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Delegations will find attached the opinion adopted by the European Economic and Social Committee on the above proposal.

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European Economic and Social Committee

OPINION

European Economic and Social Committee

Revision of the Product Liability Directive

Proposal for a directive of the European Parliament and of the Council on liability for defective products

[COM (2022) 495 final – 2022/0302 (COD)]

INT/1002

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Referral	European Parliament, 17/10/2022 Council, 28/10/2022
Legal basis	Article 114 of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Bureau decision	20/09/2022
Adopted at plenary	24/01/2023
Plenary session No	575
Outcome of vote (for/against/abstentions)	157/0/2

1. Conclusions and recommendations

1.1 The European Economic and Social Committee (EESC) recognises the relevance of the civil liability regime set out in the Commission's proposal, which offers Europeans the means to obtain compensation for damage suffered as a result of a product defect. This regime is all the more relevant given the increasing frequency with which consequences of emerging risks are dealt with through the courts.

1.2 By definition, a no-fault liability regime aims to restore the balance between the rights of manufacturers and those of potential victims. The EESC calls on the co-legislators and national authorities to maintain the balance achieved in this proposal when adopting and transposing it.

1.3 The EESC therefore supports the need to ensure legal certainty for all: for the complainant by providing access to a simplified legal framework for obtaining compensation, and for the manufacturer, who can continue to innovate, all the while being aware of their liabilities and budgeting for their risks.

1.4 The EESC recognises that the revision of the Directive in question addresses numerous consumer demands, such as the identification of those liable, access to information and compensation, and extended coverage to cover digital and psychological damage.

1.5 The EESC acknowledges the need to adapt the regime to digital challenges and supports the measures put forward in the proposal to address them. The Committee therefore supports the European Commission's decision to include artificial intelligence (AI) through a no-fault liability regime in this proposal and through a fault-based liability regime in the proposal for a parallel directive. It also stresses the need to remain technologically neutral in managing product liability.

1.6 The EESC calls for the proposal to be aligned with the *acquis communautaire* regarding the definitions and hierarchy of liability, and also simplified, in line with the laws currently being adopted.

1.7 The EESC also calls for greater consistency in the wording of identical obligations, which have been described in different ways in different legal texts. The EESC recommends that measures be simplified rather than duplicated, in particular by referring to or extending existing obligations.

2. Background

2.1 The proposal for a revision of the Product Liability Directive (PLD) and that on AI liability rules aim to update the EU no-fault regime, which dates back to 1985. The aim

of both proposals is to adapt this framework to the digital and sustainable transitions. The new rules therefore aim to provide producers with the legal certainty necessary to innovate, and to provide complainants with coverage for new emerging damage and defects, as well as the assurance that the liable party in Europe will be found and thus compensation obtained before a court.

2.2 In practice, the Directive requires Member States to establish specific rules on civil liability. In this context, all **natural persons** can obtain compensation in the event of material loss linked to damage resulting from a product defect. *A priori*, the vast majority of claims under the PLD relate to bodily injuries and, in some cases, serious property damage. Very minor claims are usually handled through an amicable settlement. The provisions in the PLD are therefore applied through an amicable agreement, an alternative dispute resolution (ADR) or online dispute resolution (ODR) procedure, or a legal proceeding[1]. To better assess the matters dealt with, the EESC calls on the Commission to obtain more information and statistics on cases handled through ADR or ODR.

2.3 Defective product liability claims are among the fastest-growing types of claims in the EU. Looking at court judgments based on this type of procedure, as well as on recent debates on **emerging risks**, the following are a list of the products and damage targeted today: asbestos, vaccines, pesticides, bisphenol A and opioids[2], as well as electromagnetic waves for those who are electro-sensitive, and even the fear of developing cancer due to exposure to a hazardous substance[3]. The proliferation of emerging risks over the past few years makes such a regime indispensable. Aware of the future challenges to which this regime could be applied, the EESC calls on all stakeholders in this legislation to take this context into account.

2.4 Another major concern is that the new text needs to be able to maintain a legal framework that provides **legal certainty** for all actors (claimants and defendants). It must be ensured that the foundations of our *acquis communautaire* are not called into question (definition, civil law, etc.).

2.5 We must also ensure that the process strikes a **balance** between our European goals to support industrial and technological **innovation**, and consumer **protection** and fair

1 See the estimates made in the European Commission's impact assessment.

2 This substance is the subject of multiple debates, in particular in Sweden. It should be noted that in France, in the 10 years preceding the COVID-19 pandemic, opioid consumption increased by more than 150%.

3 France recognises damages for anxiety on the basis of an individual's concern about developing a disease in the future. Spain and Italy seem to want to follow suit. This concept was officially recognised in 2019 for exposure to asbestos and extended to all hazardous substances and products shortly after. As a result, asbestos was banned in 1997. More than 20 years later, our companies are still at a significant risk of being held liable for compensation.

compensation for damage caused. As reiterated by the Commission[4], the proposed framework should not hinder the implementation of the recently adopted EU industrial strategy. At the same time, the EU must also provide consumers and Europeans in general the highest level of protection.

2.6 Finally, the aim of the Directive under review is to harmonise the Member States' legislation. This harmonisation is all the more important given that the incidents covered by this liability regime usually do not end at the borders. It is therefore a necessity that legislation be **harmonised to the highest degree**, and for this to happen, it must involve clear and well-defined measures.

3. General comments on the need to ensure consistency between the proposal and the *acquis communautaire*

3.1 **A very broad scope to be implemented consistently at national level**. The draft directive benefits all natural persons who have suffered damage as a result of a product defect and who wish to obtain compensation from the product's manufacturer. It is therefore not a case of consumer or end user, from B to B or from B to C. However, some Member States have used the initial version of the Directive in disputes between employees and employers, and between professionals, which fall within the remit of other regimes. The EESC draws the authorities' attention to the implementation and proper transposition of this regime.

3.2 **Some definitions need to be clarified to make the system coherent**. In Article 4, the definitions of "component", "manufacturer" and "product" must be linked, as they are all mentioned under Article 7 defining operator liability. In Article 4(10), the definition of "putting into service" should refer to the first use by the end user, as in the Blue Guide and other harmonisation legislation. The date of first use is important, as it determines the limitation periods. Finally, in Article 6, the concept of use of the product needs to be aligned with EU legislation. The incorrect use of a product cannot be used to asses and prove its defectiveness. Such use cannot be used to assess the conformity and safety of products covered by EU harmonisation legislation, for example in the case of toys. As stated in the Blue Guide, EU harmonisation legislation applies when products made available or put into service on the market are used for their intended purpose. In any event, the manufacturer cannot be held liable for damage resulting from product misuse.

3.3 **The hierarchy of liability among economic operators must be proportionate to their role in the chain**. The EESC welcomes the fact that the proposal includes the

4 In January 2020 the European Commission, in a hearing it organised on the review of the PLD, reiterated the utmost importance of this topic for strengthening the EU's industrial capacity for technological sovereignty and providing a competitive advantage for producers to innovate and compete with China and the US.

different actors liable for compliance and safety, as defined in Regulation (EU) 2019/1020[5] and the proposal for a regulation on digital services[6]. The proposal thus aligns liability for product conformity and safety with the liability regime for defective products. However, Article 7(2) does not respect the hierarchy of roles and of liability established in the European framework for harmonised products[7]. For the sake of consistency, this article should be revised to clearly mention the default hierarchy of operators, not their joint liability.

4. Assessment of measures responding to the demands of potential victims

4.1 Numerous measures now ensure that the liable operator is found in order to obtain compensation. Firstly, the manufacturer of the product and the manufacturer of the product's defective component can be found jointly liable. The EESC appreciates that this double liability is part of the European Consumer Organisation's recommendations[8]. Secondly, the hierarchy of liability among economic operators who are involved in the defective product's supply chain applies. If the first person liable is absent, the next person down the supply chain bears their liability. Where there is no manufacturer in the EU, the importer or the authorised representative/agent may be held liable. Similarly, the liability of the distributor and marketplace depends on their ability to provide information on their suppliers and traders.

4.2 The EESC recognises that these two measures make it easier to determine who is liable in the European market and thus also easier to provide access to compensation.

4.3 Additionally, the distributor's obligations are in line with those set out in the revised General Product Safety Directive and the revised legislation on harmonised products (traceability rules).

4.4 The same applies for marketplaces. The DSA establishes the obligation to "know one's traders", which includes having the contact details of the manufacturer and the person liable in the EU. Additionally, Article 5(3) of the same Directive – the original proposal on the DSA – also lays down conditions whereby platforms lose their exemption from liability for failure to provide information about the seller. The Omnibus Directive lays down a similar obligation. If the information required under the Consumer Protection Directive (2019/2161) is not provided, the platform assumes the liability for consumer

5 OJ L 169, 25.6.2019, p. 1.

6 COM(2020) 825 final – 2020/0361 (COD).

7 i) a manufacturer established in the Union; ii) an importer (by definition established in the Union), where the manufacturer is not established in the Union; iii) an authorised representative (by definition established in the Union) who has a written mandate from the manufacturer designating the authorised representative to perform the tasks set out in Article 4(3) on behalf of the manufacturer; or iv) a fulfilment service provider established in the Union where there is no manufacturer, importer or authorised representative established in the Union.

8 European Consumer Organisation – www.beuc.eu.

protection that would normally lie with the seller. Although these obligations are comparable, they are not worded the same way in this proposal. The EESC therefore calls for greater consistency in the wording of identical obligations.

4.5 **Compensation is now possible under this regime for losses resulting from defective digital services**. First and foremost, by proposing a parallel project on AI liability, the European Commission is addressing this matter specifically. At the same time, its proposal addresses the lack of a "digital component" for users through numerous measures:

- applications and other software "embedded in or interconnected with" a product will be covered by the definitions of "component" (Article 4(3)), "related service" (Article 4(4)) and "manufacturer" (Article 4(11));
- additionally, material losses caused by the loss or corruption of data are recognised as damage giving rights to compensation;
- finally, manufacturers of related services will not be exempt from liability on the grounds that the defect did not exist when the product was placed on the market.

4.6 The EESC supports measures aimed at regulating digital technologies in this proposal. However, it calls for the co-legislators to take into account parallel legislation recently adopted or under negotiation, in particular the GDPR, the proposal for an AI liability directive, the AI Act, the Data Act, the General Product Safety Regulation, the NIS 2 Directive[9] and the Cyber Resilience Act. Coherence should be ensured and the duplication of legal measures avoided.

4.7 The proposal addresses difficulties in obtaining and understanding technical information in multiple ways. The legal framework in question applies when a product has caused material damage to a person or their possessions/property. These products are often scientifically or technologically complex. In 1985, the European Commission addressed the complexity of the products concerned by introducing no-fault liability into civil law. In this context, the complainant must prove the product's defect, the damage and the causal link between the two in order to obtain fair compensation for the damage caused. The fault of the producer does not need to be proven. In the preamble, the European Union acknowledged that no-fault liability was necessary in order to face the increasing use of technology in our era. This departure from civil law was already a major simplification for the complainant. However, during the current legislative revision process, consumer organisations have advocated going further by reversing the burden of proof or banning the scientific knowledge exemption. The Commission did not keep the latter two measures, but instead introduced new proposals to address consumer demands.

4.8 The proposal therefore includes new measures on the disclosure of evidence and the presumption of defect or causation. Regarding the first point, it is first and foremost a question

9 NIS 2 Directive.

of establishing this right at European level. Today, most Member States have similar rules. The second point is a codification of case law, which is considered to be favourable to the complainant and which is addressed in point 5.

4.9 **The Commission proposal also addresses situations where damage occurs years or decades after the product has been bought or placed on the market**. It addresses this in two different ways. For digital technology (service-related), there is no exemption related to the probability that the defect did not exist at the time the product was placed on the market or put into service. Furthermore, it seems rather complex to argue an exemption related to the state of the art. Finally, for dangerous substances that cause latent bodily injuries, the limitation period is extended to 15 years.

5. Assessment of measures responding to business demands

5.1 **The notion of substantial modification is essential in this regime and should be defined and clarified**. If a product is substantially modified, the person that made the modification will be liable and the limitation period will be extended. The EESC therefore calls for this notion to be clarified on the basis of the Blue Guide[10].

5.2 **Assessment of cases where one of the three elements (defect/damage/causal link) does not need to be proven**. Article 9 states that "Member States shall ensure that a claimant is required to prove the defectiveness of the product, the damage suffered and the causal link between the defectiveness and the damage". It is therefore necessary to prove the tangible damage linked to material or immaterial damage to the person or to their personal property, or to the loss/corruption of data *and* the defect of the product or one of its components (item/service) *and* the link between the two, except in two cases. It should be noted that the burden of proof is established as part of a legal procedure that has already been initiated. The complaint has thus already been considered to be sufficiently admissible and the damage sufficiently significant for the individual to seek legal action, which is, *a priori*, financially costly for the complainant.

5.2.1 Firstly, Article 9(3) on the burden of proof specifies that the causal link between the defectiveness of the product and the damage shall be presumed where it has been established that the product is defective and the damage caused is of a kind typically consistent with the defect in question. In this case, once the defect has been proven, only the material loss associated with the damage must be established. Proof of a causal link is permitted by presumptions. This provision is also like a recognition of the potential for defects. In this context, a manufacturer who has identified a defect in a

10 A product which has been subject to important changes or a major overhaul after it has been put into service must be considered as a new product if: i) its original performance, purpose or type has changed, without this being foreseen in the initial risk assessment; ii) the nature of the hazard has changed or the level of risk has increased, compared to the relevant EU harmonisation legislation; iii) the product is made available (or put into service if the applicable legislation also includes putting into service within its scope). This has to be assessed on a case-by-case basis and, in particular, in view of the objective of the legislation and the type of products covered by the legislation in question.

product will have to recall or withdraw all products from the same batch from the market. Such management would lead to significant waste.

5.2.2 Secondly, Article 9(4) specifies the cases where the proof of defectiveness and causal link is based on probabilities. This could happen where the court decides that the claimant is experiencing undue difficulty due to the technological or scientific complexity of the evidence. Consequently, the complainant must prove not only that the product contributed to the damage, but also the probability of a defect or of a link between the defect and the damage. In this case, neither the defect nor the causal link need to be scientifically proven.

5.2.3 In order to assess this provision, reference must be made to the case law underpinning it. Thus, in the Sanofi Pasteur case[11], the courts considered that in the absence of any scientific consensus, the proof of a vaccine defect and of a causal link between the defect and the illness could be provided by solid, precise and consistent evidence. The procedure is largely simplified for the complainant, who ultimately needs to provide a set of factual and non-scientific elements. The EESC acknowledges that, in certain complex cases, the notion of "probability of defect" needs to be assessed by a judge without leading to an automatic presumption of causality.

Brussels, 24 January 2023

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11 C-621/15.