EUROPEAN
COMMISSION

Brussels, 7.5.2018
COM(2018) 246 final

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)

{SWD(2018) 157 final} - {SWD(2018) 158 final}

1. INTRODUCTION

For more than three decades, the Product Liability Directive[1] ('the Directive') has ensured that producers take responsibility for defective products vis-à-vis consumers. When it was adopted in 1985, the Directive was a bold and modern instrument that required substantial adaptations of Member States' civil codes.

The Directive was one of the first pieces of EU legislation that explicitly aimed to protect consumers. It introduced the concept of strict liability, where producers are responsible for defective products, regardless of whether the defect is their fault. The Directive also aims to contribute to economic growth by providing a stable and legal environment of equal competition that allows companies to place innovative products on the market.

The Directive complements EU product safety legislation and what is known as the 'New Approach' to product safety. Introduced at the same time as the Directive, the 'New Approach' aims to prevent accidents by setting common safety rules[2] that allow the single market for goods to function smoothly and to reduce administrative burden. The Directive is the safety net for instances when accidents nevertheless occur.

2018 is not 1985. The EU and its rules on product safety have evolved, as have the economy and technologies. Many products available today have characteristics that were considered science fiction in the 1980s. The challenges we are facing now and even more acutely in the future — to name but a few — relate to digitisation, the Internet of Things, artificial intelligence and cybersecurity.

Exponential growth in computing power, the availability of data and progress in algorithms turn are making especially artificial intelligence (AI) in particular into one of the most important technologies of the 21st century. The Commission adopted its Communication on 'Maximising the benefits of Artificial Intelligence'[3] to ensure a coherent policy response that also addresses legal challenges. Product safety and liability —– should there be damage —– are one essential aspect in finding of a policy response that enables European societies, businesses and consumers to benefit from artificial intelligence.

Given that the Directive has never been evaluated since its entry into force and in the light of these recent technological developments, the Commission carried out an evaluation of the Directive to assess its performance. The evaluation includes consideration of recent technological developments. More specifically, it analysed whether the Directive: (i) continues to be effective in meeting its original objectives; (ii) is efficient; (iii) is consistent with the relevant EU rules; (iv) remains relevant by

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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, http://data.europa.eu/eli/dir/1985/374/oj.

2 Today this 'type of legislation' covers the vast majority of products available on EU markets. It has been continuously updated to keep track of technological developments.

3 Commission Communication, 'Maximising the Benefits of Artificial Intelligence for Europe', (COM(2018)237).

embracing recent technological changes; and (v) whether EU product liability legislation continues to provide added value to businesses and injured persons[4].

The evaluation also looked at whether the Directive in its current form still serves its purpose. Does it adequately address the challenges of increasingly autonomous devices and cybersecurity? What about sustainability and reaching a circular economy? Does the Directive unnecessarily discourage producers from placing innovative products on the market? Or conversely, does it deter manufacturers from placing faulty and unsafe products on the market? Does it still protect injured persons in a changing world?

The evaluation has shown that even though products are much more complex today than in 1985, the Product Liability Directive continues to be an adequate tool.

However, we need to clarify the legal understanding of certain concepts (such as product, producer, defect, damage and the burden of proof) and look closely at certain products such as pharmaceuticals, which may pose a challenge to the performance of the Directive.

In addition, on emerging digital technologies, a preliminary analysis on how these affect the functioning of the Directive, has raised a number of open questions. In light of these findings, the Commission will consult broadly to reach a common understanding with all stakeholders. The aim is to draw up comprehensive guidance on how to apply the Directive today. In addition, it will assess to what extent emerging digital technologies can be adequately addressed by the current Directive. This guidance and the assessment will help us to pave the way forward for a product liability framework fit for the digital industrial revolution.

Our goal is to ensure that: (i) the EU continues to have a product liability regime that fosters innovation; (ii) products placed on the EU market are safe[5]; and (iii) people who suffer injury because of defective products are able to claim compensation when accidents occur. We have a responsibility both to businesses and to people who suffer injury. This is our compass. We need to navigate the coming technological changes carefully and sensibly so as to respect either objective.

2. THE MAIN CHARACTERISTICS OF THE DIRECTIVE

The Directive applies to all movable products, even if integrated into another movable product, and specifically includes electricity. It also introduces the concept of **strict liability** of producers[6]. In line with EU safety legislation[7], producers are responsible for their products. If a product is defective and causes personal injury or material damage above EUR 500 to an item of property mainly for private use or consumption, producers

4 Commission Staff Working Document, Evaluation of Council Directive 85/374/EEC, (SWD(2018)157).

5 In addition to already existing product legislation.

6 The notion of "producer" includes 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 (Article 3 of the Directive).

7 Under EU safety legislation, the manufacturer is always responsible for ensuring that a product meets the requirements of the relevant EU legislation, even if there is mandatory third party conformity assessment.

are liable regardless of whether or not they are at fault. A product is considered defective if it does not provide the safety a person is entitled to expect[8].

Example — *When driving a car, a person had to avoid an unexpectedly appearing obstacle. He swerved off the road and his vehicle started shaking strongly. The sensors of the airbag considered this an accident and went off. One of the lateral airbags hit the driver in the neck, compressed the artery and caused a stroke. Courts tried to determine whether the producer had correctly calculated the risk of a malfunctioning of the sensors. The claim was rejected by two instances, but then invalidated at a higher level. The case was ultimately settled out of Court.*

Strict liability represents a strong tool for the protection of injured persons. However, there are a number of circumstances where the Directive allows producers to take certain calculated risks when placing innovative products on the market. The producer is not liable if it can prove that: (i) the defect did not exist when the product was put into circulation; (ii) the defect is due to compliance with regulations issued by public authorities; or (iii) the state of technical knowledge at the time of putting the product on the market made it impossible to discover the defect. Member States have the possibility to obtain a derogation from this last exemption.

Example *–A person suffered severe personal injuries when the front brakes of the second-hand motorbike he was riding seized without warning and he was thrown off. The motorbike had been well-maintained, had low mileage and was only two years old. The claimant sued and won in the first instance. An appeal by the producer failed because the Court explained that the Claimant did not have to prove the existence of a specific design or manufacturing defect for there to be a finding of defect, nor did he have to show how the defect was caused. The Claimant merely had to show that a defect existed at the relevant time and that this caused the accident. The Court found on the expert evidence that there must have been a defect in the brakes of this particular motorbike. This susceptibility was not present in other bikes of the same type, and therefore the Court was entitled to infer that these particular brakes were defective, and the Claimant had proved his case*

From the day that they become aware of the defect, injured persons have 3 years to claim damages. Claims are no longer possible 10 years after the product was put in circulation. To sustain their claim, those who have suffered injury must prove the damage, the defect and the causal link between the defect and the damage.

3. IMPLEMENTATION OF THE DIRECTIVE

The Directive requires the Commission to report to the Council and Parliament[9] every 5 years on its implementation. This is the fifth report which is complemented by an evaluation.

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[8] This takes all circumstances into account, including the presentation of the product, the use to which it could reasonably be expected the product would be put, and the time the product was put into circulation. Article 6 of the Directive states that a product must not be considered defective for the sole reason that a better product is subsequently put into circulation.

[9] COM(95) 617 final, COM(2000) 893 final, COM(2006) 496 final, COM(2011) 547 final. Previous reports noted an increase in cases related to the Directive. They also noted the general consensus about having a product liability framework at EU level. However, certain debates on some of the concepts used in the Directive e.g. on the burden of proof can be considered longstanding. Apart

The Commission did not receive any complaints or launch any infringement proceedings during the 2011-2017 reporting period. However, the Directive does not cover or harmonise all aspects of product liability. There is room for different national approaches, for example on systems to settle claims for damages, or on how to bring proof of damage. These are left to Member States to decide. Member State may also introduce or maintain other national instruments for the liability of producers based on fault.

Five Member States adopted the 'development risk derogation' set out in Article 15(1)(b) of the Directive, whereby a producer is also liable if the state of scientific and technical knowledge when the product entered circulation was not such that the defect could be discovered. Two Member States apply this to all sectors[10], while two notably exclude pharmaceutical products[11] and one excludes products of the human body[12].

The findings of the evaluation suggest that most product liability claims between 2000 and 2016 were actually settled out of Court. 46 % of cases were settled in direct negotiation, 32 % in Court, 15 % through alternative dispute settlement mechanisms, and 7 % were resolved through other means such as through the insurer of the responsible party[13]. The external study commissioned for the evaluation identified 798 claims based on product liability rules from 2000 to 2016[14]. It is, however, likely that the real number of cases was higher, and not all cases were included in the public and private databases consulted. The products most concerned are raw materials (21.2 % of cases), pharmaceuticals (16.1 %), vehicles (15.2 %) and machinery (12.4 %). The types of damage identified relate to the characteristics of each product[15].

4. COURT OF JUSTICE CASE LAW DURING 2011-2017

While the number of court cases at national level and the sectors involved do not point to the prevalence of one specific sector, the situation is different when we look at matters brought before the Court of Justice of the European Union. The four judgments of the Court during the reporting period concerned medical devices and pharmaceutical products, potentially highlighting specific problems in the application of the Directive to healthcare products.

In a case where a hospital bed had burned a patient during surgery, the Court confirmed that the Directive applies only to producers, not to service providers that may use products which are found to be defective[16]. However, the Directive does not prevent

from extending the scope of the Directive by Directive 1999/34/EC, the Commission did not consider amending it to be necessary.

10 Finland and Luxembourg.

11 The Hungarian Civil Code states that the producer of any pharmaceutical product 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 7(e) of the Directive.

12 France.

13 These percentages are based on the responses to the open public consultation and are averages across 28 Member States.

14 Technopolis, Evaluation Study of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative burdens of the Member States concerning liability for defective products.

15 This is based on the analysis of 547 cases according to the Combined Nomenclature.

16 Judgment of 21 December 2011, Case C-495/10.

Member States from establishing strict liability for service providers as long as they do not in any way limit the producers' strict liability for their products as provided for in the Directive.

The single most difficult stepping stone to receiving compensation for damages is the burden of proof on the injured person to demonstrate a causal link between the product defect and the damage. The Court has made doing this considerably easier by accepting national rules that help the injured person establish this proof, provided that this does not undermine the Directive's placing of the burden of proof on the injured person. For example, the Court indicated 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[17]. Such rules make it easier for the injured person to establish the producer's liability. Also, the Court accepted national evidentiary rules under which a national court may consider certain factual evidence to constitute serious, specific and consistent evidence of a defect of a product and to constitute the causal link with the damage, even if there is no conclusive scientific evidence on this[18]. Especially for adverse effects of pharmaceutical products, where evidence often is inconclusive, this may make it easier for people who have suffered injury to obtain redress. The Court also indicated that products of one group or of the same production series with a potential defect may be considered as defective without the need to establish the actual defect of the individual product[19]. The cost of the operation needed to remove such potentially defective products is also considered damage within the meaning of the Directive[20].

***Example: Gradual degradation of pacemakers**. A producer of pacemakers informed physicians that a component used to hermetically seal their pacemakers may experience a gradual degradation. That defect could lead to premature battery depletion, resulting in loss of telemetry and/or loss of pacing output without warning. The manufacturer recommended replacing such pacemakers if necessary and said that it would make new pacemakers available free of charge. Two patients received free new pacemakers. The defective pacemakers were destroyed without further examination. The insurance company claimed compensation from the producer under the Directive also for the cost of the operation to replace the pacemakers as damage.*

5. EVALUATION OF THE DIRECTIVE

The Commission's evaluation is based on an external study whose findings are analysed in the accompanying Commission staff working document[21]. The evaluation analysed: (i) whether the Directive was still meeting its original objectives of ensuring producer liability, the functioning of the single market and the protection and compensation of injured people; and (ii) whether it was demonstrating effectiveness, efficiency, coherence, relevance and EU added value.

17 Judgment of 20 November 2014, Case C-310/13.
18 Judgment of 21 June 2017, Case C-621/15.
19 Judgment of 5 March 2015, Joined Cases C-503/13 and C-504/13.
20 Ibid.
21 See the accompanying staff working document SWD(2018)157 on the evaluation of the Directive.

5.1. Effectiveness

There is a wide awareness among stakeholders that producers are liable for defects in their products. Industry is, on the whole, satisfied with the Directive as a means of ensuring liability for defective products. Conversely, consumer organisations are critical of the fact that it is difficult for injured persons to prove the link between damage and defect, particularly because they have to advance any cost related to bringing this proof and because they are at a disadvantage in terms of technical information about the product. The evaluation identified this as the most difficult stepping stone for consumers to obtain compensation. However, it is a requirement that cannot be set aside. The EUR 500 threshold and time limitations for claims (especially for certain products such as pharmaceuticals) also limit the number of cases for which consumers can claim compensation.

Overall, the Directive can be considered to contribute to a reasonable balance between protecting those who suffer injury and ensuring fair competition on the single market. However, some of the Directive's concepts require guidance and/or clarification as they hamper the effectiveness of the Directive. In particular, a better common understanding of what is meant by 'product', 'damage' and 'defect' as well as clarifications on the burden of proof would render the Directive's application more effective.

As far as new technologies are concerned, the lack of information on specific Court cases, consumer complaints or relevant practical experience from stakeholders made it impossible to reach any definitive conclusion[22]. Given these technologies' characteristics (particularly their complexity and autonomy), it is clear that the Commission will need to follow up on any unanswered questions. Some of these characteristics may challenge whether the existing product liability framework is appropriate to ensure effective redress for consumers and investment stability for businesses. Other aspects may, by contrast, be adequately addressed by the current Directive. The Commission will closely analyse any potential challenges in the follow-up to this report.

5.2. Efficiency

The Directive is about striking a balance between injured persons' and producers' interests. Its costs are a direct trade-off: what is to the benefit of the injured persons is the producers' cost and vice versa. The main cost for producers is the strict liability. For consumers, costs are related to the burden of proof, the EUR 500 threshold and time limitations. The concepts are simple, but their application may not always be.

Overall, the Directive is considered efficient at delivering a stable legal framework for the single market and for harmonising consumer protection. However, the balance between costs and benefits relating to the Directive is not uniform across Member States and sectors or product types for injured persons. The complexity of a product determines the cost of proving a defect. For pharmaceutical products , for instance, the costs may not be fairly distributed between producers and injured persons. There are also other factors that play a significant role in determining the Directive's efficiency. One particular factor, representing the most important administrative burden, is the cost and duration of judicial proceedings. These vary substantially from one Member State to another and have a more direct effect on injured persons than on producers. However, as these are not

[22] The external study on which the evaluation was based could only identify one court case where the issue at stake was specifically related to emerging digital technologies. The case related to a data storage unit in Bulgaria. (Bulgarian case no. 20942/2012).

due to burdens that the Directive itself imposes no specific simplification potential was identified in this respect.

5.3. Coherence

The Directive does not exist in a legal vacuum and cannot be viewed in isolation. It is an integral part of an EU legal framework that exists to ensure the functioning of the single market, to promote innovation and growth through technology-neutral safety rules and to protect consumer safety and well-being.

The evaluation has found the Directive to be consistent with the overall relevant EU rules. This covered existing and proposed EU rules on consumer protection in the area of contractual liability as well as those on dispute resolution[23]. More importantly, the Directive is consistent with EU product safety rules as laid down in the harmonised EU product safety rules[24] and the General Product Safety Directive[25]. The EU product safety rules describe the safety levels that products placed on the EU market must meet. In turn, they represent the safety levels for these products that an injured person is entitled to expect under the Directive. Producers are also exempt from liability if they can prove that a defect is due to compliance with these rules. As technological changes will bring about corresponding changes in EU legislation, this consistency in the overall rules will need to be maintained[26].

5.4. Relevance

The Directive has managed to withstand three decades of technical innovation. The original needs to ensure producers' liability, consumer protection and undistorted

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23 Directive 2011/83/EU of the European Parliament and the Council 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; Directive 1999/44/EC of the European Parliament and Council on certain aspects of the sales of consumer goods and associated guarantees; Proposal for a Directive of the European parliament and Council on certain aspects concerning contracts for the supply of digital content, COM/2015/0634 final; Amended proposal for a Directive of the European parliament and Council on certain aspects concerning contracts for the online and other distance sales of goods, amending Regulation (EC) No 2006/2004 of the European Parliament and of the Council and Directive 2009/22/EC of the European Parliament and of the Council and repealing Directive 1999/44/EC of the European Parliament and of the Council, COM/2017/0637 final.

24 E.g. Directive 2006/42/EC on machinery, Directive 2009/48/EC on the safety of toys, Regulation (EU) No 305/2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, Directive 2013/53/EU on recreational craft and personal watercraft and repealing Directive 94/25/EC, Directive 2014/29/EU on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels, Directive 2014/33/EU on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts, Directive 2014/35/EU relating to the making available on the market of electrical equipment designed for use within certain voltage limits, Directive 2014/53/EU relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC, Regulation (EU) 2017/745 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, Regulation (EU) 2017/746 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

25 Directive 2001/95/EC of the European Parliament and Council on general product safety. EU rules in the field of transport allocate to manufacturers or operators the responsibility to maintain the safe state of vehicles, planes or vessels.

26 The evaluation of the Machinery Directive has already found that emerging digital technologies are not specifically addressed in the Directive's essential health and safety requirements. Attention will also have to be paid if the development risk clause and the possibility to derogate from it leads to regulatory fragmentation that may be problematic for the uptake of AI.

competition remain relevant. However, when it comes to new technological developments, stakeholders have expressed concerns about the continued relevance of the Directive's concepts as they are currently expressed. There are open questions about what separates a product from a service (e.g. for the Internet of Things, where products and services interact), the scope of damage covered (currently limited to material damage) and the notion of what constitutes a defect.

Specific analytical work will also be necessary on e.g. pharmaceutical products due to their complexity and refurbished products due to their altered nature, which could raise problems that set them apart from other categories of products.

The response to these questions will need additional research and a clear response to provide legal certainty to both producers and consumers.

5.5. EU added value

The Directive is an integral part of the EU's single market rules. Its benefits are uncontested. The Directive provides uniform consumer protection by serving as the safety net that complements EU product safety legislation. The Directive also strikes a sensitive balance between innovation and protection that can only be achieved at EU level to prevent single market fragmentation and distortion of competition.

Repealing the Directive would lead to fragmentation and differing levels of consumer protection, as national courts would only apply national rules, contract or tort law. It should be noted, however, that the Directive exists alongside national instruments and that there is therefore still room for differing national approaches.

6. CONCLUSION: A FOURTH INDUSTRIAL REVOLUTION — A PRACTICAL APPROACH TO LIABILITY

The problems we face today differ to some extent from those we had in the largely analogue world of 1985. We are undergoing another technological revolution. The economy and products themselves are increasingly becoming interconnected, digital, autonomous and intelligent. We need a coherent and global response to these challenges, as outlined in the Artificial Intelligence Initiative[27].

The Directive has until now covered a broad range of products and technological developments. In principle, it is a useful tool for protecting injured persons and ensuring competition in the single market, by harmonising rules for injured persons and businesses in the aspects that it covers. It is an area where EU level rules provide a clear added value. Having EU level rules for product liability is uncontested.

This does not mean that the Directive is perfect.

Its effectiveness is hampered by concepts (such as 'product', 'producer', 'defect', 'damage', or the burden of proof) that could be more effective in practice. As the evaluation has also shown, there are cases where costs are not equally distributed between consumers and producers. This is especially true when the burden of proof is

[27] Commission Communication, 'Maximising the Benefits of Artificial Intelligence for Europe', (COM(2018)237).

complex, as may be the case with some emerging digital technologies or pharmaceutical products.

To remain relevant for the future, the Directive would benefit from clarification to address such issues. The Directive covers a broad range of products and possible scenarios. Guidance can help to make these concepts more effective and highlight their continued relevance.

Our objective is to continue ensuring a fair balance of the interests of consumers and producers for all products:

Some of the concepts that were clear-cut in 1985, such as 'product' and 'producer' or 'defect' and 'damage' are less so today. Industry is increasingly integrated into dispersed multi-actor and global value chains with strong service components[28]. Products can increasingly be changed, adapted and refurbished beyond the producer's control. They will also have increasing degrees of autonomy. Emerging business models disrupt traditional markets. The impact of these developments on product liability needs further reflection. At the end of the day, a producer is and needs to be responsible for the product it puts into circulation, while injured persons need to be able to prove that damage has been caused by a defect. Both producers and consumers need to know what to expect from products in terms of safety through a clear safety framework.

Conversely, the development of a strong single market in cybersecurity products and services will be hampered by problems over the attribution of damage for businesses and supply chains and failure to address these issues, as highlighted by the Commission in its Communication on 'Resilience, Deterrence and Defence: Building strong cybersecurity for the EU'[29]. Again, consumers and businesses need to be aware of the security levels they can expect, and they need to know who to turn to if a failing in cybersecurity leads to material damage.

Recent large-scale cross-border issues affecting many consumers across the EU, such as the '*Dieselgate*' scandal, have had a negative impact on consumer trust in the single market. In its 'New Deal for Consumers', the Commission proposes — among other measures — to modernise redress systems and make it easier for consumers to obtain their rights[30]. To make sure that the single market lives up to its full potential we need to reassure consumers that their rights will be respected

Other wider aspects require similar attention. This is particularly relevant in the context of a more sustainable economy in which products are refurbished, patched and reused. Who will be the manufacturer of such products, e.g. in the case of repair, reuse and refurbishment? Also, is the fact that all preliminary rulings of the Court of Justice concerned pharmaceutical and medical devices indicative of specific characteristics in this sector?

The Commission has launched an expert group on liability to explore the effect of these developments in detail. The group has two configurations. One is composed of representatives from Member States, industry, consumer organisations, civil society and academia: this group will assist the Commission in interpreting, applying and possibly updating the Directive, including in light of developments in EU and national case-law,

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28 Another aspect to be taken into account are direct online sales from third countries.

29 COM(2017)450.

30 COM(2018)183, COM(2018)184, COM(2018)185.

the implications of new and emerging technologies and any other development in the field of product liability. The expert group's other configuration, composed solely of independent academic experts and practitioners, will assess whether the overall liability regime is adequate to facilitate the uptake of new technologies by fostering investment stability and consumer trust[31].

As the Commission, we aim to put in place a positive and reliable framework for product liability that fosters innovation, jobs and growth while protecting consumers and the safety of the general public. We will issue guidance on the Directive as well as a report on the broader implications for, and potential gaps in and orientations for, the liability and safety frameworks for AI, Internet of Things and robotics in mid-2019. If necessary, the Commission will update certain aspects of the Directive, such as the concepts of 'defect', 'damage', 'product' and 'producer'. However, the overall principle of strict liability will remain intact.

A coherent, technology-neutral safety framework should prevent accidents as far as possible. However, when accidents do happen, our liability framework should ensure that those who suffer injury are compensated.

[31] The Staff working Document on Liability for emerging digital technologies (SWD(2018)137) already highlights some of the issues to be discussed by this configuration.