, lawyer, proceeding costs) or cover up to a certain limit both damage compensation and proceeding costs.

Reputational costs and Research and Development (R&D) costs are definitely relevant, especially for those manufacturers that produce robotic devices. Indeed, investments in research and development could lead to the creation of products with a certain technological added value, but also with high liability risk. In these cases, producers tend to delay the introduction of the products to the market, up to the moment when the technology is considered safer to avoid potential reputational damages.[62]

5.2.2. Analysis of benefits

The Directive has set the basis for a common rule on strict liability of the producer and for consumers' right to claim compensation for damages due to a defective product.

As it is the case with the costs, the assessment of benefits is based on a qualitative analysis. A summary of the analysis appears in the table below:

Table 2: Mapping of benefits

Types of benefit	Provision	Stakeholder affected
Improved well-being	Strict liability of producer (Art. 1)	Consumers
	Joint liability of producers (Art. 5)	
Market efficiency[63]	Burden of proof (Art. 4)	Producers
	Exemptions (Art. 7)	
	EUR 500 threshold (Art. 9)	
	Three-year limitation period (Art. 10)	
	10-year limitation period (Art. 11)	

62 RoboLaw (2014). Regulating Emerging Robotic Technologies in Europe: Robotics facing Law and Ethics - Collaborative project (CP), FP7-SiS-Challenge 1-3: Regulating emerging scientific and technological developments.

63 This might include improved allocation of resources, removal of regulatory or market failures or cost savings generated by new initiatives/regulation.

Types of benefit	Provision	Stakeholder affected
Increased harmonisation[64]	Compliance with the Directive (Art. 19) and harmonisation through the cases of the CJEU	Consumers; Producers, including suppliers and importers.

Source: Study for the evaluation of Directive 85/374/EEC

Consumer's improved well-being

The strict liability of producer represents a clear benefit for injured parties. Since 1985, consumers enjoy the right to obtain compensation for damage caused by a defective product directly from its producer. Consumers' claims have been successful in 60% of the cases examined in the context of the Study for the evaluation. Therefore, the Directive has increased consumer protection.

This has been confirmed by the results of the public consultation, since stakeholders strongly agree that consumers can enjoy the same rights in terms of compensation wherever they are in the European Union.

Market efficiency

With the aim to ensure an effective internal market, the Directive provisions entailing benefits for producers are those related to the existence of burden of proof, the 500 EUR threshold and the three- and 10-year limitation period, as these provisions limit the possibility for consumers to claim for compensation. More in particular, the 500 EUR threshold limits the number of claims that can be raised against producers.

In addition, the exemptions provided in Article 7 are beneficial to producers as they limit the producer's liability in certain cases, even if a defective product has caused damage. It is up to the producer to demonstrate that he is not liable due to one of these exemptions. Five member States have derogated from the development risk clause thus potentially disadvantaging producers in these countries – even though there was no significant data to confirm this argument.

The benefits related to these provisions translate into the development of a clear and stable legal framework, confirmed by the results of the open public consultation. Stakeholders strongly agree that the level playing field created by the Directive is a benefit.

Increased harmonisation

The increased harmonisation stemming from the Directive is a benefit that most stakeholders consulted perceived. Indeed, the large majority of the respondents to the open public consultation believe that the fact that consumers can enjoy the same rights in

64 This refers to the creation of a level-playing field for producers and consumers, guaranteeing at EU level the liability of the producer in all Member States, and ensuring an increased homogeneity of procedures.

terms of compensation is a strong advantage, together with the fact that Member States cannot implement different product liability rules than those already covered by the Directive for national producers and that would lead to different levels of protection.

5.2.3. Balance and distribution between costs and benefits

EQ. Are the benefits achieved at reasonable cost for consumers and producers (with focus on SME)?

The relevant costs for consumers are equal to enforcement costs as well as the costs they bear for the financial threshold, time limitations and exceptions. This includes i.e. all requirements weighting on consumers to prove the rightfulness of the claim and to the cost relating to the damage suffered, which can be high if the claim is settled in court, and which can be a substantial obstacle when the claimant must anticipate them.

The costs for producers are mainly indirect costs related to insurance, and enforcement costs related to the settlement of claims (when consumers are successful). Overall, few producers choose to pay for specific strict liability insurance directly related to the Directive, but most of them have an insurance policy covering product liability jointly with other risks and, if they do so, they incorporate this cost in product prices and transfer it on consumers. As for the enforcement costs, they are in principle paid by producers in 60% of the cases as they are paid whenever a consumer claim is successful The cost-benefit ratio for producers remains reasonable also when SMEs are considered. There does not appear to be a specific impact on SMEs.

Thus benefits appear to be achieved at a reasonable cost for producers but – depending on the product in question – costs may be very high or sometimes even prohibitive for consumers.

EQ. Does the Directive strike the right balance between the costs borne by the producers to cover the strict liability and the requirements on the injured party to obtain compensation?

EQ. What factors influenced the efficiency of reaching the achievements which the Directive sets out?

Some products require a more complicated and costly assessment procedure, in terms of complexity of the procedure itself, whereas other products require less onerous systems of assessment.

The costs for producers are mainly the costs originating from claims and costs of insurance. For consumers, however, most of the costs are related to the burden of proof. The benefits that were shown for both parties were efficiency and legal certainty for producers, and compensation for damage for consumers. However, some concerns remain regarding fairness in this balance for consumers, especially in view of the higher cost of substantiating proof of a defect and its link with the damage in more complex products such as pharmaceutical.

Given that costs are to a very large extent related to procedures not covered by the Directive, arguments have been put forward that this should be addressed outside the scope of the Directive.

The positive or negative assessment on efficiency with respect to the provisions of the Directive depends on the category of stakeholders concerned, producer or consumer. In fact, the provisions which are considered more efficient for producers are they considered

more inefficient for consumers, and vice versa. This therefore also requires a political assessment in terms of balancing the original objectives of the Directive.

5.2.4. Conclusion on efficiency

According to the qualitative assessment, the Directive in principle has managed to strike a balance between the costs and benefits borne by producers and consumers. However, the balance between costs and benefits relating to the Directive appears to be appropriate for producers but it is not uniform across Member States and sectors or product types for consumers. There are also other factors that could play a significant role in determining the efficiency of the Directive, such as the costs and duration of judicial procedures, which vary substantially from one Member State to another and have a more direct effect on consumers. They represent the most important administrative burden. However, as these are not due to burdens that the Directive itself imposes no specific simplification potential was identified in this respect.

5.3. Coherence

EQ To what extent is the intervention consistent and coherent with the EU rules on consumer protection in the area of contractual liability?

EQ To what extent is the Directive coherent with wider EU policy, such as the free movement of goods and/or the protection of the consumers, including EU product safety legislation?

Several pieces of legislation have been identified and analysed to assess the coherence of the Directive with EU policies and rules[65]:

1. Safety sectorial legislation and the General Product Safety Directive (the "GPSD");
2. Rules on consumer protection in the area of contractual liability, and, in particular:
   - The Directive on Consumer Rights (the "DCR");[66]
   - The Sales and Guarantee Directive (the "SGD");[67]
3. Rules on applicable law, litigation and Alternative Dispute Regulation:
   - The Rome II regulation;[68]
   - The Brussels IA regulation;[69]
   - The Directive on consumer ADR.[70]

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65 The Study for the evaluation of the Directive 85/374/EEC analyses also the proposal for a directive on contracts for the supply of digital content and the proposal for a directive on contracts for the online and other distance sales of goods (COM(2015) 634 final)

66 Directive 2011/83/EU of the European Parliament And Of The Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council.

67 Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees.

68 Regulation (EC) no 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations.

69 Regulation (EU) no 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.

5.3.1. Product safety legislation

European Union product safety legislation aims at ensuring that only safe products can be placed on the internal market. Manufacturers (producers) are responsible for the safety of their product.

All products placed on the market in the internal market are subject to safety rules, set under either:

- EU harmonisation safety legislation, which that sets EU wide essential health and safety requirements (EHSR) that the products in question need to meet. , The vast majority of products marketed in the EU are covered either partly or fully by EU harmonisation safety legislation.
- The *General Product Safety Directive* (GPSD), that establishes a general obligation upon manufacturers to ensure that consumer products, which do not fall within the scope of sectorial legislation covering safety aspects, are manufactured in compliance with the general safety requirements provided therein. The GPSD has a safety net role for products and risks not covered by the harmonisation legislation.

When the product is placed on the market or brought into use for the first time, designers and manufacturers must meet all essential requirements relevant to the specific product based on the state of the art.

Then, within the market surveillance system, relevant national authorities check whether products meet the requirements of the applicable safety legislation and take necessary steps to make sure that products are compliant. Producers and distributors have also legal obligations once the product is placed on the market; for instance, according to Articles 5.3 and 8 of the GPSD, if they become aware that a product that they have placed on the market poses risks to the consumer, they shall immediately inform the competent authorities and take all the necessary measures up to the product recall if needed.

5.3.1.1. Sectorial safety legislation

Specific rules exist for example for the safety of toys, electrical and electronic goods, cosmetics, chemicals, medical devices, food and feed, and other specific product groups, as machines or pharmaceutical products.

Providing just a few examples, it is important to consider:

- Directive 2014/35/EU on *low voltage electrical equipment*[71] (hereinafter also "Low Voltage Directive" or "LVD"), which ensures that electrical equipment within certain voltage limits provides a high level of protection for European citizens. Electrical equipment under the LVD covers a wide range of consumer and professional products e.g. household appliances, cables, power supply units, laser equipment and some components such as fuses

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[70] Directive 2013/11/EU of the European Parliament and of the Council of 21 May 2013 on alternative dispute resolution for consumer disputes and amending Regulation (EC) No 2006/2004 and Directive 2009/22/EC.

[71] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits. Source: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0035&from=EN

- *Directive 2014/53/EU on radio equipment*[72] (hereinafter also "Radio Equipment Directive" or "RED") which ensures a Single Market for radio equipment by setting essential requirements for safety and health, electromagnetic compatibility, and the efficient use of the radio spectrum and applies to all products using the radio frequency spectrum, this includes embedded software.

- *Regulation (EU) 2017/745 on medical devices and the Regulation (EU) 2017/746 on in vitro diagnostic medical device*[73]*s* establish a modernised and more robust EU legislative framework to ensure better protection of public health and patient safety. Moreover both the two regulations state that software is considered, under the provisions of the regulation, as a product. Further, the Regulations on medical devices provide that the liability they set forth is without prejudice to the Product Liability Directive.

- *Regulation (EC) No 178/2002 on general food law*[74] (the GFL Regulation) sets outs an overarching and coherent framework for the development of food law (including feed) both at Union and national levels. To this end, it lays down general principles, requirements and procedures that underpin decision making in relation to food and feed, covering all stages of food and feed production and distribution. These principles, requirements and procedures are further incorporated in other Union legislative acts covering the food chain. Amongst others, the GFL Regulation sets out the primary responsibility of food and feed business operators (FBOs): they must (a) ensure compliance with all EU and national food law that is relevant to their activities and within the businesses under their control and (b) perform their own controls. Furthermore, food placed on the market must be safe, *i.e.* food must not be potentially injurious to health or unfit for human consumption (food safety requirement). Similarly, feed placed on the market must be safe (feed safety requirement). Where FBOs consider or suspect that food or feed is not safe, they must withdraw or recall such products and notify the competent authorities under certain conditions. All FBOs must be able to identify from whom and to whom a product has been supplied ('one step back – one step forward' traceability for safety purposes) and to have systems and procedures in place that allow for this information to be made available to the competent authorities upon request. Feed and food imported into the Union must comply with all requirements of Union food law. National competent authorities are responsible for enforcing food law, verifying that food and feed placed on the EU market are safe and applying effective, proportionate and dissuasive measures and penalties where a violation of food law is detected. As stated in Article 21 of the GFL Regulation, the application

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72 Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC. Source: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0053&from=EN

73 Regulation (EU) 2017/745 on medical devices of the European Parliament and of the Council of 5 April 2017 on medical devices , , amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC http://eur-lex.europa.eu/legal-content/ENG/TXT/PDF/?uri=CELEX:32017R0745&from=EN
Regulation (EU) 2017/746 on of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU Source: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC

74 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, Source: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1518796393897&uri=CELEX:32002R0178.

of the general principles and requirements underpinning Union food law are without prejudice to the Product Liability Directive.

- *Directive (EC) 2006/42*[75] *on machinery* covers a wide range of machines and equipment for consumers and commercial or industrial purposes, it is also the relevant safety legislation for robots. This Directive ensures a high level of health and safety for consumers, users and other exposed persons as regards the products in its scope, placed on the market.
- *Directive (EC) 2001/83/EC*[76] *on pharmaceutical products* sets standards to ensure a high level of public health protection and the quality, safety and efficacy of authorized medicines. In addition, it promotes the functioning of the internal market, with measures to encourage innovation. It is based on the principle that a medicinal product requires a marketing authorisation by the competent authorities before being placed on the market.

The mentioned pieces of legislation do not contain specific provisions on the liability of the concerned products, but expressly refer in the text to the application of the Product Liability Directive in case of damages caused by a defective product.

However, as it was noted already in 2011, some stakeholders, as e.g. the European Federation of Pharmaceutical Industries and Associations, have indicated on several occasions that pharmaceuticals products should be outside of the scope of the Directive and should have a specific liability regime[77].

5.3.1.2. General Product Safety Directive (GPSD)

The GPSD aims to ensure that only safe consumer products are placed on the market. A product is safe when under normal or reasonably foreseeable conditions of use, including duration and, where applicable, putting into service, installation and maintenance requirements, it does not present any risks or only the minimum risks compatible with the product use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account particular aspects such as the (i) characteristics of the product, (ii) the effect on other products, (iii) the presentation of the product, (iv) the categories of consumers at risk when using the product. The GPSD applies in the absence of other European Union laws relating to product safety, complementing sector specific legislation. The GPSD establishes obligations for both the producers and distributors, and Member States authorities.

Producers must only place products on the market which are safe and inform consumers of any risks associated with these products. They also have to make sure any dangerous products presented on the market can be traced[78] so they can be removed to avoid any

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75 Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast. Source: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006L0042

76 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Source: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02001L0083-20121116&qid=1472567249742&from=EN

77 See, for instance, Fourth report on the application of the Council Directive on the approximation of laws, regulations and administrative provisions of Member States concerning liability for defective products (already mentioned), . p.8.

78 By establishing notification obligations on producers and distributors concerning information on products that do not comply with the general safety requirements to the competent authorities, the

risks to consumers. Distributors are required to act with due care to help ensure compliance with the applicable safety requirements, they shall participate in the monitoring of the safety of the products and cooperate with the producers and competent authorities.

The GPSD states that its provisions should not affect victims' rights within the meaning of the Directive (which remains an autonomous legal regime).

The Directive and the GPSD are therefore coherent.

The concept of defectiveness *"lack of the safety which a person is entitled to expect"* provided by the Directive includes the expectation that the products placed on the market do not present risks for the physical safety and health of persons, according to the GPSD.

At the Product Liability Conference held in Brussels, stakeholders' representatives of producers and civil society were of the opinion that the Product Liability Directive is consistent with product safety legislation, and is an integral part of it. However, other stakeholders, mostly consumers and victims of drugs, claimed that one of the inconsistencies is that while pharmaceuticals are covered by the Product Liability Directive, they are not covered by the General Product Safety regime (in particular the definition of "safe product") but by a specific safety regime, and this should be adjusted by defining a specific liability regime for pharmaceuticals. This would imply that pharmaceuticals should be removed from the scope of the Directive.

To clarify, it should be noted that General Product Safety Directive is called works as a 'lex generalis', while more specific regimes, like for example pharmaceuticals, but also pesticides, chemicals, medical devices work as 'lex specialis' etc…, where the safety assessment is part of a process that is undertaken prior to the product being placed on the market due to the inherent and specific risks of the product. In addition, it should be considered that if certain deficiencies with regard to the application of the Directive to certain product categories are detected, this may need to be taken into account in future revisions of the rules.

5.3.2. Rules on consumer protection in the area of contractual liability

The *Directive on Consumer Rights (DCR)*[79] establishes rules on information to be provided for distance contracts, off-premises contracts, as well as other types of contracts. It also regulates the right of withdrawal for distance and off-premises contracts and harmonises certain provisions dealing with the performance and some other aspects of business-to-consumer contracts. Based on the DCR, both consumers and traders can rely on a single regulatory framework clearly defining legal concepts that would avoid disparities that create significant internal market barriers. The analysis identified some minor lexical divergences, for instance the definition of "goods" – though not affecting the overall implementation of the Directive – between the DCR and the Product Liability Directive. In fact, it appears that these lexical divergences are due to the different scopes

GPSD aims at having the risks notified as soon as possible in order to avoid damages caused to consumers by dangerous products.

79 Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council. Source: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0083&rid=1

of the two directives and there is no evidence that they affect the effectiveness or efficiency of the Directive.

The *Sales and Guarantee Directive (SGD)*[80] provides for a common set of minimum rules of consumer law, to strengthen consumers' confidence and to reduce difficulties encountered by consumers in relation to product non-conformity with the contract. The Product Liability Directive and the SGD do not overlap, they concur to the protection of consumers by regulating different fields.

In the context of the Digital Single Market Strategy, two proposals have been presented by the Commission for the adoption by the legislators: the proposal for a Directive on certain aspects concerning contracts for the supply of digital content[81] and the amended proposal for a Directive on certain aspects concerning contracts for the sales of goods[82]. These proposals aim to contribute to fostering growth through the creation of a true Digital Single Market, to the benefit of both consumers and businesses, by eliminating the key contract law-related barriers hindering cross-border trade.

In the light of the above analysis, there are no relevant incoherencies between the Directive and the EU pieces of legislation considered. The Directive appears as being a coherent complementary tool to ensure consumer protection.

5.3.3. Rules on applicable law and disputes resolution

The *Rome II Regulation*[83] sets forth the conflict-of-law rule in matters of product liability (Article 5) by means of a cascade system, where the first element to be taken into account is the law of the country in which the person sustaining the damage had his or her habitual residence when the damage occurred, if the product was marketed in that country; the other elements are triggered if the product was not marketed in that country and, in essence, make the law applicable to the claim depend on the place where the product was marketed. However, this does not preclude (a) that, where both the person claimed to be liable and the person sustaining damage have their habitual residence in the same country at the time when the damage occurs, the law of that country shall apply and (b) the possibility of a manifestly closer connection to another country.

The Directive and the Regulation appear synergic in allowing protection of consumer based on the possibility for the same consumer to predict the law applicable to the possible damage affecting him (first, the law of his place of residence), while striking a balance with the defendant's needs by taking into account where the product was marketed.

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80 Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees. Source: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31999L0044

81 Proposal for a Directive of the European Parliament and of the Council on certain aspects concerning contracts for the supply of digital content (COM(2015) 634 final).

82 Proposal for a Directive of the European Parliament and of the Council on certain aspects concerning contracts for the supply of digital content (Brussels, 9.12.2015 COM(2015) 634 final 2015/0287 (COD) and . Proposal for a Directive of the European Parliament and of the Council on certain aspects concerning contracts for the online and other distance sales of goods. Source: http://ec.europa.eu/justice/contract/files/directive_-digital_content.pdf

83 Regulation (EC) no 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations. Source: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:199:0040:0049:EN:PDF

The *Brussels IA Regulation* [84]aims to set clear rules on jurisdiction in civil and commercial matters. The CJEU recently clarified that claims under the Directive were subject to Article 5 (3) of Brussels I Regulation (CJEU Case C-45/13), which provided that a person domiciled in a Member State may, in another Member State, be sued in matters relating to tort, delict or quasi-delict, in the courts for the place where the harmful event occurred or may occur, just like Article 7(2) of the Brussels IA Regulation does. Further, the CJEU also stated that, where a manufacturer faces a claim of liability for a defective product, the place of the event giving rise to the damage is the place where the product in question was manufactured (CJEU Case C-45/13).

In contrast, the *Directive on alternative dispute resolution for consumer disputes (ADR)*[85] is limited to the resolution of contractual disputes and does not cover the disputes that can arise from damages from defective products according to the Directive. Indeed, there are currently no EU rules in place for the alternative resolution of claims related to the Directive. Given that their scopes are mutually exclusive, the two directives are deemed to be coherent. No comments have been received from stakeholders on this.

5.3.4. Conclusion on coherence

The Directive appears fully coherent both with the product safety legislation and with EU rules on consumer protection in the area of product safety, with the rules on consumer protection in the area of contractual liability and with those related to the conflict-of-law.

Overall, the analysis carried out confirmed that there does not seem to be any contradiction between the Product Liability Directive and the European Union safety legislation with the EU consumer protection rules nor with the rules on applicable law in cases of disputes.

However, the digitalisation of the economy will require legislative changes: safety legislation such as the Machinery Directive[86] has been evaluated, and for the Radio Equipment Directive possible action is considered. An assessment of the continued coherence of the Directive with these pieces of legislation will therefore remain necessary.

5.4. Relevance

5.4.1. Relevance of the Directive to current needs, including needs related to new technological developments

EQ To what extent do the initial objectives correspond to the current needs, including new needs created by innovative products?

The Directive was adopted in order to respond to the following needs:

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84 Regulation (EU) no 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters. Source: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:351:0001:0032:en:PDF

85 Directive 2013/11/EU of the European Parliament and of the Council of 21 May 2013 on alternative dispute resolution for consumer disputes and amending Regulation (EC) No 2006/2004 and Directive 2009/22/EC. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:165:0063:0079:EN:PDF

86 SWD Evaluation of the Machinery Directive (SWD(2018)160).

- Ensure a high degree of consumer protection against damages to health and property caused by a defective product;
- Ensure producers' liability for damages caused by a defective product;
- Enhance the free movement of products without distorting competition by setting a common rule on strict liability of the producer.

The original needs of to ensuring ensure producers' liability, consumer protection and undistorted competition remain relevant. The Directive was the first EU instrument on producer liability. The real challenge was to maximise its positive effects for consumers by ensuring the best compensation of victims, while keeping costs reasonable. As the number of claims across the EU have shown, the Directive continues to be invoked by consumers when claiming compensation for damages caused by defective products. The numbers have been relatively stable over the evaluation period of 2000-2016.

But while the needs remain the same, it is important to ask whether the tools provided by the Directive continue to be relevant and future-proof.

In a similar vein, the European Parliament has noted that it could be necessary to adapt the Directive to the challenges brought by the new digital context[87].

In the public consultation, 50% of consumers and producers do not consider the current situation to be problematic, while numbers increase when it comes to future developments. Then respondents note that there are products for which the application of the Directive is or might become uncertain and/or problematic. These products mainly come under the definition of emerging digital technologies. As a consequence, 62% of respondents considered the Directive should be adapted.

Based on the public consultation, it appears that the perception of the new technological developments depends on the category of stakeholders. The majority of producers and insurers consider that the Directive is still adequate to cover new technological developments, especially those which are already fully rolled out in the market. Consumers, on the other hand, tend to prefer a revision of the Directive[88]. The same opinions were manifested in the context of the activities launched for the "Building a European Data Economy".

The Study for the evaluation states that on the one hand, the majority of desk-research sources seem favourable to a revision of the Directive to clarify to which extent the Directive is applicable to the different new technological developments and whether the strict liability rule applies to all kinds of software. On the other hand, other authors consider it reasonable to resolve the issue created by new technological developments by means of interpretation of the courts only, waiting for the future evolution of the new technologies.

Given the lack of evidence for either approach, further analysis and fact finding appear to be advisable.

5.4.2. Relevance of specific provisions of the Directive

87 See European Parliament Resolution of 16 February 2017 on Civil Law Rules on Robotics, already mentioned.

88 See Synopsis report for the evaluation of the Directive 85/374/EEC, Annex 2 of this document

EQ How well adapted is the intervention to the changing market environment: often blurred distinction between private and professional use and the servitisation of products where products and services are often sold and consumed together?

5.4.1.1. Distinction between products and services

The Directive does not make any reference to the concept of service nor does it provide for the distinction between products and services. It solely provides for the definition of product, according to Article 2.

The notion of product mainly refers to movables even though incorporated into another movable or into an immovable. Since 1999, "primary agricultural products" (products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing) are under the scope of the Directive. Services do not fall into the definition of product.

However, the distinction between product and service is becoming increasingly blurred with regards to new technological developments.

The Study reports that, overall, 18 Member States[89] do not have any forms of extra-contractual liability in place to protect consumers from damages caused specifically by defects of either intangibles (e.g. software), or services. On the contrary, nine Member States[90] ensure an extra-contractual liability to protect consumers from damages caused by defects both of intangibles (e.g. software) and services. A distinction can be made between these Member States. In two Member States[91], the rules set forth in the Directive are stretched to ensure strict liability for services and intangibles too.

The Study also notes that there is no common doctrinal opinion on a number of these issues, for example on software. For some authors software most often takes the form of a movable item and can be considered a 'product' from the perspective of consumers and business users. For others, software is more similar to a service.

At European Union level, the CJEU has for some specific cases contributed to the classification of software, which for instance is to be considered a medical device (i.e. a product) when intended by the manufacturer to be used specifically for one or more of the medical purposes set out in the definition of 'medical devices'.[92] In addition, the Radio Equipment Directive, the Regulations on medical devices and on in vitro diagnostic[93], may include software.[94]

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89 Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Spain, Croatia, Hungary, Ireland, Italy, Latvia, Luxembourg, Poland, Portugal, Romania, Sweden and United Kingdom. Information not available for FI.

90 Germany, Estonia, Greece, France, Lithuania, Malta, Netherlands, Slovenia and Slovak Republic. In some of them (Germany, Estonia, Malta, Netherlands, Slovenia and Slovak Republic) the protection of consumers from damages caused by defects of either intangibles or services stems from *general rules, normally tort law*: in these cases, protection essentially stems from the interpretation of general rules to include services or intangibles

91 Greece and Lithuania.

92 *CJEU Case C-219/11*. This requires a case-by-case analysis, as demonstrated also in pending judgment (CJEU Case C-329/16) in which the Court has to determine whether a certain type of software should be considered a medical device where that software has at least one function that permits the use of data specific to a patient to help his doctor issue a prescription.

93 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and (ii)

Finally, for products purchased as a bundle with related services, the service part is only considered a part of the product in some Member States. This possibly creates different levels of consumer protection and of producers' liability across the internal market[95].

These views are shared by stakeholders participating in the consultation. They believe that it is sometimes difficult to distinguish a product from a service, since they can be bundled together, and that it is even more burdensome to distinguish a product from a service when they are bundled together in the context of new technological developments, especially when dealing with cloud technologies and IoT.

Today, embedded software or other specific technical features are already an integral component of many products. In terms of EU product safety legislation, the producer is responsible for the safety of the final product as a whole. Therefore, for products which include software at the moment they were put into circulation by the producer, the Directive could address liability claims for damages caused by defects in this software. The more open nature of new products, where the producer is no longer able to control software or other technical features subsequently installed in or learned by the product may however pose a challenge for establishing claims under the Directive.

With specific reference to new technological developments, the majority of producers of IoT/robotics devices responding to the open public consultation on Building a European data economy answered that they have never experienced problems so far in not knowing in which category (product/service) to classify the device in order to comply with a specific liability regime.

During the Product Liability Conference, held in Brussels, some stakeholders said that the distinction between the definitions of products and services has become obsolete. They pointed out that it should be clarified whether hardware and software are products and are cover under the Directive, as these definitions might become problematic as technology develops. Some insurers nevertheless insisted that marketed robots are finished products and fall under Product Liability Directive. According to the consumer representatives, it would be necessary to revise the Directive with a view to expressly including new risks.

In conclusion, while there is little evidence of practical problems, the distinction between products and services may in the future no longer be pertinent. Hence, there is a need to clarify what products and features are covered by the Directive.

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

94 Recital 19 of Regulation (EU) 2017/745 states that: "It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device."

95 Products purchased in bundle with services are not considered products in Greece, Italy, Malta, Netherlands and United Kingdom. In Finland and Luxembourg they are considered products.

5.4.1.2. Distinction between private and professional use

The Directive does not expressly refer to the professional use of products. The distinction between professional and private use of products emerges, nonetheless, with regard to the definition of damage to an item of property other than the defective product itself: according to article 9(b) such item of property shall be (i) of a type ordinarily intended for private use or consumption, and (ii) used by the injured person mainly for his own private use or consumption. Hence, only in such cases the damage is subject to compensation.

The majority of participants to the consultation activities for the evaluation agreed that it is sometimes difficult to distinguish between private and professional use of a product.

The Study for the evaluation shows that, in at least 150 cases, the national courts allowed the compensation even if the item of property was subject to professional use[96]. On the contrary, 23 claims were rejected because the injured person did not use the product mainly for his own private use or consumption.

The Directive must be interpreted as not precluding the interpretation of domestic law or the application of settled domestic case-law according to which an injured person can seek compensation for damage to an item of property intended for professional use and employed for that purpose as shows CJEU (*Case C-285/08*).

With regard to damage caused by death or by personal injuries (article 9(a)), the Directive does not limit its application to the private activities: this has been interpreted as meaning that in case of damage caused by death or by personal injuries the compensation shall be allowed regardless of whether the injured person was operating in his private or professional activity.

Therefore, the distinction between private and professional use of products is relevant only with regard to the damage caused to another item of property. Nowadays, the distinction between private and professional use is becoming less evident, especially with regard to smartphones, cloud technologies and connected devices. The continued relevance of this provision is therefore debatable.

5.4.1.3. Relevance of some definitions (product, producer, damage, and category of exemptions) to the new technological developments

EQ. To what extent is there a need to clarify or modify the concept of product, producer, damage or the category of exemptions in the Directive?

Definition of product

The definition of "product" as per article 2 of the Directive is related to the concept of **"**movable". This has been interpreted as meaning that only tangible goods shall be considered products: indeed, at the time in which the Directive has been adopted, no clear examples of non-tangible goods were widespread in the market. However, even today, most of these non-tangible goods are integrated into tangible goods in one form or another.

The main question in relation to new technological developments is how to classify the devices/ products resulting from these technologies. It appears that in this context the services relating to tangible products will become more prominent in the near future and

[96] These cases seem to concentrate in a few countries: Austria, Denmark and France

thus the balance between products and services may shift towards services, and products will increasingly come with the provision of services.

Indeed, the non-tangible nature of some new technological developments (software, applications, Internet of Things, Artificial Intelligence systems) makes it difficult to classify them as products rather than services. Yet, the majority of producers of Internet of Things and robotics devices responding to the public consultation on Building a European Data Economy initiative answered that they have never experienced problems in the qualification of the good as a product or as a service.[97] Other contributions obtained in the context of the consultation raise doubts over the adequacy of the definition of product vis-à-vis new technological developments, as cloud technologies. Some stakeholders raised the need for an interpretation of the concept of product or an enlargement of the concept of product, including, for instance, some new technological developments such as Artificial intelligence or cloud technologies, as well as applications. This is particularly relevant in the context of the Directive where the non-tangible element is not included in the product put into circulation by the producer but installed subsequently as a stand-alone feature.

Definition of producer

The notion of producer provided for in Article 3 reflects the definition of product for the purpose of the Directive.

For robotics, according to the European Parliament's Report[98] "*the concepts of product, producer, damage or the category of exemptions as defined in the Directive […] could not be apt anymore when dealing with the emerging field of robotics: "[…] in the scenario where a robot can take autonomous decisions, the traditional rules will not suffice to activate a robot's liability, since they would not make it possible to identify the party responsible for providing compensation and to require this party to make good the damage it has caused*".

The new technological developments, as the Internet of Things or a 3D Printer, involve different actors in the value chain, which all enable the technology to function (product manufacturers, software producers, the connectivity service, sensor manufacturers, owners of the object, service providers etc.). In addition, some of these technological developments have a very open ecosystem, (e.g. Internet of Things applications), where new features can be added by the user or even third parties to create a new one.

Thus, the question emerges of whether the concept of "producer", as defined in the context of Product Liability Directive fits with the type of responsibilities that may arise in systems encompassing software, Artificial Intelligence systems, data services, etc.

Conversely, one would expect that these technologies would have to correspond to certain requirements which give consumers expected safety levels and a producer putting these products into circulation ensures that they meet these expectations, - also with regards to interaction in a connected world.

In conclusion, the concept of the producer as responsible for his or her products remains relevant. There may be, however, a need to assess the impact of changing product (and/or product/service) configurations on this concept to see whether it should be clarified.

Definition of damage

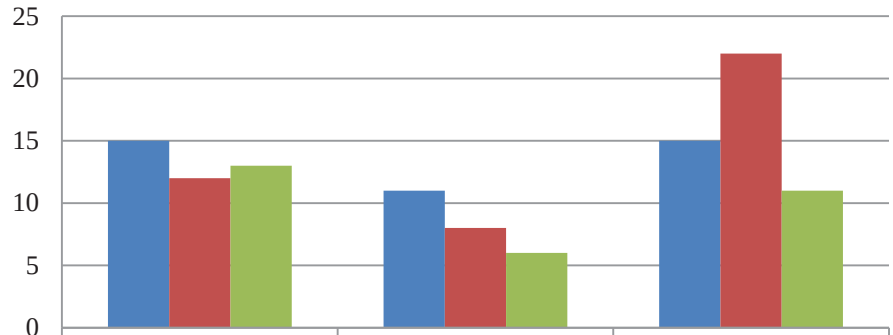
97 See Synopsis report for the evaluation of Directive 85/374/EEC.

98 See European Parliament. Resolution on Civil Law Rules on Robotics, already mentioned.

The notion of damage provided for in the Directive concerns basically two kind of damages: the physical injuries, and the damage to item of properties. The physical damage also covers economic losses, such as incapacity to work. However, financial damage is limited to damages to items of property mainly intended for private use and does not cover pure economic losses, meaning a pecuniary loss not consequential upon injury or damage. This means that e.g. infringements of privacy are cannot be regarded as damages covered by the Directive. The Directive does not foresee the compensation of non-material damage. This is without prejudice to national provisions.

Consumer representatives would like to extend the definition of damage to the non-material damage and to economic losses. The Study concludes that a large number of consumers consider that the definition of damage is not adequately defined in the Directive, because it does not cover all types of possible damages, especially with regard to the damages which can be caused by some new technological developments. Extending the concept of damage to other types of damages (e.g. economic losses, privacy infringements or environmental damage) is a political choice that would have to be studied in detail.

Compensation is granted only for property damage above € 500



	Producers	Authorities	Consumers
Future-proof	15	11	15
Needs to be adapted	12	8	22
No opinion	13	6	11

Source: Open public consultation

Definition of the exemptions from liability

According to the Study the categories of exemptions are overall well accepted by businesses irrespectively of their size. More specifically, the results of the survey shows that on average, 65% of the respondents think that definitions and the category of exceptions are adequate for their business model building upon the new technological developments. This positive result is largely due to the support of medium firms, being 85% of them positively assessing the provisions, 15% of respondents, with a significant share of small firms which consider that these provisions are not adequate.

Similarly, on average, 36% of businesses declared to be satisfied with the three-year period for the recovery of damage. However, this provision seems to cause more concern to small enterprises than to medium and large ones. Indeed 33% of small enterprises are dissatisfied while 31% are satisfied. On the contrary the majority of medium and large firms declare to be satisfied with this prescription period.

With regard to the thresholds, businesses are overall satisfied with the lower threshold of EUR 500 for damage compensation. Nonetheless, this provision is supported more strongly by medium and large firms.

On the other hand, respondents to the consultation believe that particularly the development risk clause and the exemption provided for in Article 7 are not adequate. This is specifically so when dealing with Artificial Intelligence and robotics due to their increasing rate of technological development that can cause difficulties in the interpretation of this clause. Yet, businesses are divided on removing this clause. 43% of large firms are in favour, while 38 % the medium firms think this removal would be disadvantageous. Small firms tend to think that this removal would be neutral (33%) or even disadvantageous (31%). Consumers support removing this clause.

According to the majority of the respondents to the open public consultation related to Building a European Data Economy, there should be a liability cap (i.e. an upper bound to the compensation of damages) independently of whom is considered liable. In particular 20% answered that such cap should exists only for specific products abiding by strict safety standards, 6% answered only for specific products in the experimentation/testing phase, 27% answered for all IoT products. The remaining part of respondents answered that there should not be a liability cap (47%).

At this stage, due to the lack of concrete data on their effect on new technologies and the balance between consumers' and producers' interests it is not possible to conclude whether the list of exemptions provided for in the Directive continues to be relevant to emerging technologies. Their impact needs to be further analysed.

5.4.1.4. The concept of defectiveness

EQ How well is the term 'defective' as defined in the Directive adapted to new technological or scientific advances such as apps and non-embedded software, advanced robots and autonomous/intelligent systems? For example, could software vulnerability (for instance, a cyber-attack or a failure to update security software or a misuse of information) be considered as a defect?

The defectiveness for the purpose of the Product Liability Directive is strictly connected with the concept of product safety. Something caused a damage even though this should not have reasonably happened.

The Directive states that the defectiveness of a product is determined on the basis of the legitimate expectations of the public and thus not be based on the subjective expectations of a consumer. Apart from the minimum safety requirements listed by safety legislation, it may be difficult to determine the specific level of safety that a consumer is entitled to expect. Thus the defectiveness of a product must be assessed on a case-by-case basis. The courts have a wide range of appreciation and can take into account the dynamic aspect of the safety assessment.

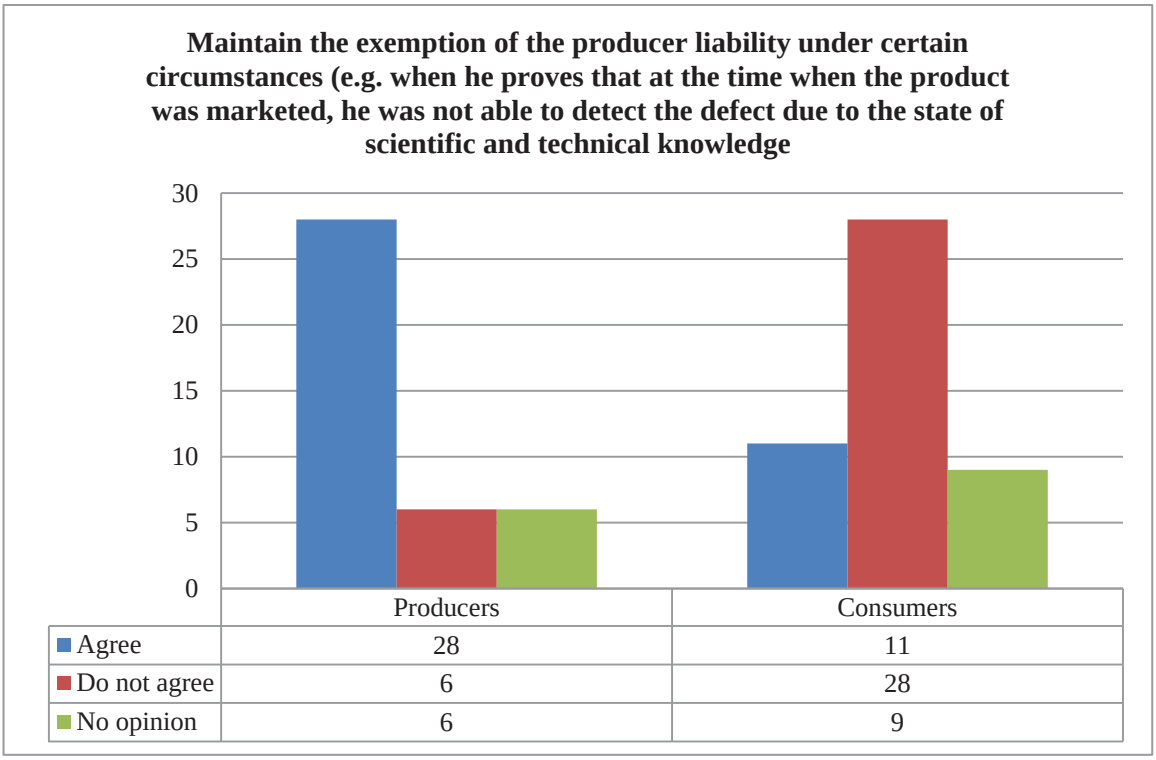
The term "defect" is therefore a relative concept. Thus, in this perspective, despite the maximal harmonisation character of the Directive, there is a risk of divergence between Member States on key issues including the core concept of defectiveness.

Also, in the field of robotics, there is a debate on whether an unintended autonomous behaviour of an advanced robot is a defect or not. Indeed, robots are meant to perform autonomous behaviours, they are programmed to do so. Given their self-learning capacities, one could, in consequence argue that not all unforeseen autonomous

behaviour is a defect. On the other hand, these robots will be employed to perform certain tasks, which will inevitably be linked to safety expectations.

As reflected in the figure below, the majority of respondents to the survey launched in the context of the consultation for the evaluation are rather aligned on the fact that the new technological developments are not adequately covered by the Directive.

Figure 6: Adequacy of the Directive to cover strict liability caused by defect in any of the following new technological developments



	Producers	Consumers
Agree	28	11
Do not agree	6	28
No opinion	6	9

Source: Open public consultation

In this new context, the definition of defect of the Directive may need to be revisited to provide certainty regarding new technological developments. As it is closely linked to the concept of damage, and an extension of damages covered would also require reassessing the notion of defectiveness.

5.4.1.5. Conclusion on relevance

Overall, as regards current states of technological developments and tangible products, the Directive and its broad concepts appear to remain relevant to meeting its original objectives. However, the debate on new technological developments shows that these concepts could be clearer as there currently seems to be a lack of understanding to what extent they apply to emerging technologies.

Due to the lack of empirical evidence, it could not be evaluated how the strict liability was allocated in case of damage caused by a product which is interconnected with other products or services in the IoT, or when the damage comes from the unintended behaviour of an autonomous system or an advanced robot.

5.5. EU Added value

EQ What is the EU added value of the Directive for stakeholders (manufacturers, including software developers and economic operators in the DSM, and consumers)?

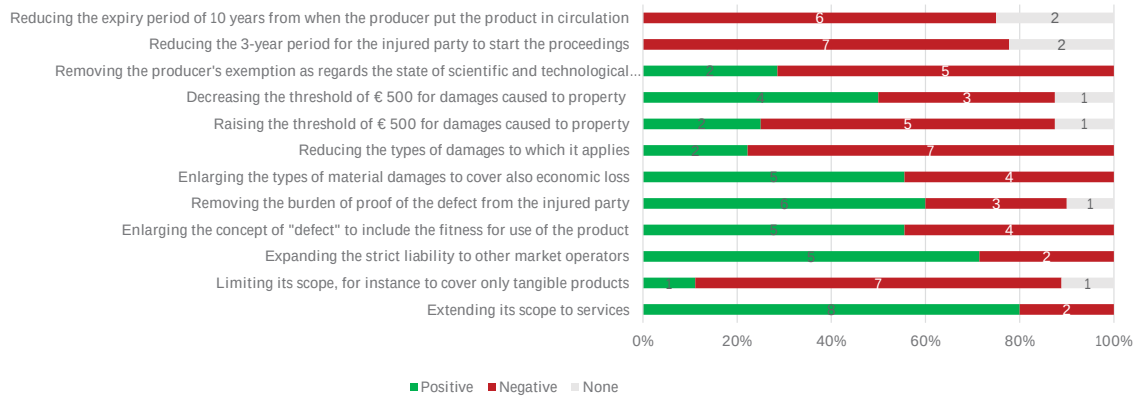
EQ To what extent does the issue of strict liability, as addressed by the Directive continue to require action at EU level?

The EU added value of the Directive is strongly acknowledged in the case of consumer protection: the large majority of stakeholders responding to the open public consultation related to the evaluation consider it to be a strong advantage to have a Directive on liability for defective products, as this allows consumers to enjoy the same rights for compensation wherever they are in the European Union. In their opinion, this could not have been achieved with national legislation only.[99] This is confirmed in the results of the targeted surveys as well as the interviews. Documentary review conducted in the Study also points to the EU added value of the Directive as striking the right balance between consumer protection and innovation in Europe.[100]

As shown by the figure below, stakeholders are generally positive towards extending the scope and provisions of the Directive rather than reducing it; especially regarding (i) the reduction of the threshold of EUR500 for damages caused to property, (ii) the enlargement of the notion of damage as to include the economic loss and the notion of defect as to include fitness for use of the product, (iii) the removal of the burden of proof related to the defect, (iv) the extension of the strict liability to other market operators and (v) the extension of the scope, covering also services.

Consistently, stakeholders negatively perceive a change in the Directive which (i) limits the scope only to tangible product, (ii) reduces the types of damage, (iii) raises the threshold of EUR 500 for damages caused to property and (iv) removes the development risk clause.

Figure 7: What would be the effects of the following modifications of the Directive



Source: Study for the evaluation of the Directive 85/374/EEC

In conclusion, the EU added value of the Directive seems largely recognised for the protection of consumers and the balance between consumer protection and innovation in Europe. There still are, however, some concerns especially among consumers with regard to new technological developments, but they do not question the value of EU level responses.

99 Summary of open public consultation

100 See section 4.5 of the Study.

EQ What would be the most likely consequences of reducing the scope of the existing EU intervention?

Support for reducing the scope of the Directive is rare among the stakeholders. However, as already indicated, some producers of pharmaceutical products and victims of medicines consider that it would be better to exclude pharmaceutical products from the scope of the Directive.

In general, stakeholders consulted for the evaluation either consider the Directive as future proof or call for a revision in order to enlarge its scope. For them, reducing the scope of the Directive may undermine consumer protection, also leading to negative consequences for producers such as uncertainty and subsequent difficulty to predict (potentially higher) costs, decrease of harmonisation, and internal market fragmentation.

EQ. What would be the most likely consequences of repealing the Directive?

Should the Directive be repealed, either tort law, contract law or both would apply with heterogeneous rules in terms of protection and liability.

Due the objective of protection of the consumers, the repeal of the Directive may have a negative impact both on consumer protection and on the uniformity of EU legislation. The general tort law usually requires that the injured party demonstrates at least the negligence or fault of the producer and that the damage is unlawful. For general contract law, it is needed that the injured party demonstrates the existence of a contract.

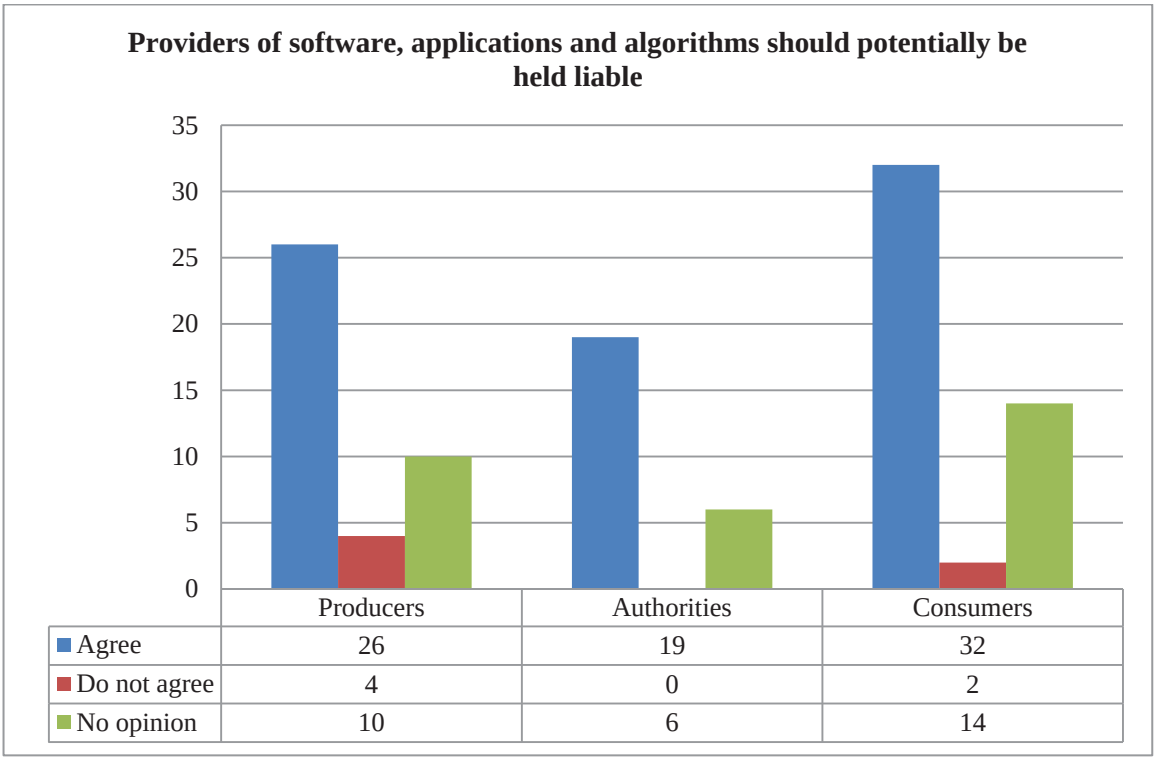
A repeal of the Directive would mean that consumer protection would depend upon the courts' interpretation of their national law (contractual and/or tort law), leading to varying levels of consumer protection in the different Member States, with potential impacts on the free movement of products and distorting competition. Therefore, the most likely consequences of repealing the Directive would be a negative impact both on consumer protection and the functioning of the single market.

EQ According to the case-law and the experience on the application of the Directive, could it be considered appropriate to enlarge the scope of the Directive, for instance so as to cover the services?

Nine Member States have rules ensuring an extra-contractual liability to protect consumers from damages caused by defects both of intangibles (e.g. software) and services. In six of these Member States, the protection of consumers from damages caused by defects either of intangibles or of services stems from general rules, normally tort law: in these cases, protection essentially stems from the interpretation of general rules to include services or intangibles. In three other Member States, the liability to damages caused by intangibles or services is covered by specific legislation.

Therefore the state of the legislation concurring with the Directive shows that, in principle, it could be possible to extend the rules of the Directive so as to cover services or other intangibles, like software. In this sense, stakeholders responding to the open public consultation considered that providers of software should be held liable according to the Directive.

In addition, the notion of damage could be revisited to cover economic losses or infringements of privacy.



	Producers	Authorities	Consumers
Agree	26	19	32
Do not agree	4	0	2
No opinion	10	6	14

Source: Open public consultation

5.5.1. Conclusion on EU Added value

In conclusion, the added value of an EU level product liability framework is uncontested. If any, the Directive is rather considered to provide too little EU added value and EU level legislation of product liability should be extended beyond the current scope of the Directive.

6. CONCLUSIONS

There is a consensus among stakeholders that overall the Product Liability Directive contributes to a level playing field in the single market and contributes to consumer protection. This is better achieved than could be done at national level. It matches expectations in the sense that consumers are aware of their right to compensation for damage caused by defective products and that it provides a clear legal framework for businesses across the EU.

A standard cost-benefit analysis was not possible due to the limitations of available data. The qualitative analysis of the Directive's efficiency has nevertheless concluded that, the Directive seems an efficient legislative instrument, achieving its objectives at a reasonable cost and ensuring a good cost-benefit ratio for all sizes of companies. However, the cost-benefit ratio is not always fair and straightforward for consumers, mainly due to the cost linked to the burden of proof, which imply costs that an injured person has to anticipate to bring a claim in court, including those related to the judicial proceedings. The cost of judicial proceedings is outside the scope of the Directive, hence there was no simplification potential identified in this respect. Compensation for damages caused by pharmaceutical products sticks out as particularly problematic, where adjustments might be needed to provide a real level-playing field.

The evaluation shows that the Directive is coherent with the existing product safety legislation and is complementary with the rules on consumer protection in the area of contractual liability. Coherence and synergies have been confirmed also between the Directive and the rules on applicable law in civil and commercial matters.

There are, however, certain aspects of the Directive that have an impact on the effectiveness of the Directive.

There are concerns about the continued balance between the interests of consumers and producers, notably with regards to the **burden of proof**. At present, it appears that especially complex products such as pharmaceutical products –but also emerging digital technologies - pose a problem in terms of e.g. access to and availability of technical information that may make it very difficult for consumers to be able to prove the links between defects and damages. Furthermore, **500€ threshold** can be identified as cost to the consumer that may excessively limit the number of claims.

Furthermore, the **definition of product** appears to no longer be as clear-cut as it may have been when the Directive was adopted for example in the light of new technological developments where the distinction between products and services becomes blurred or in the context of software. Given that the Directive applies to products, a clarification of its scope could therefore be envisaged.

In a similar vein, as products are more easily, altered adapted and combined with services, **the definition of the producer** may become less clear particularly in the context of emerging digital technologies and the circular economy. The definition of the producer, while continuing to be valuable as it ensure strict liability, may therefore no longer be fully relevant in its current form. Another question is raised by the **limitation of damage to physical and material damage** to the detriment of e.g. economic or environmental damage. Linked to this is the definition of defect which may require being updated to new types of problems such as infringements of privacy or how to link the notion of defect with the types of autonomous behaviours leading to damages. Extending the scope of the Directive in this direction is, however, a political decision that will have to be carefully assessed.

A detailed assessment of the effects of such changes within the existing framework needs to be carried out. There may be a need for guidance, clarification and if necessary adaptation of certain aspects in light of technological developments to ensure that the Directive continues to meet its objectives to the extent possible. The roll out of these technologies should be closely monitored and observed.

The evaluation has also highlighted that at present, there is a lack of empirical data that would allow for a conclusive statement concerning new technologies. There do not seem to have been a significant number of incidents where the Directive was unable to apply. Despite the on-going work on safety, over time more evidence will become available. Further fact finding is required that should allow for a more detailed assessment than is currently possible based on legal analysis to assess whether the Directive remains fit for purpose in that evolving context. This and other aspects that may become relevant will be assessed in the framework of the report on the application of the Directive.

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, D*E*CIDE PLANNING/CWP REFERENCES

- Lead DG: Directorate General Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)

- Decide/Planning: 2016/GROW/027-- V report on the application of Directive 85/374/EEC on liability for defective products and SWD on the evaluation of Directive 85/374/EEC.

- REFIT (evaluation).

2. ORGANISATION AND TIMING

- An Inter-service Steering Group oversaw the process to ensure coherence and comprehensiveness with the Commission's overall responsibilities and activities in related policy areas such as safety and consumer protection.

  The ISG met 10 times: 13 July 2016, 31 August 2016, 11 November 2016, 10 January 2017, 7 February 2017, 16 May 2017, 5 September 2017, 10 October 2017, 23 January 2018 and 8 February 2018.

- Publication in EUROPA of the Roadmap on the evaluation, 12 September 2016

- Signature of a specific contract for the Study on the evaluation, 19 December 2016

- Launch of the Open public consultation, 10 January 2017 (12 weeks)

- Approval of the Final report of the Study for the evaluation, February 2018

3. EXCEPTIONS TO THE BETTER REGULATION GUIDELINES

NA

4. CONSULTATION OF THE RSB (IF APPLICABLE)

NA

5. EVIDENCE, SOURCES AND QUALITY

- First report on the application of the Council Directive on the approximation of laws, regulations and administrative provisions of Member States concerning liability for defective products, COM (95) 617 final of 13 December 1995.

- Green Paper of the Commission "Liability for defective products". COM(1999) 396 final of 28 July 1999 .

- Second report on the application of the Council Directive on the approximation of laws, regulations and administrative provisions of Member States concerning liability for defective products, COM (2000) 893final of 31 January 2001.

- Third report on the application of the Council Directive on the approximation of laws, regulations and administrative provisions of Member States concerning liability for defective products, COM (2006) 496final of 14 September 2006.

- Fourth report on the application of the Council Directive on the approximation of laws, regulations and administrative provisions of Member States concerning liability for defective products. COM (2011) 547 final of 8 September 2011.

- Lowels Report: *Product Liability in the European Union*, 2003.

- Fondazione Rosselli Report: *Analysis of the Economic Impact of the Development Risk Clause as provided by Directive 85/374/EEC on Liability for Defective Product*, 2004.

- Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - *Digitising European Industry Reaping the full benefits of a Digital Single Market* (COM(2016) 180 final) of 19 April 2016.

- Commission Staff Working Document- *Advancing the Internet of Things in Europe*, accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions " *Digitising European Industry- Reaping the full benefits of a Digital Single Market* (SWD(2016) 110/2.

- European Parliament Resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL).

Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products- Final Report. 2018.

ANNEX 2: STAKEHOLDER CONSULTATION : SYNOPSIS REPORT

1. INTRODUCTION

Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (the "Directive") aims at guaranteeing the protection of consumers' health and property, the free movement of goods and undistorted competition among market operators in the Single Market.

The Commission launched an evaluation to judge if the Directive meets its objectives and is fit for purpose vis-à-vis the new technological developments such as Internet of Things or autonomous systems. A stakeholder consultation was part of this evaluation.

The evaluation was launched with a roadmap and a consultation strategy. The roadmap contained a description of the purpose, content, scope and evidence base of the evaluation. The Commission did not receive any comment from stakeholders on the roadmap neither on the consultation strategy as they were published.

2. OBJECTIVES OF THE CONSULTATION

The consultation strategy aimed at gathering information from stakeholders to feed the assessment of its effectiveness, efficiency, relevance, coherence and EU added value.

Relevant stakeholders include producers, importers, suppliers and their industry associations, consumers and consumer organisations, insurers and federations of insurers, technical experts, and public authorities and civil society (e.g. think-tanks, experts, law firms/legal experts).

This document presents an overview of the consultation activities and their results.

3. CONSULTATION METHODS AND TOOLS

Overall, **657 stakeholders** from all Member States (except for Latvia, Portugal, and Slovenia) and all target groups (except for technical experts) contributed to the consultation.

3.1. Public Consultation

An **open public consultation** was launched (10 January – 26 April 2017) in 23 European Union languages, consisting of three online questionnaires addressed to producers; consumers; public authorities and civil society representatives.

113 stakeholders (40 producers, 48 consumers and 23 public authorities/civil society) from 16 Member States[101] replied. 14 position papers were shared by consumers (1), business associations (9) and public authorities/civil society representatives (4).

[101] All except DK, EE, EL, HR, CY, LV, LU, HU, PL, PT, SI, SE.

3.2. Surveys

A **targeted survey** (3 April – 20 May 2017) was carried out through five questionnaires in English addressed to:

- Producers and suppliers and related industry associations (4 responses);
- Consumer associations (11);
- Insurers and related associations (0);
- Public authorities and civil society representatives (11);
- Technical experts active in courts (0).

Responses came from 14 Member States.[102]

A **Computer-assisted telephone (CATI) survey** (29 May – 14 June 2017) covering 11 Member States[103] was addressed to producers, importers, and suppliers. 457 producers responded.[104]

61 **interviews** (3 May – end of July 2017) were held with stakeholders with experience with the Directive (17 producers, 11 consumers, 9 insurers, 24 public authorities and civil society representatives).[105]

The targeted surveys encountered some limitations:

- Low level of participation in the targeted survey: more than 400 stakeholders were contacted, but only 26 replied.
- No representative from technical experts replied.

3.3. Conference on the Evaluation of the Product Liability Directive

The European Commission held a Conference on the evaluation of the Product Liability Directive[106] in Brussels on 20 October 2017, addressed to Member State's representatives and different categories of stakeholders and aimed at exchanging views on the preliminary results of the external study on the evaluation.

4. MAIN RESULTS OF THE CONSULTATION ACTIVITIES

Several stakeholders had experience with the Directive. Most businesses dealt with claims brought by injured persons and paid for insurance; consumer associations were familiar with claims by injured persons; insurers provided specific insurance policies and paid compensations; public authorities and civil society representatives dealt with the needs of specific stakeholder categories, acted in litigation or carried out research on the Directive.

102 BE, BG, DK, EL, ES, FR, IT, LT, LU, MT, NL, SI, FI, UK.
103 CZ, DE, ES, FR, IT, LT, NL, AT, PL, SE, UK.
104 From CZ, DE, ES, FR, IT, LT, NL, AT, PL, SE, UK.
105 From BE, DK, DE, EE, ES, FR, HR, IT, CY, LU, HU, MT, NL, FI, UK.
106 See minutes of the Product Liability Conference at https://ec.europa.eu/docsroom/documents/26661

4.1 Effectiveness

The consultation aimed at understanding whether and to what extent the Directive's objectives in terms of protection of consumers, undistorted competition and free movement of goods have been achieved so far at both national and EU levels.

Most stakeholders are aware of the Directive. For most public authorities and civil society representatives, the Directive is effective as consumers benefit from the strict liability of producers, and consumers' and producers' interests are fairly balanced. For these reasons, they also believe that the system of strict liability must be maintained.

Most producers deem the Directive to be effective, as it creates a level playing field across Europe by setting the same liability rules in all Member States and balances consumers' and producers' interests, setting clear rules regardless of the product type.

Finally, for insurers the Directive is effective overall, as it balances consumers' and producers' interests.

However, for most consumer associations the Directive is not fully effective, as it protects producers' interests more than those of consumers.

In particular, some provisions of the Directive are seen as more effective than others:

- ***Products, not services***

For some of the stakeholders (both producers and consumers) the distinction between products and services is not clear anymore and the Directive should also cover the damages caused by services; other producers believe that the Directive should not cover these damages.

For more than half of the public authorities and civil society representatives consulted, the distinction between products and services is not adequate and the Directive's scope should be extended to services.

The vast majority of consumers and their associations underline that it may be difficult to distinguish a product from a service, as they are often bundled together, and they would favour a regime covering both products and services.

On the contrary, for more than half of the businesses, the distinction between products and services is adequate and there is no need to extend the Directive to services.

- ***What about new technological developments?***

The application of the Directive to new technological developments is not straightforward.

The feedback from stakeholders on new technological developments is quite divergent: for some stakeholders (including many producers, some consumers, insurers and public authorities/civil society representatives) there is no need to update the Directive vis-à-vis new technological developments. Others from all consulted categories find it difficult to apply the Directive to these items, given their intangible nature and increasing complexity.

More specifically, for almost half of the public authorities and civil society representatives and almost all consumers, the scope of the Directive should be broadened to new technological developments and balance consumers' safety and innovation, considering the distinction between products and services and the concept of "defect" as not adequate for these developments.

Most businesses consider apps, non-embedded software and IoT components to be "products" pursuant to the Directive, while they have diverging views as to whether the liability is adequately allocated among the different operators. Furthermore, for them defect is adequately defined as to damages caused by an advanced robot or an autonomous system.

For a large majority of businesses the exemptions under the Directive are adequate for new technological developments and the Directive already applies to them; they consider the Directive to be fit-for-purpose and neutral to different technologies.

Similarly, for a large majority of insurer associations there is no need to adapt the Directive to new technological developments.

- ***Burden of proof***

For a large majority of public authorities and civil society representatives the proof of defect and of the link between it and the damage is burdensome to consumers.

Almost all consumer associations see this burden as the most frequent obstacle to obtaining compensation, especially with regard to new technological developments and increasing product complexity.

However, only a few insurers view the burden of proof as onerous in practice.

Most businesses think that removing this burden would be disadvantageous: indeed, the burden of proof upon the injured person is essential as a basis for the claim; removing it would make the Directive unfair.

- ***Damages to property***

For a slight majority of public authorities and civil society representatives, the €500 threshold should be removed to allow compensation of smaller damages. Also, the majority of consumer associations would lower the threshold, as the price of many products has decreased over the years.

While most businesses do not favour a modification of the threshold, a significant share of small firms (24%) favour decreasing the threshold.

For the majority of stakeholders, except for insurers, it is difficult to apply the condition that the item of property is of a type ordinarily intended for private use or consumption and was used by the injured person mainly for his own private use or consumption; they believe it should be removed.

For half the public authorities and civil society representatives this provision should be removed, as it is increasingly difficult to distinguish when an item of property is intended for professional or private use.

Most businesses (63%) and more than half of the consumer associations consider the distinction between private and professional use as not adequate, since products can have both uses, and the removal of such distinction would not cause any problems.

Almost all insurers associations consider the distinction between private and professional use of products as clear enough and no change is needed.

The Conference on Product Liability gave the opportunity to further elaborate on the views obtained through the use of other consultation tools. On effectiveness of the Directive, the majority of manufacturers and insurers considered that the Directive meets its objectives and that it is future-proof for the new technological developments. In their opinion, any revision at this stage would be premature. However, consumers were in

favour of a revision of the Directive with a view to facilitate the compensation of the injured party.

4.2 Efficiency

The consultation focused on the balance between the costs borne by the producers to cover the strict liability and the burdens on the injured party to obtain compensation, as well as on aspects making it more or less efficient in ensuring strict liability of the producer.

Data on costs and benefits were expected from the targeted survey: however, the low rate of response hampered proper quantification. Data retrieved from the other consultation activities allowed carrying out only a qualitative analysis.

In particular, for more than half of the businesses, costs and benefits deriving from the Directive are well balanced.

Yet more than two-thirds of consumer associations see costs as higher for consumers: proving the defect and its link to the damage is burdensome due to increasing product complexity. For almost half of the insurers, the burden of proof can be difficult to fulfil in practice.

As a third point of view, for two thirds of the public authorities and civil society representatives, although costs relating to the Directive are acceptable for traditional products, the new technological developments could bring new costs for producers to comply with it.

4.3 Coherence

The consultation focused also on questions relating to the coherence, complementarity and consistency between the Directive and other Union actions, in particular product safety legislation and consumer protection.

The Conference on Product Liability was the occasion for the stakeholders to confirm that the Directive is perceived as coherent and consistent with the EU product safety legislation and with the rules on consumer protection. It was recalled that products placed on the European market must comply with EU safety legislation. In case that they caused damages due to a defect, consumers can bring legal action against the producer in the context of the Directive (extra-contractual liability) but also against the seller according to the contractual liability rules.

4.4 Relevance

The consultation activities aimed at understanding whether the initial needs still correspond to current needs, including needs created by innovative products. They also aimed at investigating whether the definitions of product, producer, defect and damage or the exemptions under the Directive are adequate to the technological and scientific developments.

Outcomes are quite fragmented: for most stakeholders there is a need to update the Directive vis-à-vis new technological developments, even though they have not experienced any issues in applying the Directive.

Overall, for the majority of public authorities and civil society representatives the Directive is future-proof, and the harmonisation it brought across the EU confirms its current relevance; however, they suggest a revision of the Directive in relation to new technological developments. For the vast majority of businesses the Directive is future-proof and relevant due to the harmonisation it brought.

For the vast majority of consumer associations the Directive has harmonised product liability rules. However, they favour a revision of the Directive to take into account the new technological developments, as do public authorities and civil society representatives, because of the lower relevance of the Directive vis-à-vis the new needs and the limited applicability of the concepts of the Directive to new technological developments.

4.5 EU added value

The consultation aimed at gathering feedback on whether strict liability continues to require action at the EU level. Moreover, the consultation focused on understanding the most likely consequences in case of scope reduction or repeal of the Directive or extension of its scope.

Overall, all stakeholders acknowledge the EU added value of the Directive and no stakeholder suggested to repeal it.

A majority of businesses agree that the level playing field achieved would not be possible with individual Member States action. In addition, for almost all consumer associations the protection of consumers achieved would not be feasible with only national action.

The vast majority of public authorities and civil society representatives deem that the Directive added value to the EU legal framework and policies.

The Conference on Product Liability confirmed the positions defended by the different categories of stakeholders. In addition, many participants emphasised: (i) the link between product safety and product liability rules, (ii) the difficulty for victims of undesirable effects of pharmaceutical products to prove the defect and the casual link between defect and damage in order to get compensation, (iii) the lack of evidence on the application of the Directive to the new technological developments, and (iv) the need to maintain a fair balance between the interests of the parties.

5. MAIN CONCLUSIONS

Consultation activities allowed to gather a wide range of views on the Directive in terms of what has worked well and what has not worked so well so far, as well as on expectations for the future.

Overall the Directive was viewed as being generally **effective** in achieving its objectives by public authorities, civil society, businesses and insurers representatives, though consumer organisations were more critical especially on obstacles to obtaining compensation, in particular related to the increasing complexity of providing the burden of proof, a more difficult delineation of products and services as well as the 500€ threshold for material damages.

Most stakeholder categories recognised the **efficiency** of the Directive. In particular, all categories, except for consumer associations, think the costs and benefits due to the Directive for consumers and producers are balanced.

The Directive is seen as **coherent** with the EU legislation protecting consumers, **relevant and future-proof**. Nonetheless, representatives from public authorities, civil society and consumer associations agree there are issues not adequately covered by the Directive with regard to new technological developments, while businesses are more reluctant to amending the Directive.

There was a large consensus among stakeholders that the Directive has **EU added value**.

The Conference on the Evaluation of the Product Liability Directive gave the opportunity to confirm the need to pursue the reflection on the future of the Directive in order to ensure legal certainty, in particular in relation to its application to new technologies, such as Artificial Intelligence systems and advanced robots and internet of Things.

ANNEX 3: METHODS AND ANALYTICAL MODELS

Evaluation questions

The table below lists all final evaluation questions from the Study on the Evaluation of the Product Liability Directive.

EFFECTIVENESS

EQ 1: To what extent the Directive meets its objective of guaranteeing at EU level the liability of the producer for damage caused by a defective product and in turn, contributes to an effectively operating internal market for goods and to the protection of the consumer?

EQ 2/3: Which are the main drivers to the objectives achieved?

EQ 5/6/13: What is the impact of the new technological developments on the effectiveness of the Directive?

EQ 8/12: What are the systems used to settle the claims by injured persons from damages caused by defective products?

EQ 9: Which products have been most frequently at cause for the purpose of recovery of damages?

EQ 10: Which types of defects have been most frequently detected in those products?

EQ 11: Which type of damages (personal injuries or property) have been more often the object of recovery?

EQ 14: How many cases have been brought to the courts on the applicability of the Directive? Which was the issue in question and the ruling?

EQ 15: In the judicial cases, what have been the most frequent difficulties encountered by consumers when obtaining compensation, in particular during the last five years? The identification of the defect? The establishment of the causal link between damage and defect? The threshold of €500? The allocation of the liability among the economic players? Other?

EQ 16: In general, have the claimants been successful in the litigation? Is there a trend to be observed in the last five years?

EQ 17: Have cases been brought to the national courts relating to the application of the Directive to damages caused by a defect, for instance the malfunctioning, in apps or in another non-embedded software? If it is the case, which was the issue at stake and what was the ruling?

EQ 18: Have there been cases brought to the national courts or solved through an out-of-court settlement relating to the application of the Directive to damages caused by a robot, in particular in an advanced robot or an autonomous system? If it is the case, what was the issue at stake and the

ruling?

EQ 19: Have there been cases in which the damage was caused by a product interconnected with other products or services, for instance in the context of IoT and automated systems? How has the liability been allocated in those cases?

EQ 20: In the context of new technological developments, have there been discrepancies between the judgements made by the courts on similar cases? What were the problems at stake?

EFFICIENCY

EQ 21: What are the regulatory (including administrative) costs for relevant stakeholders stemming from the Directive?

EQ 22: What are the main benefits for stakeholders and civil society that derive from the Directive?

EQ 23: Are the benefits achieved at reasonable cost for consumers and producers (with focus on SMEs)?

EQ 24: Does the Directive strike the right balance between the costs borne by the producers to cover the strict liability and the requirements on the injured party to obtain compensation?

EQ 25: What aspects of the Directive are most efficient or inefficient to reach the objective of having a system of strict liability on the producer?

COHERENCE

EQ 26: To what extent is the intervention consistent and coherent with the EU rules on consumer protection in the area of contractual liability (for example, new Commission initiatives in the digital context)?

EQ 27: To what extent is the Directive coherent with wider EU policy, such as the free movement of goods and/or the protection of the consumers, including EU product safety?

RELEVANCE

EQ 28: To what extent do the initial objectives correspond to the current needs, including new needs created by innovative products?

EQ 29: To what extent does the distinction between products and services when dealing with product liability continue to be apt for dealing with the new technological developments?

EQ 30: How well adapted is the intervention to the changing market environment: often with a blurred distinction between private and professional use of products?

EQ 31: To what extent the concepts of product, producer, damage or the category of exemptions as defined in the Directive are adequate to correspond to the technological and scientific developments?

EQ 32: How well is the term 'defective' as defined in the Directive adapted to new technological or scientific advances such as apps and non-embedded software, advanced robots and autonomous/intelligent systems? For example, could software vulnerability (for instance, a cyber-attack or a failure to update security software or a misuse of information) be considered as a defect?

EU ADDED VALUE

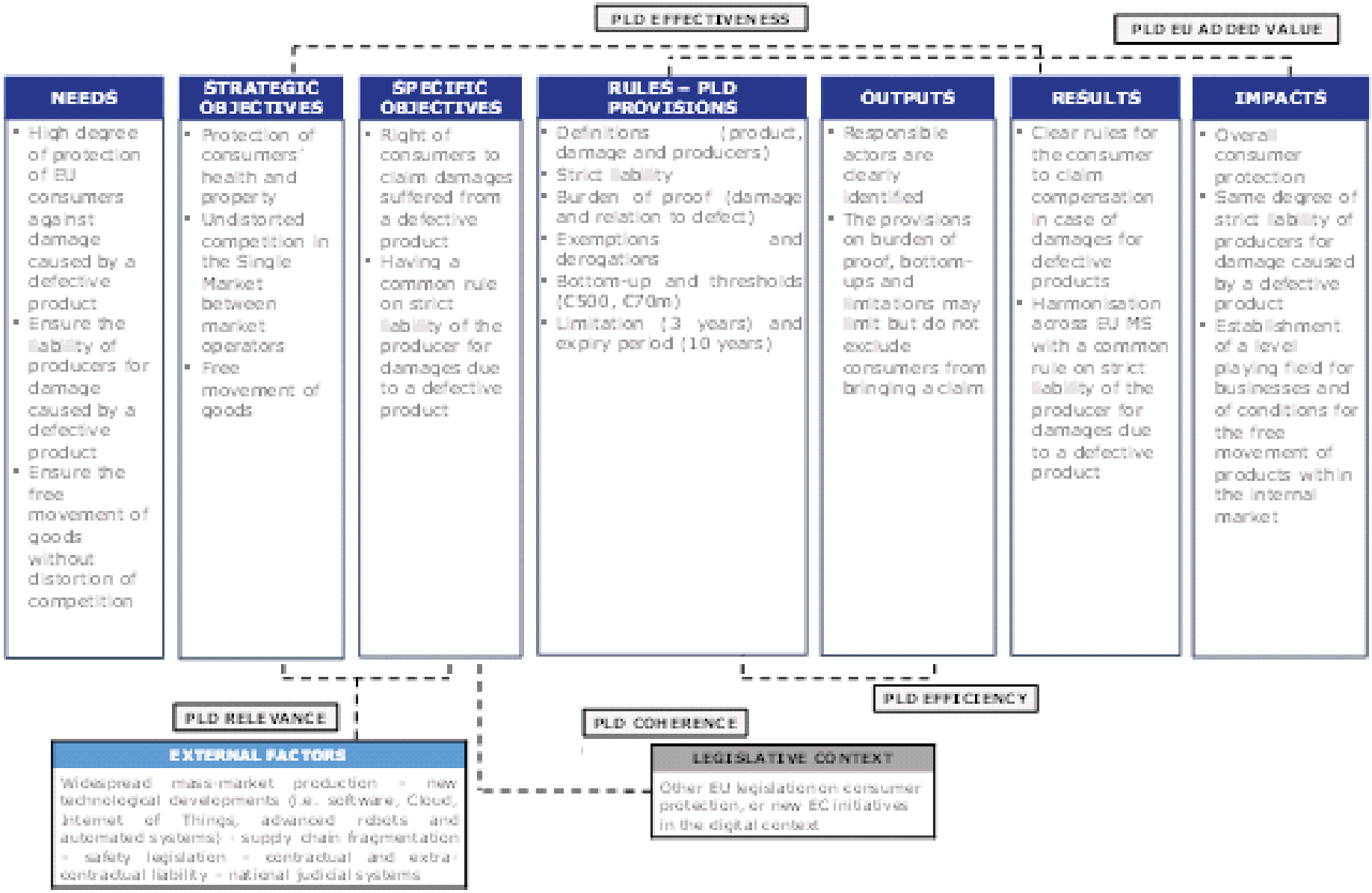
EQ 33: What is the EU added value of the Directive for stakeholders (manufacturers, including software developers and economic operators in the DSM, and consumers)?

EQ 34: To what extent does the issue of strict liability, as addressed by the Directive continue to require action at EU level?

EQ 35: What would be the most likely consequences of reducing the scope of the existing EU intervention?

EQ 36: What would be the most likely consequences of repealing the Directive?

EQ 37: According to the case law and the experience on the application of the Directive, could it be considered appropriate to enlarge the scope of the Directive, for instance so as to cover the services?



Evaluation grids

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
Effectiveness	Q1. To what extent does the Directive meet its objective of guaranteeing at EU level the liability of the producer for damage caused by a defective product and in turn, contribute to an effectively operating internal market for goods and to the protection of the consumer?	**JC1** The Directive meets its objective in guaranteeing at EU level the strict liability of the producer for damage caused by a defective product	Assessment of the extent to which the Directive has led to recognition of liability (in and out of courts). The analysis is based on stakeholders' perception and other secondary sources.	1. Level of satisfaction on the effectiveness of the Directive in guaranteeing the liability of producers for damages caused by defective products		x	x	x	x (CQ20, PAQ19)	TS (Q23)		TS (Q3)	I (Q1 – Q6)	I (Q1)
Effectiveness	Q1. To what extent does the Directive meet its objective of guaranteeing at EU level the liability of the producer for damage caused by a defective product and in turn, contribute to an effectively operating internal market for goods and to the protection of the consumer?	**JC2** The Directive contributes to an effectively operating internal market for goods	Assessment of the extent to which the Directive has led to a level playing field for producers The analysis is based on stakeholders' perception and other secondary sources.	1. Level of satisfaction on the effectiveness of the Directive on its contribution to a level playing field				x		TS (Q12)	TS (Q2)	TS (Q3, Q4), I (Q1 – Q6)	TS (Q7, Q6)	TS (Q12)
Effectiveness	Q1. To what extent does the Directive meet its objective of guaranteeing at EU	**JC3** The Directive contributes to the protection of the consumers	Assessment of the extent to which the Directive contributes to a more effective protection of consumers. Analysis of the extent to which consumers have obtained	1. Level of satisfaction on the effectiveness of the Directive for		x	x	x	x (CQ20, PAQ19)	TS (Q11), I	TS (Q3, Q4)	I (Q1 – Q6)		TS (Q11), I

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
	level the liability of the producer for damage caused by a defective product and in turn, contribute to an effectively operating internal market for goods and to the protection of the consumer?		compensation compared to what was requested The analysis is based on stakeholders' perception, and other secondary sources.	consumer protection 2. Ratio compensation requested/ compensation awarded										
Effectiveness	**Q1.** To what extent does the Directive meet its objective of guaranteeing at EU level the liability of the producer for damage caused by a defective product and in turn, contribute to an effectively operating internal market for goods and to the protection of the consumer?	**JC4** The Directive contributes to other not originally planned consequences and effects	Identification of aspects that go beyond the liability of producer for damages from defective products, through both desk and field research.		x	x	x	x		I (Q2)	TS (Q16, Q17) I (Q1 - Q2 - Q3 - Q4 - Q9)	I (Q2)	I (Q2)	I (Q2)
Effectiveness	Q2/3. Which are the main drivers to the objectives achieved?	**JC1** Some provisions have been implemented more consistently in MS	Assessment of the extent to which the following terms have been implemented consistently in the MS: 1. Producer 2. Defective 3. Damages 4. Product (also including new technologies) 5. Safety 6. Material thresholds of €500	1. Level of uniformity of implementation 2. Number of case law references evidencing extension of the Directive by way of similarity 3. Number of case	x	x	x	x				I (Q13)	I (Q4)	

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
				law references evidencing exclusion of liability of the producer and/or other economic operators 4. Rate of recurrence of specific factors										
Effectiveness	Q2/3. Which are the main drivers to the objectives achieved?	**JC2** It is possible to identify specific aspects in the Directive that render it more or less effective	Assessment of the extent to which specific characteristics of Directive make it more effective: - application of the Directive to many products - strict liability of the producer - notion of "defective" - proof of defect - proof of damage - proof of the link between the defect and the damage - identification of the producer - material threshold of €500 - private use - three-year period - expiry period of 10 years	Ranking of drivers				x	x (PQ25, CQ19, PAQ18)	I (Q7)		I (Q4)	I (Q4)	I (Q7)
Effectiveness	Q4. Have any gaps, uncertainties or inadequacies occurred in the application of the Directive, in particular during the last five years? If yes, which ones and with which	Please consider that such question has been deleted because covered in terms of Relevance, below.	N/A	N/A	N/A	N/A	N/A	N/A		N/A	N/A	N/A	N/A	N/A

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
Effectiveness	Q9. Which products have been most	**JC1** There are products whose defect	Identification of the products most frequently subject to claims through the analysis of case	1. Ranking of products		x	x		x (PQ15, CQ16, PAQ11)	I (Q22)				
Effectiveness	Q8/12. What are the systems used to settle the claims by injured persons from damages caused by defective products?	**JC1** There are different systems in place to settle the claims by injured persons	Identification of the main systems used to settle claims by injured persons from damages caused by defective products through the analysis of case law and stakeholder consultation. The analysis shall focus on how many claims are settled in court and out of court with possible identification of any kind of trend in the use of these systems.	1. Percentage of claims settled by each system		x	x							
Effectiveness	Q5/6/13. What is the impact of the new technological developments on the effectiveness of the Directive?	**JC1** The Directive properly covers new technological developments new technological developments	Analysis of the extent to which new technological developments are covered or not, and why, by the Directive, by looking at - how new technological developments new technological developments are treated by national legislation. - there are new contractual arrangements covering the risks created by new technological developments (notably insurance contracts, in general, specific professional insurances). Analysis of the extent to which the Directive has impacts on economic operators in the digital economy, through interviews.	1. Number of case law references relating to new technological developments 2. Percentage of claims relating to new technological developments	x	x	x	x	x (PQ28, CQ22, PAQ23)	TS (Q3, Q4, Q5), I (Q13 - Q14)	TS (Q4, Q5, Q6, Q7, Q16, Q17), I (Q11-Q12)	TS (Q5, Q6, Q7, Q8, Q9, Q14), I (Q4, Q5 - Q9)	TS (Q5), I (Q16)	TS (Q3), I (Q8)
	consequence? A particular attention should be paid to any potential regulatory lacunas relating to the new technological developments and how these were filled-in at national level?													

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
	frequently at cause for the purpose of recovery of damages?	caused damages object of recovery in claims from 2000 onward	law and stakeholder consultation											
Effectiveness	Q10. Which types of defects have been most frequently detected in those products?	**JC1** There are defects that have been frequently detected in products from 2000 onward	Identification of the different types of defects most frequently subject to claims through the analysis of case law and stakeholder consultation	1. Ranking of types of defects		x	x		x (PQ17, CQ9)					
Effectiveness	Q11 Which type of damages (personal injuries or property) have been more often the object of recovery?	**JC1** There are damages (personal injuries or property) that are more often subject of recovery in the cases from 2000 onward	Mapping and distribution of types of damages: - personal injuries - property through the analysis of case law and stakeholder consultation	1. Distribution of types of damages		x	x		x (PQ18, CQ10, PAQ13)					
Effectiveness	Q14 How many cases have been brought to the courts on the applicability of the Directive? Which was the issue in question and the ruling?	**JC1** Cases brought to courts on the applicability of the Directive	Identification of claims brought to court from 2000 onward, with particular mention and details from 2011 onward, analysed by subject matter and ruling. Identification and mapping of the main issues behind the claim and final outcome of the judicial proceedings	1. Number of cases brought to court 2. Number of cases per type of issue 3. Number of cases per result of the ruling and per type of issue		x	x							
Effectiveness	Q15 In the judicial cases, what have been the most frequent difficulties encountered by consumers when obtaining compensation, in particular during the last five years? The identification of the defect? The	**JC1** There are specific difficulties faced by consumers in obtaining compensation from 2000 onward	Identification of difficulties faced by consumers in obtaining compensation in judicial proceedings through the analysis of the reasons for rejecting the claim or reducing the compensation in case law from 2000, and particular mention and details from 2011 onward.	1. Number of case law references where the claimants did not receive the compensation or the claim was rejected.							TS (Q16, Q18, Q19)			

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
	establishment of the causal link between damage and defect? The threshold of €500? The allocation of the liability among the economic players? Other as for instance that the product was purchased as a bundle with a related service?													
Effectiveness	Q15 In the judicial cases, what have been the most frequent difficulties encountered by consumers when obtaining compensation, in particular during the last five years? The identification of the defect? The establishment of the causal link between damage and defect? The threshold of €500? The allocation of the liability among the economic players? Other?	**JC2** There are specific difficulties faced by consumers in obtaining compensation from 2000 onward	Analysis of the recurrence of the following types of difficulties faced by consumers in obtaining compensation: - identification of the defect - establishment of the casual link between damage and defect - threshold of €500 - allocation of liability among economic players The analysis is based on case law from 2000, and particular mention and details from 2011 onward.	1. Number of cases where the injured party did not receive compensation 2. Ranking of difficulties		x	x					TS (Q16, Q18, Q19) I (Q9)			TS (Q2)
ect ive ne	Q16 In general, have the claimants	**JC1** Success of claimants in the	Identification of the number of claims for damages of defective products that have been	1. Number of claims brought to		x	x		x (CQ17, CP23, PAQ14)		Q9, Q1			

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
	been successful in the litigation?	litigation	won by injured parties from 2000 onward (in courts and out of courts)	court in relation to damages for defective products from 2000 onward 2. Number of judicial cases in which the claimant has been successful in obtaining compensation in case law from 2000 onward										
Effectiveness	Q17 Have cases been brought to the national courts relating to the application of the Directive to damages caused by a defect, for instance the malfunctioning, in apps or in another non-embedded software? If it is the case, which was the issue at stake and what was the ruling?	**JC1** Existence of claims relating to damages caused by malfunctions in apps or in another non-embedded software which have been ruled: i) based on application of the Directive; or ii) based on application of other legislation	Identification and analysis of case law showing whether the Directive covers or does not cover claims relating to malfunctions in apps or in other non-embedded software.	1. Number of cases brought to court for defects of apps or another non-embedded software at national level		x	x	x		TS (Q12, Q13, Q14)	TS (Q20, Q21, Q22, Q23, Q24, Q25, Q26, Q27, Q28)	TS (Q8, Q9), I (Q10)		
Effectiveness	Q17 Have cases been brought to the national courts relating to the application of the Directive to damages caused by a defect, for instance the malfunctioning,	**JC2** Existence of problematic questions arising out of the abovementioned cases	Identification of main issues relating to the application of the Directive in case of damages caused by malfunctions in apps or in another non-embedded software, in terms of extra-contractual liability of the producer, considering the following: - definition of product - definition of defect - allocation of liability	1. Ranking of issues		x	x	x		TS (Q12, Q13, Q14)	TS (Q24, Q25, Q26, Q27,	TS (Q8)		

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
	in apps or in another non-embedded software? If it is the case, which was the issue at stake and what was the ruling?													
Effectiveness	Q18 Have there been cases brought to the national courts or solved through an out of court settlement relating to the application of the Directive to damages caused by a robot, in particular in an advanced robot or an autonomous system? If it is the case, what was the issue at stake and the ruling?	**JC1** There are cases of claims relating to damages caused by robots which have been ruled based on the application of the Directive by way of similarity	Identification and analysis of settlements showing whether the Directive covers or does not cover claims relating to damages caused by a robot/ automated or autonomous system.	1. Number of cases relating to the application of the Directive to damages caused by a robot, by type of settlement system		x	x	x		TS (Q15, Q16, Q17, Q18, Q19)	TS (Q20, Q21, Q22, Q23, Q24, Q25, Q26, Q27, Q28)	TS (Q9), I (Q10)		
Effectiveness	Q18 Have there been cases brought to the national courts or solved through an out of court settlement relating to the application of the Directive to damages caused by a robot, in particular in an advanced	**JC2** Existence of problematic questions arising out of the abovementioned cases	Identification of main issues relating to the application of the Directive in case of damages caused by a robot/ automated or autonomous system, considering the following: - definition of product - definition of defect - allocation of liability	1. Ranking of issues		x	x	x		TS (Q15, Q16, Q17, Q18, Q19)	TS (Q20, Q21, Q22, Q23, Q24, Q25, Q26, Q27, Q28)	TS (Q10, Q11), I (Q11)		I (Q10)

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
	robot or an autonomous system? If it is the case, what was the issue at stake and the ruling?													
Effectiveness	Q19 Have there been cases in which the damage was caused by a product interconnected with other products or services, for instance in the context of IoT and automated systems? How has the liability been allocated in those cases?	**JC1** There are cases of claims relating to damages caused by interconnected products, services (for instance IoT items, automated and autonomous systems and other New Technological Developments).	Identification of cases in which the damage was caused by a "defect" of a product interconnected with other products or services, for instance in the context of IoT and automated systems.	1. Number of cases on damages caused by a product interconnected with other products or services	x	x	x	x	x (PQ12-13, CQ5, PAQ8-9)	TS (Q20, Q21, Q22), I (Q15)	TS (Q20, Q21, Q22, Q23, Q24, Q25, Q26, Q27, Q28), I (Q14)	TS (Q12, Q13, Q32), I (Q10)	TS (Q14)	TS (Q16)
Effectiveness	Q19 Have there been cases in which the damage was caused by a product interconnected with other products or services, for instance in the context of IoT and automated systems? How has the liability been allocated in those cases?	**JC2** Allocation of strict liability in case of damages caused by a defect in a product interconnected with other product or service (for instance IoT items, automated and autonomous systems and other new technological developments).	Identification of how the liability has been allocated in the context of IoT in case of damages due to defects of new technological developments products. Focus on those possible areas already covered and those not covered yet by a protection similar to the one granted by the Directive.	1. Number of cases where the liability was allocated to stakeholders other than the producer	x	x	x	x		TS (Q2) I (Q16)	I (Q15)	TS (Q12)		I (Q9)
Effective ne	Q20 In the context of new	**JC1** There are interpretative	Identification of cases in which the courts of each MS might have applied other legislation	1. Number of cases in which legislation		x	x	x			Q2			

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
	technological developments, have there been discrepancies between the judgments made by the courts on similar cases? What were the problems at stake?	problems arising out of new technological developments	and/or the principles of the Directive by way of similarity to claims relating to new technological developments to claims relating to new technological developments from 2000 onward with reference to: - apps and other non-embedded software - robots/automated/autonomous systems - interconnected products Analysis of the reasons for discrepancies based on stakeholders perception	other than the Directive was applied to claims on damages caused by new technological products, directly or by the way of extension of its principles by type of "new technological developments" 2. Number of cases in which other legislation was applied to damages caused by defects in new technological developments										
Efficiency	Q21 What are the regulatory (including administrative) costs for relevant stakeholders stemming from the Directive?	**JC1** There are regulatory and administrative costs stemming from the Directive	Mapping of costs distinguishing between: - direct (i.e. administrative) - enforcement - indirect based on the preliminary mapping provided in the inception report Quantification of costs	1. Costs on total production value for producers; 2. Ranking on the level of burden for consumers; 2. Costs for consumers (where available).				x	x (Q19C, Q25P, Q18PA)	TS (Q6, Q7, Q8, Q9)	TS (Q29 - Q30 - Q31)			
Efficiency	Q22 What are the main benefits for stakeholders and civil society that derive from the Directive?	**JC1** It is possible to identify some benefits that are deriving from the Directive that are particularly relevant for stakeholders	Mapping of benefits distinguishing between: - direct (i.e. administrative) - enforcement - indirect based on the preliminary mapping provided in the inception report	Rating of identified benefits				x	x (Q19C, Q25P, Q18PA)	TS (Q24), I (Q4 - Q6))	TS (Q35), I (Q3 - Q24)	TS (Q18, Q19)	I (Q3)	I (Q3, Q4)

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
			Quantification of benefits											
Efficiency	Q23 Are the benefits achieved at reasonable cost for consumers and producers (with focus on SMEs)?	**JC1** The ratio between the benefits and the costs is perceived as reasonable by stakeholders	Analysis of the balance between costs and benefits based on the perception of consumers, distinguishing between "traditional products" and "products relating to New Technological Developments", overall and by type of stakeholder. Information will be gathered through the survey to consumers and producers and the results of the OPC	1. Level of satisfaction of stakeholders on the balance between costs and benefits, by type of product				x	x (PQ9, PAQ15-16)	TS (Q38, Q39), I (Q5-Q6-Q7)	TS (Q35), I (Q5)	I (Q6)		
Efficiency	Q24 Does the Directive strike the right balance between the costs borne by the producers to cover the strict liability and the requirements on the injured party to obtain compensation?	**JC1** The ratio between the insurance costs of the producer and the compensation received by the consumers is appropriate	Analysis of the ratio between insurance premiums and compensation costs (loss ratio) for damages caused by defective products compared to the overall average ratio, where possible distinguishing between "traditional products" and "products relating to new technological developments" Analysis of stakeholder perception	1. Ratio between the specific and average loss ratio 2. Ratio of loss ratio for traditional products and products relating to new technological developments				x	x (CQ21, PAQ22, PQ26)	I (Q7)	I (Q4 - Q5)	TS (Q15), I (Q6 - Q7)	I (Q8)	
Efficiency	Q25 What aspects of the Directive are most efficient or inefficient to reach the objective of having a system of strict liability on the producer?	**JC1** There are some elements of the Directive that are more or less efficient than others.	Analysis of the level of efficiency of specific aspects of the Directive based on stakeholders' perception from OPC and interviews (specific elements: proof of defect, proof of damage, proof of link, attribution of liability to specific person/entity, threshold of €500, proof of private purposes, three year expiry period)	Ranking of most efficient/inefficient aspects					x (CQ20, PAQ19)	I (Q10)	I (Q7)		I (Q9 - Q10)	I (Q4 - Q6 - Q13)
Coherence	Q26 To what extent is the intervention consistent and coherent with the EU rules on	**JC1** The Directive is coherent with EU rules on consumer protection in the area of contractual	Analysis of the extent to which the Directive interacts with other EU rules on consumer protection in the area of contractual liability in terms of discrepancies, inconsistencies and applications, considering specifically the	1. Level of coherence (i.e. number of discrepancies, inconsistencies,				x					I (Q11)	

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
	consumer protection in the area of contractual liability (for example, new Commission initiatives in the digital context)?	liability, in particular with regard to the EU initiatives in the digital content	following: - Proposal for a Directive of the European Parliament and of the Council on certain aspects concerning contracts for the supply of digital content COM(2015) 634 final; - Proposal for a Directive of the European Parliament and of The Council on certain aspects concerning contracts for the online and other distance sales of goods COM(2015) 635 final; - Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I); - European Consumer Agenda Communication from the Commission to the European Parliament, the Council, the Economic And Social Committee and the Committee of the Regions A European Consumer Agenda - Boosting confidence and growth	applications) with EU Rules										
Coherence	Q27 To what extent is the Directive coherent with wider EU policy, such as the free movement of goods and/or the protection of the consumers, including EU product safety?	**JC1** The Directive is coherent with EU policy, in particular the one relating to principle of free movement of goods, protection of the consumers and EU product safety policies.	Analysis of the extent to which there are conflicts or gaps between the Directive and other EU policy, with regard to safety, free movement of goods and protection of the consumers, with specific reference to 2001/95 General Product Safety Directive, or Regulation 765/2008 on accreditation and market surveillance relating to the marketing of products.	1. Level of coherence with wider EU Policy				x						
Relevance	Q28 To what extent do the initial objectives correspond to the current needs,	**JC1** There are no additional needs besides those connected to the protection of	Mapping of case law relating to new technological developments to understand to which extent the Directive applies. Analysis of the approximation of national law and case law.	1. Proportion of case law relating to new technological developments on all case law under		x	x	x	x (CQ24, PAQ20-21, PO27)	I (Q20)	I (Q16)			I (Q12)

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
		"consumers" and liability of "producers" for defective "products"	Analysis of stakeholders' perception on needs not covered by the Directive. Analysis of results from Q29, Q30, Q31, Q32.	relating to the Directive; 2. Level of satisfaction of stakeholders of the relevance of the Directive;										
Relevance	including new needs created by innovative products?													
	Q29 To what extent does the distinction between products and services when dealing with product liability continue to be apt for dealing with the new technological developments?	**JC1** The distinction between products and services is still apt for new technological developments products	Analysis of any difficulties encountered in distinguishing products from services due to new technological developments. Analysis of stakeholder perception	1. Number of cases ruling on the concept of products and services in the framework of new technological developments.	x	x	x	x	x (PQ30, CQ25, PAQ26)	TS (Q25, Q26), I (Q17 - Q18)	TS (Q13, Q40), I (Q13)	TS (Q20), I (Q8)	TS (Q6), I (Q14 - Q15)	TS (Q9), I (Q7 - Q11)
Relevance	Q30 How well adapted is the intervention to the changing market environment: often with a blurred distinction between private and professional use of products?	**JC1** The distinction between private and professional use is still apt to the changing market environment	Analysis of any difficulties encountered in distinguishing private and professional use of products, due to new technological developments. The analysis shall focus on case law and existing national legislation relating to damages caused by defects in products intended and used in the professional activity. Analysis of stakeholders' perception on the need to extend the Directive to professional use.	Number of claims brought by consumers and professionals for damages caused by defective products.	x	x	x	x	x (PQ30, CQ25, PAQ26)	TS (Q27), I (Q11)	TS (Q14), I (Q8)	TS (Q21, I (Q5)	TS (Q7), I (Q5)	TS (Q10), I (Q5)
Relevance	Q31 To what extent are the concept of product, producer, damage or the category of exemptions as defined in the Directive adequate	**JC1** Existence of cases where claims are referred to terms different to the ones in the question	Analysis of the extent to which the terms "product" (Art.2), "producer" (Art.3), "damage" (Art.9), "exemption of liability" (Art.7) of the Directive are fit for purpose vis-à-vis the new technological developments. Therefore it is important to understand whether the Directive is still apt to cover such developments. In order to verify it, desk	1. Number of case law references relating to the concepts in the question applying to new technological developments;	x	x	x	x		TS (Q26, Q28, Q29), I (Q17- Q18 – Q19)	TS (Q15), I (Q13)	TS (Q22, Q23), I (Q8)	TS (Q8), I (Q14 – Q15)	TS (Q11), I (Q11)

▲	▲ Question	▲ Judgment Criteria	▲ Analytical framework	▲ Indicators	MS legis-lation	MS case law	EU case-law	Desk review	◀ OPC	◀ P	◀ C	◀ IC	◀ PA / CS	◀ T
			research and stakeholders' consultation shall be carried out. In particular, the main points to take into consideration are: 1. The importance of the role played by the individuals who are involved in trade chain; 2. Uncertainties with the new technological developments; 3. Existence of different kinds of damage caused by new technological developments.	2. Level of satisfaction of stakeholders on the adequacy of the definitions										
◀ Relevance	to correspond to the technological and scientific developments?													
	Q32 How well is the term 'defective' as defined in the Directive adapted to new technological or scientific advances such as apps and non-embedded software, advanced robots and autonomous/intelligent systems? For example, could software vulnerability (for instance, a cyber-attack or a failure to update security software or a misuse of information) be considered as a defect?	**JC1** There are cases relating to new technological developments where it was difficult to apply the term defective	Analysis of cases relating to new technological developments where it was difficult to apply the term defective. Analysis of the perception of stakeholders on the difficulties to apply the term "defect" in case of specific new technological development.	1. Number of case law references relating to defects of new technological developments products 2. Level of adequacy			x	x			TS (Q2, Q20)	TS (Q18)		TS (Q12)
EU Added Value	Q33 What is the EU added value of the Directive for stakeholders (manufacturers,	**gSnmmrJC1** The objectives of the Directive could not be reached only with national legislation	Analysis of the extent to which stakeholders consider that the Directive generates an EU added value for them, with particular focus on the new technological developments.	1. Rating based on stakeholders' perception					x (CQ24-26, PQ27,	TS (Q23, Q24, Q30 -	TS (Q21, Q24, Q34)	TS (Q25), I	TS (Q10)	TS (Q8, Q6)

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
	including software developers and economic operators in the DSM, and consumers)?													
EU Added Value	Q34 To what extent does the issue of strict liability, as addressed by the Directive continue to require action at EU level?	**JC1** The issue of strict liability continues to require action at EU level	Analysis of the extent to which the rule of strict liability on the producer in case of damages caused by a defective product is harmonised and MS may not adopt legislation jeopardising the application of the principle. Analysis of the extent to which national legislation of different MS interferes, overlaps and/or conflicts with the Directive, so as to require the intervention of the European institutions -i.e. European Court of Justice, with specific reference to i)contractual law, ii) extra-contractual based on fault on the producer	1. Number of cases for (contractual, fault and non-strict) liability of defective products 2. Level of approximation of practices among MS	x	x	x	x		TS (Q40, Q41, Q43, Q44, Q45)	TS (Q38, Q39, Q41, Q42)	TS (Q24, Q30, Q31, Q33, Q34)	TS (Q9, Q12, Q13, Q17, Q18, Q19)	TS (Q17, Q18)
EU Added Value	Q35 What would be the most likely consequences of reducing the scope of the existing EU intervention?	**JC1** Effects derive in case of reducing the scope of the Directive	Analysis of the extent to which reducing the scope of the Directive has impacts on the uniformity of legislation of MS, with regard to: 1. the free movement of goods in terms of intra EU trade; 2. different protection of injured persons according to national liability rules; 3. liability of producers for damages caused by defective products.	1. Level of harmonisation of MS national legislation 2. Rating based on stakeholders perception	x			x		TS (Q31, Q32, Q35), I (Q20)	TS (Q32, Q33), I (Q17)	I (Q12)	I (Q17)	I (Q14)
EU Added Value	Q36 What would be the most likely consequences of repealing the Directive?	**JC1** Effects derive in case of repealing the Directive	Analysis of the extent to which repealing the Directive has impacts on the uniformity of legislation of MS, with regard to benefits and obstacles that would arise in absence of the Directive, with regard to: 1. the free movement of goods in terms of intra EU trade;	1. Level of uniformity of MS national legislation on civil liability for damages caused by defective products 2. Rating on	x			x		TS (Q31, Q32, Q35), I (Q21)	TS (Q32, Q33), I (Q17)	I (Q12)	I (Q17)	I (Q14)

	Question	Judgment Criteria	Analytical framework	Indicators	MS legis-lation	MS case law	EU case-law	Desk review	OPC	P	C	IC	PA / CS	T
			2. differentiation of protection of consumers and other clients according to national rules on liability for damage; 3. liability of producers for damages caused by defective products.	possible asymmetries across MS based on stakeholders' perception										
EU Added Value	Q37 According to the case-law and the experience on the application of the Directive, could it be considered appropriate to enlarge the scope of the Directive, for instance so as to cover the services?	**JC1** Opportunity to enlarge the scope of the Directive so as to cover, for instance, services	Analysis of the extent to which it would be appropriate to enlarge the scope of the Directive, in light of the spread of services and new technological developments, taking into account the EU safety rules.	1. Percentage of cases for producers' liability relating to new technological developments and/or services that are settled without application of the Directive 2. Rating based on stakeholders' perception	x	x	x	x	x (CQ26, PAQ27, PQ31)	TS (Q33, Q34, Q35, Q36, Q37 - Q28)	TS (Q36, Q37)	TS (Q28, Q29, Q26)	TS (Q11, Q15, Q16)	TS (Q15, Q13, Q14)

ANNEX 4: COST-BENEFIT ANALYSIS

I. Overview of costs – benefits identified in the evaluation									
		Citizens/Consumers		**Businesses**		**Administrations**		**Insurers**	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
COST 1: Enforcement costs	**Description:** These costs are associated with activities linked to the implementation of initiatives such as monitoring, enforcement and adjudication They are recurring costs **Type of cost:** Claims raised in court: clawyers', bailiffs' and experts' fees, court fees, taxes, and all costs relating to judicial proceedings. Claims raised out of court: lawyers' and experts' fees, insurance fees **Expected?** Yes	**Yes.** **A. in court claim:** These costs vary considerably across Member States and depend, among other factors, on the type of litigation, the overall proceeding length, the compensation amount, the court, and the final decision. B. **out of court claim:** **This type of enforcement cost weighs on consumers and producers (or insurance companies).** **Sources:** country fiches; CATI survey However, these costs (including procedural, court, experts' and lawyers' fees) do not	A quantification of enforcement costs is not possible due to data limitations and to the fact that they are determined on a case-by-case basis depending on specific systems in each Member State jurisdiction and the type of litigation, as well as the final decision. Considering	**Same as for citizens/consumers**	**Same as for citizens/consumers**	The Directive is a private law instrument. Therefore, there is no involvement of any public authorities to ensure that its rules are enforced. As a private instrument, it leaves to the parties (i.e. to consumers) the burden to "enforce" its rules, i.e. to raise a claim in case of damage caused by a	N/A		

I. Overview of costs – benefits identified in the evaluation									
		Citizens/Consumers		**Businesses**		**Administrations**		**Insurers**	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
	Unexpected? No, even though they vary from jurisdiction to jurisdiction, depending on whether claims are raised in court or out of court	seem to have any connection to the Directive, being that they mainly relate to national practices and judicial systems	cases settled in court, proceeding fees in a civil proceeding can range from less than €200 (e.g. in BE, EE and SE) to over €1,000 (e.g. in HU and SK).			defective product.			
COST 2: Substantive compliance costs	**Description:** Substantive compliance costs encompass those investments and expenses that are faced by businesses and citizens to comply with obligations or requirements contained in a legal rule. They are recurring costs.	**Yes.** This cost (and a potential benefit for producers/businesses) is represented by: 1. The burden of proof, which appears to be the most burdensome element for consumers. In particular it is related to the difficulties in proving the link between the defect and the damage, attributing liability, proving the	N/A	**Yes** • Strict liability costs (Article 1): introduces a cost that – if the claim is successful–will be equal to the amount of compensation to be paid. This cost is case-dependent. Moreover, the actual cost will depend on the definition of "producer" adopted	N/A	N/A	N/A	yes	N/A

I. Overview of costs – benefits identified in the evaluation									
		Citizens/Consumers		**Businesses**		**Administrations**		**Insurers**	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
	Type of cost: The amount of compensation to be paid to the counterpart. Related provisions: Strict liability of producer (Art.1); Burden of proof (Art.4); Joint liability of producers (Art.5); €500 threshold (Art.9); three-year limitation period (Art.10); 10-year limitation period (Art.11) **Expected?** Yes	defect of the product, discovering where the defect occurred and proving the damage. Time (and related burden and therefore cost) to prove the right to be compensated varies across Member States, as well as across sectors (e.g. they seem to be particularly relevant in the pharmaceutical and medical sector). 2. The The €500 threshold (Article 9), which represents a cost		by the Member State when transposing the Directive. As a consequence, this cost is likely to be unequal across the EU; • Joint liability of producers costs (Article 5): the study identified no cases where this provision was applied. Source: interview and survey					

I. Overview of costs – benefits identified in the evaluation									
		Citizens/Consumers		**Businesses**		**Administrations**		**Insurers**	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
	Unexpected? No	for consumers inasmuch as it prevents any claims (and related possible compensation) under €500 from being raised, which is often the case. 3. The three-year limitation period (Article 10) for the recovery of damages, which entails a cost for consumers in terms of missed compensation after its conclusions. However, the this elements does not seem to represent a major cause for rejection of a claim (4% of the cases mapped at national level). 4. The 10-year limitation period (Article 11) to make a claim from the date on which the producer put into circulation the product which caused the damage potentially entails a significant cost in terms of missed							

I. Overview of costs – benefits identified in the evaluation									
		Citizens/Consumers		**Businesses**		**Administrations**		**Insurers**	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
		compensation. This provision is particularly costly in the case of damages caused by defective pharmaceutical products (among the products most frequently subject to claims). Moreover, it is reasonable to assume that damages caused by defective pharmaceutical products are likely to have significant consequences (and costs). However, the cost related to the burden of proof cannot be fully attributable to the Directive, since this element is at the basis of the Western legal tradition and judicial system Source: country fiches; stakeholders' interviews and survey							

I. Overview of costs – benefits identified in the evaluation									
		Citizens/Consumers		**Businesses**		**Administrations**		**Insurers**	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
COST 3: Administrative burden	**Description:** Administrative burdens are costs borne by businesses, citizens, civil society organisations and public authorities as a result of administrative activities performed to comply with information obligations included in legal rules. However, the only provision of the Directive entailing an information obligation is Article 15(2), requiring Member States to inform the Commission in case they derogate to the development risk clause (i.e. to Article 7(e)). **Type of cost:** Communicate to the Commission the derogation to Art.7(e) (Art.15(2))	N/A	N/A	N/A	N/A	**Yes** This cost is deemed to be residual, given that, based on findings of the desk research at the national level, it affected only five Member States, it is one-off, and the provision per se does not require anything more than a simple transmission of information Source: country fiche	N/A	NA	N/A

I. Overview of costs – benefits identified in the evaluation									
		Citizens/Consumers		**Businesses**		**Administrations**		**Insurers**	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
	Expected? Yes **Unexpected?** No								
COST 4: Indirect costs	**Description:** Indirect costs are not introduced by the Directive, but are its direct consequence. These costs are experienced by consumers, government agencies or other stakeholders that are not directly targeted by the initiative/regulation. These costs are usually transmitted through changes in the prices and/or availability and /or quality of the goods or services produced in the regulated sector **Type of cost:** e.g. specific liability insurance, reputational costs **Expected?** Yes **Unexpected?** No	N/A	N/A	**Yes**. These costs mainly relate to the payment of insurance premiums related specifically to strict liability. In particular, reputational costs and research and development costs are definitely relevant, especially for those manufacturers that produce robotic devices. Source: stakeholders' interview, CATI survey, OPC	N/A	N/A	N/A	N/A	N/A

I. Overview of costs – benefits identified in the evaluation									
		Citizens/Consumers		**Businesses**		**Administrations**		**Insurers**	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
BENEFIT 1: Improved well-being	**Description:** Such benefits include, most notably, health, safety and environmental benefits **Provisions:** Strict liability of producer (Art. 1) Joint liability of producers (Art. 5)	**Yes** Both strict and joint liability represent a clear benefit for consumers, which enjoy the right to obtain compensation for damage caused by a defective product directly from its producer. Therefore, at least in principle, the Directive has increased consumer protection and reduced the legal costs related to claims for defective products. Stakeholders strongly agree that consumers can enjoy the same rights in terms of compensation wherever they are in the EU **Sources:** OPC, country fiches (number of successful claims is higher than the number of non-successful claims in favour of consumers)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

I. Overview of costs – benefits identified in the evaluation									
		Citizens/Consumers		**Businesses**		**Administrations**		**Insurers**	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
BENEFIT 2: Market efficiency	**Description:** This might include improved allocation of resources, removal of regulatory or market failures or cost savings generated by new initiatives/regulation **Provisions:** Burden of proof (Art. 4) Exemptions (Art. 7) €500 threshold (Art. 9) three-year limitation period (Art. 10) 10-year limitation period (Art. 11)	N/A	N/A	**Yes** The benefits related to the provisions of the Directive translate into the development of a clear and stable legal framework. Provisions such as the €500 threshold and the three- and 10-year limitation period limit the possibility for consumers to issue claims for compensation, thus reducing the claims against producers or the likelihood for a compensation to be paid to consumers **Source**: country fiches; desk research; stakeholders' survey, OPC, interview	N/A	N/A	N/A	N/A	N/A

I. Overview of costs – benefits identified in the evaluation									
		Citizens/Consumers		**Businesses**		**Administrations**		**Insurers**	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
BENEFIT 3: Increased harmonisation	**Description:** This refers to the creation of a level playing field for producers and consumers, guaranteeing at EU level the liability of the producer in all Member States, and ensuring an increased homogeneity of procedures **Provisions:** Compliance with the Directive (Art. 19) and harmonisation through the cases of the CJEU	yes **Source:** stakeholders' interview, OPC	N/A	yes **Source**: stakeholders' interview, OPC	N/A	yes **Source**: stakeholders' interview, OPC	N/A	yes **Source**: stakeholders' interview, OPC	N/A

ANNEX 5: BACKGROUND ON THE DIRECTIVE

The initial proposal of the Commission implemented the Council Resolution of 14 April 1975 on the preliminary programme of the European Community with a view of a policy of protection and information of the consumer[107]. By this Resolution, the Council engaged itself to harmonise the right on the liability for defective products within a short period.

The adoption of the Directive took around ten years. The initial proposal of the Commission of 1976[108] was amended according to the opinion of the European Parliament and the Economic and Social Committee and resubmitted in 1979[109]. The Council adopted the Directive in 1985. This long time-span shows the complexity of the matter and the time needed to obtain a compromise among the Member States during a period when a unanimous vote in the Council was still necessary. In fact, the agreement was reached due to compromises in controversial areas, namely the exclusion of primary agricultural products and game from the scope, the availability of a defence for the producer based on the state of scientific/technological knowledge and the imposition of a ceiling on liability for death or personal injury caused by identical products.

At the same time, the Council of Europe was drafting a Convention on the same topic, (European Convention on Products Liability in regard to Personal Injury and Death)[110] which was adopted on 27 January 1977. Only three States have ratified the Convention. This text was quite similar to the Commission's proposal, but the Convention did not cover material damages.

In 1990, the Commission tabled a proposal for a directive on the liability of the suppliers of services[111] as a follow-up to its Three year plan for consumer policy (1990-1992)[112]. The draft provided for the liability of the supplier of services for direct damage caused (by his fault in the provision of the service) to the health and physical integrity of persons or their property. It was to apply to any transaction carried out on a commercial basis or by a public body and in an independent manner, whether or not in return for payment, which did not have as its direct and exclusive object the manufacture of goods. The proposal obliged the injured party to provide proof of the damage while setting a causal relationship between the performance of the service and the damage. Only services that compromise private safety, i.e. services which could damage the health or physical integrity of private persons or property were concerned. Services causing only financial damage were excluded. The proposal was withdrawn in 1994 due to the lack of an interinstitutional consensus. [113]

In the aftermath of the "mad cow" crisis, Directive 1999/34/EC[114] enlarged the scope of the Directive 85/374/EEC to all products, including the primary agricultural products and game, which in fact were already mentioned in the proposal of 1976. The objective of

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107 JO C 92, 25 April 1975, p.1

108 See Doc. COM (76) 372 final of 23 July 1976- (OJ C 241, 14 October 1976, p.9

109 See Doc. COM (79) 415 final, 26 September 1979 (OJ C 271, 26 October 1979, p.3. The initial proposal was amended with a view to excluding primary agricultural products, artistic and craft made products from the scope of the Directive.

110 https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/0900001680077321

111 See Doc. COM(1990) 482

112 See Doc. COM(1990) 98 final

113 See Doc. COM (1994) 260.

114 JO L 141, 4 June 1999, p.20
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:141:0020:0021:en:PDF

this amending Directive was to establish a common rule on strict liability for all kind of products and to facilitate a legitimate compensation for damage to health caused by defective agricultural products.

By Resolution of 19 December 2002[115], the Council suggested to the Commission to evaluate the need to modify the provisions related to the liability of the supplier, particularly Articles 3 and 12 of the Directive, due to problems in several Member States with the attribution of liability to suppliers. However, the Commission considered that if this Resolution were given effect, this would mark a departure from the objective of harmonisation of product liability rules under the Directive[116]. No legislative action was taken.

115 Council Resolution of 19 December 2002 on the modification of the Directive related to the liability for defective products (2003/C 26/02). JO C 26, 4 February 2003, p.2

116 See Third report concerning liability for defective products. COM (2006) 496 final.

ANNEX 6: CONCEPTS OF THE PRODUCT LIABILITY DIRECTIVE IN DETAIL

The fundamental elements of the Directive are the following:

- "**Strict liability**"(Article 1) means that producers are liable for damages caused by a defect in their product; independently of whether the defect is due to negligence or ill-intent. Producers are liable without fault on their part.

  Indeed, according to the Preamble of the Directive, adequate protection of consumers necessitates a liability regime without fault: *'it is the sole means of adequately solving the problem of increasing technicality*' and to have '*a fair apportionment of the risks inherent in modern technological production*'.

- '**Product**' (Article 2**)** means any movable, even though incorporated into another movable or into an immovable, including electricity.

  The Court of Justice indicated that the Directive applies to products used while providing any service (*Case C-203/99)*[117] but that the liability of a service provider does not fall within the scope of the Directive (*Case C-495/10)*[118] However, the Directive does not prevent Member States from applying national rules under which a service provider using a defective product is liable for damage thus caused.

- A product is '**defective**' (Article 6) when it does not provide the safety a person is entitled to expect, taking all circumstances into account, including the presentation of the product, the reasonably expected use and the time when the product was put into circulation.[119] This provision also points out that a product may not be considered defective for the sole reason that a better product is subsequently put into circulation.

  The main concept of the product liability regime is the defectiveness of the product which is, in turn, related to the expected safety of the product[120]. It is irrelevant whether the product is fit for purpose or fit for use This question of fitness for use belongs to the rules related to the sale of goods, outside of the scope of the Directive.

  According to this provision the defectiveness must be assessed based on the average consumer expectation test. This text represents however an objective analysis; thus the defectiveness must be assessed on the basis of the legitimate

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117 CJEU. Judgment of 10 May 2001. *Case C-203/99*.Henning Veedfald v Århus Amtskommune.

118 CJEU, Judgement of 21 December 2011, *Case C-495/11*, Dutrueux and Caisse primaire d'assurance maladie du Jura.

119 Distinction is to be made between product "liability" and product "safety". Directive 85/374/EEC seeks to compensate ex-post for damages suffered by consumers due to a defective product. However, there are other pieces of European Union legislation that prevent damages ex-ante, by ensuring that products placed on the EU market are safe (for instance, the General Product Safety Directive or other sector-specific legislation such as the directives related to machinery, electrical equipment, radio equipment, medical devices, cosmetics, pharmaceutical products or toys. To the extent that safety legislation ensures the safety of products on the market, it will reduce the need for consumers to seek for compensation under product liability rules.

120 However, this definition does not always fit with all product categories, for example for products such as pharmaceuticals, which by their very nature may be considered as high-risk products. For those products the (unexpected) harmfulness becomes more relevant than the defectiveness of the products as such.

expectation of the public and not on the subjective expectations or predisposition of one person.

The defectiveness of a product should be assessed on a case-by-case basis, considering all the relevant circumstances, on the basis of objective criteria, including especially product safety legislation. This leaves a large margin of interpretation to the national courts.

In 2015, the CJEU gave further guidance to national courts on how to assess the safety which the public is entitled to expect. The case concerned pacemakers and cardioverter defibrillators and the Court ruled that where is found that such products belonging to the same group or forming part of the same production series have a potential defect, such a product may be classified as defective without there being any need to establish that the individual product has such a defect *(Joint Cases C-503/13 and 504/13*).[121]

This ruling reaffirmed the protective function of the Directive, in particular related to specific products, such as medical devices, which require a particularly high level of consumer protection. In these cases, the potential lack of safety is considered as being a potential defect due to the high potential for damage that the malfunctioning of those products might cause to patients.

As provided in Article 6, when it comes to assess the legitimate safety expectation of the public, all relevant circumstances should be taken into consideration. Three elements are listed as examples:

i) the presentation of the product, i.e. how the product has been put into circulation and how is it presented to the public. It includes marketing, packaging, instructions, warnings, etc. In case of inaccurate or missing information, this may render a product defective, especially in the case of products such as medical devices or pharmaceutical products [122].

   Even though it is impossible to warn the public about all the potential dangers of a product, EU legislation obliges the producer to provide the consumer with the relevant information to enable her or him to assess the risks during normal use and to take precautions against those risks.

   However, this does not mean that a warning or other form of precautionary information will automatically render an unsafe product safe. Even the presence of an exhaustive list of warnings does not guarantee the safety of the product; therefore, the judge will have to determine if the warnings correspond to the safety expectations of the public at large.

   Finally, warnings and instructions about the use of a product will be also taken into consideration by the court for the assessment.

ii) reasonable expected use includes consumption, but also other activities such as storage. The producer has also to anticipate that the product could be misused by the consumer by designing the product in a safer way or, if it is not enough, by warning the consumer.

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121 CJEU. Judgment of 5 March 2015. Joint Cases C- 503/13 and 504/13.Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt.

122 The outcome of CJEU Judgement of 20 November 2014, Case C-310/13, Novo Nordisk Pharma GmbH also shows that some aspects, which may be considered as closely related to an exhaustive liability scheme, such as the access to relevant information, are not covered by the current scope of the Directive. However, those rules may be nowadays seen as essential for a balanced system.

iii) the time when the product was put into circulation; Later technical developments, as well as subsequent circumstances that may affect the product, should not be taken into account. The fact that new rules apply for those products is not per se an element to consider the product as unsafe.

- '**Producer**' (Article 3) means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer, as well as any person who imports into the European Union a product for sale, hire, leasing or any form of distribution in the course of his business. The producer defined as such shall be liable for damage caused to consumers by a defect in his product.

  Where the producer cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured party, within a reasonable time of the identity of the producer or of the person who supplied him with the product.

  The term "producer" is deliberately broad so that an injured person easily find a liable person. In case of an anonymous product, the supplier will be held liable unless he discloses the identity of the producer.

  The Directive does not define the term "supplier", but according to the case-law of the Court of Justice, the supplier must be regarded as any intermediary involved in the marketing or distribution chain of the product.[123]

  The Directive foresees that where two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse (Article 5). Pursuant to Article 12, the liability of the producer may not, in relation to the injured person, be limited or excluded by a provision of national law limiting his liability or exempting him from liability.

- **Exemptions of liability** (Article 7): the Directive establishes a catalogue of defences or circumstances that could exclude liability.

  In particular, the producer shall not be liable if he proves some circumstances, including:

  g) that he did not put the product into circulation; or
  h) that, having regard to circumstances, it is probable that the defect which causes the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or
  i) that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business; or
  j) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or
  k) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered (the so-called Development Risk Clause); or

123 CJEU, Judgement of 21 December 2011, Case C-495/11, Dutrueux and Caisse primaire d'assurance maladie du Jura.

l) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fifted or to the instructions given by the manufacturer of the product.

Member States are obliged to include in their transposition laws the circumstances listed in Article 7 releasing a producer from strict liability. However, according to Article 15(1)(b), each Member State may provide that the producer shall be liable even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered.

The Court of Justice noted in *Case C-300/95*[124] that, in accordance with the principle of fair apportionment of risks between the injured person and the producer, the latter has a defence if he can prove certain facts exonerating him from liability. For this purpose, it should be considered that the relevant scientific and technological knowledge must have been accessible at the time when the product was put into circulation. It follows that, in order to have such a defence, the producer of a defective product must prove that the objective state of scientific and technological knowledge was not such as to enable the existence of the defect to be discovered.

In *Case C-203/99*, the exemption from liability based on the fact that the product was neither manufactured by him for sale or any form of distribution was interpreted as meaning that the exemption from liability where an activity has no economic or business purpose does not extend to the case of a defective product which has been manufactured and used in the course of a specific medical service which was financed entirely from public funds and for which the patient was not required to pay any consideration.

In the context of defect due to compliance with mandatory regulations, it should be noted that compliance with voluntary standards would not provide a defence.

- '**Burden of proof**' (Article 4): the injured person is required to prove the damage, the defect and the causal relationship between defect and damage for the purpose of compensation.

  The Court of Justice stated, in *Case C-621/15*[125], that this proof could be facilitated by accepting national evidentiary rules according to which certain factual evidence may constitute serious, specific and consistent evidence, even if there is no conclusive scientific evidence to the matter.

- '**Damage**' (Article 9) for the purpose of the Directive means:

  c) any damage caused by death or by personal injuries, and
  d) any damage to, or destruction of, any item of property other than the defective product itself, provided that it was intended and used for private use and consumption with a lower threshold of EUR 500.

  By subjecting the compensation of damages to property to a minimum threshold of a fixed amount (EUR 500), the Directive aims to avoid litigation in an excessive number of cases. The Directive limits the compensation for damage to property for

124 CJEU. Judgment of 29 May 1997. Case C- 300/95. Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland.

125 CJEU. Judgment of 21 June 2017. *Case C-621/15*. N. W and Others v Sanofi Pasteur

goods for private use or consumption (as opposed to business property, for instance, damage caused to a company car would be excluded).

As the Court of Justice ruled in *Case C-285/08*[126], compensation for damage to an item of property intended for professional use and employed for that use is not covered by the scope of application of the Directive. However, the Directive does not prevent a Member State establishing such a system of liability corresponding to the one established by the Directive.

The Court has also stated that Member States cannot restrict the damages resulting from death, personal injury or the types of material damage to or destruction of an item of property, which is to be compensated (*Case C-203/99).*

Compensation of economic loss is only taken into account in case of personal injuries (for instance, incapacity to work due to the injury).

- **Time-limits** (Articles 10, 11 and 16)

  According to Article 10, a limitation period of three years shall apply to proceedings for the recovery of damages and the rights conferred upon the injured person pursuant to this Directive expire after ten years from the date on which the producer put the defective product into circulation (Article 11).

  These time-limits aim at creating a balance between the interests of producers and those of injured parties. They are there to give legal certainty and reduce financial burdens for producers.

  Any Member State may provide that a producer's total liability for damage resulting from death or personal injury and caused by identical items with the same defect shall be limited to an amount which may not be less than 70 million EUR (Article 16).

- **Other liabilities**:

  The Directive does not affect any rights an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive was notified (Article 13).

  While the Court clarified that Member States may not maintain a general system of product liability different from that provided for in the Directive *(Case C-52/00)*[127], it does not preclude the application of other systems of contractual or non-contractual liability based on other grounds, such as fault or a warranty in respect to latent defects (*Case C-183/00 and C-310/13).* [128]

126 CJEU. Judgment of 4 June 2009. *Case C-285/08*. Moteurs Leroy Somer v Dalkia France.

127 CJEU. Judgment of 25 April 2002. Case C-52/00. Commission of the European Communities v French Republic.

128 CJEU- Judgement of 25 April 2002. Case C-183/00 María Victoria González Sánchez v Medicina Asturiana SA. and Judgement of 20 November 2014, Case C-310/13, Novo Nordisk Pharma GmbH