

EVALUATION AND FITNESS CHECK (FC) ROADMAP			
TITLE OF THE EVALUATION/FC	Evaluation of the Directive 85/374/EEC concerning liability for defective products		
LEAD DG – RESPONSIBLE UNIT	DG for Internal Market, Industry, Entrepreneurship and SMEs Unit B4 Enforcement of the Internal Market	DATE OF THIS ROADMAP	06/2016
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This indicative roadmap is provided for information purposes only and is subject to change.			

A. Purpose
(A.1) Purpose
<p>The purpose of this evaluation is to assess the functioning and the performance of Council Directive 85/374/EEC concerning Liability for Defective Products (LDP) as modified by Directive 1999/34/EC of the European Parliament and of the Council.</p> <p>In particular, the evaluation will assess whether and to what extent the Directive meets its objectives of guaranteeing at European Union level the strict liability of the producer for damage caused by a defective product while also ensuring the free movement of goods and offering in an efficient way a high degree of protection to EU consumers. By the same token the evaluation should assess the coherence of the Directive with other relevant EU actions and whether it still corresponds to the stakeholders' needs and has EU added value. The evaluation will also assess if the Directive is fit-for-purpose vis-à-vis the new technological developments such as the Internet of Things and autonomous systems. Where appropriate, the evaluation should identify possible issues in the application of the Directive and, depending on the conclusions, improvements could be envisaged.</p>
(A.2) Justification
<p>Since its adoption in 1985, the Directive has not been subject to any formal evaluation. The European Commission has regularly reported to the Council and Parliament on the status of its application according to Article 21 of the Directive. The next (fifth) report will cover the period 2011-2015 and is due by 2017. The reporting obligation does not foresee an evaluation <i>per se</i> but the Commission took this opportunity to carry out a fully-fledged assessment of the performance of the Directive.</p> <p>In the context of the fourth application report, which was adopted on 8 September 2011, the Commission noted that the Directive contributes to maintaining the balance between the interests of</p>

producers and consumer as regards liability for defective products. The Commission furthermore concluded that there was no sufficient evidence to justify a proposal for amendments taking also into account the fact that any amendment to one or more provisions would affect the overall balance of the Directive.

Recently, liability issues are progressively being investigated notably within the framework of the Digital Single Market Strategy (DSM). In the context of preparing the Free flow of Data initiative, a key issue is to reflect whether Directive 85/374/EEC is fit for purpose vis-à-vis new technological developments (i.e. software, Cloud, Internet of Things¹ (IoT), advanced robots and automated systems) and whether it covers cases of malfunctioning apps and non-embedded software. Furthermore, issues have been raised on whether the unintended, autonomous behaviour of an advanced robot could be considered a defect and how should strict liability for damages be allocated between the different participants in the Internet of Things or, in more general terms, in case of connected objects relying on each other. These issues have further supported the Commission in its decision to perform an evaluation of the Directive.

B. Content and subject of the evaluation

(B.1) Subject area

Retrospective assessment of the fitness of the Directive to meet its objectives also with a view to the new technological developments.

Directive 85/374/EEC guarantees the liability of the producer in the event of damage caused by malfunctioning products. The Directive lays down a common rule for strict liability (i.e. "liability without fault") of producers at EU level and offers a real possibility to consumers to claim financial compensation for death or 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.

The "strict liability" approach extends the liability of producers to injured consumers who suffer loss through defective products without the need to prove a contractual link, a duty of care or failure to take reasonable care to comply with relevant legislation.

Directive 85/374/EEC applies to all movable products, even when incorporated into other movable or immovable property, including primary agricultural products and also electricity. It establishes that a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including the presentation of the product or the time when the product was put into circulation.

(B.2) Original objectives of the intervention

The Directive aims to guarantee the consumer that the producer is liable for damage caused by the defectiveness of his product and seeks to achieve within its scope, the approximation of laws, regulations and administrative provisions of the Member States.

By guaranteeing the same, high degree of protection to all EU consumers against damage caused to health or property by defective products, the Directive facilitates the free movement of goods and ensures undistorted competition between economic operators.

In a nutshell, LDP is a measure that seeks to compensate *a posteriori* for injuries suffered by consumers due to a defective product. Other EU pieces of legislation prevent *a priori* injuries by ensuring that products placed on the EU market are safe (e.g. the General Product Safety Directive, other sector-specific Directives such as the ones related to machinery, electrical equipment, radio

¹ In general terms, the IoT is a network of (digital) products, communicating and interacting with the environment and other devices. In some cases, the IoT may create interdependencies between products, gathered or generated data and service providers. There is a wide variety of IoT systems and ways that these systems can be used.

equipment, medical devices, cosmetics etc). The safety legislation requires that producers place only safe products on the EU market. Otherwise the unsafe product should be withdrawn or recalled from the market.

As regards the product liability, the producer is liable for the damage caused by a defective product. In both cases, the purpose is guaranteeing the functioning of the internal market ensuring at the same time the protection of the consumers. To the extent that safety legislation ensures the safety of products in the market, it will reduce the need for consumers to seek compensation under product liability rules.

The evaluation will assess whether the scope of the Directive is still fit for purpose.

(B.3) How the objectives were to be achieved

In order to achieve the above mentioned objectives, Directive 85/374/EEC establishes the principle of 'strict liability' (or liability without fault), imposed on the producer in the event of damage caused by a defective product. The strict extra-contractual liability of the producer for defective products under the Directive does not permit any contractual derogation in relation to the injured person and ensures the effective protection of consumers.

To meet its purpose and objectives, the Directive determines the meaning of the terms 'product', 'producer', 'defective' and 'damage'. More specifically, by 'product', the Directive includes "all movables, even if incorporated into another movable or into immovable property – expressly including the unprocessed agricultural products and electricity". Services are outside the scope of the Directive. The wording 'producer' is used to mean "the manufacturer, the person putting his name or trade mark on the product, the importer and, when the producer cannot be identified, each supplier of the product under some conditions". 'Defective' for the needs of the Directive is the product which does not provide the safety which a person is entitled to expect taking into account all circumstances to this end. The Directive sets the rule on liability for defective products when the 'damage' relates to the death, personal injury or destruction to property with a lower threshold of 500 euros.

Further to determining these terms, the Directive lays down the proceeding for recovering of the damages, notably by setting the burden of proof on the injured party who should prove the damage, the defect and the causal link between the two. The producer may be exempted from this liability in cases expressly mentioned in the Directive and this liability expires in any case after ten years from the date that the product was put into circulation.

The Directive has been examined by the European Court of Justice in several rulings, especially as regards the defectiveness of a product, definition of damage, the producer's exemption from liability and the development of risk defence.

The Directive does not establish an exclusive basis for product liability claims. However, as the CJEU said in several decisions, the Directive cannot be interpreted as giving the Member States the possibility of maintaining a general system of product liability different from that provided for in the Directive, neither precluding 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.

C. Scope of the evaluation/FC

(C.1) Topics covered

The evaluation will assess the functioning and effectiveness of the Directive, with a particular focus on its implementation by Member States. It will also identify any gaps or overlaps in terms of scope and identify possible shortcomings in its application. Furthermore, the evaluation will examine how Member States are using the Directive when it comes to damage caused by advanced robots, autonomous systems, complex IoT products, defective apps or other non-embedded software. In this context, the evaluation will investigate whether the objectives and requirements of the Directive are still fit for purpose in light of these technologies.

From the geographical point of view, the evaluation should cover the EU-28 Member States.

In terms of temporary scope the assessment will cover the period 2000 – 2015 as this is the first fully-fledged evaluation of the Directive and as it will provide feedback for the 5th application report for the period 2011- 2015.

(C.2) Issues to be examined

The reports on the application of the Directive which have underlined the overall satisfactory implementation of the Directive and pinpointed that it has managed to strike the balance between consumer interest and internal market policies. The main issue highlighted in the two last reports referred to the EUR 500 threshold foreseen in the Directive on claims regarding property damages. In precise, consumers were in favour of more protection by removing the EUR 500 threshold whereas producers and insurers pinpointed the risk of increasing the number of claims for minor damages and were in favour of increasing the threshold.

Further to these reports, the Directive has never been subject to an evaluation since its adoption and as this is the first fully-fledged evaluation, the impact and effects of the most important aspects of the Directive will be examined systematically. In this context, the concept of "product", "producer", "defective", "damage" and also the category of exemptions provided in the Directive will be analysed with a view to assessing whether they are still fit for purpose.

In reply to questions related to the current application of the Directive by Member States as regards the new technological developments, the evaluation will provide an evidence-based assessment per country of how the Directive to software, the Internet of Things based products, advanced robots, autonomous systems and other "smart products". In this context, the following indicative aspects will be investigated :

- whether apps and non-embedded software or the Internet of things based products are considered as "*products*" for the purpose of the Directive;
- whether an unintended, autonomous behaviour of an advanced robot could be considered a "*defect*" according to the Directive;
- how the strict liability for damages between the different participants in the IoT is allocated, in particular in case of connected objects or sensors relying on each other that are not necessarily under the control of a single *producer*;

To this end, the questions below will be answered.

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 context²)?

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?

² http://ec.europa.eu/justice/contract/digital-contract-rules/index_en.htm

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?

(C.3) Other tasks

N/A

D. Evidence base

(D.1) Evidence from monitoring: N/A

(D.2) Previous evaluations and other reports

According to Article 21 of the Directive, the Commission should present a report on the application of the directive every five years. Until now the Commission has presented four reports on the application of the Directive to the European Parliament and to the Council. The reports, not related to the evaluation of the directive, have pointed out its overall satisfactory implementation to the interest of both sides (consumers and producers) and have not raised any need for amendments.

In the context of liability for defective products, certain studies such as the Lowells Report (2003)³ regarding procedural aspects of claims for defective products and the Fondazione Roselli (2004)⁴, have analysed the economic impact of the development risk clause provided in Article 7(e) of Directive.

In addition to the above reports and studies the evaluation will also take into account on-going Commission initiatives which entail liability aspects, notably:

- The ‘Free flow of data’ initiative aimed at tackling restrictions on the free movement of data for reasons other than the protection of personal data within the EU and unjustified restrictions on the location of data for storage or processing purposes. It will address the emerging issues (data ownership, interoperability, usability and access to data) and liability
- The Commission Staff Working Document on advancing the Internet of Things raises questions related to safety and liability and indicates that the current acquis (Directive 85/374/EEC) might no longer be fit for purpose and needs to be revised;
- Reflections and work on the deployment of advanced robotics (and autonomous and A-I based systems, for instance in the framework of GEAR 2030 on highly automated vehicles) seeks to clarify liability at each level of automation;

³ <http://ec.europa.eu/DocsRoom/documents/7106>

⁴ <http://ec.europa.eu/DocsRoom/documents/7104>

- The EP Draft report on Civil Law Rules on Robotics calls for adequate rules on civil extra-contractual liability at EU level. In fact, this draft report highlights that the development of autonomous and cognitive features in a robot (especially its ability to learn from experience and take independent decisions) makes the current rules on strict liability insufficient and pleads for clarifying responsibility for harmful action/damage caused by robots.
- In the context of the Digital Single Market, a study (SMART 2016/0030) is being conducted on emerging issues (data ownership, interoperability, usability and access to data) and liability, with a point related to the analysis of the legal issues arising in the context of the IoT, in particular extra-contractual and contractual liability. The study should be finished at the end of May 2017.

(D.3) Evidence from assessing the implementation and application of legislation (complaints, infringement procedures)

The CJEU has interpreted questions related to the application of this Directive in preliminary rulings. Some of the most recent judgements: *judgment of 5 March 2015 (cases C-503/13 and C-504/13)* related to the interpretation of "defective" and "damage"; *judgment of 20 November 2014 (case C-310/13)* on the application of Article 13 of the Directive related to rules on a special liability system; *judgment of 21 December 2011 (case C-495/10)* and *judgment of 2 December 2009 (case C-358/08)* on the responsibility of the producer and *judgment of 9 February 2006 (case C-127/04)* on the time-limit for bringing recovery proceedings.

There have been no formal complaints as far as known. In few occasions, stakeholders raised informal questions to the Commission services about the implementation of the Directive. The majority of them were from the pharmaceutical industry suggesting removing pharmaceutical products from the scope of the Directive or suggesting that the Directive should provide a defence for producers in industries where the safety of products is closely regulated, if products comply fully with the applicable rules.

In the workshop "Digital Revolution: Challenges for Contract law in practice" organised by the University of Munster, 1-2 October 2015, certain academic legal experts were suggesting that Directive 85/374/EEC might no longer be fit for purpose in this context and needed revision.

(D.4) Consultation

The evaluation is supported by a consultation strategy, encompassing an open public consultation, a complementary survey targeted to stakeholders involved in the application of the Directive as well as interviews with stakeholders.

- An online open public consultation of 12 weeks will be launched. The questionnaire will be published on the website 'Your Voice in Europe': http://ec.europa.eu/yourvoice/consultations/index_en.

- The online complementary targeted survey will be addressed to public authorities of all Member States, industry and consumers associations, academia, law firms and consulting, insurers and federations of insurers with a view to collect quantitative and qualitative data;

- The face to face interviews will be conducted with selected stakeholders from the main groups concerned by the application of the Directive (e.g. businesses, industrial associations, consumer associations etc.).

The consultation tools aim at collecting input from stakeholders such as:

1. Public administrations,

2. Industry associations, producers, importers and suppliers, including small and medium enterprises,
3. Consumers, Consumer organisations,
4. Federations of insurers, insurers,
5. Other stakeholders e.g. academia, think-thanks, consultants, relevant public/private partnerships as the PPP on robotics, the Alliance of Internet of Things etc.

Other tools might also be proposed where deemed appropriate, in the course of the evaluation study, depending on the level of information needed.

(D.5) Further evidence to be gathered

The evaluation will be supported by an external study.

E. Other relevant information/ remarks

N/A