

Client Briefing

November 2024

Update: The new EU General Product Safety Regulation and Product Liability Directive

The General Product Safety Regulation will come into force on 13 December 2024. The new Product Liability Directive was published in the Official Journal of the European Union on 18 November 2024. Member states must transpose the Product Liability Directive into national law by 9 December 2026.

The European legal framework for product safety and product liability is being fundamentally revised with the new General Product Safety Regulation and the new Product Liability Directive. The new General Product Safety Regulation replaces Directive 2001/95/EC. The Product Liability Directive will replace Directive 85/374/EEC, which has been in force for almost forty years. The declared aim of the legislative amendments is to improve the level of consumer protection. To this end, the obligations of economic actors regarding product safety and consumer claims in the context of dangerous or defective products will be considerably expanded. It is therefore essential for the affected economic actors to prepare for the impending tightening of the rules.

I. The General Product Safety Regulation (EU) 2023/988

With the adoption of the **General Product Safety Regulation (GPSR)**, the European legislator has created a completely new regulatory framework. By opting for a regulation instead of the previously used legal instrument of a directive, the aim is to ensure the uniform application of product safety regulations throughout the EU. The GPSR applies directly in all member states of the European Union without the need for national implementation. Key element of the GPSR is the introduction of the consumer's right to claim remedies from the party responsible for the recall in the event of a product recall (Art. 37 GPSR).

1. Requirements for the safety of a product

The GPSR extends the criteria relevant for assessing the safety of products (previously Art. 2 lit. b of Directive 2001/95/EC). When assessing the safety of a product, it is now also necessary to consider whether the appearance of the product may cause consumers (especially children) to use the product in a way other than for its intended purpose. In addition, cyber security features are included in the product safety assessment if they are necessary, given the type of product, to protect the product

from external influences.¹ This is to protect consumers from risks to their health and safety arising from products equipped with new technologies and from external attacks on these products (such as hacker attacks).² The Union legislator also sees the increasing product connectivity as a potential safety risk. The effects of a product on other products, connections and interactions of a product with other objects must not impair the safety of a product.³ Against this background, economic actors will have to pay particular attention in their product compliance to the area outside their own company sphere, i.e. to the interaction of their product with external factors and influences.

2. Economic actors concerned

The GPSR also extends the personal scope of application of European product safety legislation to include fulfilment service providers and providers of online marketplaces. Providers of online marketplaces are subject to extensive obligations.⁴ In particular, providers of online marketplaces must set up a central contact point for the purpose of communicating with market surveillance authorities and consumers as well as an internal product compliance process.

3. Obligation to report accidents

Additional burdens for both market surveillance authorities and the economic actors concerned are likely to result from the reporting requirements for accidents related to product safety.⁵ The manufacturer must immediately report an accident caused by a product placed or made available on the market. The provision contains a large number of vague legal terms that cause considerable difficulties in the application of the law when determining the scope of the reporting obligations.

There is no definition of the terms "accident" and "immediate" used in Art. 20 GPSR. The rule also provides no information on the type and weight of the required causal contribution to the accident. The specific reference subject of the knowledge of the accident also remains undetermined.

It is yet to be seen what effect the considerable legal uncertainty associated with the vagueness of the terminology will have in practice. It cannot be ruled out that market surveillance authorities will be pushed to the limits of their capacity in the event of a very high number of notifications, thus reducing their ability to carry out their tasks effectively. This would ultimately counteract the goal of improving the level of consumer protection.

4. Safety Gate

The rapid alert system, RAPEX, is to be further strengthened and renamed Safety Gate.

The Safety Gate from now on consists of three components: the rapid alert system for dangerous (non-food) products (Safety Gate), a web portal for informing the public (Safety Gate Portal) and a web portal via which companies can comply with the extensive reporting obligations imposed by the regulation⁶ (Safety Business Gateway).

A "reporting tool" will be set up on the public information website (Safety Gate Portal) to give consumers the opportunity to inform the EU Commission about products that pose a risk to consumer health and safety.⁷

¹ Art. 6 (1) number g Regulation (EU) 2023/988.

² Recital 25 Regulation (EU) 2023/988.

³ Art. 6 (1) number b, c, Recital 24 Regulation (EU) 2023/988.

⁴ Art. 22 Regulation (EU) 2023/988.

⁵ Art. 20 Regulation (EU) 2023/988.

⁶ Art. 9 (8) and (9), Art. 10 (2) number c, Art. 11 (2) and (8), Art. 12 (4), Art. 20 and Art. 22 Regulation (EU) 2023/988.

⁷ Art 34 (3) of Regulation (EU) 2023/988.

5. Right to remedy

The most far-reaching reform of the GPSR lies in the provision on remedies in the event of a product safety recall under Art. 37 GPSR. The economic actor responsible for the recall must offer the consumer an effective, free and timely remedy and a choice between at least two remedies. By offering consumers a choice of remedies, the European legislator hopes to increase the effectiveness of recalls.

a. Remedial measures

The remedies to be offered to the consumer include the repair of the recalled product, the replacement of the recalled product by a safe product of the same type with at least the same value and quality or an adequate refund of the value of the recalled product (equal to at least the price paid by the consumer). The economic actor may limit himself to offering only one remedy if other remedies would be impossible or disproportionate.

The remedy of replacing the recalled product shows similarities to supplementary delivery under sales law. However, the claim for replacement is limited to a safe product of the same value and quality. The product must therefore always be replaced in its used condition at the time of remedy. In contrast to the law on supplementary delivery under sales law, it will not be necessary to offer a replacement in the form of a new product at a later point in time, even if a new product was purchased and a product safety remedy is claimed.

The remedy of appropriate reimbursement of the value of the recalled product (at least equal to the price paid by the consumer) allows the consumer to be relieved of the monetary loss suffered as a result of the purchase of the product and is therefore comparable to the right of withdrawal from a contract. How-

ever, the GPSR does not provide for compensation for use to be charged to the consumer. The GPSR also does not explicitly state that the recalled product must be returned, but merely states that the consumer does not have to bear any costs in this regard. In a multi-level supply chain, the reference to the price paid by the consumer can lead to the economic actor responsible for the recall and manufacturing a dangerous individual component having to reimburse the consumer a significantly higher sum than he himself could achieve with the sale of his component product. This can result in considerable economic burdens and even existential risks.

b. Relationship to German national sales and tort law

The proximity of the described remedial measures to claims under German national warranty law is undeniable. The GPSR's remedies apply in addition to the statutory warranty rights under sales law.⁸ The unique feature of the remedies is that they are not subject to any time limit for claiming and therefore - unlike claims under warranty law - are not subject to a statute of limitations. Furthermore, the remedies must be offered to the consumer proactively; the economic operator responsible for the recall may not wait passively for the consumer to make a claim. The newly created right to remedy also does not fit into the system of tort law. This is because the scope of the remedies clearly goes beyond the tortious producer liability, which is limited to the protection of the integrity interest. It remains to be seen how the right to remedy, which is alien to the German civil law system, will be applied in practice alongside the warranty rights under sales law and the law of torts.

c. Practical consequences

The right to remedy will immensely increase the cost and litigation risks for those responsible for recalls. Due to the lack of a time limit on the right to a remedy, consumers can be expected to take action

⁸ Recital 88 of Regulation (EU) 2023/988.

against those responsible for recalls to a significantly greater extent. After the limitation period for warranty claims for material defects has expired, the consumer can continue to hold the party responsible for the recall liable. If the limitation period for his claims for defects in quality has not yet expired, the consumer will be able to decide on the basis of opportunity whether to pursue his claim against his contractual partner or the person responsible for the recall (who is often - outside of direct sales - not identical). In addition, the right to remedy can be asserted in class actions, which means that affected economic actors will be increasingly exposed to bundled claims in the future.⁹

II. The Product Liability Directive (EU) 2024/2853

The new Product Liability Directive also brings the European legal framework for product liability into the digital age. Against this backdrop, the European legislator is expanding the definition of both the term product and product defect. The provisions on the disclosure of evidence and on the distribution of the burden of proof have the potential to be highly dangerous for economic actors.

1. Extension of the liability regime

The Product Liability Directive expands the definition of the term "product" to include digital production files, raw materials, electricity and software.¹⁰ Both standard software and AI systems are to be covered, with the exception of non-commercial and open-source software.¹¹ The principle of strict liability is thus extended from material goods to digital products. As the Product Liability Directive also includes other liability subjects in the scope of the law (authorized representatives of the manufacturer, fulfillment service providers, providers of an online platform), the risks for economic actors increase at all levels of a multi-level value creation process. In addition, anyone who significantly modifies a product outside the manufacturer's control and then

makes it available on the market or puts it into operation will also be considered a manufacturer.¹² For lower levels of a supply chain, the risk of being held liable in the same way as the manufacturer of the completed product will increase.¹³ Similar to the expansion of the criteria for assessing product safety under the General Product Safety Regulation, the European legislator is also significantly expanding the criteria for determining the defectiveness of a product under the Product Liability Directive. Due to the constant technological progress and digital connectivity of products, the effects of a product's ability to learn and expand its functions after it has been placed on the market or put into service, as well as product safety requirements, in particular cyber security, should now also be taken into account when assessing the existence of a product defect.¹⁴ Companies must therefore ensure that external interventions or the technical development of a product, for example through software updates, do not impair product safety. This is because an economic actor remains liable for a product's defectiveness after it has been placed on the market or put into service, for as long as it is subject to the manufacturer's control, for example through software updates.¹⁵

2. Disclosure of evidence

With the transposition of the Product Liability Directive into national law, a claim for disclosure - foreign to the existing system - will be introduced into German product liability law.¹⁶ The claim for disclosure is intended to enable the injured party to gain access to relevant evidence available to the manufacturer before a national court in order to be able to prove his product liability claim. The requirements for the procedural right to disclosure of evidence are set quite low: Only the plausibility of the claim for damages must be sufficiently demonstrated. The national court will order the disclosure of the evidence designated by the injured party if it considers the required disclosure of evidence to be necessary and proportionate. When deciding whether to order

⁹ Art. 39 Regulation (EU) 2023/988.

¹⁰ Art. 4 (1) Directive (EU) 2024/2853.

¹¹ Art. 2 (2) Directive (EU) 2024/2853.

¹² Art. 8 (2) Directive (EU) 2024/2853.

¹³ See Art. 12 (1) Directive (EU) 2024/2853.

¹⁴ Art. 7 (2) number c, f Directive (EU) 2024/2853.

¹⁵ See Art. 11 (2), Recital 50 Directive (EU) 2024/2853.

¹⁶ Art. 9 Directive (EU) 2024/2853.

disclosure, the court shall take into account, in particular, the protection of confidential information and business secrets. Nonetheless, the disclosure requirement entails a considerable risk of "illuminating" internal company information of manufacturers, as the courts are granted considerable leeway in assessing the scope of the disclosure obligation due to undefined legal terms such as necessity and disproportionality.

Practical note:

In the future defense against excessive disclosure requests, the focus should therefore be on clearly highlighting the significance and weight of the requested evidence as confidential information or as trade secret for the company concerned. Overall, particular caution should be exercised in the internal monitoring and documentation of a potential product liability case. This is because the European legislator's far-reaching disclosure obligation deprives the affected company of the discretion to decide on its course of action in the context of product defense. The content and quality of internal documents that must be submitted by court order are likely to determine the prospects for a successful product defense.

3. Distribution of the burden of proof

There is no possibility of "evading disclosure", because this would be associated with considerable procedural disadvantages that could result in a procedural defeat. Failure to disclose evidence is sanctioned with a legal presumption that the product is defective. In addition, the Product Liability Directive contains further presumption rules for the existence

of a product defect and for the causality between the product defect and the damage. Thus, the general rule of the burden of proof in civil proceedings, according to which the plaintiff must prove the facts on which the claim is based (in his favor), is in danger of being eroded in the area of product liability. A de facto reversal of the burden of proof to the detriment of economic actors is to be feared. In the future, the inability to clarify the facts of the case ("non liquet") is likely to have more frequent adverse effects on the defendant in product liability proceedings than it has in the past.

4. Further extensions of product liability

The Product Liability Directive also signals the end of liability-limiting provisions. The currently applicable deductibles for property damage pursuant to Section 11 ProdHaftG (amounting to € 500) and the maximum liability limit for personal injury pursuant to Section 10 ProdHaftG (amounting to € 85 million in Germany) will no longer apply in future. In addition, the limitation period for product liability claims (see Section 13 ProdHaftG) will be extended from 10 to 25 years if an injured person was unable to initiate proceedings against an economic actor within 10 years due to the latency of their personal injury.

5. Practical consequences

The Product Liability Directive will fundamentally change the way product liability disputes are handled in German courts. Due to the expansion of the subjects of liability, a significantly larger number of economic actors will be exposed to product liability litigation. Due to the disclosure obligations and the burden of proof rules of the Product Liability Directive, the defense costs will also increase significantly, particularly for the purpose of protecting confidential information and trade secret.

This client information merely contains a non-binding overview of the subject area addressed in it. It does not replace legal advice. If you have any questions about the General Product Safety Regulation, the new Product Liability Directive or other issues in this context, please do not hesitate to contact us:



Michael Molitoris
Attorney at Law | Partner
Litigation and Arbitration | Compliance, Internal Investigations

T +49 89 4111417 414
E Michael.Molitoris@sza.de



Dr. Maïke Dickmann
Attorney at Law | Associate
Litigation and arbitration

T +49 89 4111417 447
E Maïke.Dickmann@sza.de