MASON HAYES & CURRAN

SUBMISSION FOR CLE ACCREDITATION

SESSION TITLE: EU UPDATES ON LIABILITY FOR AI AND SOFTWARE

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TWO ADDITIONAL SPEAKERS TO BE CONFIRMED

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1 Session Overview: The Evolving Legislative Landscape

1.1 Historically, the concepts of product safety and liability used to be confined to 'bricks and mortar' products. Now, the term 'products' encompasses much wider concepts, including software, AI systems, mobile apps, hardware products with integrated software, and IoT-connected products.

1.2 As adoption of Artificial Intelligence (**AI)** continues to accelerate across the EU, civil liability rules relating to damage that is traceable back to AI systems remain underdeveloped and unclear.

1.3 To address these developments, the product safety and liability legislative frameworks have undergone significant reform at the European Union level in recent years. As part of this reform, the EU has adopted a range of complementary product safety and liability measures designed to meet the challenges of the digital age and deployment of AI.

1.4 A cornerstone of this package of measures is the EU's Artificial Intelligence Act 2024[1] (**AI Act**), which entered into force on 1 August 2024. The focus of the AI Act is fostering trustworthy AI through compliance with regulatory requirements and managing the relationship between providers and regulators. The AI Act is part of a set of complementary product safety and liability measures designed to support the roll-out of AI in Europe. The other measures include a revision of horizontal product safety rules (the General Product Safety Regulation (EU) 2023/988 or GPSR) and sectoral product safety legislation as well as the rules to address liability issues related to AI systems.

1.5 The Revised Product Liability Directive[2] (**Revised PLD**) is a central component of this reform agenda and works alongside the AI Act. It has adapted the strict liability regime applicable to producer liability for defective products[3] to address liability issues arising from digital technologies and AI, circular economy business models, and global value chains.

1.6 Originally intended to operate in tandem with the now-shelved proposal for an EU Artificial Intelligence Liability Directive (**AILD**), which sought to revise and harmonise certain aspects of fault-based EU civil liability frameworks as they apply to AI, the Revised PLD now assumes a more prominent role.

1.7 These significant reforms underscore the EU's holistic approach to safety and liability, recognising that they are two sides of the same coin. While legislation like the AI Act and the GPSR aim to prevent harm through risk management and regulatory compliance, the Revised PLD ensures that where such measures fail, effective remedies and redress are available to consumers. In this way, the Revised PLD plays a critical role in reinforcing consumer trust and legal certainty in the use of digital technologies across the internal market.

1.8 In that regard, one of the key functions of the Revised PLD is to close existing gaps in liability by extending strict liability to cover software and digital products, clarifying the definition of "defect" in the context of software and AI, enhancing access to evidence and easing the burden of proof for claimants in certain circumstances. These changes aim to ensure that injured parties can obtain redress in situations where software and AI systems cause harm, even where fault is difficult to establish.

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[1] Regulation (EU) 2024/1689
[2] (EU) 2024/2853
[3] Product Liability Directive 85/374/EEC

1.9 On 11 February 2025, the European Commission announced the withdrawal of the AILD from its 2025 Work Programme[4]. The reason provided for its withdrawal was that there was no foreseeable agreement. The Commission stated that it would assess whether another proposal should be tabled, or another type of approach should be chosen. This provides an opportunity for stakeholders to express their opinions on what, if any, new proposal or approach should be adopted to specifically address damage caused by AI systems.

1.10 In contrast, the Revised PLD entered into force on 8 December 2024 and will apply to products placed on the market 24 months after this date. It aims to modernise the existing no-fault strict liability regime for products, including by the expansion of the definition of 'product' to include software and the addition of additional factors to be considered when determining whether a product is defective, such as a product's interconnectedness, self-learning functionality and cybersecurity vulnerabilities.

2 Key Themes for Discussion

2.1 Through an interactive panel format, including the use of a hypothetical case study, the panel will examine the application and impact of the complementary frameworks under the AI Act and the Revised PLD to software and AI systems. As part of this analysis, the panellists will discuss important practical considerations for what these reforms will mean for developers and users of AI. As part of this assessment, the panel will discuss the core concepts of the AI Act, why a Revised PLD was necessary and the key features of the Revised PLD, including as set out below. The panel will also explore how these legislative instruments interact in practice, unpacking the implications for providers, deployers, importers, distributors, and end users of AI systems.

3 The AI Act

3.1 The AI Act is the world's first comprehensive piece of AI law. The Act prioritises trustworthy AI by ensuring compliance with regulatory requirements and managing the relationship between providers and regulators. In contrast, the Revised PLD and the AILD focus on addressing harm caused.

3.2 The AI Act entered into force on 1 August 2024 with staggered implementation and is fully applicable 36 months after 2 August 2024. High-risk AI software systems must be compliant by 2 August 2026, subject to a legacy provision. Other products, such as AI-enabled medical devices, lifts, and toys, will have additional time to meet their regulatory requirements. The applicable obligations will not take effect until 36 months after the Act enters into force, on 2 August 2027.

4 Core concepts of the AI Act and Applicability

4.1 The AI Act adopts a risk-based approach to the regulation of AI systems. It seeks to regulate them by imposing a range of obligations on providers and deployers of those AI systems depending on the risk categorisation of the AI system. These obligations include requirements related to transparency, control and risk management, training and support

[4] https://commission.europa.eu/publications/2025-commission-work-programme-and-annexes_en

and recordkeeping. The aim of the AI Act is to foster trustworthy AI in Europe and beyond, by ensuring that risks of powerful and impactful AI systems are addressed.

4.2 The AI Act has broad territorial application and is applicable to:

(A) Providers and manufacturers of AI systems

(B) Deployers, or users, of AI systems

(C) Importers, distributors, affected persons, and authorised representatives of AI systems

4.3 The AI Act imposes a far greater regulatory burden on AI developers rather than on users. The AI Act lays down an enforcement framework that is designed to regulate AI systems on a sliding scale of risk. The compliance obligations will be dictated by the risk category into which the AI system falls. There are four risk categories, more particularly:

(A) **Unacceptable risk:** AI systems which are considered a clear threat to the safety, livelihoods and rights of people are banned. This includes systems such as social scoring by governments and toys using voice assistance that encourages dangerous behaviour. These will be banned from the EU market from 2 February 2025.

(B) **High risk:** High-risk AI covers a broad range of applications. These include AI used in medical devices, as a safety component in toys, and for managing critical infrastructure such as electricity supply. It can also include employment recruitment tools, credit scoring applications, and grade prediction technology in education. High-risk AI will be broadly divided into two categories:

(1) AI systems that are used as a safety component in products or are themselves products falling under certain specified EU harmonisation legislation e.g. toys, medical devices etc. These are known as Annex I high risk AI systems.

(2) AI systems in certain areas will require registration in an EU database. These include educational and vocational training, law enforcement, and the management and operation of critical infrastructure, among others. These are referred to as Annex III high risk AI systems.

Before these categories of high-risk AI systems can be put on the EU market, they will be subject to a stringent ‘conformity assessment’ process. This conformity assessment determines whether the system meets all requirements in the Act. Providers dealing with Annex I high-risk AI systems will enhance their existing third-party conformity assessment procedure with their existing notified body. In contrast, providers of Annex III high-risk AI systems will conduct self-assessments in order to meet the same requirements.

(C) **Limited risk:** Limited risk AI systems have a low risk of harm that can be remedied by making them more transparent. It is important that AI systems which interact directly with people are developed to ensure that the person is aware they are interacting with AI. These systems include chatbots, and generative AI.

(D) **Minimal or no risk:** Minimal risk AI systems pose a minimal risk to the safety and rights of citizens. These are not subject to the obligations or restrictions

under the AI Act. However, companies can choose to voluntarily adopt additional codes of conduct.

5 Product Liability Directive

5.1 The Product Liability Directive 85/374/EEC (**PLD**) established an EU-wide system of strict liability for product liability claims. This means that there is no requirement for a claimant to prove that a defendant producer was negligent or at fault.

5.2 The PLD provides that a producer is liable for damage caused wholly or partly by a defect in their product. A product is considered 'defective' if it fails to provide the safety that a person is entitled to expect. This assessment is an objective one. It is carried out with regard to what the public is generally entitled to expect, and with reference to a range of circumstances, including:

(A) The presentation of the product

(B) Its reasonably expected uses, and

(C) The time that it was put into circulation.

5.3 The concept of 'putting a product into circulation' isn't explicitly defined in the PLD. However, case law from the Courts of Justice of the EU (**CJEU**) clarifies that a product is put into circulation when the product leaves the production process and enters a marketing process in the form it is offered to consumers. This includes products like medical devices that are not explicitly placed 'on the market' prior to their first use.

5.4 Under the PLD, the burden of proof is on the claimant to prove the damage, the defect, and the causal relationship between the two. In Ireland, claimants commonly bring a product liability claim in tandem with a claim in negligence and/or in contract.

5.5 Several statutory defences are available to producers under the PLD and, if successfully invoked, a defendant can avoid liability for a defective product. These defences include:

(A) That the defect did not exist at the time the product was put into circulation, or that the defect came into being afterwards

(B) The 'state of the art' defence – i.e., that the defect was not discoverable due to the state of scientific and technical knowledge at the time the product was put into circulation

5.6 It is also important to be aware that there is a limitation period of three years to bring a claim under the PLD. This is subject to a long stop provision where a claimant's right of action will be extinguished 10 years after the product's date of circulation, if they haven't brought a claim in that time.

6 The Revised PLD

6.1 The PLD was adopted in 1985. In the forty years since, we have seen a dramatic change in the types of products on the market due to developments in technologies like AI and machine learning. There has also been an increase in products imported directly from outside the EU, and the emergence of new actors in the supply chain (e.g., online marketplaces). As a result, the European Commission proposed a reform of the PLD to address these challenges.

6.2 The Revised PLD was adopted by the European Parliament in March 2024. It was then formally adopted by the European Council in October 2024. The Revised PLD entered into

force on 8 December 2024 and applies to products placed on the market 24 months after this date. There will be a lengthy transitional period during which product liability claims may be brought under either the PLD or the Revised PLD, depending on which regime is applicable. Member States have until December 2026 to transpose the Revised PLD into their national legislation.

6.3 The Revised PLD is designed to ensure that the EU's strict product liability regime remains fit for purpose in an era of increasingly complex and software-driven technologies, including AI systems. As a result of this reform, a manufacturer's liability exposure for harm caused by a defective product may continue to arise in the traditional sense, or where the defect stems from complex or autonomous behaviour of AI-driven systems. As a result, manufacturers and developers in several sectors, including the Life Sciences sector, where AI and software is regularly used in products like digital health tools and medical devices, may now be exposed to greater liability risk. Accordingly, it is important for all relevant stakeholders to familiarise themselves with the with the noteworthy reforms and features under the Revised PLD, including:

(A) **Product:** Under the PLD, the general consensus was that liability applied only to software embedded in tangible products, meaning standalone or digital-only software typically fell outside the scope of the regime. This uncertainty has been categorically addressed by the Revised PLD, which expands the definition of a 'product' to expressly include software, including standalone software, and digital manufacturing files. It makes clear that software is a product, irrespective of the mode of its supply or usage and whether it is stored on a device or accessed through a communication network, cloud technologies or supplied through a software-as-a-service model. While the term 'software' is not defined in the Revised PLD, the recitals make clear that it applies to software of all kinds, including operating systems, firmware, computer programmes, applications, and AI systems.

The Revised PLD includes several limited exceptions. One exception concerns pure information, such as software source code. Another applies to free and open-source software that is not developed or used as part of a commercial activity.

This wider definition of what is considered a 'product' will expand the scope of liability for software products beyond those incorporated into a tangible product, as required under the PLD. As a result, it will have far-reaching consequences for software developers. This means that a range of technologically advanced products, including by way of example, medical apps, AI-based diagnostic tools, and software-dependent medical devices could all give rise to claims under the Revised PLD.

(B) **Defectiveness:** New factors have been added into the Revised PLD for determining whether a product is defective, including a device's cybersecurity vulnerabilities, self-learning functionality, and interconnectedness (e.g., a smart insulin pump that communicates wirelessly with a continuous glucose monitor (CGM) and a smartphone app).

(C) **Defendants:** The Revised PLD expands the pool of 'economic operators' that can be held liable for a defective product. In addition to manufacturers, importers, and in some cases, distributors of a product or a component of a product, the Revised PLD also includes:

(1) The providers of related services[5]

(2) Authorised representatives

(3) Fulfilment service providers

(4) Third parties making substantial modifications to products already placed on the market, and

(5) Online platforms in certain circumstances. This occurs when they play more than a mere intermediary role in the sale of products between traders and consumers

The Revised PLD's expanded definition of an 'economic operator' is designed to ensure that there is always an EU-based representative liable for damage caused by a defective product. This could be the designated authorised representative, importer, or fulfilment service provider.

The inclusion of related service providers is particularly relevant to the Life Sciences sector. This is because many medical devices now use and rely on cloud-based platforms, AI-driven analytics, and app integrations to deliver remote patient monitoring in real time. The Revised PLD includes as an example of such a related service 'a health monitoring service that relies on a physical product's sensors to track the user's physical activity or health metrics'. As a result, related service providers that may previously have considered themselves outside the scope of strict product liability laws, now have a potential liability exposure if their service contributes to a product's defect and ultimately, to any harm caused to consumers.

(D) **Damage:** The definition of 'damage' has been extended under the Revised PLD. It now brings in scope medically recognised damage including psychological health and damage from the destruction or corruption of data not used for professional purposes. Now, a product may be considered defective even in the absence of a physical injury, such as where using a defective product causes the claimant severe stress or anxiety.

(E) **Scope of liability:** One of the previous statutory defences allows the original manufacturer to avoid liability for defects that emerge after the product is put into circulation. Under the Revised PLD, the scope of liability may be extended to the time after a product was put into circulation where it is still under the manufacturer's control. For example, where a product has been substantially modified through software updates. This is particularly significant for connected products, where the hardware manufacturer retains the ability to supply software updates or upgrades to the hardware by itself or via a third party. As a result of these new provisions, manufacturers of products with digital elements may be liable for damage arising from changes to those digital elements that occur after the physical product is placed on the market.

(F) **Discovery:** The Revised PLD introduces a discovery model for statutory product liability claims. Under this model, a claimant who has presented facts and evidence sufficient to support a plausible claim can seek an order from a defendant to disclose relevant evidence at its disposal. While this is a significant

[5] A digital service that is integrated into or inter-connected with a product without which a product would be incapable of performing some or all of its functions.

development for civil law EU countries, it would have minimal effect in Ireland as we already have discovery in civil proceedings. In addition, the Revised PLD expressly acknowledges that it does not affect national rules on pre-trial disclosure of evidence. The Revised PLD provides that where a defendant fails to disclose relevant evidence in response to such a request, the impugned product will be presumed to be defective.

(G) **Rebuttable presumptions:** The Revised PLD contains rebuttable presumptions on defectiveness and causation designed to ease the burden of proof for claimants. For example, where it is excessively difficult for a claimant to prove the defectiveness of a product or the causal link between the damage and the defectiveness, or both because of the product's 'technical or scientific complexity', a court may, where certain conditions have been met by the claimant, presume the defectiveness of the product or the causal link between the damage and the defect.

The Recitals to the Revised PLD offer guidance on how national courts should assess technical or scientific complexity on a case-by-case basis, taking into account a range of factors. These include the complex nature of the product itself, with innovative medical devices given as an example of such a complex product. Reference is also made to other factors including the complex nature of the underlying technology, such as machine learning, and the complex nature of the information and data to be analysed by the claimant. The Recitals also highlight the potential complexity of establishing causation, such as proving a link between a pharmaceutical or food product and the onset of a health condition, or a link that would require an understanding of the inner workings of an AI system.

The Recitals to the Revised PLD also offer guidance about how an assessment of excessive difficulties should be carried out by national courts on a case-by-case basis. While a claimant should provide arguments to demonstrate excessive difficulties, proof of such difficulties should not be required. In that regard, the Recitals to the Revised PLD give an example of a claim concerning an AI system and note that a claimant should not be required to explain an AI's system's specific characteristics or how those characteristics make it harder to establish a causal link.

(H) **Limitation provisions:** The Revised PLD contains two modifications to the pre-existing ten-year 'longstop provision' or 'expiry period'[6]:

(1) First, an extension to 25 years in certain cases involving latent personal injuries, unless the injured person has, in the meantime, initiated proceedings against a potentially liable economic operator.

(2) Second, where a product has been substantially modified, the calculation of time runs from the date that the substantially modified product has been placed on the market or put into service.

(I) **Collective redress:** Businesses may not only be liable for harm caused to individual consumers by defective products. They may also be subject to a

[6] A claimant's right of action is extinguished upon the expiry of a specified time limit from the date the product was placed on the market or put into service, unless legal proceedings have been initiated against an economic operator within that period.

collective redress action if a product defect impacts the collective interests of a group of consumers/litigants under the Collective Redress Directive[7] (CRD).

7 Overarching Remarks

7.1 The extended scope of the Revised PLD reflects the evolution of product liability within the EU and the realities of modern, technologically advanced products. In the absence of the AILD, the AI Act and the Revised PLD will act a bilateral model for regulating safety and liability, resulting in greater harmonisation in how AI systems are regulated under EU product safety and liability law.

7.2 For many sectors such as the Life Sciences sector, where AI is increasingly integrated into medical devices, diagnostics, and digital health tools, the expanded scope is particularly impactful. The potential liability exposure of manufacturers and producers is increased by a range of notable features under the Revised PLD including the inclusion of standalone software and AI systems within the definition of a product, the broader range of economic operators who may be held liable for damage caused by a defective product, and the introduction of rebuttable presumptions of defectiveness and causation.

7.3 As Member States move to transpose the Revised PLD into their national legislation by the December 2026 deadline, companies in the Life Sciences sector should assess these reforms and how they may affect their product development, risk management, and litigation strategies moving forward.

8 Practical Value for Attendees

8.1 This session is intended to provide for a targeted discussion of the new liability rules for AI under the Revised PLD and its interaction with the regulatory requirements under the AI Act as well as a discussion about the future for the now-shelved AILD. It is intended to provide an overview of the legislative framework for AI under the various pieces of legislation and to identify the key issues and challenges stakeholders face in adapting their practices to comply with that framework. The session will offer practical insights into how best to prepare and adapt to these legislative developments.

8.2 The session will draw from a diverse set of legal experts, drawing on their experience in AI and product liability, to ensure thought-provoking discourse. Through the use of a hypothetical case study, the speakers will share their knowledge, expertise and practical insights on sector-specific issues, such as the healthcare and medical devices sector, and other matters in the context of the product liability reforms under the Revised PLD and their interaction with the regulatory requirements under the AI Act. Q&A and further discussion will be encouraged.

8.3 Attendees will come away from this session with a greater and real-world understanding of what is expected of them from the suite of legislation regulating AI. The session will provide for a discussion between our panel and the IADC community on the new provisions, both adopted and proposed, and how the different pieces of legislation interact with one another. It will therefore provide attendees an opportunity to express their views on these reforms and the future of AI regulation in a product liability context.

9 Learning Objectives and Takeaways

[7] 2020/1828

9.1 This panel offers legal professionals and corporate counsel a valuable chance to learn about the most important recent changes in EU product liability law.

9.2 Participants will:

(A) Understand the regulatory architecture of the AI Act, the liability implications of the Revised PLD and the interaction between these two pieces of legislation.

(B) Identify the key legislative requirements under the AI Act and the Revised PLD and assess what they mean for stakeholders in terms of their legal obligations going forward.

(C) Gain practical tips for adapting compliance programmes and mitigating litigation risk.

(D) Engage with real-world challenges facing providers, deployers, and manufacturers in today's AI landscape.

(E) Contribute to a dialogue about future EU policy development for AI liability.

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