



NEW EU PRODUCT LIABILITY DIRECTIVE BUSINESSES BEWARE

Matthew Felwick and Lara Knight of Hogan Lovells examine the EU's new Product Liability Directive, a consumer-friendly regime that poses many new challenges for businesses.

The EU's and the UK's product liability regime, which has been in place since the 1980s, has proved itself robust and flexible enough to deal with the many advances in technology that have taken place in that time. But the pace of change is ever increasing and digital technologies are now fundamentally altering the types of products that appear on the market, as well as the business models and operators through which they reach the consumers.

After a prolonged gestation period, the EU decided to update the legislation that creates the strict liability regime in the EU in order to address the challenges posed by new technologies, including AI, the circular economy model and new global supply chains. In doing so, the EU has shifted the balance of risk in favour of consumers. This creates a number of significant new risks of which businesses need to be aware. The new legislation is, of course, relevant to

UK businesses that operate in the EU but, following Brexit, it will not apply to the UK as a jurisdiction (excluding Northern Ireland which, as part of the UK-EU trade and co-operation agreement, continues to follow EU rules in areas such as product safety and liability). However, it may well influence how the UK regime develops over time.

On 10 October 2024, the EU Council adopted a new, and far more consumer-friendly, directive on the liability of defective products, the revised Product Liability Directive (revised PLD). This new directive will repeal and replace the existing Product Liability Directive (85/374/EEC), which was adopted nearly 40 years ago in 1985 (the existing PLD). The revised PLD will shortly be published in the Official Journal of the EU.

This article looks at the features of the revised PLD, its key provisions and potential impact on businesses, how they can prepare for its

obligations and the related developments in the UK.

A SHIFT IN BALANCE

Both the existing PLD and the revised PLD provide a strict liability regime, where liability does not depend on fault or negligence, but under which producers are liable for the damage that is caused by defects in their products. The injured person needs to prove that the product was defective, that they suffered damage and the causal link between the two.

The existing PLD was itself the product of significant debate and consultation within the EU. The text that resulted sought to achieve a fair apportionment of risks between consumers, manufacturers and their insurers. While consumer protection was one of the aims of the regime, it was not the primary or overriding aim. In describing the existing

PLD, the European Commission noted that the political resolve of the EU member states to have a balanced framework of liability governing relations between businesses and consumers should not be underestimated (*Green paper, Liability for Defective Products*, <https://eur-lex.europa.eu/legal-content/NL/TXT/?uri=LEGISSUM:132040>).

This balance is now shifting. Article 1 of the revised PLD expressly states that its objective, in addition to its internal market aims, is to ensure a high level of protection for consumers and other natural persons. The recitals also identify other aims, including removing divergences between the legal systems across member states that may distort competition and affect the movement of goods, while providing an increased degree of consumer protection. They also note that an aim of the revised PLD is to ensure that consumers can easily exercise their right to obtain compensation. The apportionment of risks is still there, but the balance appears to be shifting and this can be seen in some of the new measures introduced by the revised PLD.

KEY FEATURES OF THE NEW REGIME

A number of changes and additions have been made in the revised PLD that include widening the definition of product to include software, updating the type of entity that can be held liable to align with the reality of modern business models, imposing disclosure obligations on defendants, which is an unusual step in most EU jurisdictions, and, critically, introducing certain circumstances where the existence of a defect or causal link between the defect and damage will be presumed in favour of the claimant. This means that it will be for the defendant to show that the product was not defective or that any defect did not cause the damage alleged.

Expansion of the product definition

“Product” has always been defined to mean all “movables”, but this will be extended to include software, in recognition that products can be both tangible and intangible (*Article 4(1)*). The new definition will include damage that is caused by defective software, including AI systems, whether the software is integrated into a product or sold as a standalone product itself.

Digital manufacturing files, which contain the instructions to control automated manufacturing equipment, such as a 3D

printer, will also fall within the definition of a product, as will product-related digital services. These are services that are so interconnected with a product it could not be safely operated without it, a situation that is becoming more and more common; for example, a service which provides traffic and road condition data to a navigation product.

Definition of defectiveness

Defectiveness is still defined as where a product does not provide the safety that a person is entitled to expect, as it did under the existing PLD. However, the revised PLD will extend this to include circumstances where a certain level of safety is required under EU or national law (*Article 7(1)*). This means that products will be found to be defective if they do not conform to the relevant safety legislation.

Article 7(2) of the revised PLD provides that all circumstances are to be taken into account in assessing the defectiveness of a product and this still includes the presentation of the product (including warnings and instructions for use) and the reasonably foreseeable use of the product. The revised PLD also lists other circumstances that should be taken into account, many of which will introduce new areas of risk and will need to be carefully considered by businesses. These include:

- The effect on the product of any ability to continue to learn or acquire new features (see “AI and interconnectivity” below).
- The effect on the product of other products that can be expected to be used with it.
- Any relevant product safety requirements, including safety-relevant cyber security requirements.
- Any recall or any other relevant intervention relating to product safety.
- The specific needs of the group of users for whose use the product is intended.
- In the case of a product that is intended to prevent damage, any failure of the product to fulfil that purpose.

Interestingly, the recitals to the revised PLD state that warnings or other information provided cannot be considered sufficient to make an otherwise defective product safe; that is, liability cannot be avoided simply by

listing all of the conceivable side effects of a product. This is a significant change from the existing PLD, under which a business could seek to avoid liability arising from a risk or side effect if a warning to that effect had been given.

It must be assumed, if liability is alleged to arise from a factor that was warned about or included as a side effect, the fact that this warning or information was provided will still be a key factor to be taken into account, albeit the warning or information alone will not necessarily be sufficient to allow the producer to avoid liability. Exactly how courts will interpret this, in what circumstances, and the extent to which such warnings and information will still work to protect a business from liability, remains to be seen. However, including this language in the recitals clearly shows the direction of travel.

The recitals also identify that reasonably foreseeable use will be broad and is intended to encompass misuse that is not unreasonable under the circumstances, such as machinery operators failing to concentrate or the behaviour of certain user groups, such as children. This will also likely be significant for the “off-label” use of pharmaceutical products and medical devices.

AI and interconnectivity

Two of the new circumstances that are relevant to the assessment of defectiveness are clearly aimed at new technology and will catch AI: “the effect on the product of any ability to continue to learn or acquire new features after it is placed on the market or put into service” and “the reasonably foreseeable effect on the product of other products that can be expected to be used together with the product, including by means of inter-connection”. The intention with these factors is to ensure that products that use technologies such as AI and machine learning are designed so that, once released, they cannot evolve in such a way that they become dangerous.

The interconnectivity of these and other products is also recognised in the revised PLD, with the internet of things now a reality across almost every sector, from connected cars and smart appliances in the home, to connected health monitors and manufacturing equipment. To minimise their exposure, businesses will need to consider carefully what will, or could, happen to their product once it is placed on the market or

put into service, and ensure that they retain access to data logs or files that will track any such development. Businesses will need to think through the scenarios in which their products can be connected to others and consider the potential outcomes that could occur when they are connected. A broad, wide-ranging and creative approach to risk analysis will be required.

Another critical new factor is aimed at addressing the reality that many producers continue to exert significant influence over how their products operate long after they have been sold. The concept of defectiveness will now also be assessed when a product leaves the manufacturer's "control" (Article 7(2)(e)). The revised PLD retains "the time when the product was put into circulation" as the primary consideration and expressly recognises that a product is not defective simply because a better product has been subsequently released (Article 7(3)).

However, where the manufacturer supplies software updates or upgrades to a product, including through a third party, that product could still be considered to be within that manufacturer's control. This inevitably brings forward the date at which defectiveness is assessed and some products could be considered to be within the control of the manufacturer for all of their usable life.

Special use

The safety expectation is intended to be an objective test: it is not the safety expectation of the claimant that is relevant but that of an objective bystander. In recognition of certain decisions of the European Court of Justice such as *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse* and *Betriebskrankenkasse RWE*, however, the revised PLD puts an additional spin on this by identifying that there may be certain groups or users, or certain products, that may be entitled to particularly high safety expectations (Article 7(2)(h)) (C-503/13; C-504/14). For example, the safety expectation will be heightened for products whose failure would lead to a particularly high level of damage, such as a life-supporting implantable medical device.

Similarly, for products whose very purpose is to prevent damage, such as a smoke alarm, the revised PLD expressly identifies that any failure to fulfil that purpose is a circumstance that will be taken into account in assessing defectiveness (Article 7(2)(i)).

Current position in the UK

The current product liability regime in the UK is based on the existing Product Liability Directive (85/374/EEC), which was given effect by the Consumer Protection Act 1987 (1987 Act). It is a strict liability regime under which the producer of a product, any person holding themselves out to be the producer of a product, or the importer of the product into the UK can be held liable for damage caused by a defect in the product.

A product will be considered defective for the purposes of the 1987 Act if the safety of the product is not such as persons generally are entitled to expect. This is to be assessed objectively and evaluated at the time when the product was first put on the market. When considering defectiveness, all of the circumstances shall be taken into account and UK case law has made clear that courts must be able to adopt a flexible approach to the standard of safety that the public is entitled to expect, including which circumstances are relevant and the weight to be given to each (see *Gee and others v Depuy International Ltd* [2018] EWHC 1208; see News brief "Liability for defective products: how to assess defect", www.practicallaw.com/w-015-3946).

The circumstances that could, in appropriate cases, be relevant include:

- The avoidability of the harmful characteristic.
- The benefits of the product.
- The involvement of a learned intermediary in selecting a clinical product and counselling the patient.
- Regulatory compliance.
- The warnings provided with the product.

The 1987 Act does not provide any additional disclosure obligation specific to product liability claims, nor are there rebuttable presumptions shifting the burden of proof to the defendant. The long-stop for claims to be brought under the 1987 Act is ten years from the date when the producer put the product into circulation.

Interplay with product safety and cyber security

As already mentioned, a product will be defective if it fails to comply with a level of safety required under EU law. But the interaction with product safety legislation does not end there. Any recall or other relevant intervention by an authority will be used to assess defectiveness, which highlights that interactions with regulators around product issues that fall short of a formal finding of non-compliance could nonetheless still be material in a subsequent liability assessment.

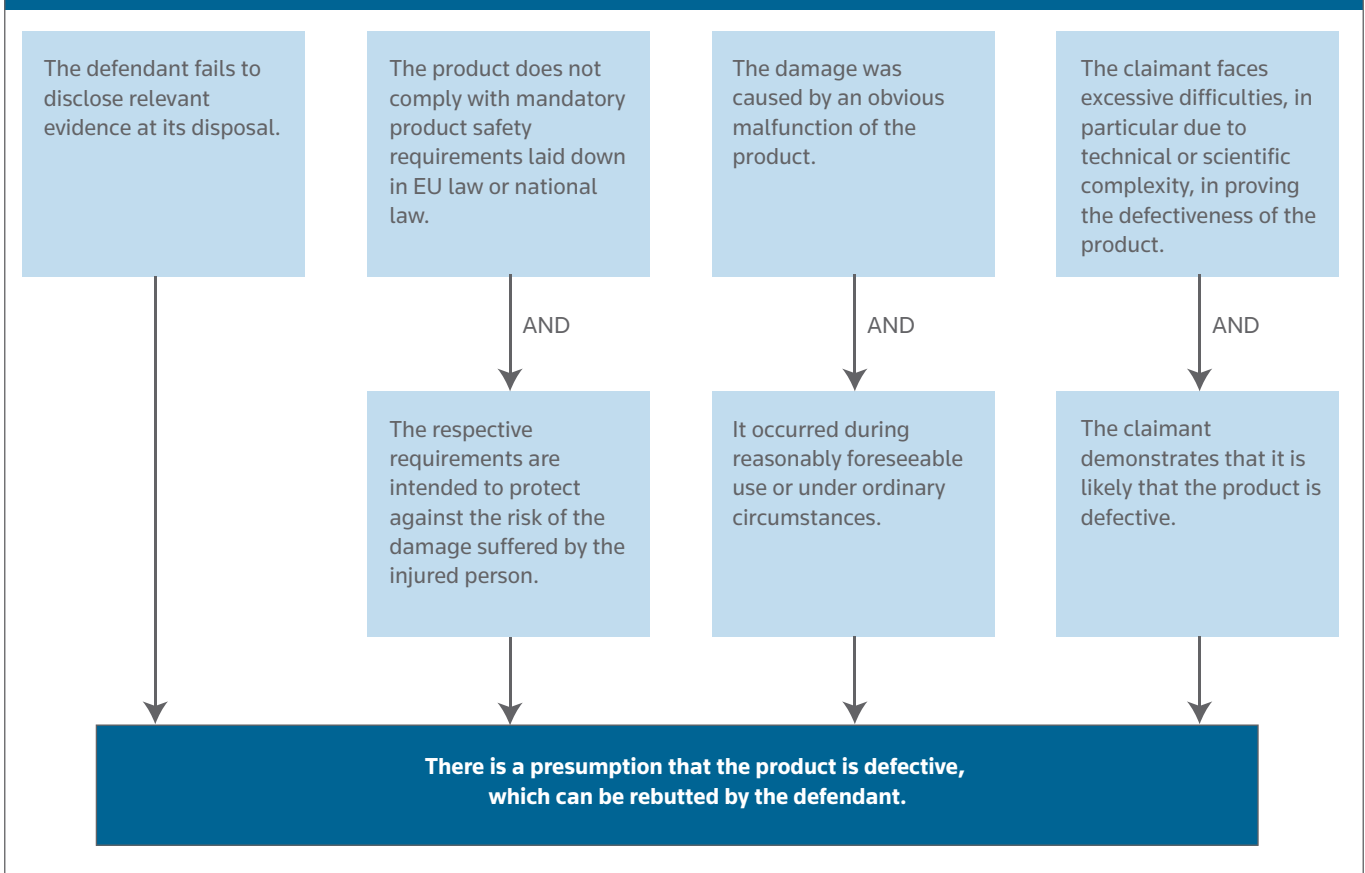
The legislation expressly identifies safety-related cyber security requirements, so that any cyber security flaws, including those that are identified or arise after the product is sold, could lead to a product being considered defective, as well as being potential breaches of any relevant cyber security legislation (Article 7(2)(f)). This means that a failure to

issue and update a product (where that is possible) to address a safety or safety-related cyber security risk could lead to liability under the revised PLD. Although this would not be the case in circumstances where the failure to update is beyond the manufacturer's control; for example, where the user did not download an available update.

More businesses in scope

The revised PLD will widen the categories of businesses that could potentially fall within the scope of the product liability regime in an attempt to address the new business models that have arisen over recent years, particularly in respect of the circular economy. Any business that makes a substantial modification to a product once it is outside of the original manufacturer's control, such as by refurbishing, repairing or upgrading it in a way that changes its functionality or compliance with safety

Rebuttable presumptions of defect



standards, will be held liable for any defects of the modified product, unless it can be shown that any defect is unrelated to the modification (*Article 8(2)*). Where it is the original manufacturer that makes the substantial modification, it will not be able to avoid liability by using the justification that the modification took place after the product was placed on the market.

No definition or guidance is provided as to what constitutes a “substantial modification” and this will be left to member states to determine. This is a clear area of uncertainty that should be monitored by any business that makes modifications to products or that is aware that its products are modified. “Substantial modification” will also result in a reset of the limitation period, as the modified product is deemed to be a new product for limitation purposes. Time will run from when the modified product is made available or put into service.

Beyond this, the revised PLD identifies additional economic operators as potential defendants to ensure that consumers have an entity in the EU that they can pursue for a remedy. This includes authorised representatives of manufacturers and, in

circumstances where there is no importer established within the EU or authorised representative, fulfilment service providers (*Article 8(1)*).

Online platforms will also be held liable in certain circumstances (*Article 8(4)*). This will include where they present the product, or enable the specific transaction, in a way that would lead the average consumer to believe that the product is provided either by the online platform itself or by a trader acting under its authority or control.

FURTHER DEVELOPMENTS

The revised PLD will impose new obligations and burdens on defendants, including in relation to disclosure and, in certain circumstances, the need to rebut presumptions of defectiveness and/or causation, and a longer time period in which claims may be able to be brought.

Disclosure

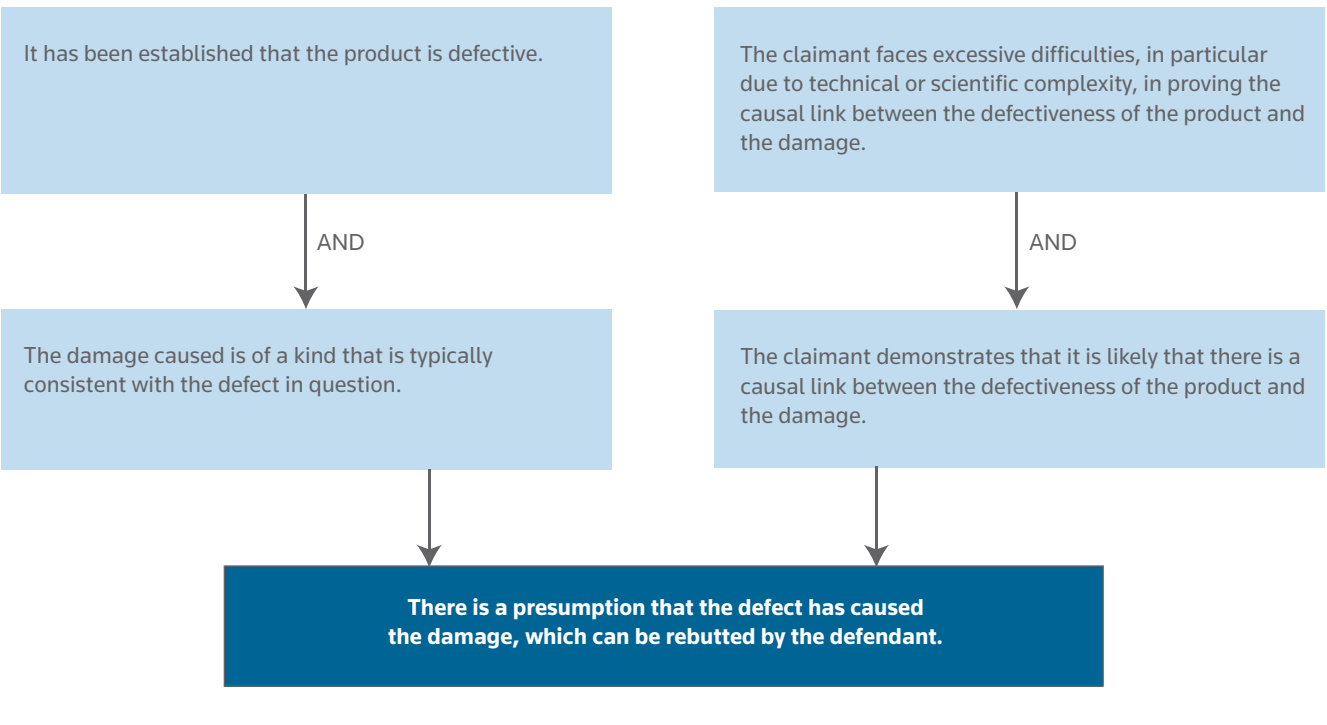
In general terms, there are only limited requirements for defendants to disclose documents in civil litigation in most EU jurisdictions, certainly that is the case when compared to common law jurisdictions. The

revised PLD, however, will introduce onerous disclosure requirements on defendants in certain circumstances. The EU legislators have expressly identified the asymmetry of information between claimants and defendants, suggesting that this asymmetry undermines the fair apportionment of risk between the parties and that it can be a significant disadvantage, or even a barrier, to a claimant receiving fair compensation. This is particularly the case in complex scientific and technical cases, as most product liability cases are.

The revised PLD will therefore impose new disclosure requirements on defendants in order to facilitate claimants’ access to evidence. Provided that the claimant has presented facts and evidence that are sufficient to support the plausibility of their claim, the defendant will be required to disclose the relevant evidence that is at the defendant’s disposal (*Article 9*).

Disclosure will be limited to what is necessary and proportionate, considering the legitimate interests of all parties, and there will be safeguards in relation to trade secrets, but this is a significant extension of the disclosure requirements on defendants

Rebuttable presumptions of causation



in most EU jurisdictions. The revised PLD even goes as far as to require that national courts are empowered, at their own discretion or the request of the claimant, to require that the disclosure should be presented in an “easily accessible and easily understandable manner” at the defendant’s cost.

Given the often significant amount of detailed technical data and documents that manufacturers hold in respect of the development of their products, this could be an onerous requirement with material risks for defendants. While there is a reciprocal requirement on claimants, in practice, this will be far less onerous as the injured party rarely has anywhere near the amount of documents that are relevant to the claim compared to the manufacturer.

As a measure to ensure compliance with the disclosure requirement, should a defendant fail to do so, the revised PLD imposes a presumption of defectiveness (*Article 10(2)(a)*).

Burden of proof

Consistent with its aim to enhance consumer protection and make it easier for claimants to obtain compensation, the revised PLD will make it significantly easier for a claimant to succeed in establishing that:

- A product is defective.

- A defect caused the alleged damage.

The revised PLD will introduce a number of rebuttable presumptions as to defect and causation in certain circumstances, thereby reducing the burden of proof on the consumer and shortcutting one of the key principles of the strict liability regime: that it is for the claimant to prove the defect, the damage and the causal link between the two.

As detailed above, a product is presumed to be defective where a defendant fails to disclose relevant evidence (*Article 10(2)(a)*). Defectiveness will also be presumed where the product does not comply with mandatory product safety requirements (*Article 10(2)(b)*).

The revised PLD also provides that the defect and the causation can be presumed where the claimant faces excessive difficulties in proving them, in particular due to technical or scientific complexity of the product or the issue (*Article 10(4)*). The claimant must show that it is likely that the product is defective or that there is a causal link, but at that point the presumption is engaged, the burden of proof is reversed and it is then for the defendant to rebut the presumption.

Whether or not the technical or scientific complexity needed to prove the defect or the causation is such that the claimant

would have “excessive difficulties” will be determined by national courts on a case-by-case basis, taking various factors into account. This could include:

- The complex nature of the product, such as an innovative health technology.
- The complexity of any technology used in the product, such as machine learning.
- Whether any information and data to be analysed by the claimant is particularly complex.
- The complexity of the alleged causal link between the defect and damage, such as a link that would require the claimant to explain how an innovative AI system works.

The causal link between defect and the damage shall also be presumed in circumstances where a defect has been established and the damage caused is of a kind that is typically consistent with the defect in question, based on other cases (*Article 10(3)*).

The revised PLD will also introduce a presumption of defectiveness where the claimant can demonstrate that the damage was caused by an obvious malfunction during

reasonably foreseeable use or under ordinary circumstances (*Article 10(2)(c)*).

Overall, it appears that, in practice, the threshold for a presumption of defectiveness or causation to be applied will be relatively low, certainly as regards medical, scientific or technical products. This means that defendants will likely be starting from a position where the presumption applies and will need to be rebutted (*see boxes "Rebuttable presumptions of defect" and "Rebuttable presumptions of causation"*).

Compensation for damage

The revised PLD will extend the right to compensation to new types of damage. In particular, damages will be recoverable for the destruction or corruption of data, provided that it is not used for professional purposes (*Article 6(1)(c)*). This is separate from, and in addition to, any liability in respect of data breaches and the claimant will not be able to recover if the data can be restored from a back-up at no cost. However, this is a significant extension to the type of damage that can be recovered from any producer or manufacturer that is found liable. In addition, medically recognised damage to psychological health will also be capable of being compensated (*Article 6(1)(a)*).

A longer long-stop

In general, all rights set out in the revised PLD will remain subject to a ten-year long-stop period. This will run from the time the actual product was placed on the market or "put into service" for a period of ten years, after which the rights expire unless proceedings have been initiated (*Article 17(1)*).

However, this long-stop period will be extended to 25 years in circumstances where the alleged damage is a latent personal injury where the symptoms were slow to emerge and this prevented the claimant from issuing a claim within ten years (*Article 17(2)*). This means that defendants could now be faced with needing to defend a claim up to 25 years after the relevant product was supplied. Businesses will need to ensure that their document retention and preservation policies are sufficient and their insurance policies are adequate to cover this scenario.

TIMING AND NEXT STEPS

The revised PLD will apply to products that are placed on the market or put into service after 24 months from the date of entry into

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force of the revised PLD (*Article 2(1)*). It will enter into force on the 20th day following its publication in the Official Journal of the EU. Each member state will then have two years to introduce domestic legislation to give effect to the revised PLD.

It therefore seems likely that the new regime will take effect from around the end of 2026. Coupled with other recent consumer-focused legislation in the EU, such as the Representative Actions Directive (*2020/1828/EU*), which aims to improve consumers' access to justice and which has already triggered cases, the EU could see a significant increase in product liability litigation in the coming years.

THE UK POSITION

As the UK is no longer an EU member state, it will not be required to implement the revised PLD into its own domestic law and

the UK's strict liability regime will, for the time being, continue to be based on the existing PLD, which was given effect by the Consumer Protection Act 1987 (1987 Act). It will therefore be very interesting to see whether, and the extent to which, the UK chooses to update its own product liability regime. In particular, some of the more consumer-friendly changes in the revised PLD, such as the rebuttable presumptions, would represent a significant overhaul to how those issues are currently approached in the English system.

One of the bills announced in the 2024 King's Speech was the Product Safety and Metrology Bill (the Bill) (*see Exclusively online article "King's Speech 2024: all change?"*, [www.practicallaw.com/w-043-9124](https://practicallaw.com/w-043-9124)). It is put forward as a bill that will support growth, provide regulatory stability and deliver more protection for consumers by, among other things, updating the UK's product

safety regime to respond to new product risks and opportunities to enable the UK to keep pace with technological advances and by identifying new and emerging business models in the supply chain. There are clear similarities here with the aim of the revised PLD to bring the EU product liability regime up to date.

However, while the Bill will enable the UK to mirror or diverge from updated EU rules in respect of product safety, there is no indication that any changes to the UK's liability regime are planned in the short term. However, in light of the shift of direction in the EU product liability regime, it certainly cannot be assumed that the UK will not follow a similar approach in due course. Practitioners will have to wait and see if and how the government intends to balance the interests of businesses, which could be seen as consistent with its growth agenda, and the protection of consumers in the future, which is consistent with the EU's updated approach.

There is comfort for UK businesses in the UK case law that addresses the key points, such as *Wilkes v Depuy International Ltd* and *Gee and others v Depuy International Ltd*, in which the High Court found in favour of the defendants and did not upset the fair apportionment of risk between business and consumers ([2016] EWHC 3096; [2018] EWHC 1208, see News brief "Liability for defective products: how to assess defect", www.practicallaw.com/w-015-3946) (see box "Current position in the UK").

Separately, the recent Retained EU Law (Revocation and Reform) Act 2023 (2023 Act) would have provided UK courts with the ability to choose not to follow EU case law on the meaning and effect of EU-related law, which includes the 1987 Act, which is EU-derived domestic legislation. It would have also introduced a new fast-track reference procedure enabling lower courts to refer points concerning the interpretation of EU-related law to the Court of Appeal or Supreme

Court for those courts to decide, where these points are of "general public importance", giving UK courts greater flexibility in terms of whether to follow or to depart from past decisions when considering new cases brought under the 1987 Act. However, the new government has revoked the regulations that were going to bring the relevant section of the 2023 Act into force, so that it can be reconsidered once the government's approach to the reset of UK relations with the EU is more developed (see News brief "Role of courts in applying EU-related case law: section 6 in limbo?", this issue).

Only time will tell how the UK intends to approach product liability in the coming years and the extent to which it will choose to diverge from the EU's new, more consumer-friendly regime.

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