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Global Practice Guides

Product Liability & Safety

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CONTENTS

CONTENTS

INTRODUCTION

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Cooley LLP is an international law firm with its roots in Silicon Valley and a reputation for being the leading firm for the world's most innovative companies. Its renowned international product liability and safety team has market-leading experience in managing regulatory investigations, litigation, product recalls, risk assessments and international compliance in complex, fast-moving and highly regulated industries including life sciences, cosmetics and consumer products.

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Rod Freeman is an international products lawyer at Cooley LLP with more than 20 years' experience supporting the world's leading and most innovative companies. He is a recognised global leader in this field, providing clients unique insights into the international liability and regulatory landscape, and has an instinct for finding practical solutions for international companies. With a background in high-stakes product liability litigation, Rod understands the challenges faced by companies in an increasingly risky global environment. He is deeply embedded in the product liability and product safety community internationally, often working with policymakers within Europe and around the world to help shape the future of product liability and product safety regulation.

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INTRODUCTION

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Modern Product Liability – Global Risks and Challenges

Product manufacturers have, over recent years, been facing an increasingly challenging liability and regulatory environment around the world. To a significant degree, those challenges have been exacerbated by the pace, and scale of change in legal regimes internationally. The wave of change has been unprecedented, both in terms of its scope, affecting all product sectors, and the volume of change. We are at an inflexion point at which we are moving from a long period of policy discussion, deliberation and consultation, into a period of active legislative and institutional reform.

A major driver for these changes has been a perceived need on the part of regulators and policymakers to address challenges raised by new technologies, by the rise of new marketing models based on e-commerce, and as a result of the growing prioritisation of the circular economy.

This is what we should consider to be "Modern Product Liability". The risks, responsibilities and liabilities of companies involved in the manufacture and distribution of products are not what they used to be. They go way beyond what has been traditionally seen as "product liability", and the regulations that need to be taken into account when designing products now go beyond considerations of "product safety".

Over the last year there has been a dramatic shift in gears, with these debates and discussions culminating in concrete reforms. Companies are starting to feel the pinch – needing to stay on top of upcoming new requirements across multiple jurisdictions, understand what they mean and implement required changes to products, processes and procedures to comply. Reforms are also impacting multiple areas of a business, making it difficult to prioritise and allocate resources. The consequences of non-compliance are also increasing. This gives rise to very practical challenges for all companies and increases product liability and litigation risks stemming from non-compliance with regulatory measures.

Companies are beginning to realise, sometimes the hard way, that their existing procedures and practices for managing product liability risks worldwide may not be adequate for confronting the challenges that lie ahead. As regulation becomes more complex and more onerous around the world, and changes occur more rapidly, companies are struggling to find practical ways to keep informed of requirements and effectively manage risk. These challenges are particularly acute when considering products currently under development, likely to launch in one or two years, and potentially remaining on the market for several years thereafter. If companies cannot anticipate the direction and shape of regulatory change on the horizon now, investments and opportunities could well be lost. There is still no "magic wand" solution to this current dilemma; however, there are steps companies can take to manage this in a sustainable way.

This guide is one example. It is an invaluable resource to help companies manage the international risks that arise from this changing liability and regulatory landscape. It highlights the current state of liability laws and applicable procedures, explains the key features of the product safety regulatory landscape in individual jurisdictions, highlighting the areas of greatest risk, and provides insight into what the future might hold and what changes might be on the horizon. Given the significant impact that future changes can have, necessitating months or even years

INTRODUCTION

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of planning, it is becoming increasingly important for those managing modern product liability issues to understand and get to grips with any changes on the horizon.

As you work through the chapters, you will see that there are certain trends and patterns in the laws. You will also see marked differences. Companies need to navigate this increasingly complex world of product law, and to find practical solutions to manage risks while meeting business demands to simplify product specifications, consolidate supply chains and get products to market quickly. In order to do so effectively, it can be important to take a step back and look for the global trends, and to try to understand why these trends exist.

New Technologies Front and Centre

Policy debates and discussions over recent years have focussed on the perceived risks and challenges posed by new technologies and whether current legal frameworks are future-proof. The prevalent view in many jurisdictions is that change is needed, and concrete reforms are now flowing through.

Basic concepts that have underpinned product safety and liability regimes for decades are changing. What is considered to be a "product" is expanding beyond physical products, with new requirements and liability being extended to software and certain digital services. The concept of "safety" is also changing around the world – beyond risks to physical health and certain property damage – to also include mental health. Liability is increasing for risks associated with cybersecurity, software updates (including lack of updates), connectivity and AI functionalities. Companies are having to adopt their own compliance and risk management processes accordingly.

Policy debates and discussions centred on new technologies look set to continue. Jurisdictions still deciding how best to future-proof their regimes will look at recent reforms made in other countries. Those jurisdictions that have recently made wide-ranging reforms, such as the EU, are starting to focus on other associated issues – such as digital addiction and its impact on children and other vulnerable groups.

E-commerce Remains in the Spotlight

Policy debates have also focussed on whether new marketing and distribution models – particularly online marketplaces – are appropriately dealt with under existing regimes.

We are seeing reforms in major markets looking to tackle these issues, including new product safety and compliance requirements imposed on online marketplaces, sitting alongside reforms to product liability laws. We expect this trend to continue as markets and marketing models continue to evolve, and other jurisdictions decide how best to tackle these issues.

Voluntary initiatives to help address the specific issues presented by online sales have continued to advance, for example the "Product Safety Pledge" initiated by the European Commission was expanded in 2023 to include a number of additional commitments by signatories. This initiative has had international influence – being replicated in some other countries, and promoted by the OECD. However, some policymakers and stakeholders still argue that such voluntary measures do not go far enough or are not sufficiently robust to ensure an adequate level of consumer protection.

The Circular Economy

Measures designed to promote the circular economy, and sustainable production generally,

INTRODUCTION

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have become a prominent feature of regulatory reform, touching every aspect of the product life cycle, from design, through to manufacture, marketing, repair and end-of-life. Manufacturers and others in the supply chain are having to grapple with new rules relating to "right to repair", recyclability, built-in obsolescence, and expanded responsibilities through the product life cycle, alongside reforms to product safety and liability laws attempting to deal with issues associated with circular economy activities.

This increasing regulation leads to greater liability exposure for companies, as failure to meet new expectations can lead to regulatory action and consumer claims.

Environmental Social Governance (ESG) Changing the Landscape

A number of new sustainability and ESG measures focus on themes of "transparency" and "traceability", requiring companies to increase due diligence throughout their products' life cycle – from inception and manufacture through to consumption and disposal. Companies also face a growing need to communicate the environmental and human rights impacts of their products and business models via public disclosures or privately to customs officials and regulators in certain jurisdictions.

Increasing regulation in this area is another factor impacting liability exposure. Companies may increasingly be held responsible for both the environmental and human rights impacts of their business models and how these are communicated – through regulatory action or claims brought by consumers, NGOs or other impacted stakeholders.

Continued Dive for Increased Enforcement

Enforcement of product safety rules continues to be sporadic and inconsistent across the world. However, there remains a clear overall trend towards increased enforcement.

Policymakers and regulators continue to look at more effective ways to enforce laws and regulations, taking a number of different approaches. Regulators in some mature markets have increased the use of the existing levers that they have available – such as the increased imposition of civil penalties and use of unilateral warnings by the US CPSC. In other markets, the focus has been on ensuring regulators have better resources – in terms of funding, powers and the information available.

Another approach is to empower third parties to participate in the enforcement of product safety regulation; for example, by enabling consumers to bring claims for breaches of product safety regulation more effectively against companies, as seen in the EU with the introduction of the Representative Actions Directive. Online marketplaces are also being given something of a quasi-regulatory role, with increasing obligations to report safety incidents and co-operate with regulators in certain jurisdictions.

Sitting alongside this, emerging regimes are increasingly benefitting from increased co-operation with more established regimes, significantly escalating the risk for companies operating in multiple jurisdictions.

Resources for Managing Changing Risks

The increasing complexity and risks of the product law world, and the rapid pace of change now upon us, are a significant source of new challenges for product manufacturers and suppliers seeking to succeed in global markets. The

INTRODUCTION

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costs of failing to understand, anticipate and manage the risks can be high, as many high-profile brands have discovered in recent years, and continue to do so.

On the other hand, it is also important to recognise the opportunities and benefits. The development of rules and regulations, together with the emergence of more active enforcement agencies, can help to ensure a level playing field and stable markets for companies that have an interest in ensuring they comply with the rules. Companies with valuable brand names and reputations to protect, and who pride themselves on delivering good customer experience, can be especially exposed when marketing their products in markets that have few controls and where players take advantage of the lack of regulation. Proportionate laws, fairly and effectively enforced, can help companies to fully realise the benefits of their investments and manage their risks.

The key is for companies to find practical ways to keep abreast of the changes, understand their implications and develop future-proof systems.

This guide, authored by experts in their field around the world, is part of the toolkit that companies can use to help them on that path.

AUSTRALIA

Law and Practice

Contributed by:
Greg Williams, Alexandra Rose, Caitlin Sheehy and Sarah Aljassim
Clayton Utz

Contents

Clayton Utz is an independent Australian firm established in 1833, with nearly 200 partners and 1,400 employees across six offices, and one of the largest commercial litigation practices in Australia, including a specialist five-partner product safety and product liability team. The firm handles the most complex, significant and high-profile matters for clients, including many of Australia's top financial institutions, multinational corporations operating in a range of sectors, and state and Australian government departments and agencies. Clayton Utz is also a global leader in pro bono, with one of the largest pro bono practices of any law firm outside the USA.

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1. Product Safety

1.1 Product Safety Legal Framework

Australian Consumer Law

The principal law governing product safety in Australia is the Australian Consumer Law, which codifies a single set of consumer protection laws for the whole of Australia, including (but not limited to) laws relating to product safety and product liability.

The Australian Consumer Law is Schedule 2 to the federal Competition and Consumer Act 2010 (Cth). However, its operation across Australia also depends on state and territory laws, which provide that it has effect as a law of each Australian state and territory.

Other Laws

In addition to the Australian Consumer Law, there are a number of specific types of products that have their own safety regimes. By way of example, gas and electrical safety continues to be regulated at a state and territory level, so that each Australian jurisdiction has its own gas and electrical safety legislation, which applies to gas and electrical appliances. Other areas – such as therapeutic goods (ie, medicines and medical devices), food, agricultural and veterinary products, genetically modified organisms and industrial chemicals (including cosmetics) – have their own federal safety regimes, pursuant to:

- the Therapeutic Goods Act 1989 (Cth);
- the Australia New Zealand Food Standards Code;
- the Agricultural and Veterinary Chemicals Act 1994 (Cth) and the Agricultural and Veterinary Chemicals Code Act 1994 (Cth);
- the Gene Technology Act 2000 (Cth); and
- the Industrial Chemicals Act 2019 (Cth).

In each case, these regimes do not prevent the products in question from being subject to the Australian Consumer Law, subject to certain limited carve-outs.

In addition to these statutory obligations, product manufacturers and suppliers are subject to obligations under the common law. In particular, persons who are injured by a product may have a right to sue the supplier of the product in negligence (as well as under statutory causes of action created by the Australian Consumer Law), and an analysis of a supplier's duty to users of its product in negligence will often be important in assessing the appropriate response to a potential product safety risk.

1.2 Regulatory Authorities for Product Safety

Federal

The principal Australian product safety regulator is the Australian Competition and Consumer Commission (ACCC), which is responsible for administering the Competition and Consumer Act 2010 (Cth), including the Australian Consumer Law.

The ACCC has regulatory, investigatory and prosecutorial powers granted to it under the Competition and Consumer Act 2010. In relation to product safety, those powers include the power to require the production of documents or the provision of information, including the power to examine witnesses and to enter premises, conduct searches and seize consumer goods, equipment and documents. Typically, the powers of entry, search and seizure must be exercised pursuant to a warrant, unless there are circumstances that require their exercise without delay in order to protect life or public safety.

The ACCC also has powers to take a range of actions to protect consumer safety, including commencing compulsory recall actions, issuing substantiation notices and product safety notices, and prohibiting the making of certain representations in relation to a consumer product. Finally, the ACCC can issue penalty notices for breach of the Australian Consumer Law, or commence proceedings seeking declaratory and injunctive relief as well as civil penalties. It may also refer certain breaches of the Australian Consumer Law to the Commonwealth Director of Public Prosecution for consideration of criminal prosecution, with associated criminal penalties.

State

In addition to the federal regulator, each state and territory has a Department of Fair Trading or similar – although the role of these entities in relation to product safety diminished following the commencement of the Australian Consumer Law in 2011. Each state also has offices or regulators responsible for safety issues relating to gas, electricity and home building products. Product liability issues in these subject areas will often require engagement with both federal and state (or territory) authorities.

Sector-Specific

The other important sector-specific regulators are:

- the Therapeutic Goods Administration (TGA) in respect of medicines, medical devices and a range of other therapeutic goods;
- Foods Standards Australia New Zealand (FSANZ) in respect of the Australian Pesticides and Veterinary Medicines Authority (APVMA) in respect of agricultural and veterinary chemicals;
- the Office of the Gene Technology Regulator (OGTR) in respect of genetically modified organisms;
- the Australian Industrial Chemicals Introduction Scheme (AICIS) in respect of industrial chemicals; and
- state and territory fair trading, electrical safety and home building regulators (as above).

The TGA, the APVMA, the OGTR and the AICIS each operate registration or licensing regimes that require certain products to be assessed and registered before they may be supplied or used in Australia. These regulators also have various investigatory, regulatory and enforcement powers – the precise scope of which varies from regulator to regulator, but which are generally similar in scope to the ACCC's powers in relation to consumer goods, tailored to the particular products in question. Subject to certain carve-outs, the regimes are not exclusive, so a product that falls, for example, within the TGA's remit may also be – in some circumstances – a consumer product that is regulated by the ACCC and subject to the Australian Consumer Law.

1.3 Obligations to Commence Corrective Action

The powers of the ACCC and other Australian regulators, as summarised in **1.2 Regulatory Authorities for Product Safety**, include powers to compel local sponsors, suppliers and/or manufacturers to take certain actions in relation to goods. By way of example, the ACCC may require corrective action or information to be supplied regarding goods, order a compulsory recall (in rare circumstances), issue an interim or permanent ban on the supply of specified products, or create an information or safety standard in relation to particular products.

However, outside situations where the ACCC or the TGA has created a specific obligation in relation to particular goods, the institution of voluntary recall action is generally a matter for manufacturers or suppliers to determine for themselves.

The concept of product recall is well recognised under Australian law as covering a range of corrective actions in relation to products in the marketplace. The analysis of whether a recall is necessary in respect of a particular product safety issue is typically conducted by reference to the standards established by the tort of negligence – that is, what are the reasonable steps required of the supplier as a result of a foreseeable risk of injury to users of the product?

If a supplier initiates a recall action, there are no specific legal requirements as to how such recalls must be conducted. However, the various regulators (in particular, the ACCC, the TGA, FSANZ and the electrical safety regulators) publish guidelines in relation to the conduct of recalls. As a result of those guidelines, there are:

- common notification requirements to regulators regarding recall actions;
- commonly expected formats for recall notices; and
- common ongoing reporting obligations regarding the progress of recalls.

1.4 Obligations to Notify Regulatory Authorities

There are two notification obligations in relation to consumer goods in Australia: one risk-based and one incident-based.

Risk-Based

A supplier who voluntarily takes action to recall consumer goods because of a safety risk (including non-compliance with bans and certain safety standards) must, within two days of taking such action, give the relevant federal minister (which is in effect the ACCC) written notice that such action has been taken (Section 128 of the Australian Consumer Law). Such notice is typically given using the online form available on the ACCC's recalls website. The online form requires the provision of relatively detailed information about the nature of the product, the extent of its distribution in Australia and the reason for the recall.

Careful and detailed completion of the notification is recommended because the information provided could otherwise be formally compelled by the ACCC.

The ACCC continues to take an active and detailed interest in the initiation and continuing conduct of recall actions, so as to ensure that the best possible return rates are achieved and that continuing recall actions are taken by suppliers and manufacturers.

Incident-Based

There is a broad-ranging requirement to report incidents related to products to the ACCC. A supplier of consumer goods who becomes aware of the death or serious injury or illness of any person that was caused, may have been caused, or in the opinion of any other person was or may have been caused, by the use or foreseeable misuse of those consumer goods must notify the ACCC of that fact within two days of becoming aware of it (Section 131 of the Australian Consumer Law).

The Australian Consumer Law defines "serious injury or illness" as meaning "an acute physical injury or illness that requires medical or surgical treatment by, or under the supervision of, a

medical practitioner or a nurse (whether or not in a hospital, clinic or similar place), but does not include:

- an ailment, disorder, defect or morbid condition (whether of sudden onset or gradual development); or
- the recurrence, or aggravation, of such an ailment, disorder, defect or morbid condition."

There are certain limited exceptions to this obligation where:

- it is clear that the death or serious injury or illness was not caused by the use or foreseeable misuse of the consumer goods;
- it is very unlikely that the death or serious injury or illness was caused by the use or foreseeable misuse of the consumer goods; or
- the goods in question are subject to one of a number of alternative incident-based notification regimes in accordance with an industry code of practice or Commonwealth, state or territory law that is specified in the regulations to the Competition and Consumer Act 2010 (Cth) (these include notification regimes relating to therapeutic goods, agricultural and veterinary chemicals, and motor vehicles).

Notification pursuant to Section 131 is also typically undertaken using an online form available on the ACCC's recalls website.

1.5 Penalties for Breach of Product Safety Obligations

Pecuniary Penalties

Under the Australian Consumer Law, the maximum pecuniary penalties that may be imposed for breach of product safety obligations generally are, in the case of a corporation:

- a fine of up to AUD50 million;
- if the court can determine the value of the benefit that the body corporate, and any body corporate related to the body corporate, have obtained directly or indirectly and that is reasonably attributable to the act or omission – a fine of three times the value of that benefit; or
- if the court cannot determine the value of the benefit, a fine of 30% of the adjusted turnover of the corporation during the breach turnover period for the act or omission.

The maximum penalty that may be imposed on an individual is a fine of AUD2.5 million.

In either case, the above-mentioned pecuniary penalties can be sought in either a criminal prosecution or a civil penalty proceeding.

The above-mentioned fines are the maximum fines payable in respect of breaches of substantive provisions of the Australian Consumer Law. There are some breaches that may attract lesser penalties – for example, penalties for breach of the recall notification obligations outlined under **1.4 Obligations to Notify Regulatory Authorities** include (at present) AUD16,500 for a corporation and AUD3,300 for an individual, but can also include orders disqualifying individuals from managing corporations for a period (on application by the regulator).

Infringement Notices

In addition to the above-mentioned criminal and civil penalty regimes, the ACCC also has the power – pursuant to Section 134A of the Competition and Consumer Act 2010 (Cth) – to issue infringement notices in respect of certain breaches of the Australian Consumer Law. The ACCC may issue an infringement notice if it has reasonable grounds to believe that a person has

contravened one of the provisions of the Australian Consumer Law specified in Section 134A.

An infringement notice issued pursuant to Section 134A will specify a pecuniary penalty that must be paid for the purported breach of the Australian Consumer Law. The maximum penalties that may be imposed by an infringement notice vary according to the particular provision said to have been breached. Payment of an infringement notice precludes any further penalty (civil or criminal) being sought from that person in respect of the breach.

Examples of Penalties and Infringement Notices

Civil penalties

There are numerous examples of the ACCC seeking and obtaining civil penalties in respect of breaches of the Australian Consumer Law.

By way of example, in relation to product safety, in February 2016 a large Australian retailer was ordered by the Federal Court of Australia to pay a penalty of AUD3.057 million in respect of false or misleading representations about the safety of five consumer products as well as breaches of the obligation to report serious injuries.

More recent examples of civil penalties being imposed in relation to breaches of the Australian Consumer Law that did not relate to product safety include:

- in December 2019, a global car company was ordered to pay AUD125 million in respect of misleading representations made to regulators about the composition, standard or grade of certain vehicles (this penalty was significantly higher than the penalty jointly proposed by the ACCC and the company, and it was upheld on appeal);
- in May 2021, a telecommunications provider was ordered to pay AUD50 million in respect of unconscionable conduct in its dealing with more than 100 Indigenous consumers across Australia;
- in June 2021, an energy retailer was ordered to pay AUD1.2 million in penalties and to pay consumer redress in respect of false or misleading representations that it made in selling electricity plans to consumers;
- in April 2022, a company operating an online hotel booking site was ordered to pay AUD44.7 million in respect of misleading representations in its advertisements about hotel room rates;
- in August 2022, a multinational technology company was ordered to pay AUD60 million in respect of misleading representations made to consumers about the collection and use of their personal location data on Android phones;
- in December 2022, a global ride-sharing company was ordered to pay AUD21 million in respect of misleading representations made about ride cancellation messages and fees associated with a specific ride option available to consumers;
- in March 2023, an Australian online bookseller was ordered to pay AUD6 million in respect of misleading statements made on its website in relation to consumer guarantee rights;
- in July 2023, a former Australian vocational training college and its marketing arm were ordered to pay a record penalty of AUD438 million for acting unconscionably and misleading students into thinking vocational courses they were enrolling in were free;
- in August 2023, an Australian technology company was ordered to pay AUD10 million in respect of false and misleading representations made on its website about discount prices for add-on computer monitors;

- in December 2023, a US-based wearable technology company was ordered to pay AUD11 million after it admitted to making false, misleading or deceptive representations to 58 consumers about their consumer guarantee rights to a refund or a replacement after they claimed their device was faulty;
- in December 2023, an Australian car company was ordered to pay AUD6 million in respect of false or misleading representations made to customers that certain dealerships had closed and would no longer service vehicles;
- in February 2024, an Australian car company was ordered to pay AUD11.5 million in penalties for false or misleading representations it made to nine consumers about their consumer guarantee rights; and
- in March 2024, an Australian online floral company was ordered to pay AUD1 million after it admitted to making false and misleading representations on its website – namely, by publishing misleading star ratings for its products, advertising products at a discount when they had not generally sold products at the "strikethrough price", and added surcharges that were inadequately disclosed.

Finally, in May 2024 Australia's national carrier Qantas reached an agreement with the ACCC to pay an AUD100 million penalty (and, in addition, approximately AUD20 million in compensation) for false and misleading conduct in selling tickets on flights that had in fact been cancelled. This agreed penalty is still to be confirmed by the Federal Court.

Criminal penalties

Examples of criminal penalties and referral to the Commonwealth Director of Public Prosecutions are much rarer and relate to breach of the cartel provisions in the Competition and Consumer Act 2010 (Cth). By way of example, in 2017 Australia's first criminal cartel case concluded with a fine of AUD25 million in a global vehicle shipping company cartel case. In 2022, the Federal Court of Australia sentenced four individuals to suspended prison terms in relation to price fixing of the Australian dollar/Vietnamese dong exchange rate and transaction fees charged to customers. This was the first time that individuals in Australia were sentenced for criminal cartel conduct.

Infringement notices

On the other hand, the use of infringement notices is quite common and almost exclusively related to breaches of Section 29 of the Australian Consumer Law (which prohibits false or misleading representations about goods or services).

The ACCC publishes a register of such notices, which identifies the person or company that is the subject of the notice and the provisions of the Australian Consumer Law (or other applicable industry standard) that have been breached. However, the register does not disclose the particular products or conduct to which the notice relates.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

Liability for a faulty or defective product that causes injury, loss or damage may be brought on a number of grounds. The causes of action most commonly pleaded are the common law tort of negligence or a breach of the Australian Consumer Law. The Australian Consumer Law creates a number of bases for liability, including:

- engaging in false, misleading or deceptive conduct (although these claims may not be relied on in personal injury cases);
- breach by a supplier of consumer goods of statutory guarantees – eg, guarantees of acceptable quality;
- derivative liability for manufacturers in respect of goods that breach the statutory guarantee of acceptable quality; and
- the manufacture of goods with a safety defect.

Negligence

Under common law, a manufacturer or supplier of products also owes a duty of care to both the purchaser and the user to take reasonable steps to protect them from any foreseeable injury when using a product as intended.

The extent of the duty owed by a particular manufacturer or supplier will depend on the role they play in the supply chain and the steps that are reasonably and practicably available to them to address the risk.

Since the early 2000s, common law negligence in Australia has been substantially impacted by statutory reforms designed to create a uniform national approach and curtail excessive negligence claims. These led to the introduction of various civil liability regimes, which are in place in Australian states and territories.

False, Misleading or Deceptive Conduct

The Australian Consumer Law prohibits persons from engaging in false, misleading or deceptive conduct in trade or commerce. It does not matter whether the person intended to mislead. Breach of this prohibition gives rise to a right to sue for loss or damage (although not for personal injury) in respect of losses suffered as a result of that conduct.

This prohibition is relied on in all manner of claims, including product liability claims for economic loss. By way of example, if goods are represented – expressly or impliedly – to have certain qualities that they do not have, a purchaser or end user of the product may sue for damages on the basis that the representations are misleading.

Statutory Guarantees

Part 3-2 Division 1 of the Australian Consumer Law provides that a supplier of goods to a consumer supplies those goods subject to a number of statutory guarantees. These guarantees cannot be limited or excluded by contract. They require that the goods:

- correspond with their description;
- are of acceptable quality;
- are fit for any disclosed purpose;
- conform to any sample provided or demonstration model in quality, state or condition; and
- comply with any express warranties given in relation to them.

Remedies for breach of the above-mentioned consumer guarantees are provided in Part 5-4 of the Australian Consumer Law. For actions against suppliers, consumers have a number of remedies available, including in some cases the right to return the goods and demand a refund, as well as the right to recover any reasonably foreseeable losses suffered by reason of the failure of the goods to comply with the guarantee.

Part 5-4 also provides an extended right to sue the manufacturer of goods for damages if they breach guarantees of acceptable quality, supply of goods by description, as to repairs and spare parts or express warranties.

Strict Liability Regime

Part 3-5 of the Australian Consumer Law imposes liability on manufacturers of goods with safety defects. It is closely modelled on the European Product Liability Directive.

Goods have a safety defect if their safety is "not such as persons generally are entitled to expect". Relevant surrounding circumstances must be taken into account in making this safety inquiry. If such goods cause personal injury or damage to land, buildings or fixtures, persons who suffer loss as a result of such injury or damage may sue the manufacturer for damages.

Expanded Concepts of Consumer and Manufacturer Under the Australian Consumer Law

There are specific definitions of "consumer" and "consumer goods" as well as "manufacturer" in the Australian Consumer Law.

"Consumer goods" or "goods acquired as a consumer" are goods that:

- cost AUD100,000 or less, are a vehicle or trailer acquired for use principally in the transport of goods on public roads or are otherwise goods that are of a kind ordinarily acquired for personal, domestic or household use or consumption;
- were not acquired for the purposes of using them up or transforming them, in trade or commerce, in the course of a process of production or manufacture or repair or treatment of other goods or fixtures on land; and
- were not acquired:
  (a) (for goods other than gift cards) for the purpose of resupply; or
  (b) (for gift cards) for the purpose of re-supply in trade or commerce.

The term "manufacturer" has a deeming function, and it means not only the actual manufacturer of goods (ie, a person who grows, extracts, produces, processes or assembles goods), but also:

- a person who causes or permits their name, or a name by which the person carries on business or a brand or mark of the person, to be applied to the goods;
- a person who causes or permits themselves to be held out as the manufacturer of the goods; and
- a person who imports the goods into Australia (if the actual manufacturer of the goods does not have a place of business in Australia).

Contract

Another cause of action for a person who has been injured or who has suffered loss or damage is under the law of contract. However, the number of these claims has diminished owing to the growth of statutory remedies and remedies available under the tort of negligence.

2.2 Standing to Bring Product Liability Claims

Under the Australian regime, the original purchaser is not the only person who may make a claim for injuries caused by a product. Apart from the remedies available for breach of consumer guarantees, which may only be sought by the consumer who received the goods from the supplier, the other causes of action outlined in **2.1 Product Liability Causes of Action and Sources of Law** may be relied upon by any person who suffers loss and damage that is compensable under the relevant cause of action.

2.3 Time Limits for Product Liability Claims

The limitation period for bringing a product liability claim depends on a number of factors, including the cause of action, the type of claim (eg, in relation to an alleged safety defect), whether the claim is brought under common law or statute, the relevant Australian jurisdiction, and the date of the alleged act or omission.

However, in relation to claims for personal injury, the applicable limitation period for an action to be commenced is:

- in most jurisdictions, either within three years of the date the cause of action is discoverable by the plaintiff (the date of discoverability), or 12 years from the date of the act or omission alleged to have caused the death or injury (the long-stop period); or
- three years from the date the cause of action accrued.

There may also be a mechanism for an extension to be granted by the courts in relation to the applicable limitation period for personal injury claims. In determining whether to grant an extension, a court is generally required to consider a number of factors, including having regard to the justice of the case. Again, in most jurisdictions an extension of up to three years can be granted. There are also circumstances in which limitation periods are suspended, such as where a claimant is suffering from a legal incapacity (eg, the claimant is a minor or suffers from a mental or physical disability), or when a class action is commenced – in which case, the limitation period will not begin to run again until a group member opts out or the proceedings are determined.

The limitation period for claims that do not relate to personal injury is, in most cases, six years from when the cause of action accrued.

2.4 Jurisdictional Requirements for Product Liability Claims

Australia has both a federal court system and a hierarchy of courts in each of the states and territories. The High Court of Australia deals with constitutional disputes and appeals (with leave) from either the Full Federal Court or a state or territory court of appeal. Both federal and state courts may exercise jurisdiction in respect of the causes of action under the Australian Consumer Law outlined in **2.1 Product Liability Causes of Action and Sources of Law**. In so far as a claim relates to defendants and conduct within Australia, proceedings may be commenced in any court of competent jurisdiction, regardless of where the conduct occurred. However, there is cross-vesting legislation that provides that the proceedings may be moved from one jurisdiction to another if they are in an inappropriate forum.

Foreign Corporations

The Australian Consumer Law has long-arm jurisdiction and also regulates the conduct of foreign corporations that are "carrying on business" in Australia. In order for an Australian court to validly exercise jurisdiction over a foreign corporation, that corporation must be validly served with initiating process. Some courts require leave to be obtained to serve overseas corporations, and for the court to be satisfied that the claim has a sufficient nexus to Australia to justify it being brought in Australia. In other courts, there is no requirement to seek leave to serve an overseas corporation when certain claims (such as those under the Australian Consumer Law) are being made. The court rules in each jurisdiction set out a list of circumstances

in which service outside Australia may be permitted. One such circumstance is that the claim is seeking recovery of damage suffered wholly or partly in Australia, and that is often sufficient in product liability claims to justify service on a foreign defendant.

Australia is party to the Hague Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters 1965, so – if authorised – service may be effected through Hague Convention means on other treaty parties.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

Under Federal Legislation

There are mandatory steps that must be taken at a federal level and in some states and territories in Australia before formal proceedings can be commenced in relation to product liability claims. Federal legislation obliges parties to take "genuine steps" to resolve a dispute before commencing proceedings in the Federal Court. Under the federal legislation, genuine steps include the requirement to file a statement specifying the steps that have been taken to resolve the issues in dispute or the reasons why such steps were not taken.

Under State Legislation

Many states and territories also have various different pre-action procedures in place, which must be undertaken before formal proceedings can be commenced. For example, the Australian Capital Territory (ACT) requires the claimant of a personal injury claim to provide a potential respondent with a notice of their claim (in the approved form), which includes brief particulars and copies of any documents directly relevant to a matter in issue in the claim. The respondent must respond to the notice of claim, acknowledging whether it is in fact the proper respondent to the claim or whether it has knowledge of who may be the proper respondent to the claim. If the respondent on whom the notice of claim was served is the proper respondent to the claim, they have an obligation to provide the claimant with copies of all documents in their possession that are directly relevant to a matter in issue in the claim. There is then an obligation on the respondent to attempt to resolve the dispute by making an offer of settlement or counter-offer to any offer made by the claimant. Queensland has a very similar pre-action procedure provided for by the Personal Injuries Proceedings Act 2002 (QLD), except that – in addition to the obligations of the parties outlined above for the ACT – parties in Queensland must also attend a compulsory settlement conference before formal proceedings are commenced. South Australia also has pre-action procedures that the parties are required to comply with before commencing formal proceedings in relation to most claims.

Consequences of Non-compliance

Non-compliance with the various pre-action procedures may mean that the claimants cannot commence or continue proceedings until those pre-action requirements have been complied with. Furthermore, non-compliance may result in the court awarding costs reasonably incurred because of the non-compliance against the non-complying party once proceedings are commenced.

2.6 Rules for Preservation of Evidence in Product Liability Claims

The general rule is that documents must be preserved as soon as there is a reasonable anticipation or reasonable contemplation of litigation. The definitions of document are extremely broad and extend to information in many forms, and to the product itself. The rule first existed

under common law, where it is expressed as an offence involving perverting the course of justice. In most Australian jurisdictions, the common-law offence has now been supplemented or replaced by statute – examples of which follow.

- The Crimes Act 1914 (Cth) contains an offence for the destruction of "a book, document or thing of any kind" that "is, or may be, required in evidence in a [federal] judicial proceeding", provided the intention is to prevent the book, document or thing from being used in evidence (Section 39).
- the Crimes Act 1958 (Vic) contains an offence for the intentional destruction/concealment of a "document or other thing of any kind" that "is, or is reasonably likely to be, required in evidence in a legal proceeding" (Section 254). The relevant intention here is the "intention of preventing it from being used in evidence in a legal proceeding" – this offence applies to a legal proceeding that is in progress or that is to be, or may be, commenced in the future.

Depending upon the jurisdiction, penalties include up to five years' imprisonment, significant fines and the ability of the court to strike out affected parts of the defence of a contravening party. Lawyers who advise their clients to act contrary to the obligations in legislation may also face sanction and penalties.

From a procedural perspective, if documents that were relevant to litigation are no longer available because of steps taken by a party who was aware of (or should have been aware of) actual or likely proceedings, this may result in that party's claim or defence being struck out, to the extent that the documents would have been relevant to that claim. It may also result in adverse inferences being drawn against the party about the content of the documents, which can then be used as a basis to make findings of fact against the non-producing party.

2.7 Rules for Disclosure of Documents in Product Liability Cases

The rules of the court in which a claim is commenced outline the applicable requirements with regard to discovery. While these rules are similar across the various Australian jurisdictions, there are nuances between the courts. To assist the parties, the Australian courts have published practice notes and directions that provide further guidance, such as in relation to the court's expectations concerning the parties' approach to discovery. Use of technology is actively encouraged by all courts in discovery and many provide suggested protocols for exchanging documents with technological assistance.

Generally speaking, the practice of Australian courts is to try to actively manage the discovery process so as to keep the level of discovery proportionate to the complexity of the issues in proceedings and the amount that is at stake.

In personal injury proceedings, documentary discovery is only available with the court's leave in most courts. Before making discovery orders, a court must be satisfied that the discovery sought is necessary and will assist the resolution of proceedings as quickly and efficiently as possible. Courts will generally not grant discovery requests that are expansive or may be "fishing" expeditions. The additional guidance provided by Australian courts via practice notes and directions emphasises the courts' expectation that parties to proceedings will take all the steps necessary to reduce the burden of discovery.

Subpoenas may also be used to obtain documents that are relevant to issues raised in a pro-

ceeding but that are held by a third party. As with discovery, in many courts a party must approach the court to request leave to issue a subpoena and must demonstrate to the court that the subpoena has a legitimate forensic purpose. A subpoenaed entity will also have an opportunity to object to the scope or timeframe of a subpoena.

2.8 Rules for Expert Evidence in Product Liability Cases

Expert evidence is typically an important part of the evidence in product liability cases, in respect of questions of both liability and quantum. This is because they often involve complex, technical questions regarding products, standards and the scientific state of the art.

Experts must be independent and have a duty to assist the court rather than to advocate on behalf of the party that calls them. Powers do exist for courts to appoint their own experts or refer particular matters to referees. Increasingly, the use of these powers is being explored by courts in Australia in complex product liability cases.

The duties of expert witnesses are usually set out in the court rules or practice notes (in addition to the common law). By way of example, the Federal Court of Australia's Expert Evidence Practice Note ("GPN-EXPT") states that any expert witness retained by a party for the purpose of preparing a report or giving evidence should – at the earliest opportunity – be provided with a copy of the Harmonised Expert Witness Code of Conduct Practice Note and all relevant information (whether helpful or harmful to that party's case) so as to enable them to prepare a report of a truly independent nature. Experts must also set out the basis for their opinions and acknowledge that they have complied with their obligations under the practice note.

Most courts also have rules that prohibit the evidence of any expert from being relied on unless the expert has served a written report well before the date for trial.

Co-ordination of Experts

In addition, product liability cases often involve a court-ordered process for the evidence of experts in the same field to be given concurrently – ie, the experts for all parties in the same discipline will be sworn in together to give their evidence. It is also usual for a conferral process to be ordered in advance of the experts giving evidence so that they can produce a joint report that details the areas of agreement and disagreement, as well as the reasons for that disagreement.

2.9 Burden of Proof in Product Liability Cases

Under the law of contract, the law of negligence and the majority of provisions in the Australian Consumer Law, the claimant bears the onus of proving the elements of their claim on the balance of probabilities.

2.10 Courts in Which Product Liability Claims Are Brought

Claimants may bring product liability claims in either the Federal Court or state or territory courts. Each state and territory has either two or three levels of court: a magistrates' or local court, a district or county court and a Supreme Court. The Federal Court has the Federal Circuit Court, the Federal Court and the Full Court of the Federal Court.

There are jurisdictional limits for lower courts, which vary from state to state (they are usually in the range of AUD750,000 to AUD1 million for the district courts). The Supreme Court of each state and territory has unlimited jurisdiction (subject

only to other laws that may separately restrict the quantum of damages payable for certain types of claims, including personal injury claims). Most product liability litigation of any complexity will be brought in either a state or territory Supreme Court or the Federal Court.

Civil juries are very rare in Australia, so in practice most product liability cases are heard by a judge alone. The usual practice in Australia is for a single judge to sit at first instance and a panel of three or more judges at appellate level.

All civil litigation in Australia is adversarial in nature. Individual parties present their evidence to the judge and make submissions on the law. After consideration of all the materials presented, the judge makes findings of fact and law.

2.11 Appeal Mechanisms for Product Liability Claims

In virtually all jurisdictions, unsuccessful parties have the right to appeal a judgment of a trial judge. The applicable appeal procedure is dictated by the jurisdiction in which the trial took place. In the case of interlocutory judgments, it is generally necessary for the unsuccessful party to apply for leave to appeal (from the original deciding judge). Appeals are typically raised on a particular question of law, but it is not unusual for some of the evidence presented at trial to be reviewed in the course of an appeal.

Parties who are unsuccessful on appeal to the Full Court of the Federal Court or a state or territory court of appeal may seek leave to appeal to the High Court, Australia's highest appellate court. There is no automatic right to have an appeal heard by the High Court. The party wanting to appeal must convince the High Court in a "special leave" hearing that the issues in dispute are sufficiently important or that the potential for miscarriage of justice is sufficiently great to justify the appeal being heard by the High Court. Once a matter has been determined by the High Court, there is no further appeal and the decision is binding on all other Australian courts.

Appeals in most Australian courts are by way of rehearing, meaning that the court has the power to consider all of the evidence afresh. However, no new evidence may be put before the appellate court unless that court grants leave. It is extremely rare for such leave to be granted in civil matters.

Timeframes

In the Full Court of the Federal Court, appeals from final judgments must be filed and served within 28 days of the trial decision. Timeframes for state and territory courts of appeal vary based on jurisdiction but are all of a similar order.

2.12 Defences to Product Liability Claims

Negligence

The following defences may be available to a claim in negligence:

- voluntary assumption of risk;
- contributory negligence; and
- the learned intermediary defence.

Voluntary assumption of risk is when a plaintiff consciously decides to take responsibility for injury, loss or damage. In establishing this defence, the defendant must show that the plaintiff properly perceived and appreciated the danger, and voluntarily chose to accept the risk. Contributory negligence may be relied upon when the plaintiff has contributed to their own injury by failing to meet the standard of care for their own safety. Typically, contributory negligence will result in apportionment of damages

according to the degree of fault, but may be a complete defence in some jurisdictions.

The learned intermediary defence has not yet been applied in Australian courts, but the existing common law principles would accommodate its use.

The introduction of various Civil Liability Acts has also led to additional specific statutory defences relating to certain types of claims. By way of example, the state of New South Wales has introduced complete defences where:

- harm was suffered as a result of the materialisation of an inherent risk (unavoidable by the exercise of reasonable care and skill) or an obvious risk (obvious to a reasonable person);
- the conduct was widely accepted at the time by peer professional opinion as competent professional practice;
- the defendant is a good Samaritan or volunteer exercising reasonable skill and care; or
- the defendant is a public or other authority (in certain cases).

Australian Consumer Law

In cases where a safety defect was not discoverable within the limitations of science and technology at the time of distribution, the manufacturer or supplier may rely on the "state-of-the-art defence" (also known as the "development risk defence"). This defence must be established on the balance of probabilities and the claim in question must be in relation to the Australian Consumer Law provisions relating to defective products.

Another defence to an action based on a safety defect may be claimed in circumstances where the defect is brought about by compliance with a mandatory standard. A mandatory standard is a standard for goods or anything relating to the goods that, under law, must be complied with when goods are supplied and which carries a penalty for non-compliance. This defence cannot be claimed in relation to statutory requirements for goods to achieve a minimum standard.

Manufacturers are also entitled to claim a defence where the alleged defect did not exist when the goods were supplied by the manufacturer. Similarly, if an entity is only responsible for the manufacture of a component of the product, that entity will be able to claim a defence against actions for claims relating to safety defects in the finished product.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Adherence to regulatory requirements is a relevant consideration in product liability cases in Australia – although it does not operate as a complete defence to such claims. In this respect, see **2.12 Defences to Product Liability Claims**. Unlike in the USA, there is no "pre-emption" defence in Australia. Compliance with applicable regulatory requirements or mandated standards will be a relevant factor considered by the courts in actions for negligence and under the statutory warranty or guarantee provisions of the Australian Consumer Law; however, the fact that a product had its safety assessed by a regulator as part of the process of granting a licence to sell that product in Australia does not preclude a product liability claim being brought in respect of it.

2.14 Rules for Payment of Costs in Product Liability Claims

Australia has a "loser pays" costs system. The precise rules that apply to calculate the costs payable by an unsuccessful party to a successful one vary from jurisdiction to jurisdiction, but

are generally calculated on a party/party basis – ie, only some parts of the work undertaken are recoverable (meaning that, in the ordinary course, the costs recovered are only a portion of the costs incurred). However, solicitor/client or indemnity costs – which would be close to the total costs incurred – may be awarded in some circumstances, particularly if a party formally rejected a settlement offer and then failed to do better than that offer at trial.

The approach taken to calculating costs differs from jurisdiction to jurisdiction. Some jurisdictions have a scale of costs, which specifies (and limits) the amount a successful party may recover from an unsuccessful party for tasks undertaken during the course of litigation (such as the drafting of correspondence or electronic document management). Other recoverable costs include court filing fees and other out-of-pocket expenses. In other jurisdictions, an assessment is made as to the reasonableness of the costs incurred.

Depending on the type of proceeding commenced, more particular rules may apply in relation to costs. By way of example, in representative proceedings or class actions, statutory provisions restrict costs orders being made against class members – other than those who commenced the proceedings.

2.15 Available Funding in Product Liability Claims

Australia has a well-established litigation funding industry. Although the exact number is unknown, in December 2020 the Parliamentary Joint Committee on Corporations and Financial Services indicated that 22 litigation funding companies were known to be operating in Australia (14 of which were foreign owned or based overseas, six were Australian-owned or Australian-based, and the information for the remaining two was unknown).

Litigation Funding Arrangements

Litigation funding arrangements typically involve a funding agreement between the funder and claimant, a retainer agreement between the lawyer and claimant, and an agreement between the litigation funder and lawyer that sets out the terms on which the funder agrees to pay the costs of the litigation. However, the models of litigation funding are evolving and the law in this area is also changing.

At the core of such litigation funding arrangements is an arrangement whereby the litigation funder promises to pay the legal costs and disbursements of the litigation and to meet any adverse costs order – in exchange for which, the claimant promises to pay the funder a percentage of any compensation they receive. Such arrangements are very common in Australian class actions; however, they are traditionally less common in product liability class actions than in other forms of class actions, such as shareholder class actions.

Reform and Development

Litigation funding is an area of rapid reform and development in Australia. Following a decision of the Full Court of the Federal Court of Australia in June 2022, amendments were introduced to the Corporations Regulations 2001 (Cth) that exempt litigation funding schemes from the managed investment scheme regime, where those schemes meet the relevant definition under the regulations. Before these amendments, litigation funding arrangements could be regulated as managed investment schemes under the Corporations Act 2001 (Cth). Further reforms to litigation funding regulations continue to be the subject of review and debate.

Contingency Fees

Australian lawyers are permitted to enter into "no win, no fee" arrangements and, in the case of such arrangements, to charge an uplift on their fees of up to 25% in the event of success. They are not otherwise permitted to charge contingency fees, except in class actions in the Supreme Court of Victoria, where the court approves the arrangement. See further discussion in **3.1 Trends in Product Liability and Product Safety Policy**.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

There are six Australian courts that have a class action procedure (referred to as a "representative proceeding"): the Federal Court of Australia and the Supreme Courts of New South Wales, Queensland, Tasmania, Victoria and Western Australia. The class action procedure is often used in product liability claims.

The rules governing representative proceedings are largely identical in each of the six jurisdictions. In order to bring representative proceedings, there must be seven or more persons who have claims against the same legal person, arising out of the same, similar or related circumstances and giving rise to a substantial common issue of law or fact. However, it is not necessary for at least seven persons to be individually identified – nor is there a requirement, as in many other jurisdictions – that the common issues predominate over those that are not common.

Australian representative proceedings are "opt out", meaning that all persons who fall within the group definition will be bound by the outcome of the proceedings unless they choose to opt out. Unlike many other jurisdictions, there is no certification requirement for Australian class actions – meaning that once a class action that meets the basic requirements is commenced, a class action is on foot unless the defendants can convince the court that representative proceedings are an inappropriate vehicle for the dispute in question. Class actions in Australia are very rarely "declassed" in this manner.

2.17 Summary of Significant Recent Product Liability Claims

In recent years, Australia has seen a number of class actions concerning product liability claims. A selection of those cases is included here.

Bayer Essure Class Action

In July 2019, a representative proceeding was commenced by Slater & Gordon on behalf of women who are alleged to have suffered injury as a result of using the Essure contraceptive device. Trial in this matter commenced in April 2023 in the Supreme Court of Victoria and concluded in August 2023. Judgment is currently reserved.

Combustible Cladding Class Action

Two class actions have been commenced by William Roberts Lawyers, funded by IMF Bentham, on behalf of owners of buildings who have suffered or will suffer financial loss due to the need to remove and replace Alucobond PE and Vitrabond PE combustible cladding products. The claimants seek to recover the cost of rectification, loss of property value and the legal cost of experts from the product manufacturers. The Alucobond class action is presently listed for hearing commencing in August 2024.

Mesh Implant Class Action

In 2012, a representative proceeding was commenced by Shine Lawyers on behalf of Australian women who alleged injuries as a result of

pelvic mesh implants. The first-instance trial in the pelvic mesh class action was held in the Federal Court of Australia in 2017. Judgment was delivered in late 2019 in favour of three applicants. An appeal in respect of the trial judgment was heard by the Full Court of the Federal Court in February 2021, with judgment delivered in March 2021 in favour of the three applicants. The appellants sought special leave to appeal to the High Court of Australia. This application was rejected in November 2021. In March 2023, the Federal Court approved a settlement between the parties for AUD300million. Numerous class actions have been filed on behalf of women not captured in the original proceedings against other manufacturers of pelvic mesh.

Roundup

Three competing class actions were commenced in 2019 and 2020 in relation to the weedkiller, Roundup. In June 2020, the Federal Court ruled that the latest of those class actions (commenced by Maurice Blackburn) ought to proceed, in preference over the competing claims. The hearing of this matter concluded in January 2024 and judgment is currently reserved.

Automotive Class Actions

There have been numerous class actions against Australian automotive companies in recent years for a wide range of issues, including emissions non-compliance, Takata airbags and allegedly faulty diesel particulate filters. These claims typically rely on consumer guarantee provisions in the Australian Consumer Law and allege that vehicle owners are entitled to compensation because their vehicles were worth less than they paid for them at the time of purchase. This theory of loss is the subject of a reserved decision of the High Court of Australia on appeal from two Federal Court class actions.

Further Claims

In addition, there have been a number of highly contentious toxic tort class actions relating to bushfires and floods – some of which resulted in significant multimillion-dollar settlements.

Separately, the ACCC has also been active in recent years, particularly in its oversight of product recalls and allegedly unsafe products.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

The maximum penalties for breach of the Australian Consumer Law, as set out in **1.5 Penalties for Breach of Product Safety Obligations**, increased five-fold in late 2022 and substantially increased the penalties available (the previous maximum corporate penalty for a breach of the Australian Consumer Law was AUD10 million). The amendments also introduced penalties relating to unfair contract terms, which came into effect in November 2023.

Even apart from these amendments, the penalties being imposed by courts for breaches of the Competition and Consumer Act 2010 (Cth) (including but not limited to those relating to product safety breaches) have been steadily increasing, with a new high being set by the AUD438 million penalty mentioned in **1.5 Penalties for Breach of Product Safety Obligations**. This trend is expected to continue with the application of the new penalty regime.

Class action procedure, in particular as it relates to litigation funders, has been the subject of considerable activity by the court and the federal

legislature. The following are of particular relevance.

- In January 2019, the Australian Law Reform Commission (ALRC) tabled to Parliament its report on class actions, *Integrity, Fairness and Efficiency – An Inquiry into Class Action Proceedings and Third-Party Litigation Funders*.
- In December 2019, the High Court held that neither the Federal Court nor the New South Wales Supreme Court has the power to make common fund orders (which enabled funders to obtain a commission from group members who had not signed a funding agreement) – at least at an early stage of the proceedings.
- In April 2020, the New South Wales Court of Appeal held that the New South Wales Supreme Court did not have the power to make an order closing an otherwise open class in order to facilitate a mediation.
- In August 2020, the Corporations Regulations 2001 (Cth) were amended to subject litigation funders to regulatory regimes relating to managed investment schemes and the supply of financial products – from which they had previously been exempt. Central to the changes was the requirement that litigation funders were required to hold an Australian Financial Services Licence.
- In December 2020, the Federal Government Joint Committee on Corporations and Financial Services published a report titled *Litigation Funding and the Regulation of the Class Action Industry*. The report made 31 recommendations for further legislative and procedural reforms across class actions and litigation funding.
- In October 2021, the Australian government responded to these recommendations, making its priorities:
  (a) to ensure that Australians receive a fair and proportionate amount of any class action settlement or judgment and to reduce the windfall gains made by litigation funders – draft legislation has been proposed to this effect;
  (b) to expand the regulation and supervision of litigation funders;
  (c) to ensure that "economically inefficient class actions" are not detrimental to Australia's economic recovery from COVID-19;
  (d) to enhance the Federal Court's powers to protect class members and regulate class actions; and
  (e) to consider whether the Federal Court ought to have exclusive jurisdiction for class actions commenced under the Corporations Act 2001 (Cth) and the Australian Securities and Investments Commission Act 2001 (Cth).
- In June 2022, the Full Court of the Federal Court of Australia found an earlier authority of the court to be wrong, which had held that litigation funding arrangements were managed investment schemes for the purposes of the Corporations Act 2001 (Cth).
- In December 2022, the Corporations Amendment (Litigation Funding) Regulations 2022 came into effect, amending the Corporations Regulations 2001 (Cth) to exempt litigation funding schemes that meet the definition under the regulations from the managed investment scheme regime. These amendments apply in relation to litigation funding schemes that meet the relevant definition and were entered:
  (a) on or after the commencement of the Corporations Amendment (Litigation Funding) Regulations 2022; and
  (b) before the commencement of those regulations, but only in relation to as much of the duration of the scheme that occurs on or after that commencement.

- In October 2023, the Full Court of the Federal Court of Australia confirmed that section 33V of the Federal Court Act 1976 (Cth) does empower the court to make a common fund order when approving settlement of a class action proceeding.
- In October 2023, the Victorian Supreme Court of Appeal reaffirmed that contingency fees are limited to proceedings in the Supreme Court of Victoria until such time as they are introduced in other courts.

In relation to product liability, the current product liability regime has remained relatively unchanged since its introduction in 2011 as part of the Australian Consumer Law. However, class actions are now a significant driver of a number of different forms of litigation, including product liability litigation.

3.2 Future Policy in Product Liability and Product Safety

Amendments to the Australian Consumer Law

In March 2017, Consumer Affairs Australia and New Zealand published the report of its review of the Australian Consumer Law. The report made a number of recommendations in relation to amendment of the Australian Consumer Law – some of which (eg, the increased penalties described in **3.1 Trends in Product Liability and Product Safety Policy**) have already been implemented. However, one that has not been implemented is the recommendation that Australia should introduce a general safety provision that imposes:

- an obligation on suppliers in Australia to ensure the safety of a product before it enters the market; and
- penalties on suppliers in accordance with the new penalty regime for failing to do so.

Product Safety Priorities

The ACCC remains committed to minimising and raising awareness of the risks posed by unsafe consumer goods. In its product safety priorities for 2023–24, the main areas of focus for the regulator include:

- undertaking compliance, enforcement and education initiatives focused on high-risk safety issues for young children in products such as sleep aids, toys for children under the age of three, products with button batteries and toppling furniture;
- implementing strategies to prevent injuries and deaths related to infant sleep products;
- strengthening product safety online, including through using technology to prevent unsafe product listings online, as well as using best practices to reduce safety risks from second-hand goods sold online; and
- supporting Australia's transition to a sustainable economy through education and awareness raising.

Product Liability Perspective

From a product liability perspective, much will depend on:

- how the recent amendments to the Corporations Regulations 2001 (Cth) to exempt litigation funding schemes from the managed investment schemes regime shape the product liability landscape in Australia; and
- the impact of contingency fee reforms in Victoria, where legislative changes in 2020 permitted lawyers to charge – under some circumstances – percentage-based contingency fees in class actions before the Supreme Court of Victoria.

Since the introduction of the contingency fee reforms, there has been a consistent increase

in class action proceedings filed in the Supreme Court of Victoria, including for the reasons described in the case summary of the October 2023 decision of the Victorian Supreme Court of Appeal in **3.1 Trends in Product Liability and Product Safety Policy**.

Finally, the High Court's judgment on appeal regarding the above-mentioned two Federal Court automotive class actions will have a significant effect on the future conduct of such claims, which have been particularly frequent in recent years.

Trends and Developments

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Clayton Utz

Clayton Utz is an independent Australian firm established in 1833, with nearly 200 partners and 1,400 employees across six offices, and one of the largest commercial litigation practices in Australia, including a specialist five-partner product safety and product liability team. The firm handles the most complex, significant and high-profile matters for clients, including many of Australia's top financial institutions, multinational corporations operating in a range of sectors, and state and Australian government departments and agencies. Clayton Utz is also a global leader in pro bono, with one of the largest pro bono practices of any law firm outside the USA.

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CLAYTON UTZ

The Australian Competition and Consumer Commission's Crackdown on Greenwashing by Businesses

A continuing focus of the Australian Competition and Consumer Commission (ACCC) and the financial consumer regulator, the Australian Securities and Investments Commission (ASIC), in 2023-24 has been greenwashing in the advertising of goods and services to consumers. In December 2023, following the receipt of submissions from more than 150 stakeholders, the ACCC published guidance in an attempt "to improve the integrity of environmental and sustainability claims made by businesses and protect consumers from greenwashing" – in recognition of a shift in consumer preferences towards more environmentally sustainable goods and services as well as to help businesses facilitate consumers making informed choices.

The Australian government is also considering legislative changes that may deliver the ACCC and ASIC further powers to protect consumers.

The ACCC broadly defines "greenwashing" as false or misleading environmental claims and indicates that it will consider a business to have been engaging in greenwashing in circumstances where claims are made that present goods or services as "better for or less harmful to the environment than [they] really [are]". The ACCC similarly defines an "environmental claim" broadly as any representation made by a business in relation to its environmental impact, including claims that the goods or services offered by the business – or the business itself – have a neutral or positive impact on the environment, are less harmful for the environment than alternative goods or services, or have specific environmental benefits.

An environmental or "green" claim made by a business on (among other things) packaging or labelling, in advertisements, or on social media and websites without an accurate or factual basis may amount to a breach of the Australian Consumer Law – specifically, of the prohibitions against:

- engaging in misleading or deceptive conduct in trade or commerce; and/or
- making false or misleading representations about specific aspects of goods and services.

Importantly, it is enough for the conduct only to be likely to mislead or deceive for a breach to be established, and it is not necessary to prove that the conduct was intentional or actually misled or deceived any person and resulted in actual loss or damage. In certain circumstances, silence or omitting information may also be considered misleading or deceptive conduct or amount to a false or misleading representation. The ACCC will consider whether the "overall impression created would be misleading to the ordinary and reasonable consumer".

The release of the guidance follows a speech made by the then ACCC Deputy Chair Delia Rickard at the Sydney Morning Herald Sustainability Summit on 20 September 2022, where she warned that the ACCC would be actively targeting greenwashing and that businesses would be expected to "back up" any claims they are making, including by providing "reliable scientific reports, transparent supply chain information, reputable third-party certification, or other forms of evidence". Delia Rickard further commented that the ACCC would "be asking businesses to substantiate their claims" in circumstances where the regulator had concerns about their veracity.

It also follows an internet sweep conducted by the ACCC in October and November 2022 of the environmental and sustainability claims made by 247 businesses in Australia. Overall, the ACCC found that 57% of businesses had made claims that were potentially misleading or deceptive and, more specifically, that:

- in the cosmetics and personal care sector, 73% of businesses made concerning claims;
- in the clothing and footwear sector, 67% of businesses made concerning claims; and
- in the food and drink sector, 65% of businesses made concerning claims.

ACCC's eight principles to follow for good practice

The ACCC guidance outlines eight principles that businesses should apply to avoid misleading consumers and promote "good practice", as follows.

- Make accurate and truthful claims – it is important that the claims made by businesses are accurate, true and factually correct, even in circumstances where products are provided by a third party in a business' supply chain. The ACCC expects that businesses will not exaggerate the benefits of a claim, will only make claims that represent a "genuine environmental impact", and will take reasonable steps to verify information provided by suppliers.
- Have evidence to back up claims – any claims should be supported and substantiated by "clear evidence" (ie, preferably independent and scientific evidence or research). Businesses should avoid making claims in relation to future matters where they do not have "reasonable grounds" for making the representation, as this may be misleading or deceptive under the Australian Consumer Law.
- Do not hide or omit important information – consumers need to be provided with all the relevant information in order to make an informed decision. As such, providing incomplete information or hiding relevant or important information from consumers will also be considered misleading.
- Explain any conditions or qualifications on claims – if claims will only be accurate or true in certain circumstances or after certain steps are taken (especially by the consumer), these conditions or qualifications should be explained to consumers "clearly and prominently". By way of example, if a business claims that their product is "recyclable", but the consumer would need to take the product to an industrial recycling facility, this may be misleading if not clearly drawn to the attention of the consumer.
- Avoid broad and unqualified claims – claims should be clear and specific, as opposed to broad and unqualified, which may more easily mislead consumers. If there are any qualifications to a business's environmental claims, the ACCC expects these to be accompanied by prominent disclaimers. In addition, the ACCC recommends that businesses avoid using vague and ambiguous terms that do not inform consumers of the environmental benefits of products or services (eg, "green" or "clean", "environmentally friendly" or "eco-friendly", and "sustainable"). The ACCC also expects certain terms to be qualified or explained if used by businesses, including "recyclable", "recycled content", "renewable energy" and "free", in order to ensure that consumers do not get the wrong impression.
- Use clear and easy-to-understand language – scientific and technical language should be avoided, as this language is likely to be diffi-

cult for ordinary and reasonable consumers to understand, and can therefore be misleading.
- Visual elements should not give the wrong impression – as images and logos will influence a consumer's impression of the environmental impact of a product or service, these should be avoided in circumstances where they would give the wrong impression about the environmental benefits of a product or service. Any visual elements (including images, colours, symbols and logos) will be considered by the ACCC along with wording when considering the "overall impression" on the consumer that is created.
- Be direct and open about sustainability transition – the ACCC is aware that transitioning to a more environmentally sustainable business model takes time and, during the transition, a business' products are likely to continue to have a negative impact on the environment. The ACCC expects businesses to be direct and open with consumers in relation to this impact and not overstate environmental improvements and initiatives where they have not been formally and genuinely committed to. This applies to, for example, claims made by businesses in relation to future net-zero emissions targets.

ASIC's guidance includes Information Sheet 271 ("How to Avoid Greenwashing When Offering or Promoting Sustainability-Related Products"), which contains analogous guidance for sustainability-related financial products. Concepts of interest include:

- truth in promotion – using clear labels and defining sustainability-related terminology; and
- clarity in communication – providing clear explanations of how sustainability-related considerations are factored into investment strategies.

Compliance and enforcement action

It is likely that the guidance will form the basis for the ACCC's approach to surveillance and enforcement, with environmental claims and sustainability at the top of the ACCC's list of compliance and enforcement priorities for 2023–24 and 2024–25.

The ACCC has various powers to investigate and commence action against misconduct, including:

- issuing Section 155 notices (to obtain information and documents and/or require a person to attend an examination and give evidence to investigate potential contraventions of the Australian Consumer Law);
- issuing substantiation notices (to require a person to give further information and/or produce documents that could be capable of substantiating or supporting an environmental claim);
- issuing infringement notices (where there are reasonable grounds to believe that a person has contravened certain provisions of the Australian Consumer Law); and
- commencing civil and/or criminal proceedings.

The maximum penalties available for contraventions of the Australian Consumer Law are not insignificant and (for a body corporate) will be the greater of:

- AUD50 million;
- if the court can determine the value of the benefit that the corporation (and any corporation related to it) obtained directly or indirectly and that is reasonably attributable to the act

or omission – three times the value of that benefit; or
- if the court cannot determine the value of the benefit – 30% of the company's adjusted turnover during the period of the act or omission.

The ACCC will consider a number of factors when determining whether to take enforcement action, including:

- whether the ACCC's action will help clarify aspects of the law, especially newer provisions of the Australian Consumer Law; and
- whether the conduct:
  (a) is of significant public interest or concern;
  (b) results in substantial consumer or small business detriment;
  (c) is national conduct by large businesses, recognising the potential for greater consumer detriment and the likelihood that the conduct of large businesses can influence other market participants; and
  (d) involves a significant new or emerging market issues or where the ACCC's action is likely to have an educative or deterrent effect.

Court proceedings and enforceable undertakings

The ACCC accepted a court-enforceable undertaking from MOO Premium Foods Pty Ltd (MOO) in November 2023 in relation to claims it made for a number of years that its yoghurt tubs comprised "100% ocean plastic". The ACCC was concerned that the statements gave the impression that the plastic was collected from the ocean, when it was in fact collected from coastal areas. Although the products included disclaimers on the top and back of its packaging to this effect, they were considered inadequate to overcome the headline "100% ocean plastic" representation. As part of the undertaking, MOO committed to – among other things – conducting internal audits of the "ocean bound plastic" resin used in its packaging.

Most recently, in April 2024, the ACCC (for the first time) commenced proceedings in the Federal Court of Australia against Clorox Australia Pty Limited (Clorox) for allegedly making false or misleading representations that some of its GLAD-branded kitchen and garbage bags were made of 50% recycled "ocean plastic". Despite qualifying statements included in small font on the back of the packaging, the ACCC considers that the headline "ocean plastics" statement – together with the wave imagery and blue colour of the bags – created the impression that they were made from plastic waste collected from the ocean or sea. Instead, the ACCC alleges the bags were partly made from plastic collected from communities up to 50 kilometres in land.

Notably, both MOO and Clorox had disclaimers on the back of the packaging of their respective products to qualify the claims made in relation to the composition of the plastic, but these are (or have been) considered insufficient by the ACCC to avoid or prevent misleading consumers. Moving forwards, businesses should refer to the ACCC guidance and ensure any disclaimers or qualifications with regard to environmental claims are of appropriate size and readily visible to consumers on the product's packaging.

In addition, enforcement action has been taken by ASIC under the analogous provisions of the ASIC Act, which serve to protect consumers from misleading or deceptive conduct in relation to the supply – in trade or commerce – of financial products and services. Although the ACCC will focus on consumer products and services, and ASIC will focus on financial prod-

ucts and services, the regulators have indicated an intention to work closely together to address misconduct in circumstances where there may be overlap between their jurisdictions.

Outlook

The ACCC has indicated plans to release further guidance for businesses and consumers in relation to emission and offset claims, the use of trust marks, and consumer guidance to assist with assessing environmental claims. ASIC will also release updated guidance in connection with foreshadowed mandatory climate disclosures reporting. In the meantime, it is likely that the ACCC and ASIC will continue to work together on the detection and investigation of potential greenwashing claims, and further enforcement action by both regulators can be expected. In turn, this area is becoming one of increasing interest for private litigants and potential consumer class actions against government and corporations.

The Australian government is also expected to continue to consider further options in this area, with the Senate committee inquiry "into greenwashing, particularly claims made by companies, the impact of these claims on consumers, regulatory examples, advertising standards, and legislative options to protect consumers" due to report in 2024. Its terms of reference include legislative options to protect consumers from greenwashing in Australia.

AUSTRIA

Trends and Developments

Contributed by:
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Fellner Wratzfeld & Partners

Fellner Wratzfeld & Partners (fwp) is one of Austria's leading business law firms and is based in Vienna. The firm has a team of more than 70 highly qualified legal practitioners and provides legal advice in all major legal areas. The fwp dispute resolution practice has extensive experience in product liability cases in both in court and out-of-court disputes. fwp's advice in this area ranges from product safety and product compliance to product recalls.

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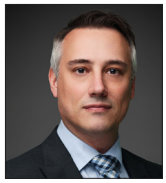

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Product Liability in Austria – Current Situation

In Austria, the Austrian Federal Act on liability for a defective product – Product Liability Act (*Produkthaftungsgesetz*) (PHG), the Austrian Federal Act on Protection against Dangerous Products – Product Safety Act (*Produktsicherheitsgesetz*) (PSG) – the PSG transposes Directive 2001/95/EC on general product safety into Austrian law – and the Austrian General Civil Code – *Allgemeines Bürgerliches Gesetzbuch* (ABGB) regulate product liability and product safety.

The PHG presupposes that damage has occurred in order for liability to apply, whereas the PSG regulates the obligation to market safe products.

In contrast to the PHG, the PSG is intended to have a preventative effect. It is intended to prevent people from being put at risk by dangerous products by obliging manufacturers and importers to only place safe products on the market. Safety is assessed according to use, among other things. Particular attention must be paid to "vulnerable" consumer groups such as children, the elderly and people with disabilities. Non-compliance with the rules in the PSG can have negative consequences, even if no harm is caused. Violations of the PSG are punishable by administrative penalties.

The safety of products and the associated liability play an important role for various reasons. A company's products are its link to its customers and the public. Product safety and liability issues have a direct impact on a company's image and reputation.

In the event of liability claims, the consequences can be severe depending on the type of product or defect. Measures to avoid liability due to defective products are therefore important.

Liability Under the PHG

Liability under the PHG does not depend on the fault of the contractor against whom a claim is made. It is therefore "independent of fault". It is not necessary that the entrepreneur be accused of negligent or intentional behaviour. The only decisive factor is whether there is a product defect within the meaning of Section 5 PHG that caused the damage. An "objective" liability, an atypical form of "strict liability", is thus imposed on those liable under the PHG.

Companies are liable even if they are not responsible for the error that has occurred (liability for the safety risk).

Liability under the PHG also does not require a direct contractual relationship or a connection via a sales chain between the person injured by a defective product and the person responsible for it. As a non-contractual liability, it applies in principle to anyone who is injured by a defective product.

Companies along the distribution chain that manufacture or sell goods in the broadest sense can be held liable for defective products. Within a company, product liability affects various areas such as production, management, purchasing and sales. Purchasing and sales, for example, must ensure that their own company's liability is minimised and that defective products can be traced in the event of an emergency.

Only pure service providers or consulting companies are least affected by product liability. However, this assumes that such a company does not actually place any products on the market (including the sale of promotional items).

Product liability is not about the defect in the product itself, but about the damage caused by the defective product to another object or person. The protective effect covers not only the individual contracting parties, but also innocent bystanders.

In principle, the manufacturer, quasi-manufacturer or importer is liable for damages if they have placed a defective product on the market and the product has caused damage. The term "manufacturer" within the meaning of the PHG is very broadly defined and by no means only refers to those companies where the product came off the assembly line.

Dealers are only liable if the manufacturer or importer cannot be identified by the injured party. However, the retailer can exempt themself from liability if they can provide the injured party with the name of the manufacturer or their supplier within a reasonable period of time (approximately one to two weeks).

Product liability claims must therefore be asserted against the manufacturer and only in exceptional cases against the retailer.

Parts manufacturers or raw material manufacturers are only liable for the defective products they have manufactured if this partial product or the basic material is the cause of the damage. The manufacturer of end products is also liable for the defects of base materials or sub-products (however, the parts manufacturer has a right of recourse)

A product is deemed to have been placed on the market if it has been removed from the manufacturer's/importer's power of disposal by the manufacturer's/importer's own volition (value principle). It does not depend on whether or not it is for payment.

The PHG defines the term "product" as any movable physical object, even if it is part of another movable object or has been connected to an immovable object. Energy is also considered a product within the meaning of the PHG by express statutory order. A "thing" is defined as anything that is not a person and is intended for human use. An object is considered movable if it can be moved from one place to another without damaging its substance. An object is considered physical if it "falls into the senses", while rights are considered non-physical.

The law does not specify how a product is to be manufactured. The type of production is irrelevant: whether industrial, mechanical, manual or by other means; this does not determine liability. It is also not decisive what ultimately happens to a product. Even the installation of a product does not change the original product characteristics.

Whether a product is defective depends on the respective contractual content. The concept of defect therefore differs from the concept of defect under warranty law. Compensation for material damage under the PHG is therefore only due if the damage has occurred to a physical object other than the product. This means that the damage caused by the defect to the item itself is not eligible for compensation (so-called further damage). This also applies if an individual part of a part manufacturer destroys other parts of the overall product.

A product is considered defective if it does not offer the level of safety that can be expected under all circumstances. Design defects, production defects ("runaway damage") and

instruction errors ("instructions for use") can be considered as types of defects.

Attempts are often made to restrict the area of use of products in the instructions for use in order to reduce safety expectations. However, what matters is safety for all reasonable expected uses.

The packaging, the offer and the advertising are also relevant in connection with the normally expected use of the product. The standard for safety expectations can be raised by advertising claims or special guarantees.

It is not impermissible, but frequently common practice, for potentially liable parties under the PHG to endeavour to manage the safety expectations of product users and consumers by means of "warnings", "instructions for use" and "product declarations" as part of the "presentation of the product" in such a way that a product cannot be qualified as defective.

Product liability covers personal injury and damage to property caused by defects in the product when it was placed on the market by the liable party. Personal injury is compensated without distinction between consumer and entrepreneur (no deductibles). The property damage must have occurred to an object other than the defective product, whereby only privately used objects are compensated under the PHG.

However, not all consequential material damage is compensated, as mere financial loss, loss of profit and so-called further damage that arises as a result of the defect in the item itself (eg, defective water hose destroys the rest of the engine). The general law on damages may apply here.

With regard to private property damage, there is a deductible of EUR500 for the injured party.

Claims for damages arising from product liability expire three years after knowledge of the damage and the damaging party, and in any case ten years after the product causing the damage is placed on the market.

It is prohibited to exclude or limit the obligation to pay compensation under the PHG "in advance". Also, a contractual exclusion of liability is not permitted. The aim is to ensure that injured consumers of defective products are effectively protected: in the entrepreneur/consumer relationship, any attempt to limit or even exclude liability from the title of product liability through contractual clauses is inadmissible. Product liability claims cannot be limited or excluded in the relationship between the party liable for product liability and the injured party, even in the relationship from entrepreneur to entrepreneur, although liability in this relationship is only for personal injury in any case.

The PHG grants the claimant (within narrow limits) a number of statutory relief options, as set out below.

- The manufacturer or importer proves that the product was not placed on the market by them (eg, the product was stolen from the factory). Note: in the case of dealers, the injured party must prove that the defective product was placed on the market by this dealer.
- The manufacturer, importer or distributor can prove that the product was not defective at the time it was placed on the market, although full proof (probability is sufficient) is not required.

- The defect in the product is due to compliance with mandatory legal requirements that were in force at the time the product was placed on the market.
- The product corresponded to the state of the art at the time it was placed on the market, so that the defect could not be qualified as such at that time.

Under the PHG, liability can be excluded if the customer can be proven to have acted with gross negligence or wilful misconduct. Gross negligence is not sufficient.

Differentiation From Warranty and General Tort Law

Warranty

Warranty is the legally binding and no-fault liability of the seller for ensuring that an item was free of defects at the time of delivery. A defect can either be rectified or replaced. The buyer can choose between the two options. Only if improvement or replacement is not possible or would involve disproportionately high costs does the warranty remedy of the second stage come into consideration, namely price reduction or termination of the contract. However, termination of the contract is only an option if the defect is significant.

General tort law

In general tort law, the tortfeasor's fault is a prerequisite for liability. Only those who have caused damage intentionally or negligently are responsible for it. In the context of product damage, this fault may lie, for example, in the production process (eg, a screw is not tightened correctly) or in the fact that specific product regulations were not observed (eg, the screw should have been more stable in accordance with the applicable standard). In the latter case, it is a violation of a protective law.

Limitation of liability through general terms and conditions (GTC)

It is also possible to limit compensation claims (B2B, B2C) and warranty claims (B2B). This is possible within the framework of general terms and conditions. It can be considered on a case-by-case basis whether liability for damages and/or warranty should be limited in the terms of delivery.

In this respect, limits must be observed in terms of content, as not all limitations of liability are permissible in every case. For example, the limitation of liability for personal injury is generally inadmissible. Such limitations should therefore be considered and tailored to the individual case.

Plaintiff's burden of allegation and proof

Anyone wishing to claim damages on the basis of the PHG must generally prove that they have suffered damage caused by a product defect for which the claimant is responsible.

Pursuant to Section 7 of the Product Liability Act, the party against whom a claim is made may exonerate itself by either proving that it did not place the product on the market or did not do so with entrepreneurial intent, or that the product defect causing the damage did not exist at the time the product was placed on the market. Thus, exoneration from liability can be achieved if the party against whom a claim is made proves that the defective and therefore damaging product was stolen or otherwise removed from their power of disposal against their will.

Proof that the product was at least "probably" free of defects at the time when the person against whom a claim is made placed it on the market also exempts the product from liability in accordance with Section 7 (2) PHG.

If damage is attributable to a design defect, the Supreme Court regards the proof that the product was state of the art at the time it was placed on the market can lead to exoneration pursuant to Section 7 (2) PHG: a qualitatively reduced burden of proof is regulated by Section 7 (2) PHG, which merely requires the judge to weigh probabilities based on the circumstances of the case when forming their conviction of the truth of the allegation.

The judge has a wide margin of discretion, which they must fill in accordance with the Act. "Circumstances to be taken into account" are above all:

- the type of product;
- its specific service life and resistance to wear and tear;
- the technical possibility of checking the product for any defects; and, in particular
- the duration of its use.

Section 8 PHG provides further possibilities for exoneration. However, it would have no exonerating effect if the manufacturer, importer or retailer were merely to prove that the damage occurred through no fault of their own. In product liability law, it is not a question of whether someone is at fault. Section 8 PHG provides for several grounds for exoneration known as "liability exclusions".

A party against whom a claim is made can escape liability in accordance with the Section 8 (1) PHG if it can prove that the product defect is "attributable to a legal provision or official order with which the product had to comply". The practical significance of this ground for exclusion of liability is limited.

However, if the defect of the product only becomes apparent at a later date due to a lack of marketability, the manufacturer's liability can at best be justified under the aspect of a culpable breach of the duty to observe the product in accordance with general rules. However, as the Supreme Court has stated, the product monitoring obligation "cannot be derived from the Product Liability Act" and the dogmatic justification can be found "in the doctrine of the duty to maintain safety".

Recent Developments in Product Liability Law/Forecast

The increasing digitalisation of the economy and society brings with it new technologies that pose challenges for product liability law. These include intelligent products and systems with AI, which, due to their complexity, networking and data dependency, go beyond previous legal concepts and requirements. Therefore, the EU has reached a political agreement to amend the Product Liability Directive. These are far-reaching for software manufacturers. The reform is intended to incorporate these products into European product liability law and adapt or expand the traditional legal concepts. In future, software will be a "product". Liability for damages under product liability law will then be independent of fault, and products must be continuously monitored. Security updates must also be provided in good time if "common vulnerabilities and exposures" become known.

The Directive will bring the following changes

The scope of the Directive will be extended: in future, software and digital production files (eg, for 3D printers) will also be explicitly covered as "products". This applies both to software that is integrated into another product and to standalone software that can directly cause damage.

In future, significantly more economic actors will be subject to product liability. In addition to traditional end manufacturers, parts manufacturers, quasi-manufacturers and importers, liability will be extended to include authorised representatives of the manufacturer, fulfilment service providers (ie, storage, packaging and shipping service providers) and – under strict conditions – even retailers and operators of online marketplaces. Furthermore, according to the Directive, companies that make significant changes to a product that has already been placed on the market outside the control of the original manufacturer will also be considered manufacturers.

A new definition of defect is also to be implemented

This takes even greater account of modern product safety law. For example, the lack of software updates under the control of the manufacturer, which are necessary to maintain (cyber) security, can lead to a product being defective and thus to liability.

New possible features for proceedings

It is expected that the plaintiff will be granted significant simplifications in the presentation of evidence. Among other things, it should be possible in future to (rebuttably) presume both the defectiveness of the product and the causal link between the product defect and the damage if it is excessively difficult for the plaintiff to provide evidence due to technical or scientific complexity (eg, in the case of an innovative technology) and the plaintiff can prove at least a probability that the product was defective or that the defect caused the damage. In addition, a defendant may be obliged to disclose evidence. This should only apply if the claim for damages appears plausible and if the disclosure is proportionate. If business and trade secrets are involved, their protection must be ensured.

Loss and falsification of data that is not used exclusively for professional purposes will now also be considered as compensable damage. The previous deductible of EUR500 will no longer apply.

In March 2024, the EU Parliament adopted the new Product Liability Directive. Following formal confirmation in the EU Council, member states will be obliged to implement the Directive accordingly – probably by mid-2026. It is currently unclear how the Austrian government will implement the Directive.

BELGIUM

Law and Practice

Contributed by:
Louis Hoffreumon, Vladimir Murovec, Manon De Neubourg and Fjoralba Spahiu
Osborne Clarke

Contents

Osborne Clarke is a fast-growing and dynamic firm in the heart of Brussels. The team is made up of experts in commercial, corporate, employment, EU, IT and IP, payments, tax law, life sciences and product regulatory, who collaborate to provide innovative and efficient advice across sectors. The firm's clients are established and emerging leaders in tech, media and comms, life sciences and healthcare, retail and consumer, fintech, the built environment and recruitment/workforce solutions. Osborne Clarke's Belgian office is also the base for our multi-jurisdictional EU regulatory team, advising on crucial EU-wide issues, including on physical and digital products, competition law, distribution and procurement.

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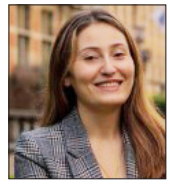

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1. Product Safety

1.1 Product Safety Legal Framework

- Regulation (EU) 2023/988 of 10 May 2023 on general product safety (hereinafter, the "New Regulation") introduces a new regime for the safety of consumer products placed on the European market. The New Regulation aims to update pre-existing rules to take account of developments in new technologies and online selling, and to strengthen the implementation of the general product safety obligation. It entered into effect on 12 July 2023 and will be applicable as from 13 December 2024. It applies mostly to non-harmonised products that were until now subject to Directive 2001/95/EC and local implementations in EU member states.
- Regulation (EU) 2019/1020 on market surveillance and compliance of products applies to harmonised products but, in order to ensure a coherent application, the New Regulation was largely inspired by Regulation (EU) 2019/1020 and shall therefore find a residual application regarding any safety measures that would not be covered by Regulation (EU) 2019/1020.
- Regulation (EU) 2019/881 on ENISA and on information and communications technology cybersecurity certification is completed by the New Regulation and shall therefore apply with respect to cybersecurity risks that could have an impact on consumer safety and thus be comprised in the safety definition.
- Code of Economic Law, Book IX contains the transposition of the requirements of Directive 2001/95/EC on general product safety and Directive 87/357/EEC on the approximation of the laws of the member states concerning products which, appearing to be other than they are, endanger the health or safety of consumers – both instruments have been replaced and repealed by the New Regulation. This general legal framework is surrounded by specific laws for certain products (such as gas or electrical appliances, playgrounds, elevators, amusement parks or fireworks) which will have to comply with all related requirements. Where specific products are subject to specific regulations, Book IX only regulates the risks that are not dealt with by such specific regulations.
- Royal Decree of 13 December 2017 establishing the Special Consultative Commission "Consumption" (hereinafter, SCC "Consumption") within the Central Council for the Economy and abolishing the Commission for Ecological Labelling and Advertising has a mission to provide opinions on the development of regulations and policies, advise the minister on the need to inform the public, and facilitate consultation among various stakeholders in relation to consumer safety and health. It is therefore the central consultative structure for consumer issues and consumer protection.
- Law of 31 January 2024 establishing the digital platform for consumers Consumerconnect entered into effect on 1 February 2024 and is now the Belgian Contact Point. The objective is to strengthen the position of consumers by first assisting in their search for information regarding consumer protection. It also allows the consumer to report issues to the inspection services of the Federal Public Services Economy ("FPS Economy") and other inspection services. Lastly, it also allows consumers to submit a request for alternative dispute resolution to a qualified entity through ConsumerConnect.

The developments that follow in **1. Product Safety** are without prejudice to additional sectorial legislation that applies to specific product categories, including in areas such as life sci-

ences and healthcare. Sectorial legislation may be more restrictive and provide for supplementary regulatory requirements around the safety, the quality, the efficacy and/or the performance of regulated products that fall within its scope, and those are not discussed in this Section. Sector-specific regulations typically uphold a risk approach that is different to the risk considerations laid down in this Section, enforcement measures may vary and additional penalties may apply in the case of infringement.

1.2 Regulatory Authorities for Product Safety

EU

Under the New Regulation, the Safety Gate System replaces the old RAPEX one as follows.

- Safety Gate Rapid Alert System: EU member states must notify corrective measures taken by authorities or by an Economic Operator (EO) in relation to dangerous products presenting a serious risk to the health and safety of consumers.
- Safety Business Gateway: EOs and providers of online marketplaces shall provide market surveillance authorities and consumers with the necessary information in relation to the product in question.

In addition, the Commission will play an important role in the implementation of the New Regulation considering that it may take any appropriate measures if the risk cannot be dealt with under any other procedures and it can be eliminated in an effective manner only at EU level. New provisions have been adopted in this respect by notably allowing market surveillance authorities to carry out joint activities on product safety and conduct simultaneous co-ordinated control actions ("sweeps").

Regarding the surveillance system at national level, a Consumer Safety Network has just been established to ensure structured co-ordination and co-operation between the authorities of the EU member states and the Commission.

Harmonised EU sectorial legislation enables additional authorities to take action to ensure the safety of products. In life sciences and healthcare, for example, this includes the European Medicines Agency (EMA) (for medicinal products) and national market surveillance authorities (for medical devices and in vitro diagnostic medical devices).

Belgium

The main regulator is the FPS Economy, which monitors the Belgian market and ensures that the products and services supplied on the market fulfil the safety requirements.

The national contact point and authority responsible for receiving and treating notifications of dangerous non-food consumer products by manufacturers and distributors is the Safety Department within the DG Quality and Safety of the FPS Economy.

The most recent Belgian response is the creation, within the FPS Economy, of the ConsumerConnect platform. It is a central contact point where consumers can obtain information and ask questions regarding consumer protection, report issues (for example, non-receipt of an ordered product, unfair practices, product defects) to the Economic Inspection Service of the FPS Economy or another inspection service, and submit requests to a qualified entity. However, it is important to note that the recently adopted law creating the platform does not make any reference to the New Regulation.

The SCC Consumption's mission is to provide opinions on the development of regulations and policies, advise the minister on the need to inform the public, and facilitate consultation among various stakeholders in relation to consumer safety and health. It is therefore the central consultative structure for consumer issues and consumer protection.

Examples of additional authorities that are empowered by Belgian law to ensure the safety of products include, in life sciences and healthcare, the Federal Agency for Medicines and Health Products (FAMHP). The FAMHP's competences are regulated by an Act of 20 July 2006 and revolve around products such as medicinal products for human and veterinary use, medical devices and in vitro diagnostic medical devices.

1.3 Obligations to Commence Corrective Action

The Framework Introduced by the New Regulation

The New Regulation will be applicable from 13 December 2024 and will not require any transposition from the part of member states, except for certain provisions that have been left to the discretion of national laws.

General safety requirements

EOs should be obliged to place only safe products on the market. Such a high level of safety should be primarily achieved through the design and the features of the product, taking into account the intended and foreseeable use and conditions of use of the product. The remaining risks, if any, should be alleviated by means of certain safeguards, such as warnings and instructions. This obligation already existed under Directive 2001/95/EC on general product safety but it is now further clarified. Article 6 of the New Regulation specifies the aspects that shall be taken into account when assessing whether a product is a safe product. Such an assessment will determine the risk "category" of the product. Just as it is the case now, the product will be presumed to be in conformity with this general safety requirement in two cases: the product conforms to relevant European standards or, in their absence, it conforms to national requirements.

Corrective measures

The corrective measures to be undertaken will depend on the quality of the EO.

- Manufacturers: where a manufacturer considers or has reason to believe, on the basis of the information in that manufacturer's possession, that a product which it has placed on the market is a dangerous product, the manufacturer shall:
  - (a) immediately take the corrective measures necessary to bring in an effective manner the product info conformity, including a withdrawal or recall, as appropriate;
  - (b) give details of the risk to the health and safety of consumers and of any corrective measures already taken and, if available, of the quantity of products still circulating on the member state's market; and
  - (c) investigate complaints submitted, and information received on accidents, that concern the safety of products on the market and which have been alleged to be dangerous by the complainant, and shall keep an internal register of complaints and any corrective measures taken to bring the products into conformity.
- Importers: as soon as importers consider that the product could be dangerous or that manufacturers have not respected their obligations in matters of identification and information before placing the product on the

market, they shall take the necessary corrective measures, including withdrawal or recall, as appropriate. Also, they shall file the complaints, as well as product recalls and any corrective measures taken to bring the product into conformity, in the manufacturer's register or in their own internal register.
- Distributors: where distributors consider or have reasons to believe that a product is a dangerous product or that manufacturers or importers have not respected their obligations to place the products on the market, they shall take the necessary corrective measures, including withdrawal or recall, as appropriate.
- Providers of an online marketplace also have several obligations in terms of corrective actions, such as:
  (a) designating two single points of contact for the authorities and consumers;
  (b) taking the necessary measures to receive and process orders to remove content relating to dangerous products from their online interface;
  (c) taking account of information on dangerous products notified by the authorities; or
  (d) suspending the provision of their services to professionals who frequently offer products that do not comply with the regulation.

Recall of dangerous products – new requirements

The objective for remedies in the event of a recall of dangerous products is to ensure both the elimination of dangerous products from the market and the adequate remedy for the consumer. The New Regulation provides for formal requirements a recall notice under its Article 36. As a general rule, the recall notice should be available in the language spoken by the consumers from the member states in which the product has been made available on the market.

On 24 May 2024, the European Commission adopted an implementing Regulation ((EU) (2024/1435) laying down the content of this recall notice. It will enter into force on 16 June 2024 and be applicable as from 13 December 2024.

Belgian Legal Framework

Please note that the considerations that follow may be subject to amendments or updates due to the new provisions introduced by the New Regulation.

Under Belgian law, in Book IX of the Code of Economic Law, EOs must take the necessary corrective measures and refrain from supplying products that they know (or should have known) do not meet the requirements of Book IX of the Code of Economic Law. This entails that they must share information about product risks, be able to demonstrate product traceability, and collaborate towards the prevention of product risks.

The FPS Economy refers to the guidelines that arose from the Commission Decision of 14 December 2004 and provides the following.

Guidelines in case of supply of products directly to consumers (B2C)

High risk or serious risk: criteria and formal requirements

High risk – product withdrawal: the EO must take the following measures:

- immediately cease the sale of the product;
- promptly and strictly follow the measures received from the supplier or from the FPS Economy to remove the Product from commerce; and

- if not contacted by the supplier, the EO is obligated to contact such supplier without delay.

Serious risk – product recall: the EO must take the following complementary measures.

- Contact all known consumers/users and inform them about:
  (a) the inherent risks associated with the use of the affected product; and
  (b) possible procedures for returning or repairing the Product, such as returning it to the point of sale or arranging for home collection.
- If not all consumers/users are known or if there is a low response rate from known customers:
  (a) the supplier's notice must be prominently displayed for at least two consecutive months in a visible location for consumers/users at the point of sale. The notice should include at least a description and a photo of the product, the risks associated with its use, the possible procedures for consumers/users to return the product, and any potential reimbursement or compensation.
- If the EO has a website and/or social media account:
  (a) the same information must be clearly visible on the homepage of the website for at least two consecutive months; and
  (b) at least one message must be posted on social media platforms.
- If the EO publishes its own newsletter, the same information must be clearly communicated at least once in the newsletter.

It will be important to preserve the necessary documentation to respond to any requests from the FPS Economy and provide the requested evidence concerning notably the list of clients and the returned or repaired products.

Guidelines in case of supply not directly to consumers (B2B)

High risk or serious risk: criteria and formal requirements

High risk – product withdrawal: the EO must take the following measures immediately or no later than ten days after identifying the risk:

- Immediately cease the sale of the product.
- Take immediate measures to remove the product from commerce, including:
  (a) immediately halt sales by distributors and provide them with a detailed description of the product and all information regarding the associated risks;
  (b) provide information to distributors on actions to be taken, such as returning, repairing or destroying the product; and
  (c) transmit to the FPS Economy the list of customers/distributors (with their addresses) who have purchased the product in question and provide evidence that customers/distributors have been informed of the cessation of sales and the required measures to be taken.

Serious risk – product recall: the EO must take the following supplementary measures.

- Immediately or no later than five days after identifying the risk:
  (a) provide the FPS Economy with a description of the planned measures for recalling the product from consumers/users, along with a list of customers/distributors (including their addresses) who have purchased the product in question;
  (b) prepare a notice for distributors containing all necessary information, including a

description and a photo of the product, the inherent risks associated with its use, the possible procedures for consumers/users to return the product to the distributor, and any potential reimbursement; and
(c) immediately instruct customers (distributors) to cease the sale of the product (while awaiting the instructions for implementing the product recall).

- Immediately and no later than ten days after identifying the risk, at the distributors' attention:
  (a) provide the aforementioned notice;
  (b) communicate the measures they should take to remove the product from the market, recall it or repair it;
  (c) instruct them to contact all known consumers/users and inform them of the necessary actions to be taken (product return, repair at the point of sale, repair at home, etc), as well as the practical procedures to be followed by the consumer/user; and
  (d) if not all consumers/users are known or if there is a low response rate from known customers, the following measures should be taken:
    (i) display the notice prominently and clearly visible for consumers/users at the point of sale for at least two consecutive months;
    (ii) the same information as on the notice must be clearly visible on their website for at least two consecutive months;
    (iii) at least one message must be disseminated via social media platforms, if available; and
    (iv) if they publish their own newsletter, the same information must be clearly communicated at least once.

No later than three months after the launch of the recall action or cessation of sales, the EO must be able to respond to any requests from the FPS Economy and provide the requested evidence.

1.4 Obligations to Notify Regulatory Authorities

Any manufacturer and/or distributor must notify the Central Contact Point for Products immediately when they are aware, or ought to be aware, based on the information they have and in their capacity as professionals, that a product or service put on the market presents safety issues either because it presents risks incompatible with the general safety obligations or does not satisfy specific legal compliance requirements.

The notification should contain at least the following information:

- data allowing an exact identification of the product(s) or the product(s) batch concerned;
- a complete description of the risk related to the product(s);
- all available information allowing tracing of the product(s); and
- a description of all actions undertaken in order to avoid any risk for the users.

1.5 Penalties for Breach of Product Safety Obligations

The New Regulation appears to have delegated the responsibility of establishing effective and proportionate penalties for non-compliance to the member states. It requires member states to lay down rules and measures to ensure that EOs and providers of online marketplaces fulfil their obligations and face dissuasive penalties for any infringements. Member states are required to notify the Commission of these rules and measures by 13 December 2024.

As of now, Belgian law has not made any amendments to its Code of Economic Law in relation to this specific requirement. It remains to be seen how Belgium will address this obligation and incorporate the necessary provisions into its national legislation.

Under the current legal regime, breaches of product safety legislation are subject to criminal fines up to EUR200,000 or 6% of the breaching party's last annual turnover in Belgium, whichever is higher.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

In Belgium, product liability is governed by the Law of 25 February 1991 on liability for defective products. This Law transposes the content of Directive 85/374/EEC of 25 July 1985 on liability for defective products and its amending directives into law. As from 1 January 2025, this Law will be repealed and its content will be integrated into Chapter 7 of Book 6 of the Belgian Civil Code, with no major amendments.

Product liability is also governed by general tort laws and some aspects are subject to criminal sanctions.

The Law on Liability for Defective Products

Key features of the Law include:

- manufacturers, importers and suppliers being jointly and severally liable;
- liability arising "for damage caused by a defect" in a product; and
- "product" being defined broadly as "all movable goods" but expressly excluding "primary agricultural products and game".

Under this Law, a party can be held liable when a product is defective, without having to demonstrate any breach or negligence from that party, and if that product causes damages due to that defect to another party.

A cause of action would require the reunion of the following three elements.

- A defect on the product: a product is deemed defective when it does not provide the safety which a person is entitled to expect, taking into account "all circumstances", including but not limited to the product's presentation, the use(s) to which it could be reasonably expected that the product would be put into, and the time it was put into circulation.
- Damage to another party: consisting in a personal injury, moral and/or property damage.
- A causal link between the defect and the damage: the injured party must establish, with sufficient certainty, that in the absence of the defect, the damage would not have occurred as it did. This principle is governed by the theory of equivalence of conditions, meaning that a party will only be held liable if it is proven that the damage would not have occurred without the defect.

The liable party for defective products is primarily the producer, which can be categorised into three types: the actual producer, the apparent producer and the presumed producer.

- The actual producer is the manufacturer of the finished product, its components, or raw materials.
- The apparent producer includes entities presenting themselves as the manufacturer by affixing their name, brand or distinctive sign on the product, such as retailers who outsource manufacturing.

- The "presumed" producer encompasses those who import products into the EU in the course of their economic activity with the intention of selling or transferring them to third parties.

General Tort Law

Liability under tort law requires the claimant to demonstrate a breach by the liable party of a duty of care or negligence, or the breach of a specific obligation or prohibition under the law. This cause of action can allow a claimant to seek damages against a party not qualifying as a producer under the Law on liability for defective products or in relation to products outside of the scope of this legislation (eg, immaterial products). It also allows a claimant to claim damages covering business losses.

Criminal Law

The absence of compliance with product safety legislation, whether or not it causes harm to another party, can also be subject to criminal sanctions governed by Book XV of the Criminal Law. For instance, offences such as consciously commercialising a product not complying with product safety legislation are subject to criminal fines up to EUR200,000 or 6% of the liable party's last annual turnover in Belgium, whichever is higher.

2.2 Standing to Bring Product Liability Claims

The Law on liability for defective products states that the "injured person" is entitled to bring an action before the competent courts.

The injured person is defined as any natural person, whether a consumer or a professional, suffering compensable damage under the Law due to a defective product. It is established that whether or not there is a "direct" contractual relationship with the actual, apparent or presumed producer is irrelevant in this regard.

Belgian law also provides for the possibility for several injured persons to bring a collective claim before the courts (see **2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**).

2.3 Time Limits for Product Liability Claims

Under the Law on liability for defective products, product liability claims must be initiated within three years from the moment when the injured person became aware, or should have reasonably become aware of the damage, the defect and the producer's identity.

Moreover, the window for filing claims is ten years after the producer put the specific product responsible for the damage into circulation, unless legal proceedings have been initiated against the producer in the meantime. This is commonly referred to as the ten-year statute of limitations.

Under general tort law, these terms are respectively of five years from the moment that the injured person became aware of the damage and the liable person's identity. The claimant has 20 years to file a claim as from the day that the fact causing the damage occurred.

2.4 Jurisdictional Requirements for Product Liability Claims

Belgian courts will have jurisdiction to know of a product liability claim in different cases.

First, under Brussels 1bis Regulation (Regulation (EU) No 1215/2012 of 12 December 2012 on jurisdiction and the recognition and enforcement

of judgments in civil and commercial matters), Belgian courts will have jurisdiction if:

- the defendant is located or established on the Belgian territory; and/or
- the harmful event occurred or may occur in Belgium; and/or
- the claimant is a Belgian consumer who bases its claim on a contract with the defendant; and/or
- Belgian courts have jurisdiction based on a valid jurisdiction clause concluded between the claimant and the defendant.

In relation to defendants located in jurisdictions outside of the EU, the Belgian Code of Private International Law provides that Belgian courts will have jurisdiction if:

- a valid jurisdiction clause was concluded between the claimant and the defendant; and/or
- the harmful event occurred or may occur in Belgium; and/or
- the damage occurred or may occur in Belgium; and/or
- the claimant is a Belgian consumer who bases its claim on a contract with the defendant or an offer to contract was directed towards the Belgian consumer.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

Prior to filing a product liability claim before courts, the injured party must send a formal notice to the producer, including details of the alleged defect and resulting harm.

Sometimes, while not mandatory, the judge may encourage the parties to engage in mediation or settlement negotiations before initiating formal litigation, and will also take into account the attempts of the parties at settling their dispute while ruling on the case.

2.6 Rules for Preservation of Evidence in Product Liability Claims

The common law of evidence applies to the evidence of product liability claims. The defect must be proven and cannot simply be inferred from the occurrence of the damage or the establishment of a causal link between the product and the damage.

Businesses are required to maintain corporate documents for a definite duration but this is often required by other legislation than law on evidence as such, meaning that businesses will often dispose of evidence for their product claim due to the need to comply with other legislation.

Moreover, the producers already need to maintain specific documentation in relation to the product and its risk assessment under product safety legislation and this documentation must be readily available following a request for information from a regulatory authority. Such documentation can of course be re-used in the framework of proceedings against another private party.

2.7 Rules for Disclosure of Documents in Product Liability Cases

The rules regarding disclosure of documents or other evidence in product liability cases are primarily governed by the Judicial Code and the Code of Economic Law.

Under the Judicial Code, parties to a dispute have to disclose relevant documents they are aware of and which may be used as evidence during the litigation. This process is often referred to as “disclosure of documents” or “production of evidence.” Parties may request the disclosure

of certain categories of documents from the other party, and in the case of a disagreement on disclosure, the court may be approached to resolve the issue.

Regarding product liability cases, the Code of Economic Law may also contain specific provisions concerning the disclosure of documents. For instance, it requires manufacturers or suppliers to disclose appropriate information in a clear and comprehensive manner regarding the product and its characteristics.

2.8 Rules for Expert Evidence in Product Liability Cases

The rules governing expertise are set out in the Belgian Judicial Code. Parties involved in a product liability case may appoint their own experts to provide opinions or analysis on technical issues relevant to the case but are not allowed to render an opinion on the legal aspects of the case.

These experts must meet certain standards of professionalism and impartiality.

In addition, the court may also appoint its own independent experts to provide opinions or conduct investigations concerning the product in question.

The court can choose to take the expert's report into account when ruling on a case but will not be bound by it if the parties can provide counterevidence that the expert's findings are not accurate for instance.

2.9 Burden of Proof in Product Liability Cases

In principle, the burden of proof in product liability cases lies with the claimant. The claimant must demonstrate the existence of the defect in the product, their damage as well as the causal link between the defect and that damage.

However, this burden of proof can be reversed by law or by the judge in several circumstances.

For instance, the claimant is not required to produce indisputable proof and can rely on the mechanism of presumptions: if the claimant brings forward several serious, precise and concordant elements of proof making the fact highly likely, while being unable to prove the fact itself, the judge can nevertheless consider the fact as proven and require the defendant to produce the opposite evidence.

Moreover, the burden of proof will also be facilitated by the appointment of an expert witness who will provide deeper technical information allowing the claimant to evidence their claim more easily. The judge is also vested with the power to revert the burden of proof in exceptional circumstances, if imposing the burden of proof on the claimant would be obviously unreasonable (because, for instance, it would require excessive costs for the claimant).

2.10 Courts in Which Product Liability Claims Are Brought

Product liability cases are brought before civil courts (the competent court may vary depending on the quality of the claimant, consumer or business). The case will be decided by one or three judges depending on the court and no jury is involved in such proceedings.

There is no specific threshold award of damages. However, the claimant is only entitled to compensation for damages that are certain and proven, whether or not of a patrimonial/financial nature, and to such an extent that the claimant is put in a position similar to the one the claim-

ant would have been in had the liability event not occurred. There is no system of punitive damages under Belgian law.

2.11 Appeal Mechanisms for Product Liability Claims

An appeal against the judgment issued by the court in first instance can be filed before the relevant jurisdiction of appeal and is only possible against final judgments (not interim judgments). The deadline to lodge the appeal is one month from the date that the judgment has been served by the bailiff. In other words, there is no specific deadline to file an appeal if the judgment has not been served.

2.12 Defences to Product Liability Claims

Producers of a defective product are not liable under the law if they can demonstrate any of the following:

- they did not put the product into circulation;
- having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by them or that this defect came into being afterwards;
- the product was neither manufactured by the producer for sale or any form of distribution for economic purpose nor manufactured or distributed by the producer in the course of their business;
- the defect is due to compliance of the product with mandatory regulations issued by the public authorities;
- the state of scientific and technical knowledge at the time when the producer put the product into circulation was not such as to enable the existence of the defect to be discovered; or
- in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Compliance with regulatory requirements is taken into account by judges to decide whether a product is defective or not, but it does not alone rule out the existence of such defects. The analysis and reasoning of the judge will also concern the determination of the user's reasonable and legitimate safety expectations for a product.

There is a parallel to be drawn between compliance with regulatory standards and building a strong product liability strategy. In complying with regulatory requirements, a product's manufacturer is required to adhere to standards that are specific to various products aspects. Those include the product's presentation, its intended use, as well as supply chain considerations (throughout the pre-marketing and post-marketing phases). At the same time, the Belgian and EU product liability regimes uphold the presentation of the product and the use to which it could reasonably be expected that the product would be put as criteria to determine whether a product is safe or not. As such, compliance with sector-specific regulations tend to offer a means and a defence to establish a product's safety from a product liability standpoint.

2.14 Rules for Payment of Costs in Product Liability Claims

The costs that can be claimed by the successful party are regulated. While all expert's costs and court fees can be claimed back, legal costs are subject to specific caps set out under the Belgian Judicial Code and its relevant executing

royal decrees. The applicable cap will depend on the total amount of damages awarded to the successful party (or if the claim is rejected, on the total amount claimed by the claimant).

2.15 Available Funding in Product Liability Claims

While third-party funding is not broadly known in Belgium, claimants will usually benefit from legal protection insurance covering their legal costs and benefits associated with legal claims and the enforcement of judgments.

Consumers may also be entitled to free or partially free legal assistance to file a claim if they meet certain remuneration thresholds (pro-bono lawyers).

Contingency fees are subject to strict ethical rules for Belgian lawyers and cannot constitute the only source of outcome of an external lawyer handling a litigation case.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Under the Belgian Code of Economic Law, class action proceedings before the courts of Brussels are open to claimants in relation to specific causes of actions, including damage claims based on the Law on liability for defective products. These claims can only be filed by consumer representatives (such as some consumer associations) which fulfil specific criteria set out by the law. The outcome of such proceedings can be the award of damages by the court or a collective settlement between the group of claimants and the defendant.

More recently, the Collective Redress Directive (EU) 2020/1828 has been transposed in Belgium by the Law of 21 April 2024. This Directive amends and completes these rules on class actions (eg, making a general opt-in regime for claimants, rendering the procedure more efficient and allowing for faster judgments) and should enter into force in the upcoming weeks.

2.17 Summary of Significant Recent Product Liability Claims

Supreme Court Case of 14 March 2024 (1st Chamber), AR C.23.0100.N

In a case involving damages caused by a cooking appliance, the Supreme Court ruled that the rules applicable to product liability (arising out of an EU directive) and the Belgian rules on tort law can coexist within the same claim but that their causes of action remain different and subject to different conditions.

For instance, if the substantive base for liability consists in the fact that a defective product has been put into circulation and has caused damage, the producer and the supplier can be held liable and the injured party can seek compensation within the conditions set out under the Law on liability for defective products. However, the mere circumstance of putting a defective product into circulation does not create sufficient legal grounds for a tort claim since the claimant should also demonstrate a breach or negligence from the producer and/or supplier.

Diesel-Gate – Judgments of the Court of First Instance of Brussels of 18 December 2017 (Admissibility) and 27 July 2023 (Merits)

The Belgian courts ruled in favour of the consumer association Test-Achats in the framework of a class action brought against Volkswagen. Test-Achats had initiated proceedings on behalf of consumers having bought vehicles from Volkswagen equipped with a EA 189 motor and containing a software distorting the results of emis-

sions tests and failing to comply with emission standards.

The court held Volkswagen liable for integrating that manipulated software into the vehicles. Following the judgments, consumers were entitled to compensation up to 5% of the vehicle's purchase price or 5% of the difference between its purchase price and the resale price. These judgments also apply to vehicles from other brands from the same group (Skoda, Seat, Audi).

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

There is undoubtedly increased regulatory scrutiny impacting several industries and the life sciences and healthcare industry in particular, with a focus on risk assessment and post-market surveillance.

Certain provisions of the New Regulation will apply to businesses involved in life sciences and healthcare, reflecting a growing trend. In fact, the provisions concerning the obligations of providers of online marketplaces, the obligations of economic operators in the event of accidents, the right to information and to a remedy for consumers as well as product safety recalls should apply to products covered by EU harmonisation legislation too.

The renowned (and recently adopted) EU AI Act will impact the healthcare industry as well. Different stakeholders will need to respond to new obligations when utilising technologies dependent on AI or AI-driven digital workflows (eg, telemonitoring tools, digital therapeutics, healthcare robots, patients' wearables, healthcare providers' prescription software, medical chatbots and various algorithms used in care centres).

Interestingly, even regulations seemingly unrelated to the life sciences sector, such as Regulation (EU) 2023/1542 concerning batteries and waste batteries, can have an impact. Manufacturers of battery-powered medical devices and in vitro diagnostic devices (such as pacemakers, electrocardiographs and robotic cameras) may in fact find themselves affected.

Regardless of sectorial impacts, efforts are being made by the European legislator to harmonise product safety standards by adopting rules that apply to both harmonised and non-harmonised products, as exemplified by the New Regulation. The choice to adopt a regulation instead of a directive further underscores the objective of harmonisation.

It is worth mentioning that the New Regulation and its many associated obligations, particularly for SMEs that may find themselves classified as importers or distributors, can pose significant compliance challenges. The level of compliance required may be particularly burdensome for smaller structures.

Recognising this risk, the Commission has acknowledged the challenges faced by SMEs and has committed to providing guidelines and advice to support them. Consequently, it is vital for companies to proactively identify compliance and implementation strategies, as the proliferation of legal requirements within the EU will affect all stakeholders.

3.2 Future Policy in Product Liability and Product Safety

In Belgium, the response to recent policy developments is still unfolding. The introduction of a new regulatory landscape is relatively recent and it may take time for national legislative production to emerge.

However, it is worth noting that Belgium is already showing signs of aligning with the direction set by the EU. Last November, a bill was introduced that aims to prohibit the marketing of products and services originating from occupied territories and whose production and/or supply result from situations arising from serious violations of international humanitarian law. The objective would be to put in place a restrictive trade measure dictated by reasons of public morality, which goes beyond mere labelling indicating the origin of the products and calls for a ban on the importation of colony products within the EU. This initiative aligns with the objectives of the proposal for a Corporate Sustainability Due Diligence Directive that was just given a final green light by the European Parliament. This Directive would require large companies to prove compliance with environmental and human rights standards within their supply chains. So, although not directly linked to product safety, it highlights how important it has become for companies operating in the EU to closely monitor updates and prepare implementation strategies covering several aspects of their practice.

CHINA

Law and Practice

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King & Wood Mallesons

Contents

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1. Product Safety

1.1 Product Safety Legal Framework

"Products" in the context of Chinese law refer to goods that have been processed or manufactured for sale. In China, a combination of laws, regulations and rules issued by the legislative and administrative agencies, as well as interpretations issued by the judicial organs, together form a complicated legal framework regulating product safety. The key legal instruments governing product safety include the following.

General Laws

General legislation governing product safety includes:

- the Civil Code of the People's Republic of China (the "Civil Code"), effective as of 1 January 2021;
- the Product Quality Law of the People's Republic of China, effective as of 1 September 1993, amended on 29 December 2018; and
- the Law of the People's Republic of China on the Protection of Consumer Rights and Interests, effective as of 1 January 1994, amended on 25 October 2013.

Sector-Specific Laws

A number of laws and regulations regulate the safety and quality of specific products. These sector-specific instruments include:

- the Food Safety Law of the People's Republic of China (effective as of 1 June 2009, amended on 29 April 2021);
- the Law of the People's Republic of China on the Quality and Safety of Agricultural Products (effective as of 1 November 2006, amended on 2 September 2022);
- the Pharmaceutical Administration Law of the People's Republic of China (effective as of 1 July 1985, amended on 26 August 2019);
- the Law of the People's Republic of China on Import and Export Commodity Inspection (effective as of 1 August 1989, amended on 29 April 2021);
- the Administrative Regulations on the Recall of Defective Automotive Products (effective as of 1 January 2013, amended on 2 March 2019);
- the Regulation on the Supervision and Administration of Medical Devices (effective as of 1 April 2000, amended on 9 February 2021);
- the Implementing Regulation for the Food Safety Law of the People's Republic of China (effective as of 20 July 2009, amended on 11 October 2019);
- the Interim Measures for the Supervision and Administration of the Quality and Safety of Food-Related Products (effective as of 1 March 2023);
- the Measures for the Implementation of the Regulation on the Administration of the Recall of Defective Auto Products (effective as of 1 January 2016, amended on 23 October 2020);
- the Provisions on Administration of Motor Vehicle Emission Recalls (effective as of 1 July 2021);
- the Interim Provisions on Administration of Consumer Product Recalls (effective as of 1 January 2020); and
- the Administrative Measures for Medical Device Recalls (effective as of 1 May 2017).

Product Standardisation

According to the Standardisation Law of the People's Republic of China (effective as of 1 April 1989, amended on 4 November 2017), the Standardisation Administration of China is responsible for administering the standardisation of products. To date, the Standardisation

Administration has released many national standards providing detailed guidelines on the safety assurance of specific products.

Standards in China can be either mandatory or recommended. Standards beginning with "GB" contain mandatory requirements; eg, the Hygienic Standard for Dried Fruits (GB 16325-2005) and the Stipulation Protecting Drivers From Injury by Motor Vehicle Steering Mechanism (GB 11557-2011). The standards beginning with "GB/T" are recommended; eg, the Education Robot Safety Requirements (GB/T 33265-2016) and the Description Specification on the Risk Information of Consumer Products Safety (GB/T 30135-2013).

1.2 Regulatory Authorities for Product Safety

Under the current product quality regulatory framework in China, administrative authorities exercise two types of regulatory powers: general and specific.

General Regulatory Authority

The State Administration for Market Regulation (SAMR) and local market supervision authorities are responsible for supervising and regulating product quality and safety, covering products manufactured in China and products imported into China. In addition, market supervision authorities are also responsible for the punishment of illegal activities related to product quality. The Standardisation Administration of China, as a branch of the SAMR, organises, coordinates and supervises the implementation of standards, including standards on product quality and safety.

Regulatory Authority for Specific Products

Other than the general regulatory authority described above, specific regulators also have the power to supervise product safety in the relevant industrial sectors. For example, the National Medical Products Administration is in charge of the supervision and administration of product safety in the drugs, medical devices and cosmetics sector.

1.3 Obligations to Commence Corrective Action

Under Chinese law, if a product is found to be defective after it is put into circulation, the manufacturer and the seller must promptly adopt remedial measures or commence corrective actions. Common remedies required by law include suspending sales, providing warnings, and implementing defective product recalls.

Suspending Sales

When a manufacturer identifies defects in its products, it is required by law to suspend manufacturing, sale or importation of the products.

Providing Warnings

A warning refers to a reminder of the relevant dangers associated with the product, or an explanation of how to correctly use the product to avoid these dangers. It is important to direct users' attention to existing or potential dangers so as to prevent or reduce harm.

Requirements to provide warnings are generally stated in specific product recall regulations. For example, under the Administrative Regulations on the Recall of Defective Automotive Products, the manufacturer of defective automotive products is required to notify automobile owners of the defect in its automobile product and the emergency steps to take to avoid damages or harm.

Implementing Product Recalls

A manufacturer is required to make a recall when it is informed, by way of self-check, reports or complaints by the general public, or notification from a regulatory department, that the products it produces or sells are defective. Where the manufacturer fails to make a recall, or the relevant quality inspection departments deem it necessary, the regulatory authorities may order a product recall to be conducted. Detailed procedures and requirements for conducting product recalls are usually found in the regulations for specific products as discussed below.

Recall of consumer products

The Interim Provisions on the Administration of Consumer Product Recalls Defects regulate the recall of consumer products. Under the regulations, recall is necessary when defects that could cause unreasonable danger compromising personal and/or property safety are found in the same batch, model number or type of consumer goods, due to issues with the product design, manufacturing, warning, etc. Recall information must be published in a "well-known" publication that is easily accessible to the public. Such well-known publications include newspapers and periodicals, websites, and radio and television channels.

Recall of defective automotive products

The Administrative Regulations on the Recall of Defective Automotive Products regulate recalls of automotive products. According to these regulations, the SAMR supervises and administers the recall of defective automotive products in China. When defects are found to exist in the same batch, model number or type of automotive product due to issues with product design, manufacturing or labels, a manufacturer must prepare a recall plan, communicate the plan to the automobile sellers, and file the plan with the SAMR. The manufacturer is also required to release recall information in an easily accessible manner to the general public.

In addition, pursuant to the Administrative Regulations on Motor Vehicle Emissions Recall, China has also introduced an emission recall system for motor vehicles, under which vehicle manufacturers are required to recall motor vehicles with "emission hazards". The emission recall regime is administered by the SAMR jointly with the Ministry of Ecology and Environment.

Recall of medical devices

Under the Measures for the Administration of Medical Device Recalls, medical device recalls are divided into three classes according to the severity of the defects:

- Class I recall – use of the medical device may cause or have caused serious health hazards;
- Class II recall – use of the medical device may cause or have caused temporary or reversible health hazards; and
- Class III recall – use of the medical device has a lower likelihood of causing any hazard but such medical device still needs to be recalled.

The different classes of recalls follow different notification time limits and the recall announcements require different levels of media exposure, according to the class.

The Measures for the Administration of Medical Device Recalls require "medical device manufacturers" (including the medical device registrant or filing holder, or the domestic agent appointed by the overseas manufacturer of imported medical devices) to be responsible for co-ordinating product recalls. However, it should be noted that under the Regulation on Administration and Supervision of Medical Devices amended

in 2021, the recall obligation explicitly lies with the medical device registrant or filing holder.

1.4 Obligations to Notify Regulatory Authorities

Where a manufacturer or a seller has discovered a defect in its goods or services, which may harm personal safety or property security, it must immediately report the defect to the relevant administrative authorities. This reporting obligation is widely required in many recall regulations for specific products.

Under the Measures for the Implementation of the Regulation on the Administration of the Recall of Defective Auto Products, upon learning of potential defects in its automobile products, the manufacturer must organise an investigation and analysis thereof, and truthfully report the result to the SAMR. Sellers, repairers, rental service providers or spare part manufacturers are also required to report any defects they identify in their business operation to the SAMR and notify the manufacturer of such information.

Under the current Measures for the Administration of Medical Device Recalls, a medical device manufacturer must immediately report any of its medical device products that are found to be defective to the provincial food and drug supervision and administration department. Medical device operation enterprises and users are also required to immediately report to their provincial food and drug supervision and administration department and notify the manufacturer or supplier of defects. In particular, if the medical device user is a medical institution, it must also report device defects to its provincial health administrative department. As discussed in **1.3 Obligations to Commence Corrective Action**, while the term "medical device manufacturer" is relatively broad in scope under the measures, according to the 2021 amendment to the Regulation on Administration and Supervision of Medical Devices, the duty of ensuring product quality and implementing product recalls now directly lies with the medical device registrant or filing holder.

1.5 Penalties for Breach of Product Safety Obligations

Failure to comply with product safety obligations may give rise to civil, administrative, and criminal liabilities.

Civil Liability

If a product causes personal injury or property damage, the manufacturer must compensate any losses suffered by the infringed person. Product liability for the manufacturer is a form of strict liability under Chinese law, which means that the manufacturer is liable for damages regardless of whether there is any fault on their part. The seller, on the other hand, is liable for damages only if it is at fault for the injury or loss. However, the infringed person may also bring claims directly against the seller. If the fault ultimately lies with the manufacturer, the seller may ask the manufacturer to reimburse its damages after it compensates the plaintiff.

The manufacturer and the seller also bear liability when their failure to adopt prompt and effective corrective actions leads to aggravated damages. In addition, if the manufacturer or seller knowingly continues to manufacture or sell a defective product, or fails to take effective remedial measures, and the defect results in death or serious damage to the health of another person, the manufacturer or seller will be liable for punitive compensation. Such punitive compensation will be determined by the court on a case-by-case basis.

Administrative Liability

The regulatory government authorities may impose administrative sanctions on manufacturers and sellers when their product fails to conform to product safety standards, including by requesting rectification of defect, imposing fines, ceasing the operation, and revoking the business licence.

In addition, the manufacturer and seller might also be subject to administrative penalties if they do not perform their product recall obligations. For example, where an automobile manufacturer breaches the Administrative Regulations on the Recall of Defective Automotive Products by failing to stop manufacturing the products, selling or importing defective auto products, withholding information about the defects or refusing to implement a recall as ordered, the regulatory authorities may order it to make correction, impose a fine of 1–10% of the monetary value of the defective products, and confiscate any illegal gains.

Criminal Liability

If the products are found to have caused death, serious personal injury, or serious property damage, the responsible manufacturers and sellers may be criminally liable. For example, in one criminal case, the defendant was sentenced to a fixed term of imprisonment of 12 years and ordered to compensate for medical fees, nursing fees, funeral expenses and other costs of the victim's family for knowingly selling counterfeit medicines, which caused the death of the victim (see Case (2018) Liao 02 Xing Chu No 59, decided by Dalian Intermediate People's Court, Liaoning Province).

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

Causes of Action

Flaws in the product itself

Firstly, a consumer can bring a claim in respect of flaws in a product where the flaw has not caused any losses beyond the product itself. Under Chinese laws, a product must conform to the quality standards or specifications as presented by the manufacturer and seller. The consumer can claim against the seller for repair, replacement or return, and for any further damages caused, if a product falls within one of the following categories:

- the product does not have the properties required for use and the consumer has not been informed of the flaws in advance;
- the product quality does not conform to the standards specified on the product or its packaging; or
- the product does not meet the quality stated in the instructions for use or demonstrated via samples provided.

Flaws that cause harm

Secondly, a manufacturer or seller, or both, will be liable for tort if they have manufactured or sold a product that has caused harm to a person's life or property. In general, the finding of product liability depends on three elements:

- the product being defective;
- the damage or loss suffered; and
- the causal relationship between the defective product and the damage.

Among these elements, the most important condition is whether a product is defective. In this regard, product defects have been categorised

into three classes: design defects, manufacturing defects, and inadequate warnings or instructions.

According to Article 46 of the Product Quality Law, there are two tests to determine the existence of product defect: (i) a statutory standard, which considers a product to be defective if it fails to meet one of the applicable national or industry standards on personal or property safety; and (ii) an "unreasonable danger" standard, which considers a product to be defective if it unreasonably endangers the life or property of the consumer. In practice, even if a product meets the relevant national or industry standard, the court will still proceed to examine whether it meets a reasonable person's expectations regarding product safety. Therefore, compliance with the statutory standard alone does not necessarily exempt a product from liability.

Administrative penalties

Thirdly, manufacturers and sellers of defective products may also be subject to administrative penalties. For example, if the product manufactured or sold is not in conformity with the national and industry standards regarding human life and health, personal safety or property safety, the regulatory authorities can stop the manufacture and sale of defective products, confiscate the defective products, impose fines on the manufacturer and seller, and even revoke their business licence(s).

Criminal penalties

Finally, the Criminal Law of the People's Republic of China (effective as of 1 October 1997, with 12 amendments so far) contains product-related crimes relating to the manufacturing and sale of fake and shoddy products in various sectors including food, cosmetics and pharmaceuticals. Manufacturers and sellers will face criminal penalties in cases of severe product liability consequences triggering one of these crimes.

Sources of Law

In the context of civil disputes, the following key legal instruments governing product liability allow the victim to raise claims against the manufacturer or the seller of products for losses caused by the product flaw to the product itself, and damages to personal or property safety:

- the Civil Code;
- the Law on the Protection of Consumer Rights and Interests (PCRI); and
- the Product Quality Law.

Over the years, the Supreme People's Court of China has also issued a series of judicial interpretations in relation to specific issues arising in product liability cases. These judicial instruments guide courts in their interpretation of key statutory definitions and concepts.

Since China is a civil law country, the principle of stare decisis does not apply in product liability litigation. However, judges may still be guided by precedents, particularly if found in judgments of the Supreme People's Court or other superior courts addressing similar facts or legal issues, or if the area of law is unsettled.

Apart from civil liability, product quality disputes may also give rise to administrative liabilities. In this regard, the Product Quality Law, the PCRI and other laws and regulations for specific products set out the power of the administrative authorities to supervise product liability and to issue administrative penalties.

Lastly, criminal penalties could also be triggered in cases where the product quality issue has resulted in severe and far-ranging conse-

quences. As mentioned above, chapter 3 of the Criminal Law contains a section titled "Crimes of Manufacturing and Selling Fake and Shoddy Goods". This section specifically provides strict criminal penalties in respect of the manufacturing and selling of fake or defective products that severely infringe upon consumers' interests.

2.2 Standing to Bring Product Liability Claims

In China's legal system, consumers and other infringed individuals have standing to bring claims for product liability if their rights or interests are impaired. An individual can file a litigation against the manufacturer or seller in court based on a contractual relationship or an act of infringement.

Multiple injured individuals involved in a product liability case may have standing to bring representative litigation. If the number of injured individuals is unspecified, the court could publish an announcement to notify potential plaintiffs to register as plaintiffs. The registered plaintiffs can nominate co-plaintiffs to be their representatives and participate in the litigation on their behalf. The judgment issued in these cases will bind all registered plaintiffs. If unregistered parties file additional claims, the original judgment will apply and bind the unregistered parties in those claims as well.

Finally, public welfare institutions, organisations or the state procuratorate may file public interest litigations when the legitimate rights or interests of multiple consumers have been harmed. For example, the China Consumers Association and consumer associations at the provincial level are eligible to initiate a public interest litigation in consumer disputes. An amendment to the Civil Procedure Law in 2017 introduced the new mechanism of public interest prosecution, allowing the procuratorate to prosecute a case relating to food and drug safety if there is no relevant institution or organisation with the power to file public interest claims, or the relevant institution or organisation does not file a claim.

2.3 Time Limits for Product Liability Claims

According to the Civil Code, the statute of limitation for a product liability claim is three years. The period of the limitation is calculated from the day when the plaintiff (eg, the consumer or other infringed individuals) knew or should have known that their right had been infringed. In any event, the court will not offer protection to the plaintiff if 20 years have elapsed since the infringement took place. Nevertheless, under special circumstances, the court may decide to extend the period upon the application of the plaintiff.

2.4 Jurisdictional Requirements for Product Liability Claims

According to the Civil Procedural Law, a product liability dispute must meet the following prerequisites:

- the plaintiff is a citizen, legal person or any other organisation with a direct interest in the case;
- there is a specific defendant; and
- the plaintiff has made a specific claim supported by facts and reasons.

In addition, the plaintiff has to file the claim before the court that has jurisdiction (see **2.10 Courts in Which Product Liability Claims Are Brought**).

2.5 Pre-action Procedures and Requirements for Product Liability Claims

To date, there are no mandatory pre-litigation procedures under Chinese law. Pre-trial preservation of evidence, which is an optional pre-action procedure, is explained in **2.6 Rules for Preservation of Evidence in Product Liability Claims**.

2.6 Rules for Preservation of Evidence in Product Liability Claims

If any evidence may be lost or subsequently become hard to obtain, a party to the dispute can apply for the court to issue an evidence preservation order, either during the proceedings or before the filing of a litigation under urgent circumstances (the latter is also known as pre-trial preservation of evidence).

Evidentiary preservation measures ordered by the court may include making copies in advance, sealing evidence or taking other actions to preserve evidence, depending on the format and location of the evidence in individual cases. The court may impose a fine or detain anyone who forges or destroys important evidence, or it may adopt a presumption of fact against a party found to have breached the rules.

2.7 Rules for Disclosure of Documents in Product Liability Cases

Unlike common law jurisdictions, there is no general process of document production during civil litigation in Chinese courts. Except where the burden of proof is specifically allocated elsewhere (see **2.9 Burden of Proof in Product Liability Cases**), each party bears the evidentiary burden of proving its claims.

However, if a party and its representative find it difficult to obtain a particular piece of evidence due to objective difficulties, that party may apply to the court for investigation and evidence collection. For example, in product quality disputes, if the consumer is unable to obtain a vital inspection report regarding product defects kept by the product manufacturer, the consumer could apply to the court to collect the report from the manufacturer.

In addition, if a party refuses to provide evidence without any proper justification, despite indications that the evidence is in its possession, and the other party bearing the burden of proof for a particular fact claims that the evidence is unfavourable to the party that possesses it, a court may presume that the relevant claim has been established.

2.8 Rules for Expert Evidence in Product Liability Cases

To resolve technical issues in a product liability dispute, the court may instruct a qualified institution or person to inspect and test the product in detail upon application by a party or on its own motion. The person responsible for the inspection may be present during the hearing to give testimony on the results of inspection, upon the application of a party or if the court considers it necessary to hear the testimony. The judge hearing the proceedings may pose questions to the expert, and any party may cross-examine the expert. Either party may also introduce other experts to provide professional opinion on the inspection or other technical issues during the hearing. Where permitted by the court, experts may address each other regarding issues arising in the proceedings.

2.9 Burden of Proof in Product Liability Cases

In product liability proceedings, the plaintiff has the burden of proving that:

- the product is defective;
- damage or loss occurred; and
- a causal relationship exists between the defect and the damage suffered.

Shifting the Burden of Proof

To the defendant

In many cases brought by consumers, the plaintiff usually has limited technical knowledge about the product in dispute. Out of consideration for fairness, courts will generally not impose overly stringent evidentiary burdens concerning the product defect and the causal relationship on the plaintiff. As long as the plaintiff can present prima facie evidence that the product may be defective, the court tends to shift the burden of proof to the manufacturer or seller to prove that the product is not defective. For this purpose, the defendant will usually need to prove that the product meets the national and industry standards (if any), does not present any unreasonable danger to a person's health, and will not damage a person's property.

The "presumptive approach"

The same is true in demonstrating the causal relationship between the defect and the damage incurred. Given the difficulty for ordinary consumers to establish an unequivocal causal relationship, the plaintiff is only usually expected to prove the existence of a "connection" between the injury or damage and the defect. When this has been done, the courts usually take a "presumptive approach" and establish the causal relationship when there is a high possibility that the defect is the cause of the injury.

The inspection procedure

In practice, the inspection procedure plays an important role in determining the existence of product defect and causation. A party may apply to a court for an inspection to determine whether a product is defective or the cause of the injury. The inspection will be conducted by inspection institutions with appropriate qualifications or by judicial inspection institutions, which are either appointed based on an agreement between the parties or designated by the court. If necessary, the court may also decide to appoint an inspection institution on its own motion. As mentioned in **2.8 Rules for Expert Evidence in Product Liability Cases**, the plaintiff or the defendant may also apply to introduce an expert to give an opinion on the inspection opinion.

2.10 Courts in Which Product Liability Claims Are Brought

Courts and Procedures

There are no special courts or procedures for product liability cases. However, if a product liability dispute is relatively simple and the amount in dispute is relatively small, a simplified procedure or small claims procedure may apply. These two types of procedures are more flexible and are concluded more quickly than the normal procedure for civil litigation. In addition, the judgment or ruling of the first instance court in a small claims procedure is final and not subject to appeal.

District Jurisdiction

In a contractual dispute the parties may, by written agreement (subject to the statutory rules on hierarchical jurisdiction and exclusive jurisdiction), select the court at the place of:

- the domicile of the defendant;
- the signing or performance of the contract;
- the domicile of the plaintiff;
- the location of the subject matter; or
- any other place with a connection to the dispute.

In the absence of a prior agreement of the parties, the court at the place of the domicile of the defendant or where the contract is performed will have jurisdiction over the case.

Product liability claims based on tort are under the jurisdiction of the court at the place where the tortious act occurred or the domicile of the defendant. In addition, courts in places where the disputed products are manufactured or sold also have jurisdiction over such claims. Accordingly, the infringed party may file the lawsuit to any of the competent courts.

Specifically, the place where the tort occurred includes the place where the tortious conduct was committed and the place where the consequences of the tortious conduct occurred. If the manufacturer and seller are domiciled in China, the Chinese courts will, without a doubt, have jurisdiction over the proceedings. If the manufacturing and selling take place outside China, the manufacturer and seller may still fall under the jurisdiction of the Chinese courts if the damage occurs within China.

Hierarchical Jurisdiction

Depending on the amount in dispute, a civil dispute may be heard by courts at different levels including district courts, intermediate courts or high courts. The precise threshold for each level of court to hear a case varies by region. In practice, since the underlying amount in product liability cases is relatively small, these cases are usually heard by the district courts.

The "People's Juror"

Since China has a legal system based on civil law, there is no trial by jury in Chinese courts. However, there is a "People's Juror" system, by which a non-judge citizen can serve on the hearing panel in a case governed by normal procedure, with the same power as a judge. The juror can participate in fact-finding, the application of law and the decision-making process.

2.11 Appeal Mechanisms for Product Liability Claims

The rules for appeal in product liability disputes are the same as in other civil proceedings governed by the Civil Procedure Law and its judicial interpretations. The judgments or certain rulings made by the court of first instance may be appealed on grounds including fault in fact-finding, incorrect application of laws, and serious procedural violations.

Once the court of first instance delivers the ruling or judgment, either party may file an appeal with the People's Court at the higher level within 15 days from the date of service of the judgment, or ten days from the date of service of the ruling. The appellate court may decide to uphold, withdraw or revise the original ruling or judgment, or remand the case back to the lower court.

2.12 Defences to Product Liability Claims

Under Chinese law, the defendant in a product liability dispute can raise procedural and substantive defences. In terms of substantive defences, product quality laws and regulations outline the following three statutory defences under which a manufacturer may avoid liability:

- the products have not been put into circulation;
- the defects did not exist when the products were put into circulation (in other words, the manufacturer can demonstrate that the defect was caused by the victim); and
- the scientific and technological standards at the time the product was put into circulation

had not reached a level to enable the manufacturer to discover the defect in the product.

Additionally, as outlined in **2.1 Product Liability Causes of Action and Sources of Law**, the plaintiff has to meet its burden of proving three elements in a product liability claim (ie, defects, injuries or damage, and a causal relationship between these). A defendant may also avoid liability by successfully challenging any of these three elements. In legal practice, defendants in general tend to challenge the existence of "defects" and a "causal relationship".

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Regulatory requirements, especially national standards, play an important role in deciding product liability cases. As stated in **2.1 Product Liability Causes of Action and Sources of Law**, "defect" is one of the three elements necessary for the establishment of product liability. Compliance with national standards is one of the criteria for courts to determine whether a product is defective.

Under the Product Quality Law, where a product is governed by national or industry standards for the protection of health, personal safety or the safety of property, the term "defect" includes non-compliance with those standards. Similarly, sector-specific regulations also refer to non-compliance with national standards as one of the criteria for defects. For example, the Administrative Regulations on the Recall of Defective Automotive Products provide that products that do not meet the national or industry standards on personal and property safety are deemed to be defective.

That said, regulatory compliance is only a bottom line in product liability disputes. Products that meet the national or industry standards or other administrative requirements are not automatically considered "free from defects". They also have to meet a reasonable person's expectations regarding safety (see **2.1 Product Liability Causes of Action and Sources of Law** for further details).

2.14 Rules for Payment of Costs in Product Liability Claims

In China, a court fee is calculated in proportion to the amount of the claim and must be prepaid to the court in all cases (including product liability cases) before the hearing by the plaintiff, unless the plaintiff applies for a postponement, reduction or exemption of the court fee and the court permits this.

The court will decide the allocation of the court fee between the parties in the final judgment, as well as other fees such as expert costs and inspection fees. Such fees are usually allocated to the losing party. As for attorneys' fees, the court usually considers whether the losing party should bear such costs according to the facts in the particular case, taking into account relevant provisions in the parties' sales contract and whether the attorneys' fees can be classified as a reasonable expense.

2.15 Available Funding in Product Liability Claims

Litigation Funding

No statutory litigation funding system is currently established in China. It is also difficult to receive legal aid in product liability cases. In practice, however, specific state-supported funding is available for public interest litigation (see **2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**) for parties who cannot afford the cost of litigation.

By law, a court can, after investigating the situation, decide to exempt, reduce or postpone the court fee upon application if it finds that a party is financially disadvantaged and has genuine difficulties in paying court fees. Eligible applicants include disabled persons without a steady source of income, persons on minimal welfare benefits, and persons affected by natural disasters or other types of force majeure. In particular, victims of product quality accidents are allowed to apply for postponement of court fees.

Contingency Fees

In civil cases involving property, which covers most product liability disputes, a contingency fee can be agreed upon between attorneys and clients.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

To date, China's legal system has not provided for class actions as they exist, for example, in the USA. However, China does allow public interest litigations and representative litigations when a product quality dispute affects multiple individuals (see **2.2 Standing to Bring Product Liability Claims**).

In practice, many public interest litigations in China are filed by procuratorates. As an example, a procuratorate in Guangdong province commenced litigation against two individuals for selling pork that did not meet the food safety regulatory requirements and impairing public health. The People's Court supported all the claims of the procuratorate and ordered the two defendants to remedy the damage caused by their products (by making payments to the State Treasury) and apologise to the public in the newspaper (see Case (2019) Yue Min Zhong No 379 decided by the Higher People's Court of Guangdong Province).

2.17 Summary of Significant Recent Product Liability Claims

There have been many published decisions concerning product liability in China recently. The cases discussed below – about punitive damages, food safety, product defects and public interest litigation – are significant to judicial practice in interpreting key concepts and supporting new trends in public interest litigation.

Punitive Damages for Good Faith Purchases Only

On 30 November 2023, the Supreme People's Court released "Typical Cases on Punitive Damages Concerning Food Safety". The following case involves the calculation of punitive damages in the circumstance where the purchase of goods unreasonably exceeds household needs.

In Case (2021) Hu 03 Min Zhong No 86 (decided by the No 3 Intermediate People's Court, Shanghai), the plaintiff purchased 30 boxes of biscuits from the online store operated by the respondent. After discovering that the biscuits contained ingredients not permitted by law, the plaintiff continued to purchase another 200 boxes. The plaintiff then claimed punitive damages for the unqualified biscuits, which was ten times the total price of the 230 boxes of biscuits.

The court determined the amount of the punitive damages merely based on the price of the 30 boxes originally purchased. The court reasoned that the repeated purchase of large quantities of biscuits was unreasonable and exceeded the household needs, and the plaintiff bought such biscuits in bad faith for the purpose of obtaining high compensation, which shall not be supported.

Punitive Damages due to Excessive Food Additives

On 15 March 2024, the Supreme People's Court published "Typical Cases Concerning Judicial Protection of Food Safety for the Juvenile", one of which targeted the addition of excessive food additives to products. In the case, the plaintiff purchased 18 cans of solid drinks and the ingredient list of the products indicated the addition of four types of amino acids which however were not allowed to be added to solid drinks. The plaintiff claimed punitive damages against the dairy company, namely the manufacturer, the amount of which was ten times the purchase price of the solid drinks.

Upon review, the court held that the applicable national standard only permitted the addition of the additives concerned to certain products, which did not include solid drinks. The dairy company also failed to demonstrate that the additives could be used in the products concerned in the case. Therefore, the court determined that the products manufactured did not meet the national standard on food safety and the dairy company shall bear the punitive damages.

Interpretation of "Unreasonable Danger"

Since the establishment of the "People's Court Case Database", several product liability cases have been selected as "Case for Reference", indicating their referential value in adjudication. One of these selected cases concerns the interpretation of "unreasonable danger" under the concept of product defect.

In (2022) Lu 0113 Min Chu No 5595 (decided by Changqing District Court, Jinan), the plaintiff's wife purchased a multifunctional steamer from the respondent who claimed that the equipment had therapeutic effects. Since the plaintiff was paralysed, his wife held him over the equipment for half an hour before finding that the plaintiff was injured. The plaintiff then claimed compensation and punitive damages against the respondent.

Despite the seller having submitted inspection reports to prove the product quality and arguing that the reason for such injury was that the plaintiff was paralysed, the court held that the determination of "unreasonable danger" shall take into account whether the product safety can be reasonably expected during the course of normal use. Therefore, the equipment shall guarantee that it was safe when being used by people other than those explicitly prohibited from use. However, the court found that the product did not explicitly exclude paralysed people from use, and the seller was at fault for not notifying the customer in advance and thus shall bear the compensation. The court did not find any fraud and rejected the claim for punitive damages.

Public Interest Litigation Commenced by the Procuratorate

Since the Civil Procedure Law granted procuratorates the power of commencing public interest litigation, procuratorates have developed the model of "Criminal Sanction Plus Public Interest litigation" in product liability disputes to better protect the interests of consumers. On 15 March 2024, the Supreme People's Procuratorate released "Typical Cases of Public Interest Litigation Filed by Procuratorates on Consumer Rights Protection".

One of the typical cases where the procuratorate pursued public interest litigation in addition to criminal procedures involved the sale of baby products. During the investigation on the respondent's selling of baby feeding bottles that infringed trade mark rights, the local procu-

ratorate in Shenzhen also found clues relating to infringement of interests of consumers and infants. Further inspection demonstrated that the infringing products were mainly made of polycarbonate, thus failing to meet the relevant national standard on infant products and harming the health of infants. The local procuratorate then commenced public interest litigation in the Shenzhen local court on grounds of the respondent selling unqualified counterfeit infant products that harmed public interest. The court ultimately ordered the defendant to pay punitive damages and issue a public apology on the state media.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Recent trends regarding punitive damages, strict protection of food safety, determination of product defect and public interest litigation have been discussed in **2.17 Summary of Significant Recent Product Liability Claims**.

Introduction of New Rules to Further Protect Consumer Rights

On 15 March 2024, China introduced the Implementation Rules on the Law on the Protection of Consumer Rights and Interests, which will come into force on 1 July 2024. The new rules have elaborated on the following aspects concerning product quality.

Duty to ensure product safety

The new rules require business operators to ensure the safety of the products or services provided, including those offered free of charge in the form of prizes, gifts or samples. Moreover, business operators shall notify consumers if such free products or services have flaws which however do not contravene mandatory rules nor affect their normal performance.

Recall of defective products

The new rules provide in general the requirements for recalling defective products. Consumers are encouraged to notify the business operators or authorities if they find potential defects in the products or services, and business operators are required to react promptly when discovering potential defects that could harm physical or property safety. Meanwhile, business operators that sell, lease, or repair the products, suppliers of components and those entrusted with manufacturing are obligated to co-operate with product recalls.

Calculation of warranty period

Under the new rules, the warranty period for return, replacement and repair as agreed between the business operator and the consumer shall not be shorter than any statutory rules. In general, the warranty period shall start from the date when the product is delivered to the consumer or the service is completed. Where the business operator has performed its replacement duty, the warranty period shall be reset, starting from the date of the completion of the replacement.

Expansion of the mandate of consumer associations

In addition to responsibilities set out in the PCRI, the new rules accord additional mandate to consumer associations. Consumer associations may hold talks with the business operators or industrial organisations on consumer protection issues. They are also mandated to carry out investigations on infringement of consumer rights and require the business operators to submit statements and evidentiary materials.

Determination of consumer fraud

While the new rules reiterate the compensation for consumer fraud, it is also clarified that such fraud does not cover the circumstance in which the flaws in markings or labels, manuals or promotional materials will not impact the quality of products or services nor mislead consumers. Further, the new rules stipulate that punitive damages for fraud do not apply to those intending to obtain compensation through fraudulent acts. In this respect, administrative and criminal penalties (if any) shall be imposed on such bad-faith entities.

Ongoing Amendment to the Product Quality Law

On 18 October 2023, the SAMR released a revised version of the Product Quality Law for public comments. To date, the draft amendment has yet to be officially promulgated. Major features of this new draft are illustrated as follows.

- The term "business operator" is specifically defined in the new draft, covering, among others, manufacturers, sellers, product storage and transport operators, online sellers, e-commerce platforms, operators of centralised trading markets, counter renters, organisers of trade fairs, and service industry operators. Accordingly, a separate chapter is dedicated to setting out product quality responsibilities of business operators other than manufacturers and sellers.
- The new draft aims to implement more stringent supervision of the quality of "special consumer products" which include products for children, pregnant and breastfeeding women, the elderly and the disabled. Such products are subject to stricter standards, shall pass safety assessment and third-party inspection before being put into circulation and shall implement special labels.
- A new chapter of the draft targets the measures for quality innovation and the building of quality infrastructure. For example, the new draft intends to introduce the regulatory sandbox so as to encourage innovation while mitigating risks and preserving consumer safety.
- The new draft proposes to unify the concept of "defect", which is defined as "products having unreasonable danger compromising physical safety and/or security of other properties".
- The new draft also plans to establish the product quality credit system under which product quality credit information shall be disclosed to the public in the national enterprise credit system. Entities severely violating product quality regulations shall be included in the list of dishonest enterprises committing grave illegalities, which are subject to further restrictions on access to government procurement and obtaining government support.

Changes to the Regulation of Selling Edible Agricultural Products

To better regulate the selling of edible agricultural products in markets, the SAMR adopted a new amendment to the Administrative Measures on Supervision of Quality Safety of Selling Edible Agricultural Products in Markets on 30 June 2023, which came into effect on 1 December 2023. Below are key features of the revised measures.

- The measures further underscore the various responsibilities of market operators and sellers. The former is obligated to keep records of sellers in the market, conclude contracts with them and carry out inspections; the latter is required to verify the products for sale, conduct regular inspections and put up proper labels.

- The measures have listed the quality certificate as one of the valid proofs for verification during the procurement of the edible agricultural products. Sellers are encouraged to first procure products attached with such quality certificates and present the certificates in the market.
- In particular, the measures explicitly prohibit sellers from using specific lighting equipment to change the original colour of the agricultural products so as to mislead consumers. Moreover, sellers selling ready-to-eat products that go through simple peeling and cutting shall take effective measures to protect food safety and prevent cross-contamination.

Emphasis on Quality Safety Responsibilities of Manufacturers and Sellers

On 4 April 2023, the SAMR released the Regulation on Administration and Supervision of Manufacturers of Industrial Products Implementing Quality Safety Responsibilities, and Regulation on Administration and Supervision of Sellers of Industrial Products Implementing Quality Safety Responsibilities, both of which took effect on 5 May 2023. The two regulations aim to ensure quality safety of certain industrial products and the key features are summarised as follows.

- The "industrial products" targeted by the regulations include those subject to production licensing and compulsory certification, as well as those concerning physical and property safety that are subject to mandatory national standards.
- Manufacturers and sellers of such industrial products are required to appoint quality safety director(s) and officer(s). The director(s) and officer(s), together with the principal person in charge of the enterprise, shall perform their respective quality safety responsibilities in daily operation of the business.
- Based on a careful listing of quality safety risks, manufacturers and sellers shall conduct daily management, weekly screening and monthly scheduling relating to the inspection and handling of relevant risks, and keep records of the results.
- Failure to establish the mechanisms as required is subject to rectification and warning, and refusal to rectify is subject to a fine of CNY5,000 to CNY50,000.

Amendment to the Warranty Obligations of Vehicles Manufacturers

A new amendment to the Regulations on Repair, Replacement and Return of Household Automotive Products came into force on 1 January 2022. The newly amended regulation introduced several important changes to the obligations of vehicle manufacturers in guaranteeing product quality and providing after-sale services.

- The amended Regulation has expanded vehicle manufacturers' warranty obligations to major components of renewable energy vehicles, requiring manufacturers and repairers to provide free replacement if the power battery or the driving motor of a renewable energy vehicle exhibits major quality issues within 30 days of purchase or within the mileage range of 3,000 km.
- The amended Regulation has lowered the threshold for consumers to claim warranty service, requiring repairers to provide a replacement if a vehicle has already undergone repair four times for the same issue or over a 30-day period.
- Under the amended Regulation, vehicle manufacturers, sellers and repairers cannot refuse to provide warranty because the consumer has chosen a specific maintenance provider.

3.2 Future Policy in Product Liability and Product Safety

The general tendency in product liability, as outlined in **3.1 Trends in Product Liability and Product Safety Policy**, is to extend the level of protection to consumers, and to clarify the product quality responsibilities assumed by various entities at different stages. Based on that, the legislature also plans to do the following.

- Unify the standard for the determination of defects – to date, "unreasonable danger" and "national or industrial technology standard" are both applied (see **2.13 The Impact of Regulatory Compliance on Product Liability Claims**); some believe that these standards are vague and difficult to apply, particularly as regards the meaning of "unreasonable danger".
- Increase the use and function of punitive damages in product liability cases.
- Expand the use and application of mental distress damage in product liability cases.
- Strengthen supervision of specific categories of sensitive products, including among others, food, drugs, and infant products.

The topics of new energy vehicles, autonomous vehicles, international e-commerce, online shopping, public interest litigation and others are also under discussion in the context of new legislation.

DENMARK

Law and Practice

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Contents

Kennedys has a team of 11 legal professionals in Copenhagen who provide specialist insurance law services to Danish, Scandinavian and international insurers. The team's expert advice is based on a deep understanding of the Danish, Scandinavian and global insurance markets. Its primary focus is the insurance and reinsurance sector, including collective redress class actions within banking and finance, construction and engineering, directors' and officers' liability, employers' liability, cyber incidents and more, working closely with the Kennedys offices in EMEA, APAC, LATAM, the US and the UK. The Kennedys Copenhagen office has represented insurers in several cases of material importance for the insurance sector in arbitration, the high courts and the Supreme Court. The Kennedys team in Copenhagen has panel lawyer appointments and co-operation agreements with several leading insurers in the Danish, Scandinavian and global markets, supporting its status as the go-to law firm within insurance.

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1. Product Safety

1.1 Product Safety Legal Framework

The Danish Product Safety Act

This is the primary act in Denmark concerning product safety. Additionally, there are several sets of regulations for specific types of products. This applies, for instance, to toys, electrical products, and machinery. The Product Safety Act establishes the obligations of manufacturers, distributors, and importers ("traders") to only place safe products on the market and to take relevant measures if a product is found to pose a risk to users. The Product Safety Act complements the Market Surveillance Regulation and expands the safety regulation of products and the authorities' capacities in this regard.

Regulation on General Product Safety

From 13 December 2024, consumer products must comply with the new EU regulation on product safety when sold in an EU country. The EU regulation came into effect on 12 June 2023, however, there is an 18-month period for implementation. Generally, there are no changes to the material requirements for safe products, but new rules are set for labelling, product safety in e-commerce, and the use of new technologies.

1.2 Regulatory Authorities for Product Safety

The Danish Safety Technology Authority is a government agency overseeing product safety regulations and enforcement in Denmark. The Danish Safety Technology Authority conducts inspections, monitors compliance, and has the authority to order a withdrawal or recall.

Additionally, there are sector-specific regulators responsible for overseeing product safety in certain industries. For instance, the Danish Medicines Agency oversees regulations concerning medical equipment and products, while the Danish Environmental Protection Agency oversees regulations related to products' chemical properties.

1.3 Obligations to Commence Corrective Action

According to the Danish Product Safety Act, the responsibility for product compliance lies with the commercial operators, who is obligated to actively ensure that products placed on the market complies with legislation and are safe to use.

If a product is not compliant, it must not be advertised or made available on the market. Therefore, all commercial operators have a general duty to ensure that the products they place on the market are safe to use. The assessment of whether a product is safe or not must be based on factors such as the product's characteristics and purpose, the users' conditions and the possibility of providing guidance on and warning against any potential dangers associated with the product.

If a commercial operator becomes aware that a product they have placed on the market is not safe when used in an usual and expected manner, they must immediately notify the Danish Safety Technology Authority and take the necessary measures.

It is up to the commercial operator to decide which measures, given the specific circumstances, can most effectively prevent damage or injuries resulting from the product's risk. However, this "voluntary" approach to determining the necessary measures must be viewed in the context of the Danish Safety Technology Authority's ability to intervene and impose further measures if the commercial operator's voluntary measures are deemed insufficient.

1.4 Obligations to Notify Regulatory Authorities

As mentioned in **1.3 Obligations to Notify Regulatory Authorities**, a business operator who becomes aware that a product they have placed on the market is not safe when used in the usual and expected manner must immediately notify the Danish Safety Technology Authority and take the necessary measures.

The obligation to notify the regulatory authority applies to all commercial operators involved in the supply chain. However, it is sufficient for a single commercial operator in the supply chain to notify the Danish Safety Technology Authority, provided that the notification is sufficient.

The notification to the Danish Safety Technology Authority should enable the authority to assess the risk, including whether the measures taken by the commercial operator to mitigate the risk are adequate. Therefore, the notification should typically include a description of the product and the risk.

If the product is sold in several EU countries, the notification to the authorities can be made as a joint communication to all relevant national authorities using the EU Commission's Product Safety Business Alert Gateway.

Regarding the deadline for notification, it should be made "immediately" when the commercial operator becomes aware that a product poses a safety risk. According to Danish law, this is interpreted as a reasonable and prompt action in relation to the specific circumstances of the case, with emphasis on whether the notification was made without undue delay after the business operator became aware of the safety risk associated with the product.

1.5 Penalties for Breach of Product Safety Obligations

The Danish Safety Technology Authority is granted a range of remedies over commercial operators to ensure compliance with the law's requirements. If a product does not comply with product safety regulations, the Danish Safety Technology Authority can issue an enforcement notice against the commercial operator. Enforcement notices can be issued against all levels of the supply chain.

For example, the Danish Safety Technology Authority can instruct the commercial operator to warn users about the risks associated with the product or to remedy conditions that do not comply with product safety regulations. Among the most intrusive enforcement notices are orders to cease sales, recalls, withdrawals, and destruction of products. Violations of product safety regulations can result in a fine or, in severe cases, imprisonment.

As a starting point, fines begin at EUR6,700, but fines may be determined based on the expected profits from selling a dangerous product. Under aggravating circumstances, imprisonment of up to two years may be imposed. This could occur, for instance, when the product has caused serious personal injury, in cases of repeat offences, or in instances of systematic violations of the regulations.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

In Denmark, personal injury and property damage are the main reasons for legal action in product liability matters.

In Denmark, the legal framework regarding defective products are governed by a dual system. The Product Liability Act governs cases involving personal injuries and consumer property damage, while broader categories of damage, such as commercial property damage, are regulated by product liability rules develop through case law.

Both the Product Liability Act and case law-develop rules are applicable solely to damage or injury other to anything other than the product itself. Liability for damage to the product itself is governed by contractual agreements between the parties and Danish laws such as the Sale of Goods Act and standard contracts including the AB-regime, CISG and FIDIC.

2.2 Standing to Bring Product Liability Claims

According to the Danish Product Liability Act, individuals who have suffered personal injury or property damage as a result of a defective product have standing to bring claims for product liability. Whether the defective product is used commercially or privately is irrelevant. The rules governing the standing of companies and other commercial operators who have suffered damage to bring a claim are regulated by product liability rules developed through case law. A common feature of both sets of product liability rules is that they do not cover damage to the defective product itself.

2.3 Time Limits for Product Liability Claims

According to the Danish Act on Limitation, the time limit for bringing a claim for product liability is typically three years from the date when the claimant became aware, or should have become aware, of the claim, the defect in the product, and the identity of the party responsible for the defect. However, the three-year time limit can be suspended if the claimant neither had nor should have had knowledge of the claim. A claim based on the rules of the Product Liability Act are time-barred after ten years. The Product Liability Act does not restrict the claimant's access to damages by the product liability rules developed through case law, where the absolute limitation period for personal injuries is 30 years.

2.4 Jurisdictional Requirements for Product Liability Claims

In Danish law, the general rule is that the claimant must initiate proceedings against a producer at their domicile. However, Danish law also allows the claimant to bring the case where the damage occurred, which is often the claimant's place of residence.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There are no mandatory steps that must be taken before legal proceedings can be commenced in product liability cases under Danish law.

2.6 Rules for Preservation of Evidence in Product Liability Claims

There are no explicit rules under Danish law for the preservation of evidence, including the product itself, in product liability cases. Failure to preserve key evidence will, however, render it difficult for both the claimant and the producer to lift the burden of proof.

2.7 Rules for Disclosure of Documents in Product Liability Cases

If a party seeks disclosure of documents held by the opposing party in a product liability case, Danish courts have the authority to compel this, provided that the requesting party clarifies the specific issues for which the documents are needed. Failure to comply with the court's dis-

closure order may lead to adverse inferences being drawn. Similarly, if a party wishes to disclose documents held by a non-party, the court may impose disclosure based on the relevance of the documents to the case, unless the non-party is exempt from providing testimony on the content of the documents. Non-compliance may result in sanctions similar to those for failing to comply with a court appearance, including fines or imprisonment.

2.8 Rules for Expert Evidence in Product Liability Cases

In Denmark, the decision to involve expert evidence typically rests with the parties, though the court may reject such evidence if it deems it unnecessary, either upon request or at its own discretion. Court-appointed experts, rather than party-appointed experts or witnesses, are more commonly relied upon, providing written statements and court explanations based on queries posed by the parties. Pre-proceeding statements acquired by the parties are generally admissible, with the opposing party granted similar access post-commencement. Parties may also, with court approval and mutual agreement, secure their own expert statements (party-appointed experts) after proceedings have begun.

2.9 Burden of Proof in Product Liability Cases

Under the Danish Product Liability Act, producers bear a strict liability for damage resulting from defects in their products. To seek compensation for incurred damage, claimants must establish the existence of the inflicted damage, a defect, and the causal link between the defect and the damage. Consequently, there's no requirement for the claimant to prove negligence or fault on the part of the producer.

Under product liability principles established through case law, a presumption of negligence applies. Upon the claimant proving the existence of a defect, the burden of proof shifts to the producer to prove that the defect is not a result of their negligence.

Both the Product Liability Act and case law-derived product liability principles impose a presumption of negligence on intermediaries. Consequently, the intermediary may be held liable for injury or damage resulting from a defective product unless it can demonstrate lack of intentionality or negligence.

Danish law do not have formal rules concerning the assessment of evidence by courts and the requisite level of proof. Therefore, in each instance, the court must assess the evidence presented and determine whether the claimant has met the burden of proof. Additionally, the court is not obligated to adhere to expert evidence.

2.10 Courts in Which Product Liability Claims Are Brought

Product liability cases, irrespective of the disputed claim's value, are adjudicated in Danish civil courts, including district courts, the Maritime and Commercial Court, High Courts, the Supreme Court, and, if parties have mutually agreed, in arbitration.

Generally, there are no specific procedural requirements for such cases, and jury hearings are not available for product liability cases, as juries are exclusively involved in specific criminal cases.

2.11 Appeal Mechanisms for Product Liability Claims

With some exceptions, the two-tier principle enables all civil cases, eg, product liability cases, to be adjudicated by at least two courts in Denmark. If a district court or the Maritime and Commercial Court serves as the initial instance, its verdict can be appealed to the High Court without requiring special permission. Conversely, if the High Court acts as the first instance, its decision can be appealed to the Supreme Court. However, if a dispute is heard by the High Court as the second instance, an appeal to the Supreme Court requires third-instance leave of appeal from the Appeals Permission Board.

2.12 Defences to Product Liability Claims

Various defences are available to producers in product liability cases. For instance, a producer may demonstrate that the product is not defective, in which connection a frequently used defence is expert evidence, including expert opinions on the producer's safety and quality control of the product. The producer is exempt from liability if it can prove that the defect arises from the product's compliance with mandatory public regulations. Additionally, a producer cannot be held liable if it can prove that, based on scientific and technical knowledge available at the time of circulation, the defect was undetectable. Furthermore, a producer is not liable if the defect arises after the product has been put into circulation. Lastly, evidence of the claimant's contributory negligence or assumption of risk may absolve the producer of liability.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

If a product fails to meet safety regulations or authorisation requirements set for that specific product, it may be deemed defective, as consumers are entitled to expect a certain level of safety as mandated by relevant product legislation. Some products are, however, inherently associated with known adverse effects; for instance, tobacco is widely recognised for its harmful effects. Likewise, it is commonly understood that certain products may trigger allergic reactions. Damage resulting from an unavoidable risk associated with using the product is not considered a defect despite non-compliance with regulation.

2.14 Rules for Payment of Costs in Product Liability Claims

According to Danish procedural law, the court determines which party shall cover both court fees and legal costs associated with the case, often placing this burden on the losing party. However, the costs awarded by Danish courts typically do not reflect the actual legal expenses incurred during the proceedings. As a result, the parties involved often end up bearing a considerable portion of their own legal costs.

2.15 Available Funding in Product Liability Claims

In 2017, the Danish Supreme Court endorsed the use of third-party funding at a group level. This occurred when the bankrupt estate of OW Bunker entered into an agreement with a third-party funder. The Supreme Court ruled that third-party funding was not contrary to Danish legal procedures.

As a result, third-party funding of product liability claims is allowed under Danish law, and there is full contractual freedom concerning third-party funding, provided that the governing contract for the third-party funder meets the general requirements for contracts under Danish law.

In addition to third-party funding, alternative methods of funding for product liability claims are available. These include legal expenses insurance and legal aid.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

In essence, product liability claims may be pursued through class-action proceedings, subject to meeting specific eligibility requirements. Up until now, class actions have rarely been used in product liability proceedings, however, the potential rise of, for example, PFAS-related product liability claims (see **3.2 Future Policy in Product Liability and Product Safety**) could change this and lead to an increase in product liability class actions as well.

According to Danish law, a class action suit must be initiated by a group representative and meet the criteria set out in Section 254b(1) of the Administration of Justice Act, before the court will allow the suit to proceed. These criteria include ensuring that the claims share a similar essence, that they all fall under Danish jurisdiction, and at least one of the claims is within the court's jurisdiction. Additionally, the court must have subject-matter jurisdiction over all claims, and class action must be deemed the best procedural option. Moreover, the group members must be identifiable and informed about the class action suit.

These criteria are stringent. Specifically, the requirement that a class action suit must be the most suitable procedural option to address a certain claim implies that the court will only issue a group certificate if no other option for addressing the claim is better suited, making this condition difficult to fulfil.

2.17 Summary of Significant Recent Product Liability Claims

In 2024, the Danish High Courts have rendered two judgments in which key statutory definitions of Danish Product Liability were subject to interpretation indicating potential adverse effects on all electricity distribution system operators and their insurers.

Both matters concerned electricity supplied by electricity distribution system operators, which was over-voltage upon delivery to consumers, causing damage to their properties. The judgments establish that electricity distribution companies are deemed as producers of electricity under the Danish Product Liability Act, as they alter the voltage level before distributing it to end-users. Moreover, it clarifies that the point of connection, where the operator's supply network meets the consumer's property, marks the commencement of electricity circulation. Thus, this point is pivotal in determining whether the electricity is defective.

Since the electricity in question was over-voltage at the connection point, the grid operators were held liable under the Danish Product Liability Act.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

The General Product Safety Regulation, which entered into force in June 2023, stands as a pivotal addition to the EU's legal framework concerning product safety. It will be applicable to products entering the market from December 2024 onward, replacing the General Product Safety Directive established in 2001. This regu-

lation encompasses all products lacking specific EU regulation and is designed to enhance the safety standards of products sold both in physical stores and online. It also aims to bolster market surveillance against illicit products and fortify consumer rights for individuals who have acquired unsafe products. Products introduced to the market without adhering to safety regulations or approval criteria will generally be deemed defective.

By the conclusion of 2023, a political agreement to amend the nearly 40-year-old EU Product Liability Directive from 1985 was reached by the EU Parliament and the Council. The objective of the new EU Product Liability Directive is to adapt the Directive to the digital era and the principles of the circular economy, which includes promoting the increased reuse of previously traded products.

3.2 Future Policy in Product Liability and Product Safety

The evolution of technology and AI and the amendment of the Product Liability Directive will influence product liability regulation and litigation in Denmark in the coming years. According to the Danish government, the new Product Liability Directive will not only have legislative consequences, as changes to the Danish Product Liability Act are required, but is also expected to lead to an increase in product liability claims filed at Danish courts.

Recent concerns regarding the environmental and health hazards associated with PFAS-substances, commonly known as "forever chemicals", have led to a noticeable rise in PFAS-related claims across the EU. This prompts speculation on whether Denmark will experience similar litigation. Much like trends observed in the US, PFAS claims, including class actions (see **2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**) may arise in Denmark, alleging that the presence of PFAS substances renders products unsafe.

EU

Law and Practice

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Contents

Ashurst has a reputation for successfully managing large and complex multi-jurisdictional transactions, disputes and projects and delivering outstanding outcomes for clients. Ashurst has 31 offices in 18 countries and offers the reach and insight of a global network of legal, new law and risk professionals, combined with the knowledge and understanding of local markets. With over 490 partners and a further 2,000 lawyers working across 11 different time zones, the firm is able to respond to clients wherever and whenever required.

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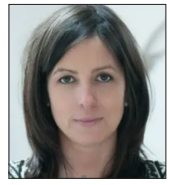

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1. Product Safety

1.1 Product Safety Legal Framework

General Overview

The EU product safety regime is a sophisticated, multi-faceted one which seeks to balance the rights of consumers, patients and users of products, with the rights of businesses. Its principal aim is to provide the highest level of public and patient safety without stifling innovation, framed around the three key legislative pillars set out below.

Underpinned by the EU's core principles of free movement and maximum harmonisation, and with the public's safety as its goal, the regime has three complementary limbs consisting of:

- mandatory obligations for all economic operators within the supply chain;
- minimum competence requirements for any third parties assessing product or quality management systems; and
- market surveillance mechanisms.

The product safety regime includes numerous pieces of legislation which both complement and overlap each other.

Separate product safety regimes

The following products, which give rise to unique and distinct risks, are subject to their own legislative frameworks which operate independently from other product safety legislation:

- medical devices;
- pharmaceuticals; and
- food and nutrition supplements.

Supplementary sector-specific safety requirements

These work in concert with the general product safety regime detailed below, to have effect where there are specific risks introduced by recognised product categories. Sector-specific laws include those relating to:

- biocides;
- cosmetics;
- chemicals;
- toys;
- low-voltage electrical equipment;
- motor vehicles;
- machinery;
- radio equipment; and
- personal protective equipment.

General product safety regime

For consumer products that fall outside the sector-specific regimes listed above, or where regimes are silent, the general product safety framework applies by way of the General Product Safety Directive or GPSD (Directive 2001/95/EC), which mandates overarching requirements for product safety of consumer products in the EU. The GPSD requires all products to be safe in their normal or reasonably foreseeable usage. Member states hold powers to take suitable action should this obligation not be met.

The General Product Safety Regulation (GPSR), which entered into force on 13 June 2023, is set to replace the GPSD, as well as the Food Imitating Product Directive, from 13 December 2024. This key new EU measure has the objective of modernising the EU product safety regime responding to risks posed by advancements in technology. It updates the existing framework to enable it to adapt to the challenges posed by the modern digital age and reinforce safety for products sold both offline and online. Please refer to **3.1 Trends in Product Liability and Product Safety Policy** for further detail.

It is possible that other relevant regimes may apply, including:

- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the "CLP Regulation"), which places obligations on manufacturers to appropriately label, classify and pack products containing any dangerous substances and mixtures;
- Regulation (EC) 1907/2006 on the registration, evaluation, authorisation and restriction of chemicals (REACH), which acts to regulate both production and use of chemical substances;
- Directive 2009/48/EC on the safety of toys, which lays down criteria that toys must meet before they can be marketed in the EU;
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (the "recast RoHS Directive"), which regulates the restriction on the use of certain hazardous substances in electrical and electronic equipment;
- Directive 2012/19/EU on waste and electronic equipment (the "recast WEEE Directive"), which regulates waste electrical and electronic equipment (WEEE) and allows for collection schemes in respect of consumer products;
- Regulation (EU) 1007/2011 on textile fibre names and related labelling and marking of the fibre composition of textile products (the "Textiles Regulation"), which outlines fibre names and related labelling requirements for textile products;
- Directive 2014/53/EU Radio Equipment, which outlines the framework for placing such equipment on the market; and
- Directive 2014/30/EU on Electromagnetic Compatibility (EMC), which outlines the requirements for the design and testing of electronic and electrical products to ensure they do not give rise to electromagnetic interference.

Member states are involved in drafting the above-mentioned applicable regimes to a varying degree, dependent on the nature of the EU laws applicable – with Regulations being directly applicable and member states needing to implement Directives into local laws to make them legally binding. Evidently, although the EU system always strives for maximum harmonisation across the laws of all EU member states for which an EU law is the basis, local implementa-

tion of laws tends to increase the likelihood for local deviations and variance.

When Does the Product Safety Regime Apply?

Generally, the product safety regime applies:

- where a product is "placed on the market" in the EU, and to any subsequent action which could be considered placing the product on the EU market until it reaches the end user;
- in respect of all forms of selling, including e-commerce or tangible stores;
- in respect of newly manufactured, used or second-hand products;
- to products that enter the EU for the first time after being imported from a third country;
- to finished products; and
- to products that have been subjected to important changes or amendments aiming to modify their original performance, purpose or type.

Determination of which EU regime is applicable can be a complex process and should always be carefully considered.

1.2 Regulatory Authorities for Product Safety

There is no EU-level regulator that oversees product safety. Generally, there are member state/national-level regulators for product safety – those that oversee and regulate general consumer products and product-specific regulators that oversee specific product categories, such as medical devices and consumer health products. Generally, the demarcation between these types of regulators is along the lines of the applicable regulatory regimes, as outlined in **1.1 Product Safety Legal Framework**.

Across the EU, there is generally no hierarchy of regulators. Regulators of specialist product categories have different ambits of work, however, and regulators are therefore not layered in terms of oversight and there is generally a single layer of regulation.

EU-Wide Regulatory Agencies for Specific Product Categories

Whilst there are no regulators at an EU-wide level per se, there are relevant EU-wide regulatory agencies for some product categories, including medicines (the European Medicines Agency (EMA)) and chemicals (the "European Chemicals Agency" or ECHA). Whilst these organisations do not typically get involved in actual enforcement practices, or authorisation processes, they do provide expert guidance and broader policy input.

The European Commission (EC) also regularly produces relevant guidance and interpretation, including with expert groups who are specialists in specific product categories. For example, the Medical Devices Expert Group (MDG) of the EC produces comprehensive guidance in respect of the medical devices regime, in the form of the MEDEEV guidance documents. The EC's key role in ensuring compliance with EU-level product safety regulations also extends to requiring member states to take specific actions in certain circumstances where warranted, for example, requiring a temporary ban, recall or withdrawal from market of unsafe products on the EU market.

Generally, specialist regulators are also empowered to enforce the specific regimes.

Greater Centralisation of the EU Product Safety Regime

In general, the issue of enforcement of product regulatory regimes was historically left to the member states, and was not governed at EU level. This led to widely discrepant regulatory enforcement practices across the EU – and often resulted in criticism that the enforcement of the EU product safety laws was a weak link in an otherwise sophisticated regime.

Against this backdrop, there has been an increasing focus in recent years on increased, and more robust, enforcement practices, but also increased EU-wide enforcement practices for product safety generally, as part of the EU's Goods Package. In particular, the new Market Surveillance Regulation (2019/1020, MSR) aims at enhancing, as well as harmonising, enforcement powers across the EU, as does Directive (EU) 2019/2161 on the better enforcement and modernisation of EU consumer protection rules, which came into force in January 2020 and introduced changes to four consumer protection laws, namely the Unfair Commercial Practices Directive (2005/29/EC), the Unfair Contract Terms Directive (93/13/EEC), the Consumer Rights Directive (2011/83/EU) and the Price Indications Directive (98/6/EC).

1.3 Obligations to Commence Corrective Action

Post-market Surveillance Requirements

Alongside pre-market requirements, post-market requirements are a fundamental aspect of product safety regimes in the EU. There are varying requirements and trigger points for post-market surveillance obligations and record-keeping practices across various product categories. Some examples of the more onerous requirements are set out below.

Manufacturers, and in some instances other actors in the supply chain, have an obligation to address any product safety risks that become apparent in their products once they are circulating in the market, including by way of recall or withdrawal from the supply chain.

Post-market surveillance obligations for medical devices, for example, generally require the existence of:

- a comprehensive system to gather information on patient use of the product (post-market surveillance system);
- the appointment of a responsible person to ensure continued compliance of products;
- the existence of a post-market surveillance system for collecting information and characterising the safety and performance of the device, or family of devices; and
- methods and processes to assess the collected information.

Under Article 5(1) of the GPSD, producers must "adopt measures commensurate with the characteristics of the products they supply". This would typically include, for example, warning consumers, withdrawing products from the market where required, and, if required, recalling products. Similar provisions exist in sector-specific legislation.

Risk Assessment

Classification of product safety risks is determined, according to the GPSD, by undertaking a risk assessment. Such an assessment determines risk by assessing the possible severity of harm and likely probability of any risk identified. Though the GPSD itself is silent on how such an assessment should be performed, the EC has previously published guidance on how to

approach said assessment as well as an online tool.

In general, risks determined can be categorised as follows:

- low risk – not normally requiring action for products on the market;
- medium risk – normally requiring some action;
- high risk – normally requiring rapid action; and
- serious risk – normally requiring rapid action.

Specific products may have more prescriptive rules or guidance for recall (for example, motor vehicles, medicinal products and medical devices).

The GPSR expands on what should be considered when assessing the safety of a product and provides that all relevant aspects of the product should be taken into account, in particular its physical, mechanical and chemical characteristics, its presentation, as well as specific needs and risks which the product represents for particular categories of individuals such as persons with disabilities, older persons and children. It further states that any health risks, physical and mental, posed by connected products should be considered and when assessing the safety of digital connected products likely to have an impact on children, manufacturers should ensure that their products meet the highest standards of safety, security and privacy.

1.4 Obligations to Notify Regulatory Authorities

Article 5(3) of the GPSD requires producers and distributors to "immediately inform the competent authorities" of the member state in which the products in question are or have been, marketed or otherwise supplied to consumers where they "know or ought to have known" that the product they have marketed is unsafe.

Notification involves, depending on the nature of the product in question, the following.

- Pharmaceutical products: marketing and/or manufacturing authorisation holders are obliged to report to the EMA and any affected member states regarding any product quality defect, including a suspected defect, of a centrally authorised medicine which could result in a recall or abnormal restriction on supply.
- Cosmetic products: cosmetics regulations require notification to relevant member state competent authorities, without delay, of any serious undesirable effects (SUEs) attributable to the use of cosmetics.
- Products where the general consumer product safety regime applies in terms of reporting obligations: generally, there is a risk-based requirement to report to authorities in the event a product is not compliant with the applicable product safety regime.
- Medical devices: medical device manufacturers are legally required to report adverse incidents and Field Safety Corrective Actions (FSCAs) to EU Competent Authorities.

The EC "Safety Gate" system is an online platform that facilitates notification of several relevant member states simultaneously. This system was formerly known as "RAPEX".

The GPSR bolsters notification obligations. Under Article 9(8) thereof, where a manufacturer considers or has reason to believe that a product it has placed on the market is dangerous, it must immediately inform, through the Safety Business Gateway, the market surveillance authorities of

the member states in which the product has been made available.

1.5 Penalties for Breach of Product Safety Obligations

Given the need for EU-level product safety laws to be implemented into national legislation by member states, member states are empowered to impose penalties for a breach of product safety regulations. Such penalties can range considerably, and include monetary fines and, in rare instances, imprisonment of key individuals.

The GPSR gives discretion to member states to lay down rules on penalties and directs that such penalties should be effective, proportionate and dissuasive.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

The EU mechanisms for product liability claims apply regardless of product classification, and generally can be divided into four main categories, as set out below. These mechanisms of liability all work together in the EU. The strict liability regime is generally preferred by claimants for the primary reason that it requires no proof of fault. However, in reality, parallel causes of action tend to be pursued by claimants in order to benefit from as many regimes as possible.

Generally, the below offences create civil liability. However, criminal offence provisions also exist under the GPSD.

Statutory Liability Under Product Liability Laws

EU Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products (the "Product Liability Directive" or PLD) establishes strict liability offences for defective products, also referred to as a "no fault" regime. Key features of the legislation include:

- manufacturers, importers and suppliers being jointly and severally liable;
- liability arising "for damage caused by a defect" in a product; and
- "product" being defined broadly as "all moveables" but expressly excluding "primary agricultural products and game".

In bringing a claim, claimants are required to prove the following elements exist:

- damage, including personal injury and/or property damage;
- defect – a product is generally defective when "it does not provide the safety which a person is entitled to expect", taking into account "all circumstances", including but not limited to the product's presentation, the use(s) to which it could be reasonably expected that the product would be put, and the time it was put into circulation; and
- a causal relationship between the damage and defect, as based on the application of national member state laws on causation.

Those entitled to bring claims under the PLD are "injured persons". There can be multiple claimants bringing a joint action in many instances, though not to the extent of amounting to a so-called class action in many instances.

Generally, claims under the PLD must be brought within three years from "the day on which the plaintiff became aware, or should reasonably have become aware of the damage, the defect

and the identity of the producer". Member state laws may also apply to allow for a suspension of this time limit in some circumstances. The PLD also stipulates that the period for bringing claims is completely extinguished "10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer". This is known as the ten-year long stop period.

The new EU Product Liability Directive, which was approved by the European Parliament on 12 March 2024, is set to address the risks and challenges posed by the digital age, modern supply chains and the circular economy. The legislative measure contains significant changes to the existing regime (as described throughout **2. Product Liability**), which are likely to make it easier for EU claimants to pursue product liability claims, particularly in respect of cases involving new technologies. It will enter into force 20 days after its publication in the Official Journal of the EU and must be transposed within 24 months by member states. Please refer to **3.1 Trends in Product Liability and Product Safety Policy** for further detail.

Liability in the Tort of Negligence

Unlike the above-mentioned PLD-based action, negligence claims require establishment of some fault on the part of the manufacturer and/or defendant party. The elements of this claim are determined by member state laws that apply.

Liability in Contract

Liability in contract can be made out under the Consumer Sales and Guarantees Directive (1999/44/EEC) where a seller, that is "any natural or legal person who, under contract, sells consumer goods in the course of his trade, business or profession" sells a product that does not conform to the contract of sale.

Breach of Product Safety Regulation

In respect of unsafe products, there is also a possible cause of action for breach of product safety regulation.

2.2 Standing to Bring Product Liability Claims

Article 4 of the PLD stipulates that the "injured person" is entitled to bring an action.

Individual claimants injured by a defective product may choose to commence proceedings under the PLD. However, as noted in **2.1 Product Liability Causes of Action and Sources of Law**, in reality, parallel causes of action tend to be pursued by claimants in respect of a single product.

Under Article 5 of the new PLD, any natural person who suffers damage caused by a defective product is entitled to compensation.

2.3 Time Limits for Product Liability Claims

Generally, claims under the PLD must be brought within three years from "the day on which the plaintiff became aware, or should reasonably have become aware of the damage, the defect and the identity of the producer". Member state laws may also apply to allow for a suspension of this time limit in some circumstances. The PLD also stipulates that the period for bringing claims is completely extinguished "10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer". This is known as the ten-year long stop.

The new PLD similarly provides a limitation period of three years. The period within which claims can be brought is extinguished upon the expiry of ten years from the date on which the actual defective product which caused the damage was placed on the market, put into service or, indeed, substantially modified.

2.4 Jurisdictional Requirements for Product Liability Claims

PLD and/or Negligence Claims

The rules for determining whether the jurisdiction of EU courts is triggered, and if so which courts (in terms of which member state) in respect of PLD and/or negligence claims are notoriously complex.

Regulation (EC) 864/2007 on the law applicable to non-contractual obligations ("Rome Regulation II"), provides the following parameters to help determine in which EU court the claim can be validly brought (on the proviso the product was marketed in that country):

- the "habitual residence" of the person bringing the claim and/or the person against whom the claim is brought;
- the location where the product was acquired; and
- the location where the damage was sustained.

Contractual Claims

For contractual claims, unlike the above-mentioned PLD and negligence claims, choice of law/forum is usually a feature of any contractual agreement such that the above laws are not relevant. However, in the absence of such common contractual provisions, Regulation (EC) 593/2008 on the law applicable to contractual obligations (the "Rome I Regulation") can apply to product liability matters. Generally, the requirement under this law provides that "a contract for a sale of goods shall be governed by the law of the country where the seller has 'habitual residence'". This requirement supplements any country-specific requirements in that regard.

Given the complexity of these above regimes, careful legal analysis must be deployed to ensure the correct jurisdiction of the claims applies, as often this can be the determining factor of whether a claim succeeds or fails.

Regulation (EU) 1215/2012 of the European Parliament and of the Council on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast) (the "Recast Brussels Regulation") regulates jurisdiction and the recognition and enforcement of judgments between EU member states.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

The member state in which the product liability claim is made often has specific pre-litigation steps a claimant must take before being permitted to bring a formal claim.

2.6 Rules for Preservation of Evidence in Product Liability Claims

Member states within which a product liability claim is made often have their own rules protecting against the destruction of evidence and/or maintaining preservation of evidence in respect of product liability claims.

Within the EU, claims can and do proceed even in the absence of the "defective" device or product itself.

2.7 Rules for Disclosure of Documents in Product Liability Cases

Requirements for disclosure in product liability cases are heavily reliant on the rules of each member state within which the claims are brought. The rules for which documents may be withheld on the basis of legal privilege differ vastly from member state to member state. In addition, common law system countries tend to have wider concepts of disclosure than civil law system countries.

2.8 Rules for Expert Evidence in Product Liability Cases

Rules in respect of expert evidence in product liability cases are heavily reliant on the rules of each member state within which the claims are brought. Generally, however, EU rules governing such evidence are strict.

In a similar vein to the concept of disclosure, civil law systems often have more stringent formalities attached to and greater weight placed on expert evidence, in comparison with common law systems. It is also the case for oral vs written testimony and collaboration between opposing parties and their experts. Additionally, the courts in some EU jurisdictions are heavily guided by a court-appointed expert.

2.9 Burden of Proof in Product Liability Cases

Under the PLD, the strict liability mechanism means claimants are not obliged to prove negligence or fault of the defendants. Article 4 of the PLD specifies that the "injured person" is entitled to bring an action and must only prove damage, the defect and the causal relationship between defect and damage.

Similarly, Article 5 of the new Product Liability Directive provides that an injured person can bring an action if they have suffered damage caused by a defective product.

The mechanism and standard of proof required are determined in the member state within which the claim is brought.

2.10 Courts in Which Product Liability Claims Are Brought

The applicable civil procedure rules for any claim brought under the PLD will be determined by the laws of the member state within which the claim is brought.

Article 267 of the Treaty on the Functioning of the European Union allows the Court of Justice of the European Union (CJEU) to hear matters referred to it from national courts in respect of any claims stemming from the PLD. As the highest European court, the CJEU is the final decision-maker in any interpretation of EU law. Pending any judgment of the CJEU, local proceedings in member states are stayed.

2.11 Appeal Mechanisms for Product Liability Claims

Any mechanisms available to claimants in product liability claims are determined by the laws of the member state within which the claim is brought.

As noted in **2.10 Courts in Which Product Liability Claims Are Brought**, the CJEU is the final decision-maker in any interpretation of EU law and any matters referred from national courts.

2.12 Defences to Product Liability Claims

The statutory defences available to a defendant, the subject of a product liability claim, are set out under Article 7 of the PLD. These include the following:

- The defendant did not manufacture or distribute the product.
- The defect which caused the damage did not exist at the time the product was put into circulation.
- At the time the product was put into circulation, the state of scientific and technical knowledge was not such that it would enable the defect to be discovered (the "state of the art" defence).
- The defect is due to compliance with a mandatory regulatory requirement. In order to benefit from this defence, the defect must be caused by compliance with a specific regulatory requirement rather than mere compliance with all regulatory compliance obligations relating to that product. Compliance with relevant regulatory obligations does, however, remain a useful factor for defending a product liability claim.
- For any potential liability of a component manufacturer, the defect of the product is attributable to the design or instructions of the product in which the component has been fitted.

The new Product Liability Directive also provides that liability may be avoided by a person who modifies a product where the defectiveness that caused the damage is related to a part of the product not affected by the modification.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

The issue as to whether a product, which is subject to strict EU safety regulations and the requirements therein, can be defective if it complies with said regulations, remains a point of contention.

Whilst it appears that regulatory compliance will rarely be a full defence, compliance with the requirements of product safety regulations remains an important factor when considering a consumer's legitimate expectations under the PLD.

It is also the case that a breach of regulatory obligations can, on its own, give rise to separate liability which, in some circumstances, can lead to criminal sanctions against individuals of defendant companies.

2.14 Rules for Payment of Costs in Product Liability Claims

Rules for payment of costs are determined by the laws of the member state within which the claim is brought.

2.15 Available Funding in Product Liability Claims

Rules in respect of the availability of funding are determined by the laws of the member state within which the claim is brought. Third-party litigation funding is permitted and available in some member states, although to date, it has not been subject to any EU-wide regulation framework. The European Parliament's Legal Affairs Committee has put forward a proposal for a Directive on regulation of third-party litigation funding, titled the "Responsible private funding of litigation". The resolution proposing the Directive was approved by the European Parliament on 13 September 2022.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Each member state has its own specific procedures and rules in relation to mass litigation/collective redress with a wide disparity in the quality of such systems across the member states. Some countries have a high functioning system

of collective redress in mass harm situations, for example the Netherlands and Denmark, whilst others, including Ireland, Cyprus and Latvia, have poorly functioning systems regarding actions for mass harm.

Member states are, however, in the process of being required to implement into local laws an EU-wide collective redress regime. Directive (EU) 2020/1828, the Collective Redress Directive, which came into force in December 2020 and will become effective across the EU in June 2023, aims to improve consumers' access to justice and to facilitate redress where a number of consumers are victims of the same infringement of their rights. The Directive mandates that a procedure for representative actions is available across the entirety of the EU and introduces safeguards for the avoidance of abusive litigation and illegal practices. This will have a sizeable impact on EU jurisdictions with non-existent or poorly functioning systems for collective redress/mass tort litigation. Further detail is provided in **3. Recent Policy Changes and Outlook**.

2.17 Summary of Significant Recent Product Liability Claims

Product liability cases that interpret the PLD are relatively infrequent in the EU. However, a recent case offers an interesting insight into the CJEU's views on what constitutes a defective product and, perhaps more widely, the potential application of the PLD to software and other digital content.

In the case of Krone, Case C-65/20, a product liability claim was raised against Krone, an Austrian newspaper publisher, for damages suffered by a reader who had followed incorrect herbal medicinal advice for treating rheumatic pain that had been included in an issue of the newspaper of which she had referred to a printed copy. The question was referred to the CJEU for consideration.

The CJEU considered "whether health advice which, by its nature, constitutes a service, can […] result […] in the newspaper itself being defective in nature". It found that the printed newspaper acted as "merely the medium" of the service of providing inaccurate health advice. In separating the health advice from the printed newspaper and labelling it as a service, the CJEU concludes that the information – the medical advice – is excluded from the scope of the PLD and therefore inaccurate health advice included in a printed newspaper copy does not constitute a "defective product".

Given the growing presence of consumer goods that use software and digital content along with the complex liability risks involving digital technologies that blend both the physical and digital spheres, such as the internet of things (IoT) and AI, this judgment has the potential to have far-reaching consequences, particularly as to whether non-tangible products, such as software and other digital content, can qualify as a "product" for the purposes of the PLD.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Though there continues to be disparity between member states, it is widely acknowledged that product liability risks continue to rise. The availability and frequency of litigation are also increasing.

New Enforcement Practices

In response to the renewed focus on product safety enforcement, increased attention is being paid to market surveillance and regulators are being given greater powers, including by way of the implementation of new legislation in this area. This is reflected in the new General Product Safety Regulation, which seeks to align market surveillance rules, clarify obligations for economic operators, enhance market surveillance of dangerous products and facilitate more effective recalls.

Focus on Online Selling

In line with the general principles of EU product liability laws, there is now an increased focus on properly ascribing responsibility to online sellers in respect of product safety compliance obligations and breaches of the same, including by way of a requirement to have a local entity in place to nominally be responsible for these issues.

In July 2021, the MSR came into force to bring online platforms (OPs), including online marketplaces, within the remit of the EU's product safety framework, establishing more robust processes for market surveillance, compliance controls and promoting closer cross-border cooperation among enforcement authorities.

The EU-led "Product Safety Pledge" is a voluntary commitment, which goes beyond product safety legal obligations. It contributes to the faster removal of dangerous non-food consumer products offered for sale online and sets out actions by online marketplaces to strengthen product safety, such as providing a clear way for customers to notify dangerous product listings.

In addition, the new GPSR seeks to regulate the conduct of online marketplaces and lays down specific obligations for companies operating the same. Online content will also be regulated through the Digital Services Act, which came into force on 16 November 2022 and applied from 1 January 2024. The DSA aims to combat the risks posed by online content, reduce harm and protect users' fundamental rights.

The Digital Markets Act, which came into force on 1 November 2022 and applied from 2 May 2023, aims to regulate unfair practices amongst online platforms by levelling the playing field for digital companies.

Given the further growth of online sales during the COVID-19 pandemic, this topic has become one of particular focus for regulators and law makers alike.

Cybersecurity

Whilst cybersecurity regulation is not a new concept, with cybersecurity requirements having been accounted for in sector-specific regulation such as the EU Medical Devices Regulation, the EU has introduced a series of laws and initiatives in order to strengthen the framework governing cybersecurity risks, including those arising from connected products. The EU Cybersecurity Act which came into force in 2019 establishes an EU-wide cybersecurity certification for ICT products and services. The more recent NIS 2 Directive (EU) 2022/2555 which replaces the NIS Directive, aims to harmonise cybersecurity requirements and implement cybersecurity measures in member states.

The Cyber Resilience Act is also one step closer to becoming law after it was approved by the European Parliament in March this year. The Act sets obligations that apply to manufacturers of products with digital elements such as the implementation of essential cybersecurity

requirements, the carrying out of conformity assessment procedures and the notification of vulnerabilities and serious cybersecurity incidents to relevant bodies.

Development of Collective Redress Regime

Over the last decade, the EC has worked towards providing the means by which all EU consumers can bring collective actions in respect of infringements of EU law, referred to as "collective redress".

The Directive of the European Parliament and of the Council on representative actions for the protection of the collective interests of consumers 2020/1828 (the "Collective Redress Directive") empowers qualified representative entities to bring collective actions and seek injunctive relief and/or redress on behalf of groups of EU consumers who have been harmed by "illegal practices" that breach European laws, including the PLD and the GPSD and going forward the GPSR and new PLD.

The Directive, now in force, and due to apply from June 2023, supplements existing national procedural mechanisms aimed at the protection of collective consumer interests and is in the process of being transposed into member states' domestic legislation.

Modernisation of Product Safety and Liability Regimes

Significant reform has taken place with the GPSR and the new PLD, due to enter into force shortly, responding to issues created by modern technologies. However, this is an area which will need to be continually monitored as products continue to evolve and ensuring the fitness of its product safety and liability regimes will remain an going priority for the EU.

Corporate Social Responsibility and Environmental Sustainability

There continues to be a broadening of product compliance obligations to incorporate concepts of corporate social responsibility, environmental sustainability and increased focus on these areas. On 23 February 2022, the EC adopted a proposal for a Directive on corporate sustainability due diligence which was adopted in May this year. The aim of this Directive is to foster sustainable and responsible corporate behaviour and to anchor human rights and environmental considerations in companies' operations and corporate governance. The new rules will ensure that businesses address the adverse impacts of their actions, including in their value chains inside and outside Europe.

3.2 Future Policy in Product Liability and Product Safety

There are wide-ranging imminent policy developments in respect of product liability and safety in the EU in response to long-standing issues that have been major concerns for some time.

Artificial Intelligence

On 21 April 2021, the EC published its proposal for a regulation laying down harmonised rules on AI with the first ever legal framework on AI to address the risks and trustworthiness of AI, known as the AI Act. The AI Act adopts a risk-based approach to the regulation of AI, with the most stringent requirements and obligations imposed on those providing AI systems that are considered "high risk", such as AI-enabled medical devices. Certain "blacklist" AI technologies, which are at risk of causing individuals physical or psychological harm, are completely prohibited. On 16 June 2024, the Act was signed into law and awaits publication in the Official Journal. The proposed AI Act is now complemented by a proposal for a civil liability regime for AI, titled

the Directive on adapting non-contractual civil liability rules to artificial intelligence, published on 28 September 2022.

The measure is set to modernise and complement the EU liability framework by introducing new rules specific to damages caused by AI systems and enabling individuals who have suffered harm at the hands of AI systems to sue the provider.

The draft rules are intended to ensure persons that are harmed by AI systems have an equal level of protection as those harmed by other non-AI technologies in the EU. It also seeks to introduce a rebuttable "presumption of causality" which would alleviate the burden of proof in establishing damage caused by an AI system.

Digital Content and Services

On 1 January 2022, the new EU rules on digital content and the sale of goods entered into force. Directive (EU) 2019/770 on certain aspects concerning contracts for the supply of digital content and digital services and Directive (EU) 2019/771 on certain aspects concerning contracts for the sale of goods, are intended to harmonise key consumer contract law rules across the EU and introduce harmonised rules for digital content and digital services within the EU. For example, if digital content is or digital services are faulty, consumers now have rights similar to those they have when they buy defective tangible goods and, if the problem persists, may claim a price reduction or terminate the contract and claim a refund. This applies not only where consumers have paid for the content or services but also where they have provided personal data to the entrepreneur.

In addition, entrepreneurs who provide digital content or services as well as sellers of goods with digital elements (eg, a smartphone with its operating system or "smart products") are now required to supply consumers with updates that are necessary to keep the content, services or goods in conformity – especially but not necessarily limited to security updates. This obligation continues to apply for as long as the consumers may reasonably expect such updates in the individual case, which could be significantly longer than the statutory warranty periods.

Sustainability and the Environment

On 5 July 2024 the Directive on corporate sustainability due diligence was published in the Official Journal of the European Union. The aim of this Directive is to foster sustainable and responsible corporate behaviour and to anchor human rights and environmental considerations in companies' operations and corporate governance. The new rules will ensure that businesses address the adverse impacts of their actions, including in their value chains inside and outside Europe.

On 20 January 2022, the EC launched a public consultation seeking views on the proposed revision of REACH aiming to align the EU chemical rules with the EC's ambition for safe and sustainable chemicals and a high level of protection of health and the environment, while preserving the internal market. Movement on this has been notably slow and very little progress has been made.

The consultation is wide in scope and covers a range of topics, including the revision of registration requirements, such as establishing the obligation to register polymers, simplification of communication in supply chains and the revision of provisions for control and enforcement.

In a similar vein, the EU opened a public consultation, which closed on 21 June 2022, to consider how Cosmetics Products Regulation No 1223/2009 could be improved in order to protect public health and the functioning of the internal market. The EC's adoption of the proposal is awaited and progress is similarly slow on this. This proposed targeted revision of the Cosmetics Products Regulation sits alongside the proposed revision of other key chemicals legislation, including REACH and the CLP Regulation No 272/2008 regarding the classification, labelling and packaging of substances and mixtures, forming part of the EC's ambitious Chemical Strategy for Sustainability, and the wider European Green Deal, which seeks to protect citizens and the environment against hazardous chemicals and encourage innovation to foster the development of safer and more sustainable alternatives.

EU sustainability initiatives have developed further momentum in 2023. On 1 February 2023, the EC published its Green Deal Industrial Plan, which aims to provide a more supportive environment for the scaling up of the EU's manufacturing capacity for net-zero technologies and products to meet the EU's climate targets.

On 22 March 2023, the EC published proposals for a Green Claims Directive to tackle "greenwashing" and unsubstantiated environmental claims. On the same date, it published its proposal for a Directive on common rules promoting the repair of goods. Whilst the Green Claims Directive is still working its way through the machinations of the legislative process, the right to repair Directive on Common Rules has been signed into law.

The Directive promotes the repair of broken or defective goods, making it easier for consumers to seek repair instead of replacement, and making repair services more transparent and accessible. It increases manufacturers' obligations, requiring them to repair products that are technically repairable under EU law and making a voluntary repair form available with clear information on the repair process. Examples of products in scope include washing machines, dishwashers, and refrigerators.

Food Technological Practices

In 2022, the EC opened two public consultations to address the EU's goals outlined under the European Green Deal and the "farm to fork" strategy.

The proposal for a legislative framework for sustainable food systems (FSFS), one of the flagship initiatives of the farm to fork strategy, aims to accelerate, and make the transition to sustainable food easier. It was originally hoped that it would be adopted by the end of 2023; however, this has failed to materialise and it was notably absent from European Commission President Ursula von der Leyen's 2023 State of the Union address, nor was it present in the EU's 2024 Commission Work Programme.

The food waste initiative aims to propose legally binding targets. These targets will help limit the food supply chain's impact on the environment and climate and ensure more food is available for human consumption, thereby creating a more sustainable food system. In a similar vein, the Initiative on plants obtained by new genomic techniques aims to maintain a high level of protection for human and animal health and the environment, and enable innovation in the agri-food system. The Initiative will propose a legal framework for plants obtained by targeted mutagenesis and cisgenesis and for their food and feed products. It is based on the findings

of a Commission study on new genomic techniques.

Chemicals

Perfluoroalkyl and polyfluoroalkyl substances (PFAS) are subject to stringent regulation, including REACH restrictions, the Classification, Labelling and Packaging Regulation, and the Drinking Water Directive. The EC has also pledged to phase out all PFAS, allowing their use only where they are proven to be irreplaceable and essential to society. The European Chemicals Agency opened a six-month public consultation on 22 March 2023 on the proposed PFAS restriction. Please refer to the EU Trends and Developments article in this guide for further information.

Trends and Developments

Contributed by:
Sarah-Jane Dobson and Louise Forrest
Ashurst

Ashurst has a reputation for successfully managing large and complex multi-jurisdictional transactions, disputes and projects and delivering outstanding outcomes for clients. Ashurst has 31 offices in 18 countries and offers the reach and insight of a global network of legal, new law and risk professionals, combined with the knowledge and understanding of local markets. With over 490 partners and a further 2,000 lawyers working across 11 different time zones, the firm is able to respond to clients wherever and whenever required.

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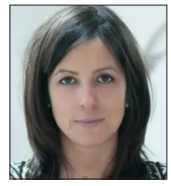

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EU Product Safety and Liability: a Rapidly Evolving Regulatory Landscape

In recent years, legislative and regulatory bodies in the EU have been prolific in bringing forward measures which have significant impacts in the fields of product safety and liability in a bid to keep pace with the latest developments in an ever-changing consumer world. Advances in technology and increases in digitalisation have brought changes to products on the market, as well as to how consumers purchase these products.

Coupled with this is the EU's drive to tackle both the environmental and social impact of companies. This is resulting in additional regulation impacting the product safety and liability regimes in the EU. The net effect is a complex and detailed regulatory system, with economic operator obligations and consumer rights spread across many diverse pieces of legislation.

Legal exposure

Representative actions

Against the backdrop of an increasing trend of consumer-led group actions globally, the EU Directive on Representative Actions for the Protection of the Collective Interests of Consumers (EU) 2020/1828 (the "Representative Actions Directive" or RAD) establishes a pan-European mechanism for collective redress to stop or prevent unlawful business practices that affect multiple claimants or compensate for the harm caused by these practices.

The Representative Actions Directive came into force on 24 December 2020 and member states were given two years to transpose it into their national laws. It became effective from June 2023. This expansion of access to collective mechanisms is likely to result in an increase in large group actions across the EU in relation to consumer products, as well as in other areas.

Increase in regulatory enforcement

The EU General Product Safety Regulation (GPSR), which entered into force on 13 June 2023 and will take effect from 13 December 2024, heralds a modernisation of product safety legislation in the EU. With it, and other recent measures, comes increased regulation of consumer products and it is highly likely, as a result, that this will have the knock-on effect of regulators being more active in the field of enforcement. The regulation aims to align market surveillance rules, clarify obligations for economic operators,

enhance market surveillance of dangerous products, and facilitate more effective recalls.

Focus on online platforms

There has been a significant increase in the use of online platforms in recent times, particularly since the COVID-19 pandemic. With this has come rising concern about the risks posed by online marketplaces and other platforms and a recognition of the need to protect the consumers using them.

In response, Regulation (EU) 2019/1020 on Market Surveillance and Compliance of Products (MSR) was put in place, coming into force from 16 July 2021. The regulations bring online platforms such as marketplaces within the scope of the EU's product safety framework and establish more robust processes, surveillance and enforcement of these platforms, particularly for consumer product sales.

Whilst the new GPSR will help regulate the conduct of online marketplaces, the increased use of such platforms is already giving rise to product liability litigation in the USA. In particular, US findings that e-commerce platforms can be considered a key part of the supply chain and are therefore integral to the sale of a defective product will inevitably impact any answers to similar questions posed to EU regulators and/or courts. It is expected that the EU will follow the same trend.

On a similar note, online content will also be regulated through the Digital Services Act (DSA), which came into force on 16 November 2022 and applied from 1 January 2024. The DSA aims to combat the risks posed by online content, reduce harm and protect users' fundamental rights.

The Digital Markets Act, which came into force on 1 November 2022 and applied from 2 May 2023, aims to regulate unfair practices amongst online platforms by levelling the playing field of digital companies.

Environmental, Social and Governance Considerations

A raft of different measures have recently come to fruition in the EU, incentivised by the EU's goal to reduce greenhouse gas emissions, minimise the use and waste of resources and achieve climate neutrality by 2050, while continuing to achieve economic growth.

Right to Repair

One such measure is the Directive on Common Rules promoting the repair of goods, published in the Official Journal on 10 July. The directive promotes the repair of broken or defective goods, making it easier for consumers to seek repair instead of replacement and making repair services more transparent and accessible. It increases manufacturers' obligations, requiring them to repair products which are technically repairable under EU law and making a voluntary repair form available with clear information on the repair process. Examples of products in scope include washing machines, dishwashers, and refrigerators.

Deforestation

Other measures making for more environmentally and socially conscious products include the deforestation regulation, requiring companies trading in certain commodities, as well as products derived from these commodities, such as leather, wood and rubber, to conduct comprehensive due diligence on their value chain to ensure such goods do not breach local environmental and social laws or cause deforestation.

Obligations in this regard will start to apply from 30 December 2024.

Chemicals

The PFAS restriction proposed by Sweden, Norway, Denmark, Germany and the Netherlands in 2022 is still with the European Chemicals Agency (ECHA), which is currently reviewing comments received during the consultation process and is due to meet in June and September.

Perfluoroalkyl and polyfluoroalkyl substances (PFAS), known as "forever chemicals" due to their persistent qualities, are an expanding group of man-made chemicals found in a wide range of products. Growing concern about their use has triggered wide-scale investigations and studies with regulators in many jurisdictions considering steps to address the potential risks they pose. Both businesses and the insurance market have voiced concerns over the potential for a tidal wave of PFAS contamination claims.

Green Claims

Given increasing consumer preference for sustainable products, greater pressure is being placed on both industry sectors and government to lower the environmental impact and carbon footprint of all products. Reacting to these rising demands from socially and ethically conscious consumers, there has been a surge in the prevalence of "greenwashing" – the practice of making exaggerated and misleading environmental claims to promote sales.

In response to this growing issue, the EC has launched several initiatives with a view to establishing jointly a coherent policy framework to help the Union to make sustainable goods, services and business models the norm, and to push consumption patterns in a more sustainable direction. The European Green Deal states that "[c]ompanies making 'green claims' should substantiate these against a standard methodology to assess their impact on the environment".

Greenwashing is addressed in the EU's 2020 Circular Economy action plan (the "Action Plan"), an initiative that targets how products are designed, promotes circular economy processes, encourages sustainable consumption, and aims to ensure the prevention of waste and re-use of resources within the EU economy for as long as possible. The Action Plan commits that "the Commission will also propose that companies substantiate their environmental claims using Product and Organisation Environmental Footprint methods".

The EC has noted the importance of ensuring that measures of the environmental performance of companies and products are reliable, comparable and verifiable across the EU. Not only would this allow consumers, companies and investors to make greener decisions, it would also undoubtedly reduce the risk of reputational damage or potential legal action by either environmental action groups or consumers for any company that fails to heed the greenwashing warnings.

These initiatives have culminated in the publication of a proposal for a Directive on substantiation and communication of explicit environmental claims, known as the Green Claims Directive, with a view to providing consumers with clarity on environmental claims and labelling. The Directive aims to tackle false green claims by ensuring that environmental claims and labels are credible and trustworthy. It also aims to boost the competitiveness of businesses that are striving to increase the environmental sustainability of their products and activities.

Manufacturers should be prepared for this to continue in the long term and even expand further as these topics impact all aspects of the manufacturing process. Companies should review any claims made in respect of ESG and ensure they can be supported by appropriate data if required.

Many other measures and proposed measures have implications for products, including the ban on products made with forced labour, the corporate sustainability due diligence directive, the draft regulation on packaging and packaging waste and new rules on empowering consumers for the green transition.

Advances in Technologies and Products

Artificial intelligence

With the rise in the deployment of artificial intelligence and proliferation of connected products, new considerations have arisen which continue to shape the landscape of consumer product regulation in the EU. These technologies are welcome given the unrivalled opportunities for innovation they create within consumer industries, but they also give rise to numerous liability risks, including in respect of product liability, security and privacy. The EU has reacted swiftly, enacting new laws and regulations to respond to the challenges they present.

The Artificial Intelligence (AI) Act, is the first of its kind and regulates AI in a comprehensive manner. It has wide-ranging applicability and will affect both AI providers and users inside and outside the EU. It adopts a risk-based approach, banning applications and systems that create an unacceptable risk, such as government-run social scoring. High-risk applications of AI, for example in robot-assisted surgery, are subject to specific legal requirements. Other applications where the risk is not categorised as either unacceptable or high are left largely unregulated.

The requirements set for high-risk applications are strict and aimed at ensuring the technologies invoked are both safe and transparent. They include:

- adequate risk assessment and mitigation systems;
- high quality of the datasets feeding the system to minimise risks and discriminatory outcomes;
- logging of activity to ensure traceability of results;
- detailed documentation providing all information necessary on the system and its purpose for authorities to assess its compliance;
- clear and adequate information to the deployer;
- appropriate human oversight measures to minimise risk; and
- high level of robustness, security and accuracy.

Another measure making its way through the legislative process, but at a much earlier stage, is the proposal for a Directive on adapting non-contractual civil liability rules to artificial intelligence, published on 28 September 2022. The measure is set to modernise and complement the EU liability framework by introducing new rules specific to damages caused by AI systems and enabling individuals who have suffered harm at the hands of AI systems to sue the provider.

The draft rules are intended to ensure persons that are harmed by AI systems have an equal level of protection as those harmed by other non-AI technologies in the EU. It also seeks to introduce a rebuttable “presumption of causal-

ity", which would alleviate the burden of proof in establishing damage caused by an AI system.

Cyber resilience

The Cyber Resilience Act is also one step closer to becoming law after it was approved by the European Parliament in March this year. The Act sets obligations that apply to manufacturers of products with digital elements, such as the implementation of essential cybersecurity requirements, the carrying out of conformity assessment procedures and the notification of vulnerabilities and serious cybersecurity incidents to relevant bodies.

Product liability modernisation

The new Product Liability Directive (PLD), which was formally adopted by the European Parliament on 12 March this year, updates a 40-year-old regime to take account of the digital age and circular economy activities. It covers digital products such as software and AI as well as remanufactured and refurbished equipment. The new rules will apply to products placed on the market 24 months after the entry into force of this Directive.

Given the significant advancements in technology and products, as well as methods of selling, regulators have found themselves in a race to keep up with the pace of change and address risks that may be posed to consumers. This game of cat and mouse shows no signs of abating, but recent measures have offered a glimmer of hope. These new regulations may provide a much-needed respite, allowing manufacturers and other economic operators to adapt and confidently navigate the ever-growing maze of compliance requirements.

FRANCE

Law and Practice

Contributed by:
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LexCase

Contents

LexCase was founded in 2009 as an entrepreneurial project to establish a multidisciplinary law firm. It is present in Paris, Lyon and Marseille and has close links with foreign law firms. Regional, national and international, LexCase relies on the proximity with its clients with a view to excellence. On the strength of its recognised expertise, LexCase continues to grow by acquiring leading experts to advise and support its private and public clients in the implementation and success of their various projects. The firm created "Fondation LexCase", hosted by the Fondation de France. Through this initiative, the firm joined the international collective 1% for the planet, pledging 1% of its turnover to provide financial and operational support to projects run by associations dedicated to environmental protection.

Author

Diane Bandon-Tourret has experience in French and English law firms, and has developed a practice in industry law (pharmaceutical laboratories, medical device manufacturers, cosmetics and food supplements, food, and so on), on which she has been advising and litigating for over 15 years. At LexCase, she advises manufacturers on their regulated activities, including marketing, pricing, promotion, compliance with the sector's anti-corruption and ethics regulations, and the distribution and withdrawal of products. She also represents her clients in disputes with the relevant authorities. She handles serial product liability litigation as well as unfair competition disputes on a daily basis.

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1. Product Safety

1.1 Product Safety Legal Framework

In France, product safety is governed by several regulations, depending on the nature of the products and their intended use, as well as by general or sector-specific legislation. In France, consumer law, understood as all the legal and regulatory provisions designed to protect the consumer (any natural person acting for purposes which do not fall within the scope of their commercial, industrial, craft, liberal or agricultural activity) has been particularly developed under the influence of EU law.

The Consumer Code has been comprehensively overhauled to make the texts easier to read and the regulations more accessible, by the Order of 14 March 2016 for the legislative part and the Decree of 29 June 2016 for the regulatory part. It is now divided into eight books dealing respectively with consumer information and commercial practices, formation and performance of contracts, credit, conformity and safety of products and services, powers of investigation and follow-up to inspections, dispute resolution, handling of over-indebtedness, approved consumer protection associations and consumer institutions and is regularly the subject of reform.

It lays down a general obligation for products to comply with regulations in force relating to the health and safety of individuals, fair trading and consumer protection, when they are first placed on the market. General compliance measures are detailed, as well as special obligations according to the nature of the products concerned.

There is a general safety obligation, under which products must, in normal conditions of use or in other conditions reasonably foreseeable by the professional, be as safe as can legitimately be expected and not be harmful to people's health. A product is considered to meet the general safety requirement if it complies with the specific regulations applicable to it for the protection of consumer health or safety. A product is presumed to satisfy the general safety requirement, as regards of the risks and risk categories covered by the standards applicable to it, when it complies with the non-mandatory national standards transposing the European standards (whose references have been published by the European Commission in the Official Journal of the European Union pursuant to Article 4 of Directive 2001/95/EC of 3 December 2001 on general product safety).

In other cases, the compliance of a product with the general safety requirement is assessed by taking into account the following elements in particular, when they exist:

- 1. Non-mandatory national standards transposing European standards applicable to the product other than those whose reference is published in the Official Journal of the European Union pursuant to Article 4 of Directive 2001/95/EC of 3 December 2001 on general product safety.
- 2. Other French standards.
- 3. European Commission recommendations establishing guidelines for product safety assessment.
- 4. Good practice guides on product safety in force in the sector concerned.
- 5. The current state of knowledge and technology.
- 6. The safety that consumers can legitimately expect.

It should also be noted that the new European Regulation (EU) 2023/988 of 10 May of 2023 on general product safety, published 13 days later

will come into force in France on 13 December 2024.

In the area of liability, Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products was transposed into French law within the Civil Code after a certain delay. In French liability law, fault-based liability, which has a different basis from liability for defective products, is also frequently used in product safety matters, as the basis of hidden defects. Product safety issues also involve the criminal liability of the individuals and companies concerned, based on general or special criminal law offences. They may also give rise to financial penalties from the competent authorities.

1.2 Regulatory Authorities for Product Safety

The DGCCRF is the reference authority for product safety. The DGCCRF's scope of intervention is very broad and covers a wide variety of products. Indeed, the DGCCRF is also involved in all non-food products and services, and at all levels (production, import, and distribution). Action is stepped up in high-risk areas such as toys and childcare articles, sports and leisure activities, and everyday accidents. Most of the safety actions are based on the expertise of laboratories (Joint DGCCRF and Customs Laboratory Service).

As part of the administrative c-operation organised by Regulation (EU) 2017/2394 of the European Parliament and of the Council of 12 December 2017 on co-operation between national authorities responsible for the enforcement of consumer protection laws and repealing Regulation (EC) No 2006/2004, when a request for mutual assistance is made by a member state of the European Union or by the European Commission, the investigation, detection and cessation of infringements or breaches are carried out by the DGCCRF in accordance with the provisions of the Consumer Code.

Other authorities have jurisdiction depending on the products concerned.

For example:

- In the area of food safety, while this mission was previously shared between the Directorate-General for Food of the Ministry of Agriculture and Food Sovereignty (DGAl) and the DGCCRF, in mid-2022 the DGAl was transferred the responsibilities of the DGCCRF, which since 1 January 2024 has taken on missions relating to food safety, and on the management of health crises or contamination.
- The French National Agency for the Safety of Medicines and Health Products (ANSM) is responsible for monitoring the safety of health products regulated by the Public Health Code. It should be noted, however, that as part of the Finance Act for 2023, Decree No 2023-1113 of 28 November 2023 relating to the competent authorities for the supervision and vigilance of cosmetic and tattoo products removed cosmetic and tattoo products from the remit of the ANSM and the DGGCRF has been designated as the competent authority for inspection, control, and market surveillance missions.

1.3 Obligations to Commence Corrective Action

The consumer code states that producers shall adopt measures which, taking into account the characteristics of the products they supply, enable them:

- 1. To keep informed of the risks that the products they market may present.
- 2. To take the necessary action to control these risks, including withdrawal from the market, appropriate and effective warnings to consumers and recalls from consumers of products placed on the market.

These measures may, in particular, consist of carrying out sample tests or indicating on the product or its packaging instructions for use, the identity and address of the producer, and the reference number of the product or batch of products to which it belongs. These indications may be made compulsory by order of the Minister for Consumer Affairs and the minister(s) concerned (Article 423-3 of the Consumer Code).

When a producer or distributor is aware that products it has placed on the market for consumers do not meet the legal requirements, it must take the necessary action to prevent risks to consumers and immediately inform the competent administrative authorities. The details of this information are defined by order of the Minister for Consumer Affairs and the ministers concerned. The producer or distributor may not exonerate itself from its obligations by claiming not to have been aware of the risks of which it could not reasonably have been unaware.

When withdrawal or recall measures are implemented, professionals draw up and keep up to date a quantified statement of the products withdrawn or recalled, which they make available to authorised agents.

Since 1 April 2021, professionals have also been obliged to declare their product recalls on the official Rappel Conso website, in accordance with Article L423-3 of the French Consumer Code.

Specific obligations are also set out for certain types of products, in particular food and health products.

1.4 Obligations to Notify Regulatory Authorities

First, the Consumer Code lays down a general safety obligation for any producer or distributor who has marketed a product or service that does not meet safety requirements (Articles L423-3 and L421-3 of the Consumer Code). The operator must then immediately initiate the necessary measures (notably withdrawal and/or recall) and notify the authorities. This provision applies regardless of the product placed on the market, as long as it is intended for consumers. The Article also introduces a mandatory reporting procedure on the competent authority's website (see **1.3 Obligations to Commence Corrective Action**).

Specific obligations are also set out for certain types of products, in particular food and health products.

1.5 Penalties for Breach of Product Safety Obligations

Failure to notify the competent administrative authorities is punishable by a fine of EUR1,500 (Article R452-2 of the Consumer Code), which can be increased up to five times for legal entities.

Furthermore, following an authority control, administrative police measures can be taken, such as compliance injunctions accompanied by a daily fine of up to EUR3,000 (Article L521-1 of the Consumer Code), or a one-year marketing suspension in the event of serious or immediate danger (Article L521-17 of the Consumer Code).

The operator may also be penalised for misleading commercial practices, in which case the fine will be increased to 50% of the expenses incurred by the practice constituting the offence (Article L132-2 of the Consumer Code). Article L132-4 of the Consumer Code provides for additional penalties, such as posting or distributing the decision or a press release to inform the public. Following the adoption of Regulation (EU) 2023/988 in May 2023 on general product safety, which applies from 13 December 2024, Article 2 of Law No 2024-364 of 22 April 2024 containing various provisions for adapting to European Union law in the fields of economics, finance, ecological transition, criminal law, social law and agriculture (known as the DADDUE Law) transposed the measures requiring adaptation of French law, in particular the higher penalties for product recalls now provided for in Article L452-5-1 of the Consumer Code (five years' imprisonment and a fine of EUR600,000, which may be increased to 10% of the average annual turnover of the operator in question).

Articles L521-1 et seq of the French Consumer Code lay down specific obligations in terms of measures taken by the DGCCRF to protect consumer safety. The DGCCRF may issue injunctions, which may be publicised. The injunction may be accompanied by a daily penalty payment of up to EUR3,000. The total amount requested to pay the penalty may not exceed EUR300,000.

Where the infringement is punishable by a fine of at least EUR75,000, the periodic penalty payment ordered in application of this article may be determined on the basis of the worldwide turnover excluding tax achieved by the controlled legal entity during its last financial year, but may not exceed 0.1% of this turnover. The total of the sums requested for the liquidation of the periodic penalty payment may not exceed 5% of the worldwide pre-tax turnover for the last financial year for which the accounts have been closed.

It can also take more severe measures, in particular police decisions, following a procedure described in Articles L521-1 et seq of the French Consumer Code. Specific measures are detailed for establishments and products (Articles L521-5 to L521-18) and services (Articles L521-19 to L521-26).

Specific obligations are also set out for certain types of products, in particular food and health products.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

Product Liability

This regime is covered by Articles 1245-1 et seq of the Civil Code, which transpose Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products. This is the so-called objective liability regime, under which the producer is liable for damage caused by a defect in his/her product, whether or not he/she is bound by a contract with the victim.

A producer, when acting in a professional capacity, is the manufacturer of a finished product, the producer of a raw material or the manufacturer of a component part.

Any person acting in a professional capacity is deemed to be a producer:

- who presents himself/herself as a producer by affixing his/her name, trade mark or other distinctive sign to the product; and
- who imports a product into the European Community with a view to sale, hire, with or without a promise to sell, or any other form of distribution.

If the producer cannot be identified, the seller, the lessor, with the exception of the lessor or the lessor assimilated to the lessor, or any other professional supplier, is liable for the safety defect in of the product, under the same conditions as the producer, unless he/she designates his/her own supplier or the producer, within a period of three months from the date on which the victim's claim was notified to him.

The supplier's claim against the producer is governed by the same rules as a claim by the direct victim of the defect. However, he/she must act within one year of the date on which he/she is summoned to appear in court. In the event of damage caused by a defect in of a product incorporated into another, the producer of the component part and the producer who incorporated it are jointly and severally liable.

This system applies to compensation for damage resulting from injury to the person, where the compensation for damage exceeds EUR500, or resulting from damage to property other than the defective product itself.

The claimant must prove the damage, the defect and the causal link between the defect and the damage.

Tort Law

The victim of an injury caused by a defective product also has the right to claim damages from the producer if he/she proves that his/her injury resulted from a fault committed by the producer.

This principle was reaffirmed by the Court of Cassation in a recent decision (First Civil Chamber of the Court of Cassation, 15 November 2023 – appeal No 22-21.174). In a press release relating to this decision, the Court of Cassation illustrated this principle by providing examples of fault (if the producer kept a product in circulation even though he/she knew it had a defect, or if he/she was not sufficiently vigilant as to the risks posed by the product).

The claimant must prove the fault, the damage and the causal link between the fault and the damage.

Hidden Defect

The seller is liable for any hidden defects in the goods sold which render them unfit for their intended use, or which impair that use to such an extent that the buyer would not have purchased them, or would have paid a lower price for them, had he or she been aware of them.

The seller is not liable for apparent defects of which the buyer has been able to convince themselves.

They are liable for hidden defects, even if they did not know about them, unless, they stipulated that they will not be obliged to provide any guarantee.

If the seller was aware of the defects, they are liable to the buyer for all damages in addition to restitution of the price received. On the other hand, if the seller was unaware of the defects, they will only be obliged to refund the price and reimburse the buyer for the costs incurred by the sale.

Criminal Law

In addition, common law offences may be established, in particular those relating to unintentional harm to the human body, administration of harmful substances, endangering others and failure to assist a person in danger.

There are also offences under criminal consumer law, including misleading commercial practices (Article L132-2 of the Consumer Code up a two-year prison sentence and a EUR3 million fine).

The offence of deception may also be constituted. Deception is defined as the act by any person, whether a party to the contract or not, of deceiving or attempting to deceive the contracting party, by any means or process whatsoever, even through the intermediary of a third party:

- either as to the nature, species, origin, substantial qualities, composition or content in useful principles of any goods;
- on the quantity of the goods delivered or on their identity by the delivery of goods other than the specific goods which were the subject of the contract; or
- on the suitability for use, the risks inherent in the use of the product, the tests carried out, the instructions for use or the precautions to be taken.

Deception, or attempted deception, is punishable by two years' imprisonment and a fine of EUR300,000 (Article L454-1 of the Consumer Code), which may be increased to EUR750,000 and seven years' imprisonment.

2.2 Standing to Bring Product Liability Claims

Product Liability

Any claimant is entitled to bring an action if they meet the conditions of law and if they are seeking compensation for damage more than EUR500 resulting from an injury to the person.

Tort Law

The tort action is open to all claimants or their beneficiaries who meet the conditions of law.

Hidden Defect

The buyer has the right to initiate the action against the seller.

2.3 Time Limits for Product Liability Claims

Product Liability

In the absence of fault on the part of the producer, the producer's liability is extinguished ten years after the product which caused the damage was put into circulation, unless the victim has taken legal action during this period.

An action for damages shall be barred within three years from the date on which the claimant knew or ought to have known of the damage, the defect and the identity of the producer.

Tort Law

Personal or movable actions are time-barred after five years from the date on which the holder of a right knew or should have known of the facts enabling him/her to exercise it (new Article 2224 of the Civil Code).

Liability claims arising from an event resulting in bodily injury, brought by the direct or indirect victim of the resulting damage, are time-barred after ten years from the date of consolidation of the initial or aggravated injury (new Article 2226 of the Civil Code).

Hidden Defect

A person who discovers a defect in a property sold to them has two years to bring an action

under the warranty for hidden defects. This period may be suspended if an expert assessment has been ordered. This warranty action must also be brought within 20 years after the sale of the property (Cour de cassation, 21 July 2023 Chambre mixte – Pourvois Nos 21-15.809, 21-17.789, 21-19.936, and 20-10.763).

2.4 Jurisdictional Requirements for Product Liability Claims

Unless otherwise provided, the court having territorial jurisdiction is that of the place where the defendant is domiciled. If there are several defendants, the plaintiff may choose to bring proceedings in the court for the place where one of them is domiciled. The plaintiff may also choose:

- in matters relating to a contract, the court of the place where the goods were actually delivered, or the service was rendered; and
- in matters relating to tort, the court of the place where the harmful event occurred or the court of the place where the damage was suffered (Articles 42 and 46 of the Code of Civil Procedure).

In the context of liability for defective products, there is an international convention that deals specifically with the law applicable in the event of damage caused by a defective product (the 1973 Hague Convention on Liability for Defective Products).

In consumer law, the consumer may bring the matter either before one of the courts with territorial jurisdiction under the Code of Civil Procedure, or before the court of the place where the consumer lived when the contract was concluded or when the harmful event occurred (Article R631-3 of the Consumer Code).

In group actions, the court with territorial jurisdiction is that of the place where the defendant lives. The Paris court has jurisdiction if the defendant lives abroad or has no known domicile or residence.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

This is not applicable in France.

2.6 Rules for Preservation of Evidence in Product Liability Claims

Under French law, it is incumbent upon each party to prove, in accordance with the law, the facts necessary for the success of its claim and the judge has the power to order, ex officio, all legally admissible measures of inquiry (Articles 9 and 10 of the Code of Civil Procedure).

Except where the law provides otherwise, evidence may be adduced by any means (Article 1358 of the Civil Code).

Furthermore, in a judgment handed down on 22 December 2023 (No 20-20.648), the plenary session of the *Cour de Cassation* ruled on the conditions for admissibility of evidence obtained or produced in an unlawful or unfair manner under certain strict conditions.

2.7 Rules for Disclosure of Documents in Product Liability Cases

If there is a legitimate reason to preserve or establish, prior to any legal proceedings, proof of facts on which the resolution of a dispute may depend, legally admissible investigative measures may be ordered upon request of any interested party, on application or in summary proceedings (Article 145 of the Code of Civil Procedure). The latter requires for the applicant to demonstrate the existence of a legitimate reason. The assessment of what constitutes a

legitimate reason within the meaning of this text falls within the discretionary power of the court hearing the case. The futility of the measure requested is in itself an obstacle to the existence of a legitimate reason. Indeed, case law rules out the existence of a legitimate reason when the request is not based on any precise, objective and verifiable fact, and the applicant does not therefore demonstrate the existence of a plausible, credible dispute, albeit possible and future, the content and basis of which would be identified, at least approximately (Court of Cassation, Civil Division 2, 10 December 2020, 19-22.619, Published in the Bulletin).

Civil courts have held that business secrecy does not in itself constitute an obstacle to the application of the provisions of Article 145 of the Code of Civil Procedure. Therefore, it is up to the interim relief judge to check whether the measure ordered is necessary for the applicant to exercise his/her right to evidence and proportionate to the conflicting interests involved (Cass 2nd civ, 25 March 2021, No 20-14.309).

Where, in the course of civil or commercial proceedings relating to an investigative measure requested prior to any trial on the merits or in the course of proceedings on the merits, reference is made to or the communication or production of a document is requested which is alleged by a party or a third party or which has been deemed to be of such a nature as to infringe a business secret, the judge may, of his/her own motion or upon request of a party or a third party, if the protection of this secrecy cannot be ensured otherwise and without prejudice to the exercise of the rights of the defence:

- Take cognisance of the document alone and, if necessary, order an expert report and seek the opinion, for each of the parties, of a person authorised to assist or represent them, in order to decide whether to apply the protective measures provided for in this article.
- Decide to limit the communication or production of this document to certain of its elements, order its communication or production in summary form or restrict access to it, for each of the parties, to a maximum of one natural person and one person authorised to assist or represent him or her.
- Decide that the hearing will take place and that the decision will be handed down in chambers.
- Adapt the reasons for its decision and the means of publicising it to the requirements of protecting business confidentiality (Article L153-1 of the Commercial Code).

2.8 Rules for Expert Evidence in Product Liability Cases

There are no specific rules of evidence in relation to defective products before appointed experts.

In France, experts are appointed based on lists drawn up by the *Cour de Cassation* and the Courts of Appeal. Article 275 of the Code of Civil Procedure allows the expert to ask the parties directly to provide all documents he/she deems necessary in order to carry out his/her task. This request is not subject to any formalities and the parties must respond without delay. However, if the parties fail to do so, the expert will inform the judge, who may order the submission of documents under penalty.

On the other hand, the judge can order the parties to produce specially designated documents but cannot compel them to produce “any documents requested of them” by the expert.

2.9 Burden of Proof in Product Liability Cases

The burden of proving the elements constituting liability lies with the claimant.

In the case of vaccines alleged to be defective, the Court of Cassation has accepted the use of presumptions of fault to prove the defect and the causal link between the defect and the damage where there is scientific uncertainty. This has been validated by the Court of Justice of the European Union, subject to the the fact that the national courts ensure that the practical application they make of the said evidential system does not result in disregarding the burden of proof established by Directive or in undermining the effectiveness of the liability system established by this Directive. It also states that the Directive precludes a system of proof based on presumptions which would always be regarded as established when certain predetermined factual indications of causation are met (Judgment of the Court (Second Chamber) of 21 June 2017, N. W and Others v Sanofi Pasteur MSD SNC and Others).

2.10 Courts in Which Product Liability Claims Are Brought

In civil matters, the competent courts are generally the civil courts (*Tribunal d'instance* in civil matters, for all personal actions or actions up to the value of EUR10,000 and *Tribunaux judiciaire*) or the commercial courts (*Tribunal de commerce*).

In the case of healthcare products, the administrative courts may deal with product liability under the no-fault liability regime applicable to healthcare establishments in respect of the healthcare products they use (a regime established by the Court of Justice of the European Union in its decision CJEU, 21 December 2011, CHU de Besançon c/ Thomas D... CPAM du Jura, aff. C-495/10) and subsequent warranty claims (depending on the nature of the contracts between the establishments and the producers).

In criminal matters, special courts have jurisdiction.

Finally, in the case of health products, the alternative methods introduced via the CCI or ONIAM are also likely to apply.

2.11 Appeal Mechanisms for Product Liability Claims

In civil cases, the appeal procedure is governed by the Code of Civil Procedure (CPC).

The time limit for appeal is:

- one month for contentious judgments (CPC, Article 538); and
- 15 days for orders including summary orders (CPC, Article 490) or those of the pre-trial judge (CPC, Article 795) as well as for decisions of the enforcement judge (CPC, Articles R. 121-20 and R. 311-7).

Appeals against criminal judgments are governed by specific rules set out in the Code of Criminal Procedure.

2.12 Defences to Product Liability Claims

In the case of defective products, the producer is automatically liable unless he/she can prove:

- that he/she did not put the product into circulation;
- in regards to the circumstances, it must be considered that the defect which caused the damage did not exist at the time when the

product was put into circulation by him/her or that this defect arose subsequently;
- that the product was not intended for sale or for any other form of distribution; and
- that the state of scientific and technical knowledge at the time he/she put the product into circulation did not allow the existence of the defect to be detected, except where the damage was caused by an element of the human body or by products derived from it.

On that aspect, the *Cour de Cassation* has decided to refer a question to the *Conseil constitutionnel* on the point of knowing whether, in order to exonerate the liability of the manufacturer of a defective product on the basis of the risk of development, the difference in treatment existing between the victims of bodily injury resulting from a health product, depending on whether or not this product is derived from the human body, is contrary to the principle of equality before the law (Civ. 1st, 5 January 2023, FS-B, No 22-17.439) – which was confirmed by the Constitutional Council (Decision No 2023-1036 QPC of 10 March 2023). On that matter, in a case involving Mediator, a drug used to treat diabetes, the *Cour de Cassation* recently ruled that the producer's knowledge of the product's safety defect precluded the development risk exemption from being invoked (Civ. 1re, 6 December 2023, F-D, No 22-21.238).

Otherwise, the defect is due to the product's compliance with mandatory legislative or regulatory rules.

The producer of the component part is also not liable if he/she establishes that the defect is attributable to the design of the product in which that part has been incorporated or to the instructions given by the producer of that product.

The producer's liability may be reduced or eliminated, having regard to all the circumstances, where the damage is caused jointly by a defect in the product and by the fault of the victim or of a person for whom the victim is responsible.

In matters of tort, the defendant may be exonerated in the event of fault on the part of the victim or force majeure.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Regarding product liability, the producer is automatically liable unless he/she can prove that the defect is due to the product's compliance with mandatory legislative or regulatory rules. It should be emphasised, however, that the producer may be liable for the defect even though the product was manufactured in compliance with the rules of the trade or existing standards, or if it was the subject of an administrative authorisation.

Compliance with regulatory requirements may also be asserted by the defendant in an action based on tort if the alleged fault consists of a breach of the regulations.

2.14 Rules for Payment of Costs in Product Liability Claims

In matters of liability and at the end of the proceedings, the costs incurred may, under certain conditions, be charged to the unsuccessful party.

Article 695 of the Code of Civil Procedure lists the costs. Indeed, costs include notably:

- bailiff's fees incurred in serving the summons, pleadings and judgment;
- the taxable fees of the lawyers appearing in the case, where their involvement is com-

pulsory, calculated on the basis of the value in dispute and made up of the fixed fee, the proportional fee and the graduated fee;
- the costs of judicial expertise; and
- compensation received by the winning party's lawyer under the legal aid scheme.

In his/her decision, the judge will rule on the costs in accordance notably with the provisions of Article 696 of the Code of Civil Procedure:

- losing party must pay the costs; or
- by reasoned decision, he/she may order that all or part of the costs be borne by another party (in particular where a party is only partially successful, or in view of the nature of the dispute).

In all cases, the judge shall consider the fairness or economic situation of the convicted party.

2.15 Available Funding in Product Liability Claims

No litigation funding exists. If the claimant's financial resources are insufficient for a trial before a French court, he or she may be entitled to financial assistance from the State, known as "*aide juridictionnelle*".

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Collective Action

Group action was introduced in France by the Consumer Act 2014-344 of 17 March 2014 and it allows victims of the same damage caused by a professional to group together and take legal action. The plaintiffs can thus defend themselves with a single file and a single lawyer.

In force since 1 October 2014, its scope was modified by Law No 2016-1547 of 18 November 2016 on the modernisation of the justice system and Law No 2018-1021 of 23 November 2018 on the evolution of housing, development, and the digital economy. A group action can be launched in the following areas:

- consumer and anti-competitive practices;
- health;
- environment;
- protection of personal data;
- discrimination in the workplace; and
- property rental.

The court with territorial jurisdiction is that of the place where the defendant lives. The Paris court has jurisdiction if the defendant lives abroad or has no known domicile or residence. The procedure is divided into two phases: the admissibility and liability phase, followed by the compensation phase.

Group action must meet a number of conditions:

- At least two people must consider that they have suffered damage as a result of the same breach of duty by the professional.
- The individuals must have recourse to an approved association or trade union whose statutory purpose relates to the interests being defended.

Depending on the area in which the group action is launched, it may claim compensation for individual material, non-material or bodily harm.

A draft law of 15 December 2022 on the legal regime for group actions aims to simplify group actions, provide better compensation for victims and reduce the time taken to bring cases to trial. This bill was passed by the National Assembly

on 8 March 2023 (Sen., No 420, 9 March 2023) and adopted by the Senate on 6 February 2024. It provides for far-reaching changes to the group action mechanism, including a single system for group actions extended to all matters, an extension of the damages that can be compensated (personal injury, material or non-material damage) and specialised courts.

According to available information, 32 group actions have been initiated in France since 2014, including 20 in the consumer field.

Consolidated Action

In France, certain actions are brought in the form of consolidated actions, in which the plaintiffs join together and act in a single action brought by a single lawyer, claiming identical damages for all the plaintiffs.

2.17 Summary of Significant Recent Product Liability Claims

Court of Cassation, Civil Division 1, 15 November 2023, 22-21.179

This decision deals with the principle that the victim may bring an action on the basis of product liability or on other grounds with a different basis, in particular fault.

In a press release dated 15 November 2023, the Court of Cassation supported this decision by stating that the Court had made it easier for the victim of a defective medicinal product to bring an action before the courts, since the victim can ask the manufacturer for compensation for the damage suffered by choosing to invoke either the product's defect or a fault committed by the manufacturer, which gives the victim more time to bring an action.

The *Cour de Cassation* noted that the CJEU had ruled that the reference in Article 13 of Directive, to the rights which the victim of damage may rely on under contractual or non-contractual liability must be interpreted as meaning that the system established by that Directive does not preclude the application of other systems of contractual or non-contractual liability based on different grounds, such as liability for latent defects or fault (ECJ, judgment of 25 April 2002, González Sánchez, C-183/00, paragraph 31).

It follows, according to the Court, that the victim of damage attributed to a defective product may bring an action for liability against the producer on the basis of the second of those provisions, if he/she establishes that his/her damage results from a fault committed by the producer, such as keeping the product in circulation of which he/she is aware of the defect or failing in his/her duty of care with regard to the risks presented by the product.

Cour d'appel de Rouen, Ch. civ. 25 April 2024, No 23/03137 (on referral from Cass. 1re civ., 5 July 2023, No 22-18.914, FS-B), Aff. C-338/24 Sanofi Pasteur, registered by CJEU on 7 May 2024

The Rouen Court of Appeal referred to the CJEU questions relating to fault vs lack of safety, the ten-year time-limit and the three-year time-limit in the following terms:

- Article 13 of Directive 85/374/EEC of 25 July 1985, in its interpretation resulting from the judgment of 25 April 2002 (Gonzalez Sanchez C-183/00) according to which the victim of damage may rely on other contractual or non-contractual liability regimes based on grounds different from that established by the Directive, to be interpreted as meaning that the victim of a defective product may seek compensation from the producer for his/her loss or damage on the basis of the general

system of fault-based liability by relying in particular on the fact that the product was kept in circulation, on a failure to fulfil his/her duty of care with regard to the risks presented by the product or, in general, on a safety defect in the product.
- Article 11 of Directive 85/374/EEC of 25 July 1985, according to which the rights conferred on the victim pursuant to the Directive lapse on expiry of a period of ten years from the date on which the product causing the damage was put into circulation, contrary to the provisions of Article 47 of the Charter of Fundamental Rights of the European Union in that it would deprive the victim suffering progressive damage caused by a defective product of his/her right of access to a judge.
- Article 10 of Directive 85/374/EEC of 25 July 1985, which fixes as the starting point of the three-year limitation period "the date on which the claimant knew or ought to have known of the damage", can it be interpreted as running only from the day on which the full extent of the damage is known. In particular, by setting a consolidation date defined as the point at which the condition of the victim of the bodily injury is no longer evolving, so that in the case of an evolving pathology, the limitation period does not begin to run, and not from the day on which the injury definitely appeared, in connection with the defective product, regardless of its subsequent evolution.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Following the adoption of Regulation (EU) 2023/988 in May 2023 on general product safety, which applies from 13 December 2024, Article 2 of Law No 2024-364 of 22 April 2024 containing various provisions for adapting to European Union law in the fields of economics, finance, ecological transition, criminal law, social law and agriculture (known as the DADDUE Law) transposed the measures requiring adaptation of French law, in particular the higher penalties for product recalls now provided for in Article L452-5-1 of the Consumer Code (five years' imprisonment and a fine of EUR600,000, which may be increased to 10% of the average annual turnover of the operator in question).

From 17 February 2024, new obligations set out in the European Digital Services Act (DSA) of 19 October 2022 will apply to online marketplaces, to ensure that sellers are identified, that information on products sold is more complete and that measures to recall non-compliant or dangerous products are more effectively relayed. These obligations will be monitored by the DGCCRF.

Law No 2020-105 of 10 February 2020 on the fight against waste and the circular economy (known as the Agec Law) introduced a reparability index for several product categories, which will become a sustainability index, with additional criteria. The durability index will initially apply to televisions (from 1 October 2024), then to washing machines (from 1 January 2025).

3.2 Future Policy in Product Liability and Product Safety

Proposal for a Directive on adapting non contractual civil liability rules to artificial intelligence and Proposal for a directive of the European Parliament and of the Council on liability for defective products will profoundly change the conditions for implementing product liability on the one hand and fault liability in the field of artificial intelligence on the other and should significantly change the rules applied in France.

Trends and Developments

Contributed by:
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LexCase

LexCase was founded in 2009 as an entrepreneurial project to establish a multidisciplinary law firm. It is present in Paris, Lyon and Marseille and has close links with foreign law firms. Regional, national and international, LexCase relies on the proximity with its clients with a view to excellence. On the strength of its recognised expertise, LexCase continues to grow by acquiring leading experts to advise and support its private and public clients in the implementation and success of their various projects. The firm created "Fondation LexCase", hosted by the Fondation de France. Through this initiative, the firm joined the international collective 1% for the planet, pledging 1% of its turnover to provide financial and operational support to projects run by associations dedicated to environmental protection.

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Diane Bandon-Tourret has experience in French and English law firms, and has developed a practice in industry law (pharmaceutical laboratories, medical device manufacturers, cosmetics and food supplements, food, and so on), on which she has been advising and litigating for over 15 years. At LexCase, she advises manufacturers on their regulated activities, including marketing, pricing, promotion, compliance with the sector's anti-corruption and ethics regulations, and the distribution and withdrawal of products. She also represents her clients in disputes with the relevant authorities. She handles serial product liability litigation as well as unfair competition disputes on a daily basis.

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The Most Significant Current Events in French Law That Stem From Case Law and Regulatory Developments

Recent developments in case law

There has been a wealth of recent case law interpreting the provisions of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products, as transposed into the French Civil Code. The 1st Civil Chamber of the *Cour de Cassation* is continuing its interpretation of the texts to influence the new Directive on liability for defective products voted by the European Parliament (COM (2022) 0495) on 12 March 2024.

First, the *Cour de Cassation* recalled that the system of liability for defective products makes it possible to act based on fault under national rules. This results from the terms of Article 1245-17 of the Civil Code, which states that "The provisions of this chapter (of the Civil Code on liability for defective products) do not affect the rights which the victim of damage may rely on under the law of contractual or extra-contractual liability or under a special system of liability".

In four decisions handed down on 15 November 2023 (No 22.21.174, No 22.21.178, No 22.21.179 and No 22.21.180), the 1st Civil Chamber of the Court of Cassation reiterated the principle that the victim of damage attributed to a defective product may bring an action against the producer based on fault. This fault may consist of keeping the product in circulation of which he/she is aware of the defect, or in failing in his/her duty of care regarding the risks presented by the product. More specifically, it relies on the wording of Article 1386-18, now 1245-17, of the Civil Code, transposing Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products, and the judgment of the Court of Justice of the European Communities of 25 April 2002 (ECJ, judgment of 25 April 2002, González Sánchez, C-183/00, paragraph 31), in which it held that the reference in Article 13 of the Directive to the rights which the victim of damage may rely on under contractual or non-contractual liability must be interpreted as meaning that the system established by the Directive does not preclude the application of other systems of contractual or non-contractual liability based on different grounds, such as liability for latent defects or fault.

This decision was the subject of a press release from the *Cour de Cassation*, which explained the significance of this decision, in particular by specifying that, in the event that the victim is unable to bring an action alleging a product defect within the statutory time limits, he or she may nevertheless seek to hold the producer liable by proving that he or she committed a fault, thereby benefiting from the longer time limits under ordinary civil liability law. However, these decisions and the accompanying press release do not resolve the issue of the distinction between product defect and fault. Indeed, the Court of Justice of the European Union requires that the fault-based liability regime can only be used when it is based on a different ground – ie, when it does not constitute a defect.

It should be noted that the draft Directive on liability for defective products of 12 March 2024 voted by the European Parliament (COM (2022) 0495) provides that in the legal systems of the member states, an injured person may have a right to compensation on the basis of contractual liability or on grounds of non-contractual liability other than the defectiveness of a prod-

uct, for example, liability based on the warranty for latent defects or fault, and that it is therefore appropriate that these provisions – which are also intended to achieve, inter alia, the objective of effective consumer protection – should not be affected by the Directive (recital 9). This provision already existed in Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products.

Regarding the causal link, the First Civil Chamber recently ruled on the question of its assessment when it is not exclusive. Referring to Articles 1245 and 1245-8 of the Civil Code, it held that it is up to the claimant to prove by any means that his/her damage is attributable at least in part to the product in question. A partial causal link is therefore sufficient to consider that the condition has been met. It should be noted that the Directive on liability for defective products, passed by the European Parliament (COM (2022) 0495) on 12 March 2024, has extensively reviewed the proof of the causal link, using presumptions.

It has also very recently recalled the conditions of prescription applicable to this system of strict liability. The First Civil Chamber reaffirmed its interpretation of the starting point of the three-year limitation period for actions under Article 1245-16 of the Civil Code in a judgment of 15 May 2024 (Cass 1re civ, 15 May 2024, No 22-23.985, F-D). In this case, a woman suffered trauma to her eye after handling a cream siphon on 31 August 2013, resulting in complete blindness in that eye.

Referring to Article 1386-17, now 1245-16, of the Civil Code, the First Civil Chamber recalled that, according to this text, an action for damages based on the provisions of Articles 1245 et seq of the Civil Code is time-barred within a period of three years from the date on which the plaintiff knew or should have known of the damage, the defect and the identity of the producer. It considers that in the case of personal injury, the date of knowledge of the damage should be taken to mean the date of consolidation, which alone enables the claimant to measure the extent of his or her damage. In the case referred to the Court of Cassation, the Court of Appeal had held that the claimant had become aware of the damage, the safety defect in the siphon and the identity of the producer on 31 August 2013, the day of the accident, and that the action had been time-barred since 27 January 2017. The Court of Cassation drew the consequences of its reasoning, holding that the Court of Appeal had violated the law. In this decision, the 1st Civil Chamber in fact confirmed its previous case law, in particular under its decision of 5 July 2023 (Cass 1e civ, 5 July 2023, No 22-18.914, FS-B).

These decisions raise questions about the distinction between the concepts of damage and injury in French law.

On this point, the draft Directive on liability for defective products of 12 March 2024 voted by the European Parliament (COM (2022) 0495) does not change the fact that damage is one of the elements used to determine the starting point of the three-year limitation period, which remains unchanged (Article 16, point 1 of the Directive). On the other hand, the ten-year limitation period has been amended. It is specified in this respect that the member states shall ensure that an injured party is no longer entitled to compensation on expiry of a period of ten years, unless that injured party has, in the meantime, brought proceedings against an economic operator who can be held liable. This period runs from the date on which the defective

product that caused the damage was placed on the market or put into service; or in the case of substantially modified products, from the date on which the product was made available on the market or put into service following its substantial modification. Henceforth, by way of derogation from this mechanism, where an injured party has been unable to bring proceedings within a period of ten years from the aforementioned dates because of the latency period for personal injury, the injured party is no longer entitled to compensation under this Directive on expiry of a period of 25 years, unless that injured party has, in the meantime, brought proceedings against an economic operator who can be held liable (Article 17(2)).

These interpretations by the First Chamber led the lower courts to refer the matter to the CJEU. In a decision dated 25 April 2024 (No 23/03137), the Rouen Court of Appeal referred to the CJEU questions relating to the distinction between fault and lack of safety, the ten-year time limit and the three-year time limit. More specifically, the questions referred to the CJEU are based on the following.

- Article 13 of Directive 85/374/EEC of 25 July 1985, as interpreted in the judgment of 25 April 2002 (González Sanchez C-183/00), according to which the victim of damage may rely on other systems of contractual or non-contractual liability based on grounds other than those established by the Directive, to be interpreted as meaning that the victim of a defective product may seek compensation from the producer for his/her loss or damage on the basis of the general system of fault-based liability by relying in particular on the fact that the product was kept in circulation, on a breach of his/her duty of care with regard to the risks presented by the product or, more generally, on a safety defect in the product.
- Article 10 of Directive 85/374/EEC of 25 July 1985, which fixes as the starting point of the three-year limitation period the date on which the claimant knew or ought to have known of the damage, can be interpreted as meaning that the limitation period can only run from the date on which the full extent of the damage became known, in particular by fixing a date of consolidation defined as the moment from which the condition of the victim of the personal injury is no longer evolving, so that in the case of an evolving pathology the limitation period does not begin to run, and not from the day on which the injury definitely appeared, in connection with the defective product, regardless of its subsequent evolution.
- Article 11 of Directive 85/374/EEC of 25 July 1985, according to which the rights conferred on the victim under the Directive lapse on expiry of a period of ten years from the date on which the product causing the damage was put into circulation, contrary to the provisions of Article 47 of the Charter of Fundamental Rights of the European Union in that it would deprive the victim suffering progressive damage caused by a defective product of his/her right of access to a court.

The case has been referred to the CJEU, which is expected to rule in the coming months.

Legal and regulatory news

Following the adoption of Regulation (EU) 2023/988 in May 2023 on general product safety, which applies from 13 December 2024, Article 2 of Law No 2024-364 of 22 April 2024 containing various provisions for adapting to European Union law in the fields of economics, finance, ecological transition, criminal law, social law

and agriculture (known as the DADDUE Law) transposed the measures requiring adaptation of French law, in particular the higher penalties for product recalls now provided for in Article L452-5-1 of the Consumer Code (five years' imprisonment and a fine of EUR600,000, which may be increased to 10% of the average annual turnover of the operator in question).

From 17 February 2024, new obligations set out in the European Digital Services Act (DSA) of 19 October 2022 will apply to online marketplaces, to ensure that sellers are identified, that information on products sold is more complete and that measures to recall non-compliant or dangerous products are more effectively relayed. These obligations will be monitored by the DGCCRF.

Law No 2020-105 of 10 February 2020 on the fight against waste and the circular economy (known as the Agec Law) introduced a reparability index for several product categories, which will become a sustainability index, with additional criteria. The durability index will initially apply to televisions (from 1 October 2024), then to washing machines (from 1 January 2025).

GERMANY

Law and Practice

Contributed by:
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Contents

Reusch Rechtsanwaltsgesellschaft mbH is a German boutique law firm specialising in product law and regulations, with a focus on product liability and product safety. With two offices in Germany (Berlin and Saarbrücken) and around 20 lawyers, it advises national and international medium and large-sized clients in areas such as product compliance and product laws, sustainable products and supply chains, supply chain contracts, market measures such as recalls, insurance law and digital affairs, digital product and production-related data protection, IT law and cybersecurity regulations. The firm's focus lies on practical legal solutions for medium-sized German and international companies in the mobility, mechanical engineering, railway, medical devices, industrial and consumer product industries.

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1. Product Safety

1.1 Product Safety Legal Framework

Unless a consumer product is already subject to more specific EU legislation, it must meet (at least) the requirements of the General Product Safety Directive 2001/95/EC (GPSD). This Directive has been implemented into German national law by the Product Safety Act (ProdSG) and establishes a certain "basic safety net" with which all products of any kind must comply. In December 2024, however, the GPSD will be replaced by a regulation on general product safety, meaning it will be necessary to update the ProdSG almost completely.

In addition to or instead of general product safety law, which in Germany is regulated in substance by the ProdSG and formally by the Market Surveillance Act (or the EU Market Surveillance Regulation), more specific, so-called "sectoral harmonisation" laws often apply. These include, for example:

- the Restriction of Hazardous Substances Directive, implemented in Germany by the ElektroStoffV and relating to hazardous substances in electrical and electronic equipment;
- the Low Voltage Directive, implemented in Germany by the 1st ProdSV and relating to electrical products intended for operation with rated voltages between 50 V and 1000 V AC or 75 V and 1500 V DC;
- the currently still valid Machinery Directive, implemented in Germany by the 9th ProdSV and relating to machinery and partly completed machinery placed on the market in the EU;
- the Radio Equipment Directive, implemented in Germany by the FuAG (the Radio Equipment Act), which applies to all electrical/electronic products that can transmit and receive radio waves via an antenna for communication or location purposes;
- the Electromagnetic CompatibilityDirective, implemented in Germany by the EMVG (the Electromagnetic Compatibility of Equipment Act), which regulates the requirements for electromagnetic compatibility;
- the Toy Safety Directive, implemented in Germany by the 6th ProdSV;
- the EU Medical Devices Regulation;
- the EU Construction Products Regulation;
- the EU Cybersecurity Regulation; and
- the EU Gas Appliances Regulation.

1.2 Regulatory Authorities for Product Safety

Germany is a federal republic and delegates some far-reaching responsibilities and powers to the federal states. Product safety laws are also found at both the federal and state levels.

Generally, the manufacturer or importer of consumer products is responsible for the safety and legal conformity of their products. Compliance with this responsibility is randomly checked by the market surveillance authorities of the federal states.

The Federal Office of Consumer Protection and Food Safety (BVL) co-ordinates market surveillance programmes.

Products that fall under the ProdSG are monitored by the (regional) market surveillance authorities responsible for the ProdSG, such as the Top-County Offices or trade supervisory authorities.

At the federal level, the Federal Ministry of Labour and Social Affairs (BMAS) is responsible for the ProdSG, the associated ordinances and the corresponding EU directives. There are

exceptions in the areas of toys (2nd ProdSV) and recreational craft (10th ProdSV), which are also the responsibility of the Federal Ministry of Economics and Energy (BMWi), as well as, for example, the EC Regulation on the Accreditation and Market Surveillance of Products.

The Federal Ministry of Food and Agriculture (BMEL), on the other hand, is responsible for the GPSD, which was implemented nationally with the ProdSG. The customs administration is involved through the Federal Ministry of Finance (BMF), which includes the Directorate General of Customs.

The ProdSG also assigns central tasks to the Federal Institute for Occupational Safety and Health (BAuA). As the national information and communication hub, it performs reporting, notification and information tasks in the context of market surveillance. BAuA supports the authorities responsible for market surveillance in a variety of ways, as follows.

- As the national contact point, it is responsible for official notification procedures to and from the EU Commission, and makes the results of German market surveillance on dangerous products available to other member states. Conversely, it receives notifications of defective and dangerous products from other member states, which it forwards to the competent authorities in the federal states.
- In consultation with the competent authorities or the EU, BAuA also carries out its own risk assessments of products. This applies to products where there is a justified assumption that they pose an immediate danger or a significant risk to health and safety.
- BAuA supports the surveillance concept of the competent authorities by scientifically evaluating the quality defects of products.

BAuA also leads the Product Safety Committee, which advises the BMAS on all issues related to the ProdSG.

Other important stakeholders at the federal level include:

- the Federal Network Agency (BNetzA), which is responsible for monitoring products subject to Directive 2014/53/EU on the making available on the market of radio equipment and Directive 2014/30/EU on electromagnetic compatibility;
- the Federal Motor Transport Authority (KBA), which is the competent authority for all vehicles intended for use on public roads;
- the Federal Office for Consumer Protection and Food Safety (BVL), which co-ordinates the activities of the food control authorities of the German states and is responsible for products such as cosmetics, food contact materials, toys, clothing and jewellery, which are regulated by the German Food, Commodities and Feed Act (LFGB);
- the German Institute for Construction Technology (DIBt), which monitors compliance with the requirements applicable to harmonised construction products;
- the Federal Institute for Chemicals (BfC), which is responsible for international activities in the regulation of industrial chemicals and the authorisation and evaluation of biocidal products, as well as the notification of biocidal products according to the Biocide Notification Ordinance; and
- the General Customs Directorate (GZD), which plays an important role in market surveillance, inspecting products imported from third countries and notifying the market surveillance authorities which, in turn, inform the customs authorities about dangerous or non-compliant products; the customs

authorities can identify and report suspicious goods more quickly on the basis of so-called risk profiles.

1.3 Obligations to Commence Corrective Action

The ProdSG requires manufacturers, importers and distributors to place only safe products on the market. Manufacturers must also conduct active market surveillance – for example, by taking random samples, investigating complaints and informing distributors, depending on how dangerous the product is.

Manufacturers must also take precautions to ensure that, in the event of a dangerous product, the danger is eliminated quickly and reliably. These measures must be proportionate to the product's characteristics and extend to withdrawal, appropriate and effective warnings, and recall. This means that manufacturers must operate a risk management system and take precautions in the event of a recall. Very similar requirements can be found in product-specific regulations, such as those for medical devices and pharmaceuticals.

It is also important that the competent authorities are informed as soon as it is known or there are clear indications that a product on the market poses a risk to the health and safety of persons. With the application of the new EU General Product Safety Regulation, the provisions on risk mitigation measures and in particular on recalls are not only broader but also more complex. In particular, substantive, formal and systematic requirements are specified, and deviations are generally not permitted.

German tort law also indirectly obliges manufacturers to prevent harm caused by their dangerous products and thus can be seen as a source of obligation to perform market actions as well.

1.4 Obligations to Notify Regulatory Authorities

According to Section 6 (4) of the ProdSG, manufacturers and importers are obliged to immediately inform the market surveillance authority responsible for their place of business if they know – or ought to know on the basis of the information available to them or their experience – that a consumer product which they have made available on the market presents a risk to the health and safety of persons; in particular, they must inform the market surveillance authority of the measures they have taken to prevent that risk.

Distributors also have certain obligations under the ProdSG. For example, according to Section 6 (5), a distributor may not sell consumer products if it knows they do not comply with the general requirements for products according to Section 3 of the ProdSG. In addition, distributors must notify the market surveillance authorities if they become aware of risks to the health and safety of persons posed by products.

However, the reporting requirements will change with the new EU Product Safety General, which will come into force on 13 December 2024. Manufacturers will be required to report accidents caused by a product through the EU's Safety Business Gateway if the accident results in death or serious injury. This limitation was not included in previous drafts, which would have meant that all accidents, no matter how trivial, would have had to be reported.

However, the question of how to interpret causation is likely to remain a challenge. Does every accident have to be reported, or only an accident

caused by an unsafe (ie, dangerous) product? Must all accidents that occurred during the use of the product and not because of the product be reported?

Importers and distributors are also required to report accidents, but the report must be made to the manufacturer. The manufacturer must then either report the accidents on their own or instruct the importer or one of the distributors to make the report for them. The law does not provide for the importer or distributor to refuse this instruction. The new regulations therefore impose obligations on importers and distributors for which they may not currently have internal procedures in place.

Online marketplaces, on the other hand, have their own reporting obligations. It will be necessary to clarify how this reporting obligation can be harmonised with the above-mentioned obligations of the manufacturer and/or importer or distributor. There is reason to fear that, in the future, several reports on the same incident will be submitted to the authorities in an uncoordinated manner, thus burdening rather than relieving market surveillance.

1.5 Penalties for Breach of Product Safety Obligations

Prior to the revision and restructuring, the ProdSG contained provisions on surveillance and sanctions. These are now supplemented by the new Market Surveillance Act (MÜG).

According to Section 40 of the ProdSG, repeated and persistent violations of individual, specific obligations under the ProdSG can be punished with imprisonment for up to one year or a fine. Manufacturers, importers and other addressees of the standard may be fined up to EUR50,000 if they violate the ProdSG intentionally or negligently. Section 39 of the ProdSG regulates the individual provisions on fines.

For example, a manufacturer commits an administrative offence and can be fined if they (intentionally or negligently) fail to include instructions for use with the product, contrary to Section 3 (4) of the ProdSG, even though this is the only way to ensure the safety and health of persons when using the product. It would also be an administrative offence if a manufacturer, contrary to Section 6 (1) No 2 of the ProdSG, does not state their contact address or does not state it correctly, or does not comply with the requirements in connection with the CE marking in accordance with Section 7 (2) of the ProdSG. Administrative offences can be punished with a fine of up to EUR100,000.

In the case of persistent repetition or deliberate action that endangers the life or health of another person or property of a certain value, a prison sentence of up to one year or a fine may also be imposed.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

The absolute core of the initial situation for claims for damages and compensation for pain and suffering in the area of product liability is that a protected legal interest (such as health, body or property) is harmed by a defective product. The main legal bases for claims in such situations under German law are the “classic” product liability under the German Product Liability Act (ProdHaftG) and the so-called “producer liability” under Section 823 of the German Civil Code (BGB) (classic tort law).

Product liability and producer liability are not the same thing, however; this is often misunderstood or confused. Product liability and producer liability are two different bases for claims for liability due to defective products, and differ in their requirements and legal consequences. Product liability is strict liability under the German Product Liability Act, while producer liability is based on Section 823 of the BGB. However, product liability and manufacturer's liability exist in concurrence with each other. Product liability therefore does not exclude liability under Section 823 of the BGB but is examined as a no-fault basis for claims before Section 823 of the BGB.

The main prerequisites for liability claims against (quasi-)manufacturers or responsible importers in the EEA are:

- a defective product (or breach of the duty of care to place only "safe" products on the market);
- the consequential resulting violation or harm of a protected legal interest (such as the health of a human being or property); and
- no (statutory) exclusion of liability.

If the claimant builds their claim based on tort law, the level of negligence on the part of the manufacturer (and that of the claimant) – or third parties – become relevant as well.

2.2 Standing to Bring Product Liability Claims

The persons or legal bodies who suffered harm or damage to their protected legal interests due to a defective product have standing to bring claims for product liability.

2.3 Time Limits for Product Liability Claims

Claims according to Section 1 of the ProdHaftG become statute-barred after three years, according to Section 12 thereof. The commencement of the limitation period is determined by the date on which the claimant became aware of the defect, or should have become aware of it. Otherwise, a claim under Section 1 of the ProdHaftG becomes statute-barred ten years after the date on which the manufacturer put the product into circulation, in accordance with Section 13 I of the ProdHaftG.

Claims according to Section 823 of the BGB are subject to the so-called "regular statute of limitations" and expire after three years, according to Section 195 thereof; the period begins at the end of the year in which the damage and the responsible party became known (or should have become known).

2.4 Jurisdictional Requirements for Product Liability Claims

The requirements to invoke the jurisdictions of the courts in Germany are still under discussion. According to the European Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters (Article 5 No 3 of the Brussels I Regulation), the court of the place where the harmful event occurred has jurisdiction in product liability cases. According to the established case law of the ECJ, this can be either the so-called "place of performance" (or the place of the accident) or the place where the chain of causes of the damage was set in motion (the "place of action"), with the plaintiff having the right to choose between these two places.

In 2014, the ECJ had to decide whether the place of action is:

- the place where the product was manufactured;
- the place where the product was marketed; or
- the place where the user acquired the product.

The ECJ ruling clarifies that, in intra-European cross-border product liability cases, actions can always be brought at the place of manufacture, as this is the place of action.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

Under German law, there are no mandatory steps that must be taken before proceedings can be commenced formally. Product liability claims and proceedings are the usual claims and need to be treated, prepared and engaged as any other type of civil law claims.

2.6 Rules for Preservation of Evidence in Product Liability Claims

German law does not currently contain any rules for the preservation of documents and other evidence in product liability cases. However, the claimant may need to prove their claims (and the defendant theirs), in which case not having sufficient proof at hand would obviously be a problem.

2.7 Rules for Disclosure of Documents in Product Liability Cases

German law does not currently contain any rules relating to the disclosure of documents or other evidence in product liability cases, but things will change with the implementation of the new EU Product Safety Regulation on the one hand, which foresees an obligation to preserve documentation on product safety and risk-related topics and, with the currently still discussed draft of a new EU Product Liability Directive on the other. The latter foresees not only a dramatic shift in the burden of proof system in favour of claimants (under certain requirements) but also the possibility of a disclosure and discovery order by courts against the defendants in special cases – ie, when situations and technical aspects are complex and the claimant, although showing the likeliness of a string of events that lead to liability, has no option other than assessing internal documents on the defendant's part. This is a major topic that lawyers and other stakeholders should monitor very closely.

2.8 Rules for Expert Evidence in Product Liability Cases

Experts will be appointed by the court, and the general rules apply.

2.9 Burden of Proof in Product Liability Cases

Generally, the burden of proof lies with the injured party. However, for claims under the Product Liability Act or under Section 823 of the BGB ("tort law"), the burden of proof is reduced. In simple terms, this means that the injured party "only" has to prove that a product was defective and that this defect was the cause of the damage and/or pain suffered. In this regard, the time of the injury is relevant, but not necessarily that the defect was present when the product was placed on the market. The burden of proof is thus effectively reversed in this respect, as the manufacturer must now prove that the product was free from design, manufacturing and instruction defects when it was placed on the market, and/or that it did not culpably breach any of the duties of care incumbent upon it.

These principles, which are already in place, will most likely be further adjusted in the future to the benefit of plaintiffs or to the detriment of producers and other stakeholders; see **2.7 Rules for**

Disclosure of Documents in Product Liability Cases.

2.10 Courts in Which Product Liability Claims Are Brought

Germany does not have jury courts. Regular courts based on general civil procedure legislation are the competent courts and will lead the case as any other. Damages under German law are thought to provide sufficient compensation for the actual and proven damages and pain suffered. There are no punitive damages or similar.

2.11 Appeal Mechanisms for Product Liability Claims

As stated in **2.10 Courts in Which Product Liability Claims Are Brought**, product liability claims and court procedures are regular civil law cases. Therefore, appeals and timeframes are no different than for non-product liability cases. Timeframes are neither defined nor foreseeable – they depend on many factors on a case-by-case basis.

2.12 Defences to Product Liability Claims

The defences to product liability claims work the same as most other defences against civil law claims: if required, the defendant needs to show or even prove that the claimant's assumptions are not correct or true. From a strategic perspective, it is therefore most helpful to have sufficient documentation on the design, testing and use case descriptions of a product and accompanying performance of the manufacturer, such as market and product monitoring, in order to prove that the major obligations of a manufacturer are being and have always been fulfilled (placing only safe products on the market, monitoring the market, etc).

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Non-compliance with regulatory requirements may not only be a clear indication of a (further) breach of due diligence obligations but may also be a direct indication of the defectiveness of the products concerned and thus of the liability of the responsible economic operator.

Consequently, this may also mean that the management of the company is personally liable for their own company, since it is possible that their own company was not managed with sufficient care.

2.14 Rules for Payment of Costs in Product Liability Claims

If brought to regular state courts, product liability claims are treated as any other. Thus, a loser-pays principle applies, under which all costs for the court, witnesses and attorneys (based on the statutory compensation volumes) are to be paid by the party that "loses" a case.

2.15 Available Funding in Product Liability Claims

In Germany, litigation funding has gained considerable importance, particularly in the context of mass tort litigation. Litigation funding is characterised by the fact that a third party not involved in the (arbitration) proceedings provides a party with all or part of the financial resources required to conduct the litigation. In return, the financier typically participates in the proceeds obtained by the financed party in the litigation – usually in the form of a percentage share and/or a so-called multiple of its investment. If the case is lost, the financier usually bears the full risk and loses its investment, while the financed party enjoys non-recourse.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Since 1 November 2018, consumer attorneys in Germany have been able to file lawsuits against companies on behalf of consumers. In these so-called "model declaratory actions", the courts can determine – at the request of a model plaintiff acting as a class action plaintiff – whether the requirements for comparable consumer claims against the company being sued are met. The claims can be based on all areas of law (eg, product liability law), always provided that consumers were (allegedly) affected by the business activity. This is obvious in the case of consumer products. However, even companies in the supply chain that have no direct contact with consumers can be exposed to consumer claims if consumers are affected by the use of the product.

Despite these precautions, however, this new type of action remains risky for companies, because a declaratory judgment action does not replace the already possible and well-established "non-genuine class actions", in which special purpose entities assert assigned claims of allegedly injured parties, but rather takes its place alongside them. As a result, plaintiffs in non-genuine class actions will be able to free-ride on the results of the model declaratory judgment action.

However, not every consumer protection organisation is entitled to sue: only associations with legal capacity that have been officially registered as consumer protection associations for at least four years prior to the filing of the action and that have a minimum number of members (ten associations or 350 natural persons) may bring an action. Associations may not engage in commercial activities nor pursue commercial objectives. They may not receive more than 5% of their financial resources from businesses, and must disclose their financial structure in the event of a dispute. Consumer advice centres or consumer associations that receive substantial public funding may bring an action in any case. The model declaratory action is only admissible if at least 50 consumers have submitted claims to the claims register within two months of the public announcement.

Class actions based on the EU model are another important tool. EU Directive 2020/1828 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC, which was adopted on 24 November 2020, has paved the way for collective or representative actions across Europe. It sets minimum standards for representative actions across Europe, but leaves the specific form of the legal framework to the member states. The scope of representative actions is defined quite broadly by the Directive. Similar to the model declaratory action, a European representative action can only be brought by so-called qualified entities. Member states may decide whether consumers who have their habitual residence in the member state where the representative action is brought must actively join the representative action (opt-in mechanism) or explicitly opt out of the representative action.

2.17 Summary of Significant Recent Product Liability Claims

In a European Court of Justice judgment of 5 March 2015, which is still relevant (ECJ (U) C 503/13 and C 504/13), the Court ruled that it is sufficient for certain products (those with a particular potential risk to life and limb – in this case pacemakers) to be considered legally "defective" if a potential defect has been iden-

tified. By this approach, courts overcome the hurdles relevant under both product safety law and product liability law concerning proof of a "defect product". This case law was then also confirmed in Germany – eg, in its decision of 22 March 2022 (Case No 3 U 32/18), the Higher Regional Court of Brandenburg stated that certain medical devices are already deemed to be defective if a significant number of products of the same product group or production series have a malfunction, with the result being that all products of this group or series are to be classified as defective due to a potential defect, without it being necessary to prove a defect in the specific product.

Also of interest is the German jurisprudence in the "Dieselgate" scandal and the resulting clear position of the German courts on claims for damages by injured parties. Among other things, the German Federal Court of Justice ruled on 25 February 2020 (docket no 25.5.2020 VI ZR 252/19) that "it is tantamount to direct fraudulent deception of the vehicle purchaser if a vehicle manufacturer, as part of a strategic decision taken during engine development, fraudulently obtains the type approvals of the vehicles by deceiving the Federal Motor Transport Authority and then places those vehicles on the market, deliberately exploiting the guilelessness and trust of the vehicle purchaser".

Another interesting decision of the European Court of Justice of 7 July 7 2022 (case number C-264/21) shows how quickly a company can be considered a so-called "quasi-producer" with all the attendant obligations and consequences by affixing its name to a product. The Court states: "Article 3 I of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products, as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999, must be interpreted as meaning that the term 'producer' within the meaning of that provision does not require that a person who has affixed their name, trade mark or other distinguishing mark to the product or who has 'authorized' the affixing of such a mark must also identify themselves in some other way as the producer of the product."

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Both areas are on the verge of extensive renewal by the EU. Not only will the previously relevant Product Safety Directive be replaced by a regulation and thus be subject to much more direct regulation by the EU, but it is also clear that the almost 40-year-old Product Liability Directive and the almost 20-year-old Product Safety Directive will be brought into the 21st century: digital content, software, AI and nowadays absolutely common distribution channels such as trading platforms on the internet are being comprehensively regulated or at least reassessed from a current perspective. This development can also be seen in "accompanying" regulations, such as the directive on sustainable supply chains (CSDDD), the Ecodesign Regulation, the Battery Regulation, the (planned) Packaging Regulation, the AI Act, etc. The EU is stepping on the gas and rolling out an unprecedented amount of product and production-related regulations. Much of this content was also triggered and guided by the EU's Green Deal.

3.2 Future Policy in Product Liability and Product Safety

The EU and therefore Germany find themselves in front of a huge "wave" of either updates or completely new regulations that deal with product and product regulation, and therefore with product safety and liability. The most relevant are (in no particular order):

- Regulation (EU) 2023/1542 concerning batteries and waste batteries (eur-lex.europa.eu);
- Regulation (EU) 2023/988 on general product safety (eur-lex.europa.eu);
- the proposed Directive on liability for defective products (eur-lex.europa.eu);
- proposals to adjust the restriction of PFAS chemicals (echa.europa.eu/de/registry-of-restriction-intentions);
- Directive (EU) 2022/2555 on measures for a high common level of cybersecurity across the Union (eur-lex.europa.eu);
- the Cyber Resilience Act (eur-lex.europa.eu);
- the EU AI Act (europarl.europa.eu); and
- the CSDDD (eur-lex.europa.eu).

Trends and Developments

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Product Compliance, the European Market and the Green Deal

Historical development

Product liability law cannot function well without product safety law; these two are interdependent. Both are currently experiencing immense pressure, both directly and via "accompanying" areas of law – content and areas of regulation are being added, existing ones are being completely revised, and in some cases (as will be discussed in more detail later in the text) there are massive interventions in the principles of the legal system, primarily to strengthen consumer safety and consumer rights. At the same time, environmental protection in a broader context is increasingly being taken into account. The digitalisation of the world is also increasingly being regulated in this respect.

The Product Liability Directive currently forms the basis of product liability regulation in the EU countries and is being completely revised after almost 40 years. The EU Product Safety Directive, which is about 20 years old, is being replaced by a regulation.

Comparing the two main pillars of product law (ie, product safety law and product liability law), based on the status quo in Germany with the mandatory changes based on EU legislation, it becomes clear that the EU is bringing these regulations into the 21st Century, taking into account cybersecurity risks, networked products and artificial intelligence in particular. It is also acting in line with the (political) goals it has set itself.

On the one hand, it will overshoot the actual goal, but on the other hand, it will intervene massively in existing systems at the expense of economic actors and often produce results that can only be described as "unclear" in legal terms. The following section will therefore take a closer look at the General Product Safety Regulation, which will replace the existing General Product Safety Directive, and the planned Product Liability Directive, which will replace the existing Directive.

Product compliance

Product compliance regulations are becoming increasingly important. This is also true for the EU's harmonised goods market. Product compliance and its control through market surveillance have become central pillars of the EU. The adoption of the New Legislative Framework (NLF) in 2008 significantly strengthened the free movement of goods, the EU market surveillance system and harmonised product regulation.

The European Green Deal (EGD) was adopted in 2019 and is the EU's response to the global climate crisis. All sectors of the economy will be affected by the EGD, including agriculture, industry, services, energy, finance, transport and construction. It affects all areas of public product law (regulatory law) as well as civil law (product and producer liability).

Human health is a legal asset worthy of protection, and the environment is also becoming increasingly important. The handling of chemicals or energy as a resource is regulated by the following pieces of legislation, among others:

- Regulation (EC) 1907/2006 – Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (the "European Chemicals Act");
- Regulation (EU) 2019/1021 on persistent organic pollutants (the "POP Regulation"); and
- the legal framework of Directive 2009/125/EC establishing a framework for the setting

of ecodesign requirements for energy-related products.

Increasingly, external databases and registers on product conformity must be filled in, often even before the product is launched – eg, the SCIP database in the area of substances of very high concern (SVHC).

Extended producer responsibility is closely linked to product-related environmental legislation and the EU Green Deal; additional reporting and registration obligations for those responsible for products are rapidly gaining momentum in the individual member states of the European Economic Area.

Sustainability

There are also increasing social and environmental sustainability requirements for supply chains and the production and processing of goods and services. The circular economy is a production and consumption model that advocates keeping materials and products in the system for as long as possible. This means sharing, leasing, reusing, repairing, refurbishing and recycling in a way that minimises waste.

The Green Deal also includes a series of proposals aimed at reducing greenhouse gas emissions and minimising resource consumption while achieving economic growth, meaning that products sold on the EU market will also have to meet higher sustainability standards. This leads to higher sustainability requirements in primary production and industrial processes, stricter social and environmental sustainability requirements in the production and processing of goods and services, and an increased demand for information on the practices used in the production of goods.

Market surveillance

The strengthening of the European market surveillance system and the extension of notification and recall obligations in both the safety and liability areas will most likely lead to a further tightening of manufacturers' obligations in the long term.

Regulation EU 2023/988 on general product safety

One of the main objectives of the General Product Safety Regulation is to cover new technologies; the current General Product Safety Directive is now over 20 years old. According to the European Commission, new technology-based products pose new risks to the health and safety of consumers or change the way in which existing risks could materialise. New technologies are now to play an explicit role in assessing the safety of a product, and the General Product Safety Regulation contains a very detailed catalogue of criteria for assessing the safety of a product compared to the provisions of the previous General Product Safety Directive. In particular, this catalogue explicitly states that any risks arising from the use of artificial intelligence or any cybersecurity features of the product must be taken into account when assessing the safety of the product.

Other key objectives of the General Product Safety Regulation include improving the effectiveness of market surveillance rules by strengthening and adapting the importance of safety gates, and expanding the reporting obligations of responsible economic operators. In addition to the reporting obligations, the provisions on risk prevention measures and the recall obligations of manufacturers are to be renewed. According to the Commission, the General Product Safety Regulation also aims to increase the effectiveness and efficiency of recalls. Among

other changes, a so-called right to remedy is to be created, and the content of recall information is to be better regulated.

Recalls

The requirements for conducting a recall have been clarified. A recall notice must be available in the language(s) of the member state(s) where the product was marketed. The recall notice must be easy to understand, needs to be titled "Product Safety Recall", and has to contain a clear description of the recalled product, including a picture, the name and brand of the product, and details of when and where the product was sold. Certain elements may no longer be used, such as "voluntary", "precautionary", "discretionary", "in rare/specific situations" and a statement that no accidents have been reported.

As before, the manufacturer is required to recall a product when doing so is necessary and appropriate to eliminate product hazards. In addition, the law now requires the manufacturer to offer consumers an effective, free and prompt remedy in the event of a recall. Remedial measures should therefore be free of charge, without significant inconvenience to the consumer and without passing on shipping or transport costs, as is the case with subsequent performance under sales law. In particular, the responsible economic operator must offer the consumer a choice between two of the following remedies:

- the repair of the recalled product;
- replacement with a safe product of the same type and of at least equal value and quality; or
- reimbursement of the value of the product, provided that the amount of the reimbursement is at least equal to the price paid by the consumer.

This right to remedy represents a massive expansion of the manufacturer's previous product safety obligations, and even effectively encroaches on the area of civil law. Up to now, the decisive maxim for the scope of the obligation to avert danger has primarily been the effectiveness of averting danger. As long as a recall measure ensures that a product hazard is sufficiently reduced, this is generally sufficient to fulfil the manufacturer's obligations.

The German Federal Court of Justice (BGH) has consistently ruled that product safety law only protects the user's interest in the integrity of the product, but not their interest in a certain – contractually owed – performance. The right to remedy would no longer fully comply with this principle. The free-of-charge guarantee, the obligation to deliver equivalent products or the refund of the purchase price demanded by Parliament cannot be justified by the consumer's interest in integrity. There are various product risks that can be averted by offering to repair the product for a fee, by supplying a product of lesser value, or simply by offering to dispose of the product free of charge. The principle of the effectiveness of risk prevention can no longer be used to justify the replacement or renewal of the originally purchased product for the consumer, regardless of the individual case.

However, the right to remedy applies only to the risk prevention measure of a recall. The admissibility and design of milder risk prevention measures (eg, consumer warnings or product withdrawal in the supply chain) remain fundamentally unaffected by the regulation.

Proposal for a directive on liability for defective products COM/2022/495 final

On 28 September 2022, the European Commission published its proposal for a new Product

Liability Directive ("Draft Directive"), 37 years after the adoption of the Product Liability Directive. Compared to the previous Product Liability Directive, this proposal provides for a significant tightening of product liability for economic operators and for massive interventions in the civil procedural law of member states.

The draft of the new Product Liability Directive goes far beyond the Commission's stated goal of adapting European product liability to ecological and digital change. Instead, the Commission seems to have used the revision process as an opportunity to extend consumer protection at the expense of economic operators by making numerous detailed changes to the current legal situation, without always directly linking them to digital change or sustainability aspects. In the future, European product liability will apply not only to movable goods and electricity, but also explicitly to digital production files and software. By extending the product concept to software in general and AI systems in particular, the Commission is implementing a key concern. The recently finalised version of the so-called AI Regulation complements this area in a very comprehensive way.

In contrast to the current situation, in the future not only the importer but also the authorised representative of the manufacturer will be liable under product safety law if the manufacturer is located outside the EU. Under the same conditions, a fulfilment service provider can be held liable for product defects in the same way as a manufacturer. Also new is the liability of economic operators who "substantially modify" a product within the meaning of EU or national product safety law and act outside the control of the original manufacturer.

However, the draft directive also modifies the previously known exclusions to the detriment of economic operators. The current deductibles for damage to property (EUR500) and the maximum liability limits for personal injury (EUR85 million in Germany) will no longer apply.

In addition to the above-mentioned changes, the proposed directive massively interferes with the national civil procedure laws of the member states. Both the duty of disclosure and the introduction of presumptions of proof were mentioned by the Commission early in the revision process as possible provisions of a new product liability directive and have been retained in the drafts.

Probably the most noteworthy innovation in the proposed Directive is the possibility for the court to oblige the defendant economic operator to submit evidence in their possession. This allows the plaintiff to obtain access to, for example, design documents or documented findings from product monitoring to substantiate their claims. Courts have discretion in this regard. This means that not only the necessity and proportionality of the disclosure to the action brought play a role, but also the legitimate interests of all parties, in particular the protection of confidential information and trade secrets.

The disclosure obligations are accompanied by new comprehensive rules on the shifting of the burden of proof in favour of the injured party. In this respect, the proposed Directive differs significantly from the previous Product Liability Directive, which provides (only) that the injured party has to prove the defect, the damage and the causality between the defect and the damage. The rule that the plaintiff must prove the defect, the damage and the causal link is also found in the draft Directive but is mitigated by

extensive presumptions of proof in favour of the plaintiff.

With the presumptions of proof outlined below, the Commission implements one of its central concerns of the new Directive but deviates from its original plans to leave the distribution of the burden of proof untouched. The existence of an error is presumed if:

- the company has not complied with its disclosure obligations;
- the plaintiff can prove that the product does not comply with the mandatory safety requirements of EU or national law intended to protect against the risk of subsequent damage; or
- the plaintiff can prove that the damage was caused by an "obvious malfunction of the product".

The causal link between the defect and the damage is presumed if the defect is proven and if the damage is typically related to the defect. These presumptions of the burden of proof go even further if the plaintiff has disproportionate difficulties in proving the defect or the causal link (also with the help of the above-mentioned presumptions) due to "technical or scientific complexity". In this case, it should be sufficient if the plaintiff can prove that the product contributed to the damage and that it is probable that the product has a defect and/or that the defect is likely to be the cause of the damage.

The defendant economic operator is granted the right to rebut the presumptions of proof or to deny the existence of disproportionate difficulties. In reality, these presumptions will lead to a reversal of the burden of proof once the consumer can conclusively prove the defect and/or the causal link.

GREECE

Law and Practice

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Contents

Bahas, Gramatidis & Partners LLP (BGP) traces its origins to Law Office Marios Bahas in 1970 and Bahas, Gramatidis & Associates formed in 1990. In 2002, the firm became an LLP under its current trade name. BGP has five partners, 17 associates, six trainees and 12 administrative staff, and is based in Athens. At the core of the BGP's practice is business law and the representation of legal entities and individuals in any kind of business transaction and ADR/litigation. BGP is a full-spectrum law firm representing a solid number of multinational companies that are leaders in their own business areas. The firm has developed a unique and globally recognised expertise in product liability and safety issues led by Dimitris Emvalomenos. It is part of established worldwide networks such as World Law Group, the International Society of Primerus Law Firms, the European Justice Forum, DRI Europe and IADC.

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1. Product Safety

1.1 Product Safety Legal Framework

The main laws and regulations of the legal regime around product safety in Greece are as follows:

- Ministerial Decision Z3/2810/14 of December 2004, which implemented EU Directive 2001/95/EC on General Product Safety (GPSD); and
- Law 2251/1994 on the Protection of Consumers (Law 2251; as amended repeatedly and in force curretoday, especially after Law 5019/2023), which, inter alia, implemented EU Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products (as amended by EU Directive 99/34/EC; the PLD).

The above legal framework is supplemented by and interacts with:

- provisions of the legislation on various specific product categories covering safety issues; and
- Regulation (EU) 2019/1020 "on market surveillance and compliance of products" in force as of 16 July 2021 (excluding provisions on the new Union Product Compliance Network, in force as of 1 January 2021).

GPSD will be repealed by General Product Safety Regulation (EU) 2023/988 as from 13 December 2024.

1.2 Regulatory Authorities for Product Safety

The General Secretariat of Commerce via the General Directorate of Market and Consumer Protection and the Directorate of Consumer Protection (collectively hereinbelow the "General Secretariat") of the Ministry of Development ("the Ministry") is the central regulatory authority on producer compliance with product safety rules.

Various other competent authorities exist for sectoral products, such as:

- the General Secretariat of Industry of the Ministry for industrial products, such as, among others, plastics and toys;
- the National Organization for Medicines (EOF) for medicines, cosmetics and chemicals; and
- the Hellenic Food Authority (EFET), for food products.

The regulators have broad authorities and powers for exercising their duties, and may request that the manufacturer, distributor or any supplier of an unsafe product implement specific preventive or corrective actions, defining the time frame within which these actions should be accomplished. If the obliged party fails to satisfy these requests, the regulators and/or another competent authority may impose sanctions.

In exercising their duties, product safety regulators may cooperate: (a) with other non-product safety regulators in the general frame of cooperation between Greek public administrative bodies; and (b) with similar international regulators within the framework of existing international legislation – eg, the EU Rapid Alert System for unsafe consumer products (Rapid Exchange of Information System, or RAPEX; see **1.4 Obligations to Notify Regulatory Authorities**).

1.3 Obligations to Commence Corrective Action

There are no specific provisions regarding the criteria according to which corrective action has to be taken. The general framework is that

the manufacturer or distributor of a defective product must take any appropriate measures to eliminate possible hazards affecting the product's use as soon as a defect comes to their attention. These measures may vary, and can include warning notifications, instructions to consumers, invitations for servicing or updating the product at issue so that it becomes safe, or recall notifications.

A product recall is an action taken where no other measure would eliminate the danger, and may be initiated voluntarily by the manufacturer or the distributor or mandatorily following an order by the competent authority.

The European Commission provides a guide entitled "*Recall process from A-Z: Guidance for economic operators and market surveillance authorities*" dated 22 July 2021 which contains useful information on the legal framework around and process to be followed by economic operators and market surveillance authorities in determining when corrective action – specifically a recall – is required, and how best to handle it.

1.4 Obligations to Notify Regulatory Authorities

If manufacturers or distributors become aware that any of their products present a risk to consumers, they must immediately notify the General Secretariat and any other competent regulatory authority, depending on the type of product involved. The criteria determining when a matter requires notification derive from the rule that the safety profile of a product dictates any notification needed.

Article 7, paragraph 3 of Law 2251 (see **1.1 Product Safety Legal Framework**) lists the criteria to be monitored from the point of view of risks to consumers' safety and health protection, as follows:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product; and
- the categories of consumers at risk when using the product, children and the elderly, in particular.

The manufacturers may be informed about the risks of a product by any appropriate means; they may discover that the product is not safe following their own inspections and tests or based on initiatives by consumers, insurance companies, distributors, or government bodies. In all cases, the manufacturers must notify the regulatory authority as soon as a risk has been established.

The notified regulatory authority may request additional information, and the submission of relative documents or measures to be taken by the producer or distributor.

EC Decision 2004/905/EC of 14 December 2004 sets out the guidelines for notification by manufacturers and distributors of dangerous consumer products to the competent authorities of member states (the "Guidelines") based on paragraph 3 of Article 5 of the GPSD.

Section 3 of the Annex to the Guidelines sets out the notification criteria, which are as follows:

- the product is understood to be intended for, or likely to be used by, consumers (Article 2(a) of the GPSD);
- Article 5 of the GPSD applies, unless there are specific provisions established by other EU legislation;
- the product is on the market;
- the professional has evidence that the product is dangerous according to the GPSD, or does not satisfy the safety requirements of the relevant community sectoral legislation that applies to it; and
- the risks are such that the product may not remain on the market.

The notification is made in the form required by the regulatory authority, and it must include information that identifies the product, fully describes the defect or the risk involved in using the product, locates the product in the market and describes the action taken or to be taken by the manufacturer or distributor.

The European Commission's "Business Gateway to report your dangerous products to the Member State authorities" (formerly known as the GPSD Business Application) allows the manufacturers or distributors of the notified product or their authorised representatives to submit notifications under the GPSD. It also allows Greek and other EU competent national authorities to use information provided to submit a RAPEX notification if all criteria for this are met.

RAPEX is the EU Rapid Alert System for unsafe consumer products (with the exception of food, pharmaceuticals and medical devices, covered by other mechanisms), established under Article 12 of the GPSD. RAPEX allows for rapid exchange of information on measures such as repatriation or product recalls, whether carried out by national authorities or through voluntary action of manufacturers and distributors (please click on this link for further information and also visit this website). The EU Commission issued guidelines for managing RAPEX via Implementing Decision (EU) 2019/417, amended by Implementing Decision (EU) 2023/975 of 15 May 2023.

With respect to timing, notification must be made immediately. Section 4.3 of the Annex to the Guidelines provides that notification must be made without delay and specifies the deadline for making notifications in terms of days. Accordingly, in cases of serious risk, companies are required to inform the regulatory authorities without delay, no later than three days after obtaining information and, in any other instance, within 10 days. There are only minimal differences in the preconditions and time frames for notification for various specific product categories.

1.5 Penalties for Breach of Product Safety Obligations

The penalties for breach of the key obligations for product safety and related obligations were updated and expanded upon in 2023 (Articles 13(a)-3(i) of Law 2251, as revised by Law 5019/2023; see **2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**).

As an overview, subject to the provisions of the Criminal Code and the "Rules Regulating the Market of Products and the Provision of Services" (Law 4177/2013, in force), the following sanctions may be imposed by a decision of the competent organ of the Ministry (see **1.2 Regulatory Authorities for Product Safety**), acting either ex officio or after a filed complaint:

- a recommendation for compliance within a specified deadline and an order to cease the

infringement and refrain from it in the future; or
- a fine of between EUR5,000 and EUR1.5 million. The fine may reach a maximum of EUR3 million if, within the last five years, more than one decision imposing fines has been issued against the same infringer for breaches of Law 2251 (or of other laws referring to Law 2251 for the imposition of a fine).

For the imposition of the above sanctions, certain criteria are indicatively listed, including any sanctions imposed previously on the same infringer for the same breach in other EU member states regarding transboundary cases, if relevant information is available under Regulation (EU) 2017/2394 "on cooperation between national authorities responsible for the enforcement of consumer protection laws" as in force. Also, when the Greek regulatory authorities are to impose penalties under Article 21 of the same Regulation for "widespread infringements" or "widespread infringements with a Union dimension", the maximum fine may be up to 4% of the infringer's annual turnover in the relevant EU member state and, if there is no information on such turnover, it could reach EUR5 million.

Moreover, a special set of sanctions may be imposed on infringers that do not provide requested documents, or that do not respond to consumers' complaints per the stipulated proceedings.

An additional sanction imposable in certain conditions and providing for the temporary closure of the infringer's business for a period of three months to one year was abolished in 2022.

Further, appropriate injunctive measures, as a case may be, may be taken by the competent organs of the Ministry.

A summary of any decision imposing a fine that exceeds EUR50,000 (or not, if it is imposed for a repeated infringement) is publicised by any appropriate means and uploaded to the Ministry website within five working days of its issue.

Lastly, a general five-year prescription period applies for breaches falling within the remit of the enforcement authorities of the Directorate of Consumer Protection.

Fines for various breaches of Law 2251 are being imposed on a fairly regular basis and on a variety of entities with respect to their activities. Unfortunately, there are no central records or other e-bases listing such fines and the judicial development of the respective administrative decisions that imposed them since the person/entity fined may challenge the decision before the administrative courts. Based on the review carried out for the last five-year period (2019-2023) in case law bases, most of the imposed fines concern abusive general terms and conditions and various types of unfair/misleading commercial practices, including advertising, whereas fines for product safety breaches are rare. Indicatively, we would mention decision No 435/2020 of the Athens Administrative Court of Appeal which confirmed a fine of EUR9,000 imposed for the placing into the market of unsafe children's clothes (determining this as reasonable in the circumstances of that case).

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

The causes of action for product liability range from strict liability for a manufacturer to administrative and criminal liability. More specifically, these can be explained as follows.

- *Strict liability:* This derives from the PLD as transposed into Greek law by Law 2251 (see **1.1 Product Safety Legal Framework**). Article 6, paragraph 1 of Law 2251 provides that "the producer shall be liable for any damage caused by a defect in his product". Therefore, the prerequisites for a manufacturer to be held liable are: (a) a product placed on the market by the manufacturer being defective; (b) damage that has occurred; and (c) a causal link between the defect and the damage (considered under the theory of "causa adequata"). The strict liability regime does not preclude other liability systems from providing a consumer with greater protection in a specific case (Article 14, paragraph 5 of Law 2251).
- *Contractual liability*: This requires a contractual relationship between the parties where the buyer may not necessarily be a consumer (Articles 513 ff. of the Greek Civil Code (GCC) on contracts of sale of goods, as in force, following the transposition of Directive (EU) 2019/771 "on certain aspects concerning contracts for the sale of goods" (which, among others, repealed Directive 1999/44/EC), by Law 4967/2022 (in force as of 9 September 2022). A seller may be strictly liable, ie, irrespective of fault, for the lack of conformity of the sold product with the sales contract at the time the risk passes to the buyer, as such conformity is defined by law. The knowledge of the buyer releases the seller from liability under stipulated conditions, among other reasons for such release (in particular Articles 534-540 of the GCC).
- *Tortious liability*: The claimant must establish the defendant's fault in tort claims. However, case law reverses the burden of such proof in favour of the claimant/consumer based on the "theory of spheres", thus obliging the defendant to prove absence of fault in order to be released from liability (in particular, Articles 914, 925 and 932, together with Articles 281 and 288 of the GCC and case law).
- *Criminal and administrative liability:* These derive from the Greek Criminal Code and Law 4177/2013 on "Rules Regulating the Market of Products and the Provision of Services", as in force, supplemented by secondary legislation (Article 13a of Law 2251).

2.2 Standing to Bring Product Liability Claims

Any person that has suffered damages due to a product defect may bring a product liability claim subject to the general substantive and procedural requirements (in particular, Articles 127 ff. of GCC and 62 ff. of the Greek Code of Civil Procedure (GCCP).

Collective redress proceedings also exist (see **2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**).

2.3 Time Limits for Product Liability Claims

The time limits for bringing a product liability claim are as follows.

- For strict liability, a three-year prescription period applies, while the right to initiate proceedings against the producer is extinguished upon the expiry of a 10-year period from the date the producer put the product into circulation (Article 6, paragraph 13 of Law 2251). The prescription period must be properly invoked by a litigant, contrary to the time-limitation period, which is taken into account by courts ex officio (Articles 277 and 280 of the GCC).
- For a claim in tort, a general five-year prescription period applies; in all cases, the claim

is extinguished 20 years from the date of the tortious act (Article 937 of the GCC).
- For contractual liability, the prescription period is five years for immovable property, two years for movables and, in the case of continuous supply of digital elements, six months from the end of the contractual term, save for the provision of a guarantee (Articles 554–559 of the GCC, including further details thereon).
- For representative actions in force as of 26 June 2023, a special one-year prescription period is provided for seeking injunctive measures, commencing on the date of the last incident of unlawful behaviour challenged, provided the same was known to the average consumer (new Article 10l, paragraph 2 of Law 2251; see **2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**).

2.4 Jurisdictional Requirements for Product Liability Claims

There are no specific rules for product liability claims regarding the requirements for establishing jurisdiction of the Greek courts. Therefore, the general provisions for bringing private claims apply, and the civil courts have jurisdiction to hear product liability claims. Jurisdiction is examined by the courts ex officio (Articles 1-4 of the GCCP).

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There are no mandatory steps to be taken, such as pre-action procedures and requirements, before proceedings can be commenced formally for product liability claims, as generally for any civil claims. In practice, a so-called extra-judicial notice of protest is often served by the claimant on the defendant by a court bailiff before the filing of a lawsuit for warning purposes or for a potential out-of-court settlement; however, court proceedings may only be commenced by a lawsuit.

2.6 Rules for Preservation of Evidence in Product Liability Claims

Preservation of evidence, including the product itself in product liability cases, is possible either when all litigants agree or, as a rule, when there is a risk that a specific means of evidence will be lost or could deteriorate in future, or if the status of an object in dispute needs to be determined immediately. This requires the filing of a petition to the court even before the trial commences, the court being the main trial court or, exceptionally, any other court that can make an immediate decision in the case of an imminent risk. Simplified injunction proceedings apply to the petition at issue. Should the court accept the petition for preservatory evidence, it orders details such as the time frame for conclusion of the evidential procedure. The court of the main trial must take into account the preservatory evidence conducted as above, irrespective of whether the risk occurred or not (Articles 348-351 and 686 ff. of the GCCP).

2.7 Rules for Disclosure of Documents in Product Liability Cases

In general, there are no rules of discovery in judicial proceedings. The litigants disclose any evidence supporting their case, per their discretion, by filing their submissions at the specified time, depending on the court and proceeding type. Evidential means are specified, and their admissibility is subject to restrictions (Articles 335 ff. of the GCCP). The general principles of good faith, bonos mores and honest conduct apply (in particular, Articles 116 and 450 of the GCCP). The litigants may request that the court order the disclosure of documents in the pos-

session of their opponents or a third party under certain conditions (Articles 450 ff. of the GCCP and 901-903 of the GCC).

2.8 Rules for Expert Evidence in Product Liability Cases

Expert evidence is generally regulated and also covers product liability cases.

If a court finds that the issues to be proven require special scientific qualifications, it may appoint one or more court experts, describing their task and the timeframe for the expert report and adjourning the hearing for that purpose (Articles 368-392 of the GCCP). The experts obtain knowledge of the case file regarding the technical issues for which they were appointed and/or may request clarifications from the litigants or third parties. In this case, each litigant is entitled to appoint a technical advisor who submits their opinion and raises relevant questions to the court-appointed expert. The opinion of the court-appointed expert is not binding on the court.

Additionally, the litigants may submit to the court an unlimited number of expert/technical reports supporting their allegations. The reports of litigant-appointed experts are of lesser evidentiary value than those of the court-appointed experts.

Factual or expert witnesses appointed by the litigants may give sworn depositions before a notary public, a lawyer (although not the litigant's lawyer) or, if outside Greece, a Greek consular authority. The opponent must be summoned to such depositions two working days in advance, and is entitled to obtain a copy prior to trial. Non-compliance with the procedural requirements renders the deposition inadmissible. Various procedural requirements in the taking of depositions apply – eg, regarding the total number allowed, which is up to three per litigant and up to two for rebutting the opponent's depositions (Articles 421-424 of the GCCP).

2.9 Burden of Proof in Product Liability Cases

In civil litigation, including product liability claims, and under ordinary proceedings, a claim must be fully proven by the litigant raising it, who thus bears the burden of proof, unless it is reversed by law or case law (see **2.1 Product Liability Causes of Action and Sources of Law**). Exceptionally, such as in injunctive proceedings, the standard of proof may be lower and based "on the balance of probabilities" (Articles 347, 690 of the GCCP).

2.10 Courts in Which Product Liability Claims Are Brought

Private law disputes, including product liability cases, are tried by civil courts and by one to three judges, and thus not by a jury, depending on the amount involved in the dispute. As a rule, justices of the peace are competent to try claims valued up to EUR20,000; one-member first-instance courts, claims between EUR20,000 and EUR250,000; and three-member first-instance courts, claims exceeding EUR250,000 (Articles 14 and 18 of the GCCP). Following the unification of the first instance judicial level within an overall restructuring of courts' territorial and subject matter competence by Law 5108/2024, the justices of the peace will be either abolished or absorbed by the existing first-instance courts as from 16 September 2024 (or from 16 September 2026 for the judicial areas of Athens, Piraeus and Poros).

In particular, representative actions are subject to the exclusive competence of the three-member first instance courts (Article 10I, paragraph 1 of Law 2251; see also **2.16 Existence of Class**

Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims).

2.11 Appeal Mechanisms for Product Liability Claims

Every definite court decision, including one on a product liability case, issued by a first instance court may be contested before an appellate court. An appeal can be filed not only by the defeated litigant but also by the successful litigant whose allegations were partially accepted by the court. The appeal timeframe is 30 days for appellants residing in Greece and 60 days for those residing abroad or being of an unknown residence; the time period starts from the service of the definite decision. If the first instance decision is not served by a litigant on the other(s), the appeal timeframe is two years from the issue of the same (Article 518 of the GCCP).

Further, a cassation before the supreme court may be filed against an appellate court decision under restrictions and for specified reasons. The timeframe is similar to that for appeals as above (Article 552 ff. of the GCCP).

2.12 Defences to Product Liability Claims

As far as defence is concerned, manufacturers may be relieved from liability if they prove that:

- they did not place the product on the market;
- when they manufactured the product, they had no intention of putting it into circulation;
- at the time the product was placed on the market, the defect did not exist;
- the defect was caused by the fact that the product was manufactured in such a way that derogation was not permitted (subject to mandatory regulation); or
- when the product was placed on the market, the applicable scientific and technological rules at that time prevented the defect from being discovered (the so-called state-of-the-art or development risk defence; Article 6, paragraph 8 of Law 2251).

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Adherence to mandatory regulatory requirements may constitute the manufacturer's defence in product liability cases (Article 6, paragraph 8 of Law 2251; see **2.12 Defences to Product Liability Claims**).

2.14 Rules for Payment of Costs in Product Liability Claims

For costs, the "loser pays" rule applies. Court expenses are "only the court and out-of-court expenses that were necessary for the trial" and, in particular, include: (a) stamp duties; (b) judicial revenue stamp duty; (c) counsels' minimum fees set by the Lawyers' Code (Law 4194/2013, as in force); (d) witnesses' and experts' expenses; and (e) expenses paid for the submission of evidential means, as well as the successful litigants' travelling expenses in order for them to attend the hearing. However, the expenses that the successful litigant recovers are, as per general practice, substantially lower than the actual expenses.

The court offsets the expenses between the litigants in the event of a partial win or loss, while it may offset them (and does so, as a rule) between litigants who are relatives or on the basis of complex legal issues involved in the litigation. Offsetting only part of the expenses is also possible when "there was a reasonable doubt on the outcome of the trial" (Articles 173-193 and, in particular, 178-179 of the GCCP).

2.15 Available Funding in Product Liability Claims

Generally, and in product liability claims, there are various types of funding, as follows.

Public Funding

This is regulated by Law 3226/2004 on the provision of legal aid to low-income citizens (implementing Directive 2003/8/EC), together with Articles 194-204 of the GCCP.

According to Law 3226/2004 (as in force), beneficiaries of legal aid are low-income citizens of the EU, as well as of a third state, provided that they reside legally within the EU. For civil and commercial cases, low-income citizens are those with an annual familial income that does not exceed two-thirds of the minimum annual income provided by law. Beneficiaries may also be the victims of certain crimes and citizens suffering 67% disability or more, irrespective of the level of their income. Legal aid is granted on the condition that the case, subject to the discretion of the court, is not deemed unjust or uneconomical.

Legal aid in civil and commercial matters entails an exemption from the payment of all or part of the court's expenses, the submission of a relevant petition by the beneficiary, and the nomination of a lawyer, notary and judicial bailiff, in order to represent the beneficiary before the court. The exemption primarily includes stamp duty payment and judicial revenue stamp duty, and, generally, the remuneration of witnesses and experts and the lawyers', notaries' and judicial bailiffs' fees.

Contingency Fees and Other Conditional Payment Arrangements

These are allowed between clients and lawyers under the following basic restrictions: they must be made in writing, and the maximum fee percentage agreed may not exceed 20% of the subject matter of the case at issue (or 30% if more than one lawyer is involved). Further detailed regulation is provided by the Lawyers' Code (article 60 of Law 4194/2013).

Third-party Litigation Funding (TPLF)

Since this is not specifically regulated, it is informally permitted. Some insurance companies offer to cover litigation expenses. However, this is neither common nor really "culturally" accepted. Also, the lack of a legal framework could raise issues of transparency.

As of 26 June 2023, TPLF is specifically prohibited regarding representative actions (new article 10n of Law 2251; see **2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**). On a related matter, the general regulation on the financial means of qualified entities (QEs) that may bring representative actions as of 26 June 2023 is expansive vis-à-vis the previous regime, and includes grants or concessions from the Greek state and limited dues collected from consumers wishing to be represented in a specific representative action seeking redress measures (new Articles 10c, paragraph 4 and 14, paragraphs 4d and 4e of Law 2251).

At EU level, on 13 September 2022 the EU Parliament passed a resolution proposing a directive "on the regulation of third-party funding" (P9 TA(2022)0308; "Responsible private funding of litigation"). The EU Commission agreed to run a mapping in the EU on the TPLF status and timeline for the report to be issued is towards the end of 2024.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Following transposition of Directive (EU) 2020/1828 "on representative actions" (RAD) made by Law 5019/2023 ("Law 5019"), a new collective redress landscape was enacted in Greece, in force as of 26 June 2023. Law 5019 modified Law 2251 (see **1.1 Product Safety Legal Framework**) by replacing the latter's provisions on collective lawsuits former Article 10 of Law 2251) and providing for the issue of numerous Ministerial Decisions which will specify various aspects of the new regulation (Article 14 of Law 2251).

Representative actions may be only filed by QEs, either: (a) Greek QEs, being consumer associations which meet the legal prerequisites and are registered with a special registrar maintained with the General Secretariat of the Ministry (see **1.2 Regulatory Authorities for Product Safety**); or (b) bodies registered as QEs in other EU member states. A Greek QE must prove that it has a minimum 12-month actual public activity in favour of consumers' interests to be qualified as such, among other criteria imposed by Law 5019. An assessment of whether Greek QEs meet the set criteria will be made at least every two years by a special committee formed at the General Secretariat.

Representative actions may regard injunctive and/or redress measures, and may only be brought before a court. Apart from few exceptions, RAD provisions are followed on content, proceedings and the effect thereof, with required adaptations to the Greek legal framework (new Articles 10a-10r of Law 2251).

2.17 Summary of Significant Recent Product Liability Claims

Numerous lawsuits have been filed in recent years over the so-called "Dieselgate" claims on a variety of legal grounds, mainly product liability/product safety, as well as on contract-for-sale and tort rules. The vast majority of the lawsuits were dismissed on a combination of motives, such as vagueness, lack of legal basis or causal link or standing to be sued with respect to the defendants.

Indicative court decisions that rejected such claims include: Patras First Instance Court 119/2022; Thessaloniki First Instance Court 800/2020; Athens Justice of the Peace Nos 1940/2022, 1941/2022, 1463/2021, 325/2020, 1104/2020 and 3222/2020; Chalandri Justice of the Peace Nos 26/2022 and 145/2020; Amaroussion Justice of the Peace No 146/2021; and Serres Justice of the Peace No 39/2020. Conversely, Athens First Instance Court No 4749/2021 upheld the claim, although only partially.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Law 2251 has been amended several times, and the latest notable modifications affecting product liability and product safety are as follows.

- In 2018, material changes were made to: (a) the definition of "consumer", which was narrowed, having previously been extremely broad; (b) the regulatory authorities and their enforcement duties; (c) the funding of consumer associations; and (d) administrative proceedings and sanctions imposed (Articles

1a.1, 7 and former Articles 10, 13a and 13b of Law 2251).
- In 2022-2023, further changes were enacted regarding: (a) the new legal framework on collective redress in force as from 26 June 2023 (see **2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**); and (b) a new set of rules on compliance supervision, enforcement measures and sanctions (new Articles 10a-10r, 13a-13i and 14 of Law 2251).

Overall, there is a continuing trend towards increased and broader consumer rights, as well as sanctions for relevant breaches.

3.2 Future Policy in Product Liability and Product Safety

Future policy developments in product liability and product safety are expected from the EU legislator involving new digital technologies and, in particular, artificial intelligence (AI). In this context, the EU Commission proposed on 28 September 2022 two complementary Directives: (a) a revised PLD to repeal and replace the current PLD on which a political agreement was reached on 14 December 2023; and (b) the AI liability Directive to adapt non-contractual civil liability rules to AI and to ensure broader protection for damage caused by AI systems by alleviating the burden of proof in compensation claims pursued under national fault-based liability regimes.

Specifically, the revised PLD is generally expansive on: (i) "damages" (covering psychological damage and loss or corruption of data and removing the minimum claim threshold); (ii) the "product" (closely interacting with services and extending to digital manufacturing files and software, including AI); and (iii) the "producer" (including economic operators such as software developers, online marketplaces and service providers). At the same time, it introduces simplified proof of "defect" and "causation" (with more detailed definition and introduction of presumptions and of a subjective criterion) and extends the expiry period up to 25 years for when a claimant could not initiate proceedings due a latent a personal injury.

Trends and Developments

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Bahas, Gramatidis & Partners LLP (BGP) traces its origins to Law Office Marios Bahas in 1970 and Bahas, Gramatidis & Associates formed in 1990. In 2002, the firm became an LLP under its current trade name. BGP has five partners, 17 associates, six trainees and 12 administrative staff, and is based in Athens. At the core of the BGP's practice is business law and the representation of legal entities and individuals in any kind of business transaction and ADR/litigation. BGP is a full-spectrum law firm representing a solid number of multinational companies that are leaders in their own business areas. The firm has developed a unique and globally recognised expertise in product liability and safety issues led by Dimitris Emvalomenos. It is part of established worldwide networks such as World Law Group, the International Society of Primerus Law Firms, the European Justice Forum, DRI Europe and IADC.

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Dimitris Emvalomenos (LLM, QMUL; LLB, Athens), lawyer and accredited mediator (Greece and the UK), has practised since 1987 and his key areas of focus are commercial law, product liability/safety, consumer law, competition law, network contracts, M&A, and ADR/mediation. Dimitris is a member of various professional associations, such as Piraeus Bar; The Greek Commercial Lawyers' Association; The Competition Law Partnership; The Greek Association for Arbitration; The Greek Association of Law and Economics; The Hellenic Association for Financial Law; The European Justice Forum; IBA; IADC; DRI Europe; CEDR Exchange Network; The Chartered Institute of Arbitrators; The Swiss Chinese Law Association; The Athens Mediation and Arbitration Organization (EODID); The Hellenic Union of Mediators (EED); and The Greek Mediators' Association (SEDI). Dimitris is the author of numerous articles.

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The legal regime applicable for product liability and safety in Greece is continuously changing, and is materially affected by legislative developments derived from European Union (EU) initiatives. The most significant of these developments are described below.

Artificial Intelligence (AI)

The new digital technologies, and particularly AI, are the main drivers of the reform of the EU's liability regime on products and related services. In this context, on 28 September 2022, the EU Commission proposed two complementary Directives, namely:

- the revised Product Liability Directive (PLD), to repeal and replace the current PLD (Directive 85/374/EEC, as amended by Directive 99/34/EC), on which a political agreement was reached on 14 December 2023; and
- an AI liability Directive to adapt non-contractual civil liability rules applicable to AI and to ensure broader protection against damage caused by AI systems by alleviating the burden of proof in compensation claims pursued under national fault-based liability regimes (please refer to this link).

In the meantime, and since 2008, there have been widespread changes in vertical sectoral legislation affecting product safety, with notable examples being the regulation of medical devices and machinery, addressing the key issues of risk prevention, transparency and enforcement.

The key aspects aspects of the current PLD were designed with traditional products and business models of the 1980s in mind. With the progressive sophistication of the market since then due to new digital technologies, and particularly AI, the revised PLD is now generally more expansive on:

- "damage", extending this to psychological damage in addition to loss or corruption of data and removing the minimum claim threshold;
- "products", when closely interacting with services, extending these to digital manufacturing files and software, including AI;
- the "manufacturer"; including economic operators such as software developers, online marketplaces and service providers;
- simplified proof of "defect" and "causation"; with more detailed definitions and introduction of presumptions and subjective criteria; and
- an extended expiry period of 25 years when a claimant could not initiate proceedings earlier due to latent personal injury.

The above new proposed EU Directives concern and are interrelated with:

- the EU proposed AI Regulation (the "AI Act") of 21 April 2021, a worldwide and novel set of AI rules on which a political agreement was reached on 8 December 2023 and which was voted in by the EU Parliament on 13 March 2024; the Act follows a risk-based approach dividing AI systems into systems of unacceptable, high and low or minimal risk; and
- the General Product Safety Regulation (EU) 2023/988, which will repeal the existing General Product Safety Directive 2001/1995/EC from 13 December 2024.

Collective Redress

As of 26 June 2023, the EU legal landscape on collective redress, including the Greek regime previously applicable, changed following the entry into force of Directive (EU) 2020/1828 "on representative actions" (RAD), which was transposed into Greek law by Law 5019/2023 (Law 5019). Law 5019 modified Greek Law 2251/1994

on "Consumers' Protection" as in force (Law 2251) by replacing its provisions on collective lawsuits (former Article 10 of Law 2251) and providing for the issue of numerous Ministerial Decisions which will specify various aspects of the new regulation (Article 14 of Law 2251).

Representative actions may be only filed by so-called qualified entities (QEs), either: (a) Greek QEs, being consumer associations which meet legal prerequisites and are registered with a special registrar to be kept with the General Secretariat of Trade of the Ministry of Development; or (b) bodies registered as QEs in other EU member states. In order to be qualified, and among other criteria imposed by Law 5019, a Greek QE must prove that it has a minimum 12-month actual public activity that benefits consumers. An assessment of whether a Greek QE meets the set criteria will be made at least every two years by a special committee formed at the General Secretary of Trade by a decision of the Minister of Development.

Representative actions may regard injunctive and/or redress measures, and can only be brought before a court. With a few exceptions, the provisions of the RAD are followed by Law 5019 on content, proceedings and the effect of representative actions, with required adaptations to the Greek legal framework (new Articles 10a-10r of Law 2251).

Under the regime of representative actions:

- a final decision of a Greek court or another EU court or competent authority on the existence of an infringement harming the collective interest of consumers can be applied by any plaintiff as evidence (based on the general Greek rules on evidence) in the context of any other lawsuit before a Greek court claiming a redress measure against the same supplier for the same practice, subject to the provisions on res judicata;
- a court decision issued on a representative action to cease or prohibit an allegedly unlawful practice has an erga omnes effect, namely an effect towards non-litigants also; and
- the irrevocable court decision ordering a redress measure also favours individual consumers who had not explicitly expressed their wish to be represented (with no tacit representation possible); such consumers may notify their claim to the supplier within the time period set by the court and, following a period of 30 days, they may resort to the General Secretariat of Trade which requests the supplier's compliance within a five-day period; otherwise it may impose upon them the sanctions provided (new Articles 10k and 10l of Law 2251).

Third-party Litigation Funding (TPLF)

The purported EU legal framework on TPLF is expected to facilitate product liability claims in general and in particular with Greece lacking regulation today.

- At EU level, there is an ongoing discussion on the introduction of legislation on TPLF. On 13 September 2022, the EU Parliament passed a resolution proposing a directive "on the regulation of third-party funding" (P9 TA(2022)0308; "Responsible private funding of litigation"). The EU Commission agreed to perform mapping of TPLF status in the EU after RAD application (see "Collective Redress", above) and the report is expected to be issued towards the end of 2024.
- TPLD is generally not regulated in Greece, and is therefore informally permitted. Some insurance companies offer customers funding of litigation expenses. However, this is neither

common nor really considered acceptable from a cultural standpoint. Also, the absence of a legal framework could raise issues of transparency.
- However, following the transposition of the RAD and as of 26 June 2023, TPLF is specifically prohibited, particularly with respect to representative actions (new Article 10n of Law 2251).
- On the financing rules of QEs, the new regime introduced by Law 5019 as of 26 June 2023 widens the scope of the previous regime to include grants or concessions from the Greek state and limited dues collected from consumers wishing to be represented in a specific representative action seeking redress measures (new Articles 10c, paragraph 4 and 14, paragraphs 4d and 4e of Law 2251). Under the previous regime, the funding/income of consumer associations that could bring collective claims was regulated more restrictively (previous Article 10, paragraphs 6-8 of Law 2251).

Increase in Consumer Rights

Overall, there is an enduring trend towards increased and broader consumer rights, as well as sanctions for relevant breaches, including product liability breaches.

Law 2251 has been amended several times within this framework, with key revisions as follows.

- New provisions have been introduced as far back as 2007 and have covered: (a) expanding the defectiveness concept to include not only the standard safety consideration but to also take into account a product's "expected performance per its specifications"; (b) including compensation for moral harm and mental distress within the ambit of strict product liability rules, since these were previously covered by general tort legislation; and c) adding new rules on collective actions also relating to product liability infringements.
- In 2012, the right to bring collective actions in Greece (under Law 2251) was extended to other EU Member State entities authorised for this per the respective list provided for by Directive 2009/22/EC (repealed by the RAD).
- In 2013 and 2015, changes were introduced with respect to the financing of consumer organisations, the sanctions that could be imposed for non-compliance with the provisions of Law 2251 and the categorisation of complaints filed under such Law (previous Articles 10, 13a and 13b of Law 2251).
- In 2018, Law 2251 was extensively revised and, with respect to product liability rules, material changes were made to the definition of "consumer", which was narrowed; the regulatory authorities and their enforcement duties; the funding of consumer associations; and administrative proceedings and sanctions imposed (Articles 1a.1, 7 and previous Articles 10, 13a and 13b of Law 2251).
- Lastly, in 2022-2023, further changes were enacted, including significant modifications affecting product liability, such as: (a) the new legal framework on collective redress in force as from 26 June 2023; and (b) a new set of rules on compliance supervision, enforcement measures and sanctions (new Articles 10a-10r, 13a-13i and 14 of Law 2251).

Alternative Dispute Resolution (ADR) – Mediation

The EU legislation on the ADR of 2013 also changed Greece's legal landscape. Specifically, Ministerial Decision 70330/30.6.2015 implemented Directive 2013/11/EU "on alternative dispute resolution for consumer disputes" (the ADR Directive) and set supplementary rules for the application of the Online Dispute Resolution

Regulation (EU) 524/2013 ("the ODR Regulation").

The Registered Greek ADR entities within the abovementioned framework are as follows:

- the Hellenic Consumers' Ombudsman, the key ADR authority for consumers and all sectors;
- the (sectoral) Hellenic Financial Ombudsman – a non-profit ADR Organisation ("HFO ADRO", formerly "HOBIS" (link here), also part of the European Financial Dispute Resolution Network ("FIN-NET") for credit/financial cross-border disputes;
- the Alternative Dispute Resolution Centre ("ADR POINT");
- the Institute for Alternative Dispute Resolution ("StartADR"); and
- more recently, the Regulatory Authority for Energy, Waste and Water ("RAAEY"), which put into operation the "Hellenic Energy Ombudsman" from 1 February 2024.

The above EU legal ADR framework is to be extensively revised, most likely in 2025. On 17 October 2023, the EU Commission issued its legislative proposal for the amendment of the ADR Directive and the repeal of the ODR Regulation. The main objective is a new ADR framework to replace the ODR platform with user-friendly digital tools to: (i) assist consumers in finding a redress tool to resolve their disputes; and (ii) incentivise online marketplaces and EU trade associations with a dispute-resolution mechanism to align themselves with quality criteria in the ADR Directive (see link).

Moreover, various other Greek bodies/authorities exist for ADR, and these have increased in number continuously in the recent years. They include:

- the Greek Ombudsman (known in Greece as the "Citizen Ombudsman"; Law 2477/1997), which deals with disputes between citizens (in general) on the one hand and public authorities, public entities, utilities municipalities on the other;
- out-of-court redress for the settlement of disputes between customers and insurance distributors, which is managed in Greece by the above registered ADR entities (Law 4583/2018, which implemented Directive 2016/97/EC);
- the Mediation and Arbitration Organisation (in Greece, "OMED") for collective labour disputes (Law 1876/1990; however, following its amendment by Law 4635/2019, no sanction is provided for a mediation refusal);
- the Labour Inspectorate (in Greece, "SEPE") for the settlement of individual labour disputes (Laws 3996/2011 and 4808/2021);
- the Committee dealing with infringements of IP and related rights on the internet (in Greece, "EDPPI"; Law 2121/1993);
- the Hellenic Copyright Organization (in Greece, "OPI") for a variety of disputes regarding IP and related rights (Law 2121/1993; due to the Law's ambiguous wording it is currently unclear whether the procedure for certain disputes will be mediation or another form of ADR);
- the Committee for the extra-judicial settlement of taxation disputes (Law 4714/2020 and Ministerial Decision 127519/2020); and
- the police and port mediators with duties related to public open-air assemblies (Law 4703/2020).

The long-standing Committees for Friendly Settlement of consumer disputes, which were seated in and managed by the regional authorities, were repealed by Law 5019/2023, with effect as from 26 June 2023.

At EU level the following ADR authorities are worth mentioning:

- the European Consumer Centre of Greece, supported by the Hellenic Consumers' Ombudsman, regarding trans-boundary EU ADR;
- SOLVIT, the free-of-charge and mainly online service provided by the national administration in each EU country and in Iceland, Liechtenstein and Norway, regarding the breach of citizens' and businesses' EU rights by public authorities in another EU country and aiming to find a solution within 10 weeks from the time the case is taken on by the SOLVIT centre where the problem occurred, supervised in Greece by the Ministry of Finance; and
- the European Ombudsman examining complaints by any EU citizen or legal person concerning alleged maladministration in the activities of EU organs, with the exception of the EU Court of Justice.

Further, mediation plays a key role among the various ADR mechanisms and has been promoted by the Greek legislator in the recent years. Among others, in civil litigation, it is a general duty of the court to encourage out-of-court settlements and it may propose to the litigants a recourse to mediation (Articles 116A and 214C of the Civil Procedural Rules). Law 4640/2019 (as in force following amendments) is the current law on mediation, and came into force on 30 November 2019, providing for a new set of mediation rules versus the previous legal regime. These rules include mandatory mediation for specified cases (effective from 30 November 2019, 15 January 2020 or 1 July 2020, depending on the case) based on the type of litigation proceedings and also covering product liability claims.

It is worth mentioning that mediation has also been promoted specifically by Regulation (EU) 2019/1150 regarding online intermediation services and online search engines, applicable from 12 July 2020.

Finally, it should be noted that, among lawyers' duties, mediation and ADR in general for out-of-court settlement of disputes are expressly recommended and provided for by the Lawyers' Code (in particular, Article 35, paragraphs 3, 36, 1 and 130 of Law 4194/2013) and the Lawyers' Code of Ethics (Articles 7.b and 32.a)

INDONESIA

Trends and Developments

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Assegaf Hamzah & Partners Based in Jakarta and Surabaya, Assegaf Hamzah & Partners ("AHP") is a major force locally and regionally. Its Consumer Protection Practice collaborates seamlessly with a market-leading Competition and Dispute Resolution practice to offer comprehensive solutions to businesses navigating the intricate landscape of consumer protection. With a profound understanding of regulatory nuances and industry dynamics, AHP's integrated approach ensures clients receive tailored guidance and robust defence against myriad consumer-related challenges. From advising on product labelling and advertising to defending against complex consumer lawsuits, the team leverages its expertise to safeguard clients' interests while upholding ethical standards. Its expertise extends to developing compliance programmes, conducting audits, and providing specialised training tailored to the unique needs of each client, ensuring adherence to consumer-protection regulations. Furthermore, the team's advisory services on halal product assurance regulations underscore its commitment to providing holistic support, ensuring that clients adhere to both legal requirements and consumer expectations.

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Albert Boy Situmorang is a partner in Competition & Antitrust practice at AHP with over a decade of experience. He provides expert counsel on consumer protection and competition law issues, including vertical restrictions, cartels, and merger control. Albert's representation spans diverse industries such as mining, chemicals and automotive, and he offers strategic guidance across complex regulatory landscapes. His comprehensive understanding of halal regulations and extensive training in halal certification in Indonesia have made him as a sought-after authority in consumer protection and halal regulation and certification. He has assisted numerous companies in implementing halal product assurance systems to ensure compliance with industry standards.

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Wisnu Wardhana is known for his skill in Indonesian competition law, covering cartels, abuse of dominance, merger control, and SMEs. Beyond this, Wisnu extends his services to consumer law, advising on product liability, labelling, advertising, and halal certification, catering to clientele spanning sectors such as technology, pharmaceuticals, and state-owned enterprises. He has also assisted micro, small, and medium enterprises (MSMEs) through partnership cases before the Indonesian competition authority (KPPU). His broad expertise and tailored approach have earned him trust among clients from various sectors, including e-commerce, automotive, telecommunications, and energy, as well as state-owned enterprises and government bodies in Indonesia.

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Amendment to the Indonesia Consumer Protection Law (CPL)

The Indonesian government is currently amending the CPL. There is no estimated date yet on when the amendment will be issued. Some major changes in the working draft amendment concern the following:

- reasserting the definition of "consumers" as end users, thus explicitly excluding intermediaries or manufacturers that use the relevant goods as part of their production;
- dividing the definition of "business actors" into two categories, namely those that produce goods and those that provide services;
- affirming consumers' liability by stipulating that their failure to fulfil their obligations will result in no liability for the business actors, meaning that judges should no longer rule on consumers' liability on a case-by-case basis;
- introducing additional rules on standard clauses by specifying that standard agreements for industries or businesses will be modelled and determined by the relevant authorities through government regulations; and
- imposing strict liability on business actors whereby, if a customer suffers losses due to defective products, the business actor will be held liable irrespective of the fault element.

Development of Consumer Protection in Financial Services

In January 2023, the Indonesian government enacted the so-called "Omnibus Law for the Financial Sector" under Law No 4 of 2023 on Financial Sector Development and Reinforcement. The so-called PPSK Law, which became effective immediately upon introduction, amends 16 laws and revokes one law within the financial sector.

Structured around five primary pillars, one of which is strengthening state protection for consumers of financial products/services, the PPSK Law emphasises obligations and prohibitions for business actors in the financial sector. Under the PPSK Law, a business actor in the financial sector must fulfil specific obligations, such as enhancing consumer financial literacy and inclusion, tailoring products/services to consumer needs, establishing consumer complaint mechanisms, and safeguarding consumer data confidentiality and security. The PPSK Law also prohibits business actors from engaging in actions such as providing misleading information or information or documents in languages other than Indonesian, and charging fees for complaint-resolution services. Non-compliance with these obligations and prohibitions may result in administrative sanctions, including product/service restrictions or suspension, fines, and/or licence/product revocation. If a business actor that has been subjected to administrative sanctions fails to comply with or implement the sanctions, it may face criminal sanctions of up to 10 years' imprisonment and a maximum fine of IDR250 billion.

Moreover, the PPSK Law also imposes additional obligations and prohibitions aimed at safeguarding consumers. Failure to comply with these obligations and prohibitions will immediately subject a business actor to criminal sanctions of up to 10 years' imprisonment and a maximum fine of IDR1 trillion. These obligations encompass maintaining the security of consumer savings, funds, or assets under the business actor's responsibility, providing clear and accurate information regarding products/services, and preserving the confidentiality of consumer data and personal information. Meanwhile, the prohibitions include not offering products and services to consumers via private communica-

tion channels without the consumer's consent, employing standard agreements containing prohibited standard clauses, and engaging in business activities other than those regulated in the PPSK Law.

To implement the provisions of the PPSK Law, particularly concerning consumer protection in the financial sector, Bank Indonesia has issued Bank Indonesia Regulation No 3 of 2023 on Bank Indonesia Consumer Protection, while the Financial Services Authority (the Otoritas Jasa Keuangan, or OJK) has issued OJK Regulation No. 22 of 2023 on Consumer and Public Protection in the Financial Services Sector. These implementing regulations further outline the application of rules on consumer protection as specified under the PPSK Law, encompassing reporting, documentation and procedural requirements, in alignment with the responsibilities and authority of Bank Indonesia and the OJK.

The enactment of the PPSK Law and its implementing regulations carry significant implications for business actors, notably in terms of consumer protection in the financial sector. It is also worth noting that other laws and regulations related to consumer protection in the financial sector still apply if they do not contradict the PPSK Law.

Heading towards Mandatory Halal Certification in Indonesia

As part of consumer protection in Indonesia, Law No 33 of 2014 on halal product assurance and its implementing regulations (HPA Law) require all products entering, circulating and being traded on Indonesian territory be halal certified unless they originate from materials prohibited under Islamic law (*haram*). Halal-certified products must include a halal label on their packaging or on certain parts of the product that must be easy to see, read, and not easily erased, removed, or tampered with; products derived or made from non-halal materials must attach a non-halal label. Failure to comply with the obligation for halal certification will result in administrative sanctions ranging from fines to product recalls.

The halal certification obligation aims to provide reassurance and increase trust and certainty that halal products are available for the public, and constitutes a form of legal validation and a guarantee for more than 80 per cent of the Indonesian population, who are Muslim. More broadly speaking, it also encourages the development of the halal industry in Indonesia, boosting exports of Indonesian halal products to the global market.

Under the HPA Law, products and services subject to the halal certification obligation include the following.

- *Goods* – food and beverages, pharmaceuticals, cosmetics, chemicals, biological, and genetic engineering products.
- *Services* – slaughter (butchery), processing, storage/warehouse, packaging, distribution, marketing/sales, and delivery services.

The implementation and enforcement period of the halal certification obligation for the above products may vary from one product to another. The earliest deadline is set for 17 October 2024, and is applicable for: (i) food and beverage products; (ii) raw materials, food additives, and auxiliary materials for food and beverage products; and (iii) slaughtered products and related services. Subsequent stages will apply to the remaining product categories, with deadlines for mandatory halal certification ranging from 17 October 2026 to 17 October 2034.

In general, business actors have two alternative routes to apply for the halal certification, namely regular and "self-declare" registrations. Unlike regular registration, which requires an inspection and/or testing of the halal status of the products, self-declare registration is carried out based on self-declared halal statements from the business actors. However, the self-declare mechanism can be exercised only by micro and small businesses, and is applicable only for products that:

(i) do not contain any risks or use ingredients whose status halal is confirmed; and
(ii) involve a production process that is guaranteed to be halal and simple.

Currently, the primary body in charge of the halal product assurance in Indonesia is the Halal Product Assurance Administering Agency or Badan Penyelenggara Jaminan Produk Halal (BPJPH), authorised to issue and revoke halal certificates and halal labels for products registered by business actors.

It is worth mentioning that the obligation for halal certification also applies to products made outside Indonesia but distributed within the country. For imported products, halal certificates issued by foreign halal agencies can be used and recognised in Indonesia, provided that such foreign halal agencies have engaged in mutual recognition of halal certification with the BPJPH. In that case, halal-certified products will only need to be registered with the BPJPH, without undergoing the certification process. In contrast, if foreign halal agencies are not yet recognised by the BPJPH, products with halal certificates issued by foreign halal agencies and intended to be marketed in Indonesia must still apply for Indonesian halal certification.

Revitalising Consumer Protection in Indonesia – Strategic Reinforcement of BPSK and the Advent of Online Dispute Resolution

On 3 April 2024, the President of the Republic of Indonesia ratified Presidential Regulation No 4 of 2024 outlining a comprehensive National Strategy for Consumer Protection ("PR 4/2024"). One aspect of this initiative is the enhancement of the Consumer Dispute Resolution Agency, or Badan Penyelesaian Sengketa Konsumen (BPSK), tasked with resolving disputes between consumers and business actors through various forms of alternative dispute resolution, including arbitration, mediation, and conciliation.

Historically, BPSK has served as a vital forum for resolving consumer-business conflicts. However, the effectiveness of BPSK's decisions has often been tempered by the requirement for court assistance to enforce these decisions unless the involved parties voluntarily comply. Although the CPL asserts that decisions by the BPSK are final and binding, it paradoxically allows these decisions to be contested in district courts all the way up to the Supreme Court.

Addressing these concerns, in PR 4/2024 the Indonesian Government plans to update the CPL to reinforce BPSK's authority and ensure that its decisions provide clear and final outcomes. The aim is to make BPSK decisions more conclusive and enforceable without the need for costly legal battles.

Furthermore, PR 4/2024 introduces plans for an online dispute-resolution (ODR) system. This development aligns with broader regional objectives under the Association of Southeast Asian Nations (ASEAN) Strategic Action Plan on Consumer Protection 2025, which envisages the creation of an ASEAN ODR Network to streamline dispute resolution across member states. The

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Indonesian Ministry of Trade is at the forefront of this project to create a user-friendly online system where consumers can submit complaints. This initiative is expected to reduce the need for in-person visits to distant legal venues, cutting down on time and litigation costs.

This move towards online dispute resolution highlights a modern approach to consumer protection, aiming to streamline processes and make it easier for consumer-business actors to resolve conflicts. However, as this ODR system is not yet covered by the CPL, new regulations are anticipated in order to fully integrate and legitimise this innovative approach.

Through these updates, Indonesia is taking significant steps to ensure that consumer rights are supported by effective, efficient and modern dispute-resolution mechanisms and to minimise litigation costs for consumer and business actors.

ITALY

Trends and Developments

Contributed by:
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RASS Studio Legale Rinaldi e Associati

RASS Studio Legale Rinaldi e Associati was established in Milan in 1995 and has offices in Rome, Bologna, Florence and Istanbul. The firm provides legal advice to foreign corporations interested in operating in Italy, to guide them in setting up and running their business, as well as to Italian companies aiming to expand their activities abroad. The following areas of practice are covered: litigation; national and international arbitration; insurance, reinsurance, and related legal and regulatory issues; specific expertise in insurance claims concerning product and dangerous activity liability, professional indemnity, and medical malpractice; directors' and officers' liability; contractor liability; IP, IT, and corporate law; and M&A. The product liability team consists of two partners and six lawyers, and handles a broad range of matters for clients in the insurance, food & beverage and healthcare and life sciences sectors, including development and regulatory approval, marketing and distribution, product reimbursement, fraud, abuse, product liability, and intellectual property litigation.

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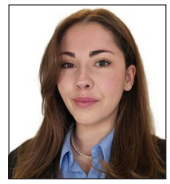

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This piece examines recent decisions that may exert influence in the Italian legal system, providing an update on changes in EU legislation expected to have immediate effect and on the main Italian regulations adopted in 2023 regarding product liability & safety.

General product liability and safety rules are contained in Legislative Decree No 206/2005 (the "Consumer Code") which covers the main provisions in force on consumer protection and rules on the relations between consumers and professionals (from advertising to correct information, contracts to product safety, and from access to justice to representative consumer associations).

For immediate reference, the following provisions will be considered:

- Articles 102-113 of the Consumer Code, implementing the provisions of Directive 2001/95/EC (transposed in Italy by Legislative Decree No 172/2004); and
- Articles 114-127 of the Consumer Code, implementing the provisions of Directive 85/374/EEC (transposed in Italy by Presidential Decree No 224/1998).

Definition of Victim/Claimant

The Court of Latina recently rendered a decision (No 2290 of 5 December 2022) on a claim made by an agricultural entrepreneur against the supplier and manufacturer of machinery alleging that the machinery did not comply with minimum safety requirements necessary to ensure the physical safety of its users, and leading to the amputation of some of the claimant's fingers.

The claimant brought an action to establish the liability of the supplier and the manufacturer for breach of the Consumer Code. The Court held that the claimant could not be classified as a consumer under the Consumer Code (ie, a natural person acting for purposes other than the exercise of an entrepreneurial, commercial, handcraft or professional activity), since the claimant had purchased the machinery to use it in the exercise of their business.

However, the Court did consider that certain provisions of the Consumer Code applied, in particular:

- Article 117, setting the circumstances under which a product may be considered defective;
- Article 123, listing the cases in which damages caused by defective products can be compensated (ie, damages caused by death or personal injury, and damages caused by the destruction or deterioration of something other than the defective product);
- Article 118, outlining the cases in which the manufacturer's liability is ruled out (eg, where the defect causing the damage did not exist when the manufacturer put the product into circulation).

In this instance, the Court held that none of the conditions supporting exclusion of the manufacturer's liability, set forth in Article 118, prevailed, that the claimant had proved the defectiveness of the machinery, the causal link between defectiveness and damage, and the damage suffered, thereby satisfying the burden of proof under the Consumer Code.

The above decision is one of the few precedents of the Italian courts where the provisions of the Consumer Code are applied to a party other than a consumer. In fact, Article 123 of the Consumer Code, under the heading "Compensable damages", provides that damages to property can

only be compensated if the goods in question (if not defective products causing the damage) are intended for private use or consumption. In line with a previous decision of Italian Supreme Court (case No 19414/2013), it has been established that damages resulting from death or personal injury can be compensated even if the death or injury occurred in the course of professional activity.

Updating of the EU Regulatory Framework on Product Liability and Safety

The EU lawmaker has recently deemed it necessary to update product liability and safety legislation to accommodate continuous challenges posed by new technologies – in particular, artificial intelligence, the new business models of the circular economy (production and consumption models that favour the reuse, repair and refurbishment of products) and new global supply chains – which are creating some legal uncertainty, and also in relation to the meaning of the term "product".

We believe the following regulations and directives adopted in 2023 will have the greatest impact on product liability and safety in Italy.

Regulation (EU) 2023/988 on general product safety, published in the Official Journal of the European Union on 23 May 2023 (the "Regulation"), applicable from 13 December 2024 and repealing Directive 2001/95/EC.

The Regulation aims at ensuring the functioning of the European market and consumer protection by adapting the legal framework to developments related to new technologies and online sales. In this respect, it is interesting to note Recital 25 of the Regulation, stating that: "New technologies might pose new risks to consumers' health and safety or change the way the existing risks could materialise, such as an external intervention hacking the product or changing its characteristics. New technologies might substantially modify the original product, for instance through software updates, which should then be subject to a new risk assessment if that substantial modification were to have an impact on the safety of the product".

The key points of the Regulation are as follows.

- The extension of the definition of "product". While Directive 2001/95/EC referred to "any product – including in the context of providing a service – which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them", the Regulation specifies that "product" means "any item, whether or not it is interconnected to other items".
- The rules for online sales, stating that "Products offered for sale online […] shall be deemed to be made available on the market if the offer is targeted at consumers in the Union".
- The new obligations for economic operators, such as manufacturers, authorised representatives, importers and distributors.
- A set of rules for online sales platforms, which are expressly defined as "providers of an online marketplace".

On product liability, the proposed Directive of the European Parliament and of the Council of 28 September 2022 "on liability for defective products" aims to modernise the framework of Directive 85/374/EEC, which will be repealed almost 40 years after its entry into force.

The Directive, which has not yet been published in the Official Journal of the European Union, will

improve consumer protection in the digital and information market, as follows:

- the definition of "product" is broader than previously, and includes "digital manufacturing files and software";
- together with manufacturers, importers and authorised representatives, economic operators liable for defective products include logistics service providers and, more generally, any entity with the power to modify the product affecting its safety;
- compensable damage includes any loss or corruption of data that is not used exclusively for professional purposes;
- the burden of proof on the damaged party is mitigated by the provision of certain presumptions (relating to defect and causal link);
- access to technical information relating to the product is easier, as the judge may order the defendant, upon request of the damaged party, to disclose such information in court.

The overall regulatory framework was completed by Regulation (EU) 2024/1689 published in the Official Journal of the European Union on 12 July 2024 "laying down harmonised rules on artificial intelligence" (the "AI Regulation") and the draft Directive by the European Parliament and the Council "adapting the rules on non-contractual liability to artificial intelligence" (the "AI Liability Directive").

The AI Regulation aims at mitigating risks to safety, health and other fundamental rights by establishing rules regarding the introduction to the market, putting into service, and use of AI systems (ie, machine-based systems designed to operate with varying levels of autonomy). In particular, the AI Regulation adopts a proportionate risk-based approach, understood as "the combination of the probability of an occurrence of harm and the severity of that harm", and sets out minimum requirements for AI systems that are deemed to pose a high risk as well as the relevant conformity assessment procedures to be followed before they are placed on the market.

The purpose of the AI Liability Directive is also "to contribute to the proper functioning of the internal market by harmonising certain national non-contractual fault-based liability rules, so as to ensure that persons claiming compensation for damage caused to them by an AI system enjoy a level of protection equivalent to that enjoyed by persons claiming compensation for damage caused without the involvement of an AI system".

The rules set out in the AI Liability Directive enable any type of claimant (individuals or businesses) to receive compensation if they are harmed due to fault or omission by a provider, developer or user of AI resulting in damage covered by national laws. To make this possible, the AI Liability Directive entitles the national courts to order the disclosure of evidence on high-risk AI systems suspected of having caused damage, and provides for a lighter burden of proof on the part of the claimant.

According to Article 3 of the AI Liability Directive, the courts may, at the request of a party and subject to certain conditions, order the defendant to disclose relevant evidence in their possession relating to a specific high-risk AI system that allegedly caused damages. If the defendant fails to comply with an order of disclosure, the judge shall infer the defendant's non-compliance with the duty of care to be proved by the non-disclosed evidence.

Furthermore, Article 4 of the AI Liability Directive lays down a rebuttable presumption of causality

by establishing, under certain circumstances, a causal link between non-compliance with a duty of care and the output of the AI system or the failure of the AI system to produce such output (if this has caused the alleged damage).

Law Decree No 19/2024 (as amended by Law No 56/2024) implementing the National Recovery and Resilience Plan (NRRP) has established a capital venture fund for artificial intelligence. Although the specific criteria for the allocation of the financial resources devoted to the fund have not yet been fully disclosed, the Decree has made it clear that it shall be used to assist companies in implementing AI security protection in the ex ante phase. The Council of Ministers also approved a draft law on 23 April 2024 to introduce provisions on AI in order to identify regulatory criteria capable of rebalancing the relationship between the opportunities offered by new technologies and the risks associated with their misuse, underuse or harmful use by providing anthropocentric risk-management solutions. The Italian government has designated the Agency for Digital Italy (AgID) and the Agency for National Cybersecurity (CAN) as the National Authorities for Artificial Intelligence, which will ensure the application and implementation of the national and EU legislation on AI.

Representative Actions in Product Liability Claims

Legislative Decree No 28/2023, implementing Directive (EU) 2020/1828, introduced the discipline of "representative actions for the protection of the collective interests of consumers" ("Representative Actions") into the Consumer Code alongside the discipline of class action already provided for by the Italian Code of Civil Procedure.

Representative Actions entitle claimants to obtain injunctive or redress measures against professionals failing to comply with national and EU legislative provisions aimed at protecting consumers, causing them harm.

Such actions may only be undertaken by qualified entities, namely consumer associations included in the public list established by Article 137 of the Consumer Code, as well as by other entities mentioned in Article 140-quater of the Consumer Code. Moreover, the public list provided for by aforementioned Article 137 contains a special section listing the subjects authorised to propose cross-border Representative Actions.

Three conditions must be met for the qualified entities to file a Representative Action in accordance with Article 140-ter of the Consumer Code, as follows.

- An infringement of the provisions contained in EU regulations or in national legislative acts implementing the EU directives, specifically identified in Annex IIsepties of the Consumer Code.
- The infringement must have been committed by professionals in the exercise of their business activity or their intellectual profession and against a plurality of "consumers", meaning natural persons interested in concluding (or who have already concluded) goods purchase agreements or services contracts for purposes not related to their entrepreneurial, commercial, handcraft or professional activity.
- The alleged conduct must be harmful to the collective interests of consumers, namely the "interests of a number of consumers who have been or may be harmed by an infringement of the provisions of Annex IIsepties" of the Consumer Code. The conduct must have caused, or must be capable of causing, an

actual prejudice to the interests of a plurality of consumers.

Finally, according to paragraph 4 of Article 140-ter of the Consumer Code, "the termination of infringements that occurred before the conclusion of the representative action does not determine the termination of the subject matter of the dispute". As an effect, the infringement does not have to persist when the action is filed, and even less at the time the judgment is issued.

Representative Actions in Product Liability Claims and Litigation Funding

Strictly related to the regulation of the Representative Actions, Legislative Decree No 28/2023 has provided a legislative framework for litigation funding as consumer protection could represent a business opportunity.

The terms "Litigation Funding" or "Third-Party Funding" generally refer to an agreement in which a third party to a dispute (funder) agrees to bear the costs that one of the involved parties (the client) would incur to initiate and pursue a dispute (whether in court or before an arbitral panel). However, the client agrees to pay the funder a previously agreed sum in case of positive outcome of the dispute.

According to national press reports, Italian litigation funding is seeing strong growth as a result of significant rulings by the Antitrust Authority and due to the presence of the Unified Patent Court in Milan. This has led to the entry of international investment funds into the country as well as the establishment of Italian litigation funding companies and several partnerships with Italian law firms specialised in litigation.

The EU lawmaker has imposed a number of information requirements on qualified entities (which are entitled to bring Representative Actions for the protection of the collective interests of consumers) since their funding, if not duly established, may put the protection of consumers' interests at risk, leading to a conflict of interests, ultimately undermining the proper administration of justice.

Recital No 52 of Directive (EU) 2020/1828 states the following: "Qualified entities should be fully transparent vis-a-vis courts or administrative authorities with regard to the source of funding of their activities in general and with regard to the source of funds that support a specific representative action for redress measures. […] The information provided by the qualified entity to the court or administrative authority should enable the court or administrative authority to assess whether the third party could unduly influence the procedural decisions of the qualified entity in the context of the representative action, including decisions on settlement, in a manner that would be detrimental to the collective interests of the consumers concerned, and to assess whether the third party is providing funding for a representative action for redress measures against a defendant who is a competitor of that third-party funding provider or against a defendant on whom the third party funding provider is dependant. The direct funding of a specific representative action by a trader operating in the same market as the defendant should be considered to imply a conflict of interest, since the competitor could have an economic interest in the outcome of the representative action which would not be the same as the consumers' interest".

In light of the preliminary considerations set out in recital No 52 and of Article 10 of Directive (EU) 2020/1828, under the heading "Funding of representative actions for redress", Arti-

cle 140-quinquies, second paragraph, letters d) and f), of the Consumer Code (as amended by Legislative Decree No 28/2023) requires the entities entitled to bring cross-border representative actions to include "in their articles of association rules, including those relating to the causes of incompatibility of legal representatives, appropriate to ensure the independence of the association and the absence of influence from persons other than consumers and in particular from professionals who have an economic interest in bringing representative actions, as well as appropriate measures to prevent and resolve conflicts of interest that may arise between the association, its funders and the interests of consumers" as well as to make public information about their sources of funding on their website.

JAPAN

Law and Practice

Contributed by:
Junichi Ikeda, Takayuki Fujii, Masashi Chusho and Satoyuki Nakano
Nagashima Ohno & Tsunematsu

Contents

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Nagashima Ohno & Tsunematsu is the first integrated full-service law firm in Japan, and is one of the foremost providers of international and commercial legal services based in Tokyo. The firm's overseas network includes offices in New York, Singapore, Bangkok, Ho Chi Minh City, Hanoi and Shanghai; associated local law firms in Jakarta and Beijing, where its lawyers are on site; and collaborative relationships with prominent local law firms throughout Asia and the rest of the world. The firm has extensive corporate and litigation capabilities spanning key commercial areas such as antitrust, intellectual property, product liability and safety, labour, and taxation, and is known for path-breaking domestic and cross-border risk management/corporate governance cases and large-scale corporate reorganisations. The approximately 550 lawyers of the firm, including over 40 experienced foreign attorneys from various jurisdictions, work together in customised teams to provide clients with the expertise and experience specifically tailored to each client matter.

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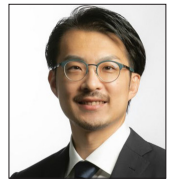

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1. Product Safety

1.1 Product Safety Legal Framework

The Consumer Product Safety Act (CPSA) is the main law for product safety in Japan. Consumer products are generally subject to the CPSA. The term "consumer products", as used in the CPSA, has a very broad scope and means any product supplied mainly for use by general consumers in their everyday lives, excluding certain products listed in the table appended to the CPSA. The excluded products include:

- medical products, cosmetics and medical devices, which are regulated by the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices;
- automobiles, which are regulated by the Road Trucking Vehicle Act; and
- food, food additives and cleaning agents, which are regulated by the Food Sanitation Act (FSA).

Consumer products that are found to be highly likely to cause harm, particularly to the lives or health of general consumers, are defined as "specified products" under the CPSA; these include climbing ropes, autoclaves and pressure cookers for household use, riding helmets and portable laser application devices. The relevant competent authority establishes the technical standards necessary for the specified products to prevent the lives or health of general consumers being endangered.

The regulatory framework under the CPSA is as described below.

Product Safety of Consumer Products (PSC) Mark System

The PSC mark system is a pre-marketing method to ensure product safety by regulating the sale and display of specified products, for sale purposes, through labelling requirements. If a manufacturer or an importer of specified products has submitted the required notification, ensured the products conform to certain technical standards set by the competent authority, and has had the products inspected (and kept the inspection record), they can affix the PSC mark on the specified products. The sale or display, for the purpose of selling, of these products is prohibited, unless the PSC mark is placed on the specified products.

Reporting Obligations

A manufacturer or importer of consumer products that becomes aware of a serious product accident that has occurred in relation to a consumer product that it manufactures or imports, must report specific information related to the product and the accident to the Secretary General of the Consumer Affairs Agency (CAA) within ten days. For non-serious product accidents, manufacturers and importers of consumer products, as well as retailers and other parties who are involved with such products, are expected to report the accident to the National Institute of Technology and Evaluation (NITE), an independent administrative agency, by an official notice issued by the Ministry of Economy, Trade and Industry (METI).

For serious product accidents, the Secretary General of the CAA will publish certain information related to the relevant product and accident, if the Secretary General finds this necessary to prevent serious danger, or an increase in danger, to consumers. For non-serious product acci-

dents, NITE generally publishes limited details of the accident.

Inspection and Labelling Requirements to Prevent Accidents Due to Deterioration

Under the CPSA, consumer products that have a high likelihood of causing a serious accident due to degradation over time; ie, oil water heaters and oil bath boilers, are called "specified maintenance products". For these specified maintenance products, a manufacturer or importer must set:

- a standard period of use during which there will be no safety issue if used under the standard conditions of use, which is called the "design standard use period"; and
- an inspection period to prevent injury due to age-related deterioration once the design standard use period has expired.

The manufacturer or the importer must place labelling which shows, among other information, the design standard use period and the time of commencement and expiration of the inspection period. The manufacturer or the importer must send a notification to the user of the specified maintenance product when the end of the design standard use period is approaching. Furthermore, when requested within the inspection period, the manufacturer or the importer must conduct an inspection of the specified maintenance product. For consumer products that do not have a high likelihood of causing a serious accident but that have a high volume of accident reports due to deterioration over time, such as electric fans and air conditioners, warning labels on deterioration and the design standard period of use must be affixed.

In addition to the CPSA, some consumer products may be subject to other laws, such as the Electrical Appliances and Materials Safety Act, the Gas Business Act and the Act on the Securing of Safety and the Optimisation of Transaction of Liquefied Petroleum Gas.

1.2 Regulatory Authorities for Product Safety

No regulator has general jurisdiction over product safety issues in Japan. When the CAA was established, jurisdiction over existing legislation involving the safety of the lives and health of people remained with the relevant ministries which then had jurisdiction. Due to this arrangement, the CAA has limited power to regulate business operators with respect to consumer safety matters. However, serious product accidents must be reported by manufacturers and importers to the Secretary General of the CAA under the CPSA.

One of the main regulators for product safety in Japan is the METI. As the METI has jurisdiction over the CPSA, under which most consumer products are regulated, the METI has broad jurisdiction over consumer products.

A ban on the sale of a specific consumer product can be imposed by the competent authority. For example, if certain specified products fail to conform to the technical requirements established by the competent authority and the competent authority finds doing so particularly necessary to prevent harm to the lives or health of general consumers, the competent authority can prohibit the manufacturer and the importer of the products from affixing the PSC mark on the products for a period of not more than one year. This effectively results in a ban on the sale of the specific consumer products, as no person engaged in the manufacture, import or sale of the specific consumer product may sell, or display such products for the purpose of selling

them, without affixing the PSC mark under the CPSA.

Certain specific products are exclusively regulated by other regulators. For example, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) regulates automobiles; and the Ministry of Health, Labour and Welfare (MHLW) regulates medical products, cosmetics and medical devices, as well as food, food additives and cleaning agents. These regulators have the power to establish technical or other relevant standards. If certain conditions are met, these regulators can order the manufacturer to implement remedial measures, including the implementation of product recalls.

1.3 Obligations to Commence Corrective Action

General

The Basic Consumer Act provides that the Japanese government must take necessary measures to ensure the safety of consumers, such as by:

- requiring that business operators recall goods that may be detrimental to safety; and
- collecting and providing information on goods and services that may be detrimental to safety.

Business operators are expected to implement a product recall if a product that they manufacture, import or sell might be detrimental to the safety of its consumers.

Under the CPSA, any person engaged in the manufacture or import of consumer products must investigate the cause of any product incidents that occur involving these particular consumer products. The manufacturer or importer must endeavour to either recall the consumer products or take measures to improve the safety of these products and prevent the occurrence of further product incidents.

Sector-Specific

Medical

Under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, holders of a marketing authorisation for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, or persons with special approval regarding the foreign manufacturing of these products, must, when they learn of the occurrence or spread of hazards in health and hygiene suspected to be caused by using such products that they have manufactured and sold or for which they have received certain approval, dispose of, recall, discontinue selling and provide information on such products, and take other necessary measures for the prevention of the occurrence or spread of hazards in health and hygiene.

Automotive

Under the Road Trucking Vehicle Act (including a guideline established thereunder), in cases where the structure, mechanism or performance of a certain range of automobiles of the same model does not, or is not likely to, conform with the necessary safety standards, and the cause relates to the design or manufacture of the automobiles, a manufacturer or importer must promptly recall the automobiles and report certain matters specified in the Act to MLIT.

Food standards

Under the FSA, a food business operator must endeavour to take all necessary measures, appropriately and immediately, to prevent food sanitation hazards resulting from the sale of food, etc, such as the provision of a certain

record to the relevant state or prefectures, and the disposal of the food that caused the food sanitation hazards.

Advertising

There is no mandatory advertising requirement under the CPSA and FSA. However, under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, in cases where holders of marketing authorisations for pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices or regenerative medicine products, or persons with special approval regarding foreign manufacturing, file for a recall, they must – in addition to promptly providing the information on the recall to each medical institution, etc – provide such information using the internet. Furthermore, under the Road Trucking Vehicle Act, if manufacturers of automobiles file for a recall, they must have the filing published in the journal of the Japan Automobile Service Promotion Association to disseminate information on the recall to providers of automobile repair services.

1.4 Obligations to Notify Regulatory Authorities

The CPSA sets out incident-based reporting. If a manufacturer or importer of consumer products comes to know of a serious product incident that has occurred with a consumer product that it manufactures or imports, it must report certain information related to the product and the incident to the CAA. The report must be submitted in the format provided for in the Cabinet Office Order within ten days from the date of knowing that a serious product incident has occurred.

Even if an incident that occurs involving the consumer product is not serious, it is expected by an official notice issued by the METI that business operators involved with such consumer products – eg, manufacturers, importers and retailers, will report the incident to NITE, which is an independent administrative agency, in the format provided for on NITE's website.

The FSA provides a reporting obligation for food recalls. Under the FSA, if a business operator recalls food, additives, apparatus, or containers and packaging which are, or are suspected to be, in violation of the FSA, it must notify the prefectural governor of the initiation of the process of recall without delay, except in cases where the MHLW or a prefectural governor has ordered the business operator to recall the products, or there is no risk of a food hygiene hazard. When the prefectural governor has received the report, it must report it to the MHLW.

1.5 Penalties for Breach of Product Safety Obligations

In cases where a manufacturer or an importer of consumer products fails to send a report to the CAA or sends a false report to the CAA in violation of the obligations explained in **1.4 Obligations to Notify Regulatory Authorities**, the competent minister may find it necessary – to secure the safety of the consumer products manufactured or imported by that manufacturer or importer – to order the manufacturer or importer to develop a system necessary for collecting information on serious product incidents that occur in relation to the consumer products manufactured or imported by it, and for the proper management or provision of that information. Failure to observe such an order issued by the competent minister may result in the manufacturer or importer and their representative facing imprisonment for up to one year and/or a fine of up to JPY1 million. However, failure to report to the CAA in itself, pursuant to the obligation explained in **1.4 Obligations to Notify Regulatory Authorities**, does not trigger criminal penalties.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

The main causes of action for product liability are tort and contract.

Tort

The general principle of tort is provided in Article 709 of the Civil Code – namely, that a person who intentionally or negligently infringes another person's right or legally protected interest is liable to compensate them for any loss or damage caused by that infringement. The tort liability under Article 709 of the Civil Code requires the following conditions to be met:

- the violation of the plaintiff's right or legally protected interest by the defendant;
- an intentional or negligent act on the part of the defendant;
- the occurrence of damage; and
- a causal relationship between the violation and the damage.

In addition, a special rule to the general principle of tort is added by Article 3 of the Product Liability Act. The special rule is that a person who is injured as a result of the defects of a product can demand compensation from the manufacturer and other involved parties without having to prove intent or negligence. Product liability under Article 3 of the Product Liability Act requires the following conditions to be met.

- The defendant corresponding to:
  (a) any person who manufactured, processed, or imported the product as a business;
  (b) any person who indicates their name, trade name, trade mark or other indication (hereinafter referred to as "representation of name, etc") on the product as the manufacturer of the product, or any person who indicates the representation of name, etc, on the product which makes others misunderstand that they are the manufacturer; or
  (c) except for the cases outlined in the two bullet points above, any person who indicates any representation of name, etc, on the product which, in terms of the manufacturing, processing, importing or selling of the product, and other circumstances, is recognised as its substantial manufacturer (hereinafter, any persons corresponding to these three bullet points are collectively referred to as "manufacturer, etc").
- Delivery of the movable product by the defendant.
- Damage being caused by the product which, at the time of delivery by the defendant, was manufactured or processed and was a movable product.
- A defect in the product at the time of delivery by the defendant.
- Infringement of the injured party's right or legally protected interest.
- The occurrence of damage.
- A causal relationship between the defect and the damage.

Contract

Buyers of defective products may, in accordance with contract law under the Civil Code, make a claim against the seller for compensation for damages, the repair of a defect, or the delivery of a substitute for the product.

Contractual liability requires the following conditions to be met:

- the conclusion of the contract;

- a defect in the product;
- the cause of that defect being attributable to the defendant (this not being required for a claim for the repair of a defect, or the delivery of a substitute for the product);
- the occurrence of damage; and
- a causal relationship between the defect and the damage.

2.2 Standing to Bring Product Liability Claims

Individual Standing

The following have the standing to bring claims for product liability, as listed in **2.1 Product Liability Causes of Action and Sources of Law**:

- under a tort – a person whose right or legally protected interest has been violated;
- under the Product Liability Act –
  (a) a person who has been injured because of the defect; or
  (b) a person whose property, excluding the defective product itself, has been damaged because of the defect; or
- under contract law – the buyer.

Collective Redress

Furthermore, in Japan, the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers has been enacted. This Act allows a specified qualified consumer organisation to bring lawsuits against a company on behalf of unspecified and multiple individual consumers in certain cases.

This Act establishes two phased proceedings for the collective redress for property damage incurred by consumers. In the first proceeding, a specified qualified consumer organisation files an action for declaratory judgment on common obligations, which is an action seeking a declaratory judgment that a company owes monetary payment obligations to unspecified and multiple consumers based on factual and legal causes common to the consumers, where property damage is incurred by a considerable number of consumers in connection with consumer contracts. In the second proceeding, simplified determination proceedings to determine the presence or absence and the contents of a claim for payment of money are carried out by the district court which made the final judgment in the first instance of the action for declaratory judgment on common obligations.

A specified qualified consumer organisation may file an action with regard to monetary payment obligations which pertain to the following claims in connection with consumer contracts (set forth in Article 3 (1) of the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers):

- a claim for performance of a contractual obligation;
- a claim pertaining to unjust enrichment;
- a claim for damages based on non-performance of a contractual obligation;
- a claim for damages based on a tort (limited to a claim based on the provisions of the Civil Code); and
- following claims for damages on the grounds that a company's employee has caused damages to a third party in the performance of their duties regarding the consumer contract –
  (a) a claim for damages based on the provisions of Article 715 (1) of the Civil Code against a company that has intentionally or through gross negligence failed to exercise reasonable care in appointing

the said employee or in supervising the business;
(b) a claim for damages based on the provisions of Article 715 (2) of the Civil Code against a supervisor of the business who has intentionally or through gross negligence failed to exercise reasonable care in appointing the said employee or in supervising the business; and
(c) a claim for damages based on a tort (limited to a claim based on the provisions of the Civil Code) against the said employee who has intentionally or through gross negligence caused damage to a third party.

Damage which cannot be compensated through collective redress actions

An action may not be filed when the damage incurred is any of the following (set forth in Article 3 (2) of the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers):

(i) damage due to the loss or damage of property other than goods, rights, or any other object of a consumer contract resulting from the non-performance of a contractual obligation or a tort;
(ii) damage due to the loss of profit which would have been gained through the disposition or use of the object of a consumer contract if that object had been provided;
(iii) damage due to the loss or damage of property other than goods pertaining to manufacturing, processing, repair, transport, or retention under a consumer contract or any other subject of the service which was the object of a consumer contract, resulting from the non-performance of a contractual obligation or a tort;
(iv) damage due to the loss of profit which would have been gained through the use of the service that is the object of a consumer contract or through the disposition or use of the subject of the service if the service had been provided;
(v) damage due to harm done to the life or body of a person; or
(vi) damage due to mental suffering (excluding the following damages (limited to the cases where the main facts on which the calculation of the amount is based are common to a substantial number of consumers)):

- damages that are claimed in conjunction with the claims listed in Article 3 (1) of the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers (regarding claims (iii) to (v) set forth in Article 3 (1), limited to those that do not include claims pertaining to damages due to mental suffering) and based on factual causes common to property claims; or
- damages that are caused by a company intentionally.

Since the damages which are subject to the claims described in **2.1 Product Liability Causes of Action and Sources of Law** correspond to (i), (ii), (v) and (vi) above, a specified qualified consumer organisation cannot bring a collective redress action with respect to a claim under the Product Liability Act.

2.3 Time Limits for Product Liability Claims

Tort

The right to seek compensation for damages in tort will be extinguished by the completion of prescription if the victim, or their legal representative, does not exercise the right within

three years from the time when they realised the damages and the identity of the perpetrator. In addition, the right will be extinguished when 20 years have elapsed from the time of the act of tort.

Product Liability Act

The right to claim damages provided under the Product Liability Act will be extinguished by the completion of prescription if the victim, or their legal representative, does not exercise the right within three years (if death or injury occur, the prescription term is extended to five years) from the time when they realised the damages and the person liable for the damages. In addition, the right will be extinguished when ten years have elapsed from the time when the manufacturer, etc, delivered the product. However, this ten-year period will start from the time of the occurrence of (i) the damage caused by substances which become harmful to human health when they accumulate in the body; or (ii) symptoms that appear after a certain latent period.

Contract Law

If the buyer fails to notify the seller of the non-conformity with the terms of the contract within one year from the time the buyer became aware of the non-conformity, the buyer cannot make a claim against the seller unless the seller was aware of the existence of the non-conformity at the time of delivery, or was not aware of the existence of the non-conformity through gross negligence. Even if the notice is given within one year, the right to claim will be extinguished by prescription if it is not exercised within five years from the time when it becomes known that the right can be exercised or if it is not exercised within ten years (in the case of a claim for damages resulting from the death or injury to persons, this period will be extended to 20 years) from the time it becomes exercisable.

2.4 Jurisdictional Requirements for Product Liability Claims

The courts of Japan have jurisdiction over an action that is brought (i) against a corporation whose principal office or business office is located in Japan; and (ii) against a corporation whose representative or person principally in charge of its business is domiciled in Japan, if the corporation does not have a business office or other office in Japan, or if the location of its business office or other office is unknown. In addition, the courts of Japan have jurisdiction in the following cases depending on the grounds of the claim.

Tort

The courts of Japan have jurisdiction if the place where the wrongful act was committed or the place where the consequences occurred are in Japan (excluding cases where the consequences of a wrongful act committed in a foreign country have occurred within Japan, but it would not ordinarily have been possible to predict that such consequences could occur within Japan).

Product Liability Act

In line with the principle applying to tort above, the courts of Japan will have jurisdiction over the product liability case if the place where the wrongful act was committed or the place where the consequences occurred was within Japan. In relation to the product liability case, “the place where the wrongful act was committed” is interpreted as the place of manufacture.

Contract Law

The courts of Japan will have jurisdiction if the place of performance of the obligation under the contract is within Japan, or if it is determined that the place of performance of the obligation is within Japan in accordance with the law of the place selected under the contract. In the case of an action regarding a contract concluded

between a consumer and an enterprise, which is brought by the consumer against that enterprise, the courts of Japan will have jurisdiction if the consumer is domiciled in Japan at the time when the action is brought or at the time the consumer contract is concluded.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There are no mandatory steps that must be taken before proceedings can be formally commenced for product liability cases.

2.6 Rules for Preservation of Evidence in Product Liability Claims

The Code of Civil Procedure provides for the preservation of evidence, under which parties to a lawsuit can file a petition with the court, either prior to or after filing the lawsuit, to conduct an examination of the evidence including documentary evidence, testimony and the product itself.

2.7 Rules for Disclosure of Documents in Product Liability Cases

Enquiry Prior to Filing of Action

If a person has provided notice of an action to the would-be defendant of the action in advance, that notifying person may make an enquiry in writing to the would-be defendant who received the notice, regarding particular matters that are obviously necessary for the preparation of the allegations or proof if the action is filed. When the would-be defendant has responded to the notifying person with a written response to that advance notice, under certain circumstances, such a would-be defendant may themselves make a written enquiry to the notifying person. Under the Act Partially Amending the Code of Civil Procedure, which was passed on 18 May 2022, and will take effect in or before 2026, these procedures (the notice and enquiry by the notifying person and the response and enquiry by the would-be defendant) can be conducted by electronic means.

Furthermore, upon petition by the notifying person or the would-be defendant who received the notice, the court may commission the holder of a document to send that document when it is necessary. However, this petition is not widely used. Under the Act Partially Amending the Code of Civil Procedure, the court may commission the sending of electronic records as well as documents.

Preservation of Evidence

Preservation of evidence (see **2.6 Rules for Preservation of Evidence in Product Liability Claims**) is often used for the purpose of collecting documentary and other evidence.

Commissioning Sending of Document

After filing an action, the parties may petition the court to commission a person who holds a document to send the document. The holder of the document is not, however, obliged to do so. Under the Act Partially Amending the Code of Civil Procedure, electronic records may be submitted as evidence and the parties may petition the court to commission the sending of electronic records.

Order to Submit Documents

After filing an action, the parties may request that the court issue an order for the submission of a document against the opposing party or a third party who holds that document. The holder of the document may not refuse to submit the document to the court when:

- the document is in the possession of a party that has referred to it in the suit;
- the party that requested the court to issue the submission order has the right to ask the

holder of the document to deliver it or allow it to be inspected; or
- the document has been produced in the interest of the party that requested the court to issue the submission order or regarding the legal relationships between that party and the person who holds the document.

If the document does not fall under any of the foregoing, the holder of the document may refuse to submit the document if it falls under the categories set forth by Article 220 of the Code of Civil Procedure, which include the categories of a document concerning confidential information in connection with a public officer's duties, and a document prepared exclusively for use by the holder of the document. Under the Act Partially Amending the Code of Civil Procedure, electronic records may be submitted as evidence and the parties may request that the court issue an order for the submission of an electronic record.

Request for Information Through the Bar Association

An attorney registered in Japan may request the bar association to make enquiries to public offices or public or private organisations for information necessary for their case. It is understood that those who have received such an enquiry should submit a report on the matters under enquiry, unless there are justifiable grounds not to do so.

2.8 Rules for Expert Evidence in Product Liability Cases

Expert Testimony

Upon the request of a party, the court may hear expert testimony to obtain the input of an expert, who will be designated by the court. The expert will state their opinion in writing or orally. Under the Act Partially Amending the Code of Civil Procedure mentioned in **2.7 Rules for Disclosure of Documents in Product Liability Cases**, the expert may state their opinion in an electronic file, etc.

As an exception to this, by its own authority and without the request by a party, the court may commission a government agency or public office, a foreign government agency or public office, or a corporation to give expert testimony.

Expert Report

In addition to this, a party may submit a report – prepared by an expert appointed by the party – to the court as documentary evidence. It is also possible to request the court to conduct a witness examination of the experts. If the opposing party wishes to rebut the content of an expert report, the opposing party may request that the court allows it to conduct an examination of the expert, or to submit a report prepared by their own expert.

Technical Adviser

In product liability cases, highly technical matters often become central issues. In such cases, the court may, after hearing the opinions of the parties, have a technical adviser participate in the proceedings to assist the judge in understanding technical matters (Article 92–2 of the Code of Civil Procedure).

The consent of the parties is not required for the court to have a technical adviser participate in the proceedings, but upon the petition of both parties, the court is required to revoke its determination for the participation of a technical adviser (Article 92–4 of the Code of Civil Procedure). Accordingly, it is unlikely that the court will have a technical adviser participate in the proceedings in the first place when it is clear that both parties are against it.

The court may have a technical adviser give an explanation of the technical matters in writing or orally. When a technical adviser submits the explanation in writing, that document is sent to both parties (Article 34-3 of the Rules of Civil Procedure), and both parties may state their opinions on the explanation of the technical adviser (Article 34-5 of the Rules of Civil Procedure). The explanation of an expert is not treated as evidence, but it is pointed out that the court may base its judgment on such explanation if both parties so agree. Under the Act Partially Amending the Code of Civil Procedure mentioned in **2.7 Rules for Disclosure of Documents in Product Liability Cases**, a technical adviser may give an explanation in an electronic file, etc.

2.9 Burden of Proof in Product Liability Cases

In principle, a party that benefits from the legal consequences bears the burden of proof of the facts which give rise to such legal consequence.

Tort

A plaintiff who claims compensation for damages suffered in product liability cases in a tort bears the burden of proving the facts that gave rise to the plaintiff's right to seek damages in a tort under Article 709 of the Civil Code, including:

- the violation of the plaintiff's right or legally protected interest by the defendant;
- an intentional or negligent act by the defendant;
- the occurrence of damage and the amount of damages claimed; and
- a causal relationship between the violation and the damage.

Product Liability

A plaintiff in product liability cases, who seeks the benefit from the occurrence of the legal effect of the Product Liability Act, bears the burden of proving the facts that gave rise to the plaintiff's right of claim under the Product Safety Act, including:

- the existence of a defect in the product;
- the occurrence of damage and the amount of damages claimed by the plaintiff; and
- a causal relationship between the defect and the damage.

Even if the plaintiff proves the above facts, the defendant may be relieved of liability by proving the following facts, which constitute exemptions of liability under the Product Safety Act:

- the defect in the product could not have been discovered given the state of scientific or technical knowledge at the time when the manufacturer delivered the product (see **2.12 Defences to Product Liability Claims**); or
- where the product of the defendant is used as a component or raw material of another product and the defect occurred primarily as a result of compliance with the instructions concerning the design given by the manufacturer of that other product, and where the manufacturer, etc, has not been negligent with respect to the occurrence of that defect.

Contract Law

A plaintiff who seeks compensation for loss or damage suffered in product liability cases, as a contractual liability, bears the burden of proof of the following facts, which constitute the right to claim such compensation:

- the execution of a contract;
- a defect in the product;

- the cause of that defect being attributable to the defendant;
- the occurrence of damage and the amount of damages claimed; and
- a causal relationship between the defect and the damage.

2.10 Courts in Which Product Liability Claims Are Brought

Product liability cases must be filed with a district court or summary court as a court of first instance. As the summary courts handle civil cases that involve claims not exceeding JPY1.4 million, product liability cases which involve more than this amount must be filed with a district court.

The lay-judge system has been introduced to criminal trials in Japan, where citizens selected as judges participate in trials, but not in civil cases. As such, product liability cases are decided without the involvement of a jury and by judges only.

2.11 Appeal Mechanisms for Product Liability Claims

As with ordinary proceedings of civil cases, the proceedings of product liability cases are governed by the Code of Civil Procedure and the Rules of Civil Procedure.

Court of Second Instance

An appeal to the court of second instance must be filed within two weeks from the day on which the written judgment is served to the parties. Even after the right to appeal to the court of second instance is extinguished, a respondent may file an incidental appeal until oral arguments are concluded in the second instance. Under the Act Partially Amending the Code of Civil Procedure mentioned in **2.7 Rules for Disclosure of Documents in Product Liability Cases**, the court renders its judgment based on the electronic judgment form.

Final Appeal

A final appeal in response to a high court judgment must be filed within two weeks from the day on which the written judgment is served to the parties. As with the first-level appeal, a respondent may file an incidental final appeal. A final appeal can be filed on the grounds that the judgment reflects an error in the interpretation of the constitution or that it is otherwise unconstitutional. A final appeal can also be filed on the grounds of the existence of a material violation of the proceedings under Article 312(2) of the Code of Civil Procedure. A final appeal to a high court can also be filed on the grounds of a violation of law or regulation that has clearly influenced the judgment. Under the Act Partially Amending the Code of Civil Procedure, the court renders its judgment based on the electronic judgment form.

Petition for Acceptance of Final Appeal

If the Supreme Court is the court where the final appeal should be filed, and the prior judgment contains a decision that is inconsistent with precedents rendered by the Supreme Court or involves other material matters concerning the interpretation of laws and regulations, the Supreme Court can, on petition, accept the case as the final appellate court.

2.12 Defences to Product Liability Claims

The manufacturer and other relevant parties are not liable where the product is used as a component or raw material of another product, and a defect occurred primarily as a result of compliance with the instructions concerning the design given by the manufacturer of that other product, and the manufacturer and other relevant parties

are not negligent with respect to the occurrence of the defect.

Furthermore, the manufacturer and other relevant parties are not liable where a defect in the product could not have been discovered given the state of scientific or technical knowledge at the time when it was delivered. As the "state of scientific or technical knowledge" is generally interpreted as the highest level of scientific or technical knowledge available when the product was manufactured, it is very difficult to successfully use this defence (there is currently no precedent in which the defence has been successfully applied).

Other general defences, such as comparative negligence and extinguished prescription (time barring), are also available.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Adherence to regulatory requirements is a relevant consideration in product liability cases.

Various regulations concerning the safety of products are implemented under a variety of laws such as the CPSA, the Road Trucking Vehicle Act, the FSA, the Pharmaceutical Affairs Act and the Building Standards Act. Since the purpose and objective of these regulations is only to establish minimum safety standards, and this differs from the purpose and objective of the Product Liability Act, it is commonly understood that conformity or non-conformity with these regulations (including voluntary regulations concerning the safety of products) will be regarded as nothing more than one of the factors to be taken into account in product liability cases.

2.14 Rules for Payment of Costs in Product Liability Claims

Court Costs

In principle, the court costs are borne by the losing party. In the case of a partial defeat, the court determines, at its own discretion, the burden of the court costs on each party. However, depending on the circumstances, the court can have one of the parties bear all the court costs.

Court costs include, among other things, filing fees, travel expenses, daily allowances, accommodation costs, expenses for the preparation and submission of documents and the fees of any court-designated expert witnesses. Court costs do not include costs relating to party-appointed expert witnesses, which are borne by each party, although they may be recovered as part of the damages.

Legal Costs

Court costs do not include legal costs, which are borne by each party, in principle. However, in practice, part of the prevailing party's legal costs can be awarded as part of the damages (generally 10% of the damages), for claims under the Product Liability Act and tort claims based on the Civil Code. For breach of contract claims, the legal costs cannot be included as part of the damages awarded to the prevailing party.

2.15 Available Funding in Product Liability Claims

There is no explicit provision permitting or prohibiting litigation funding. There are some provisions that relate to the legitimacy of litigation funding. Under the Trust Act, no trust is allowed to be created for the primary purpose of having another person conduct any procedural act.

Under the Attorney Act, no person may engage in the business of obtaining the rights of oth-

ers by assignment and enforcing those rights through lawsuits, mediation, conciliation or any other method. Whether litigation funding is allowed in light of this prohibition has not been legally tested and it is not clear whether litigation funding is permitted under Japanese law. Contingency fees or "no-win, no-fee" arrangements are not prohibited, although pure contingency fees or "no-win, no-fee" arrangements are rarely used.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

The Act on Special Measures Concerning Civil Proceedings for the Collective Redress for Property Damage Incurred by Consumers (Act No 96 of 2013) introduced opt-in collective action. Under the Act, a collective action can only be brought by a specified qualified consumer organisation, and not by a consumer.

The Act involves a two-phased procedure.

- In the first phase, a special qualified consumer organisation files an action for a declaratory judgment on common obligations. This action seeks a declaratory judgment that a company owes monetary obligations to a considerable number of consumers, based on factual and legal causes common to these consumers (except where an individual consumer has no grounds to claim a payment of money due to circumstances specific to that consumer) where property damage has been incurred by a considerable number of consumers in connection with consumer contracts.
- In the second phase, simplified proceedings to determine the presence or absence, and the contents, of a claim of each opt-in consumer for the payment of money (Simple Determination Proceedings) are carried out by the district court that rendered the final judgment at first instance for a declaratory judgment on common obligations. The scope of claims that can be brought under the Act is limited to those listed therein and compensatory claims under the Product Liability Act (Act No 85 of 1994) are out of its scope. For more details, see **2.2 Standing to Bring Product Liability Claims**. In addition to company (a corporation or any other association or foundation and an individual when the individual conducts the business), under the Act Partially Amending the Act on Special Measures Concerning Civil Proceedings for the Collective Redress for Property Damage Incurred by Consumers, which took effect on 1 October 2023, individuals other than companies can be named as defendants (the CAA assumes that a business supervisor or employee who was involved in tortious business practices can be a potential defendant).

2.17 Summary of Significant Recent Product Liability Claims

There have been no particularly significant product liability cases in Japan in recent years.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Mandatory Standards for Children's Toys

On 19 June 2023, the Order for Enforcement of the Consumer Product Safety Act was amended to prohibit the sales of magnetic amusement products and water-absorbing synthetic resin toys, in order to address reported accidents in which children accidentally swallowed such toy.

Amendment to the Consumer Product Safety Act and Other Related Acts

On 1 March 2024, a Cabinet Decision was made on the Bill for the Act for Partially Amending the Consumer Product Safety Act and Other Related Acts. The outline of the bill is as follows.

- Responses to the expansion of internet transactions (Consumer Safety Act, Gas Act, Electrical Appliances Act, and Liquefied Gas Act):
  - (a) in a case involving an overseas operator selling products directly to consumers in Japan without going through a domestic importer, the overseas operators should be clarified as an entity allowed to submit a notification under the four Acts related to product safety; and the overseas operator is required to appoint a responsible person (domestic supervisor) in Japan to ensure the enforcement of regulations;
  - (b) in a case in which consumer safety products, etc, sold on any digital platforms for shopping, are considered to cause harm to consumers in Japan and the seller of the products is not expected to take the necessary measures – eg, recall, the business providing the digital platforms for shopping is subject to measures, including a request to remove the consumer safety products, etc, to the digital platform providers; and
  - (c) any business that violates any laws, orders under the laws, or other provisions should have its name and other information publicised, including the names and addresses of the business that has made notification and its domestic supervisor.
- Responses to ensuring the safety of products for children – eg, toys (Consumer Safety Act):
  - (a) the manufacturers and importers of specified products for children are required to have the products meet the technical standards stipulated by the government of Japan and indicate a warning about using the products, including the intended age range and precautions for use; and
  - (b) a business intending to sell used products that are specified products for children is allowed to sell the used products in Japan provided that the business has established a system or other framework for raising public awareness and ensuring the safety of the used products for consumers in Japan.

3.2 Future Policy in Product Liability and Product Safety

Security Conformity Assessment Scheme for IoT Products

On 15 March 2024, METI published the "IoT Product Security Conformity Assessment Scheme Policy Draft". This document describes the draft policy for the IoT Product Security Conformity Assessment Scheme (the "Scheme") to be established. The intent of this Scheme is to improve products' added value by assigning labels to products that have undergone conformity assessment to security requirements. This document suggests that for products procured by organisations such as government agencies, it is recommended that labelled products that meet the security level required by each organisation be selected and procured. By making this mandatory in the future, IoT product vendors will be given incentives to acquire labels. According to this document, the Scheme will initially be operated as a voluntary scheme.

AI Guideline for Businesses

In April 2024, after a call for public comments, the Ministry of Internal Affairs and Communications (MIC) and METI published the "AI Guideline for Businesses Ver. 1.0". This guideline is a non-

binding soft law for AI business actors. By referring to this guideline, businesses can confirm the guiding principles for the safe and secure use of AI. This guideline has adopted a "risk-based approach" in which the measures shall be taken in proportion to the magnitude and probability of the risk. The government plans to continuously update this living document, taking into account international discussions.

Draft Act for Responsible Utilisation of AI

Considering the restrictions by the above AI Guideline for Businesses, which is a soft law, as insufficient, the ruling Liberal Democratic Party (LDP) is aiming for restrictions by a hard law which is legally binding. In February 2024, the LDP published an outline of a draft Basic Law for the Promotion of Responsible AI. Under the draft legislation, (i) the government shall designate "AI Foundation Model Developers" which meet the criteria of certain sizes and objectives and (ii) the designated developers shall have the obligations of safety verification, investment in cybersecurity, etc. The failure of compliance with these obligations may lead to criminal penalties.

Trends and Developments

Contributed by:
Masanobu HARA and Masashi Kobayashi
TMI Associates

TMI Associates has, since its establishment in 1990, strived to create a law firm distinct from any other in Japan. The firm has experienced rapid organic growth, both numerically and geographically, while maintaining its progressive culture. Based in Tokyo, TMI now has 570 lawyers and 96 patent/trade mark attorneys among a total of 1,227 personnel as of 1 May 2024, and it has become one of the five-largest law firms in Japan. In addition to TMI's domestic branch offices in Nagoya, Kyoto, Osaka, Kobe and Fukuoka, the firm has branch offices overseas, in Shanghai, Beijing, Singapore, Ho Chi Minh City, Hanoi, Yangon, Phnom Penh, Bangkok, Silicon Valley, London and Paris. TMI's legal services related to product liability and safety include litigation representation for product liability lawsuits, advice on dealing with product defects and recalls, and investigations on quality issues for a wide range of clients.

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Introduction

In Japan, over 27 years have passed since the Product Liability Act (Act No 85 of 1994) (PLA) was enacted on 1 July 1995.

The PLA in Japan consists of six articles that do not stipulate much and there appears to be no indication that the PLA will be amended in the near future.

However, depending on the type of product, it is also appropriate to refer to the Consumer Products Safety Act, the Electrical Appliance and Material Safety Act, and other product safety-related laws in addition to the PLA (hereinafter, collectively referred to as the "Product Safety-Related Laws"), for product liability, product safety and recalls. In addition, restrictions on recalls differ according to the type of product.

In the case of consumer products, it is appropriate to conduct product recalls based on the instructions in the Consumer Products Recall Handbook 2022 issued by the Ministry of Economy, Trade and Industry (METI).

The following are five recent trends and hot topics related to product liability and product safety.

Measures to ensure the effectiveness of recalls are considered and proposed

In April 2023, the Consumer Products Recall Handbook 2022, was revised. Efforts to ensure the effectiveness of recalls (in particular, in the case of notifications on the website, to bring in measures providing a higher ranking of search results) and proposals for the utilisation of recall insurance to secure funds for recall costs, etc, were added.

How to ensure product safety regarding internet transactions

In recent years, how to ensure product safety in internet transactions has become a hot topic. Examples of safety accidents include fires that often occur with foreign electrical products (eg, mobile batteries). Increased product safety measures include requirements set in 2022 that internet mall operators should confirm the labelling of products subject to the Product Safety-Related Laws.

The METI has requested that the operators of malls, etc, inform exhibitors that they may not sell products subject to Product Safety-Related Laws without labelling them with the PS mark or the name of the business operator concerned. The METI has also requested that operators of malls request exhibitors to submit images of certain products subject to Product Safety-Related Laws so that the mall operators can confirm that the products bear the PS mark, etc. The METI also continuously checks whether the PS mark and the name of the notifying business operator are properly labelled on products covered by the Product Safety-Related Laws for internet transactions, and the METI is working with mall operators regarding labelling as well.

Furthermore, in June 2023, based on the "Communiqué on Product Safety Pledges" published by the OECD (Organization for Economic Co-operation and Development), the "Japanese Product Safety Pledge" was formulated by related ministries and agencies for consumer products, in collaboration with the operators of online marketplaces.

The "Japanese Product Safety Pledge" includes a total of 12 pledges. For example, the following contents are stipulated.

- Regularly consult regulatory authorities and other relevant websites for information on recalled/unsafe products and take appropriate actions on these products once they are identified.
- Remove requested recalled/unsafe product listings within two business days of receiving a take-down request from the regulatory authorities. Inform the regulatory authorities on the action that has been taken and any relevant outcomes.
- Co-operate with regulatory authorities and sellers to inform consumers about actions taken by concerned business operators and regulatory authorities related to recalled/unsafe products.

Through these efforts, it is expected that safe products are sold at online marketplaces operated by operators that have signed the "Japanese Product Safety Pledge", and consumer safety will be further improved.

The safety of products manufactured overseas is closely watched

The safety of overseas products is being watched closely, as exemplified by the notification (October 2017) that the law applies to overseas business operators selling products in Japan via the internet.

With regard to overseas business operators, the following points apply.

- The distribution of products (including by overseas business operators) in Japan is subject to the Product Safety-Related Laws.
- The Japanese government will provide information or alert overseas business operators who have conducted, or are deemed to intend to conduct, acts that contravene the Product Safety-Related Laws. In addition, the government will provide consumers in Japan with information, including websites pertaining to concerns about overseas business operators, as necessary.
- Furthermore, according to media reports, due to an increase in accidents involving foreign products purchased at online marketplaces, the Ministry of Economy, Trade and Industry is attempting to require overseas business operators to appoint a "domestic manager" who will be responsible in Japan by amendment of the Product Safety-Related Laws. If there is a violation of laws, the Ministry of Economy, Trade and Industry is expected to request a product recall (collection or free replacement) through the "domestic manager". It is necessary to pay close attention to developments in the discussion of amendment of these laws.

Discussions are under way on autonomous vehicles

See below.

Cases of claims based on liability for cybersecurity vulnerabilities are emerging

The European Commission released a draft amendment on the Product Liability Directive (hereinafter referred to as the "EC Product Liability Directive Amendment Draft") on 28 September 2022. Discussions have been held specifically in response to the rapidly changing business environment in recent years, such as the dissemination of internet of things (IoT) products and AI. On 14 December 2023, it was announced that the Council (Coreper) of the EU and the European Parliament had reached a political agreement on a new EU Product Liability Directive. On 12 March 2024, the European Parliament approved the new Directive on liability for defective products.

It is expected that discussions will advance in Japan based on such global discussions.

In this article, we will introduce the latest discussions relating to the PLA in response to the rapidly changing business environment described above.

Legal Liability for Product Liability, etc, Related to the Software of Automatic Operation Systems

Product liability for software

The term "product" as used in the PLA in Japan refers to movable items that are manufactured or processed and are construed to be tangible (Article 2(1) of the PLA). Since software itself is intangible, software is not a "product" and is not subject to product liability. However, the movable equipment that is embedded with the software is a "product".

In recent years, products, software and digital services have become more closely linked and collaboratively provided to consumers.

Accordingly, the EC Product Liability Directive Amendment Draft states in Article 1 and Article 4(1) that the software itself is subject to product liability. Furthermore, in light of the increasingly common practice of digital services being integrated in or interconnected with a product, as exemplified by the need for the continuous supply of traffic data in navigation systems, the EC Product Liability Directive Amendment Draft states in Preamble 15 that it is necessary to extend no-fault liability to such digital services, as they determine the safety of the product just as much as physical or digital components do.

There is still need for discussion on this topic in Japan.

If the software of the autonomous operation system is defective

Examples of closely related and linked products, software and digital services include autonomous vehicles. Many manufacturers in Japan and overseas are developing technologies and conducting public road demonstration tests for autonomous operation systems while working on the commercialisation and dissemination of such technologies.

Autonomous driving is available on the market in the form of vehicles that perform partial automatic driving with a driving support system. However, it is expected that ultimately there will be a level of vehicles that are fully automated, and that the autonomous system will perform all the driving tasks and the user will not be expected to take any action. Until recently, when a traffic accident occurred, the negligence of the driver was usually a point of dispute. However, if autonomous driving is realised, even in part, it is assumed that the manufacturers of autonomous vehicles will become involved.

In Japan, as elsewhere, there are discussions on how to determine the nature of responsibility (civil and criminal) among the various entities involved in putting autonomous vehicles on the road. The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) compiled the "Report of the Study Group on Liability for Autonomous Driving" (March 2018), and subsequently another study group published a report entitled "Study on the Civil Responsibility and Social Acceptability of Autonomous Driving".

In the above study group, discussions were held on the assumption that an accident would occur due to a software failure in the autonomous operation system. If the cause of the accident was a defect in the software in the autonomous opera-

tion system, since the software itself is intangible and therefore not a "product", the software manufacturer would not be liable for product liability. However, because an autonomous vehicle or the relevant part that is embedded within the software is a "product", the autonomous vehicle manufacturer or relevant part manufacturer will be liable if the autonomous vehicle or relevant part itself is evaluated as containing a defect. In this case, the software manufacturer is not held accountable for product liability but may be liable to the victim under tort theory in Section 709 of the Civil Code. In addition, the software manufacturer and the autonomous vehicle manufacturer will need to co-ordinate regarding, for example, claims for compensation or for accepting responsibility for the default.

In the event of a defect in the updated software

In the case of autonomous vehicles, an accident may occur due to a defect in the contents of an update when the software installed in the vehicle is updated after sale.

However, based on the PLA, the time of delivery of the vehicle, which is the "product", constitutes one criterion for judging defects and so the PLA may not be applied to updates made after the time of delivery. Under the PLA, it is therefore difficult to determine responsibility for defects introduced at the time of the software update.

Furthermore, it is difficult to impose product liability on autonomous vehicle manufacturers, etc, under the interpretation of the current law, specifically in the event of an accident caused by a defect in the software update performed after the delivery of the autonomous vehicle. It is therefore being considered whether the business operator or engineer who has done the update will be liable for the tort under Article 709 of the Civil Code rather than according to the product liability theory.

However, among judicial precedents, there is a case in which a product manufacturer was found responsible under tort liability on the grounds that it failed to fulfil the following obligations in relation to a case in which there were many accidents resulting in death or injury (Tokyo District Court, 21 December 2012 – The hanreijiho No 2196, p 32):

- the obligation to notify the owners and users, etc, of the product of the risk of accidents and to stop using the product in order to avoid accidents; and
- the obligation to carry out simultaneous inspection and collection immediately.

Based on the judgment of the case, not only the business operator and engineer who made the update, but also the autonomous vehicles manufacturer, etc, may be liable for tort under Article 709 of the Civil Code if the manufacturer did not take the action mentioned in the bullet points above when the defect was identified.

Vulnerability of Cybersecurity and "Defects" Under the Product Liability Law

Vulnerability of cybersecurity

The term "defect" as used in the PLA means a lack of safety that the product should ordinarily provide, taking into account the nature of the product, the ordinarily foreseeable manner of use of the product, the time when the manufacturer delivered the product, and other circumstances concerning the product (Article 2(2) of the PLA).

Regarding the concept of "safety" here, defects in quality and performance that are unrelated to

safety are understood to be outside the scope of the PLA.

There is no judicial precedent directly ruling whether a cybersecurity vulnerability in a product constitutes a "defect" under the PLA. However, there are cases in which contractual liability for default or tort liability was pursued on the grounds of security vulnerability (Tokyo District Judgment, 23 January 2014 – The hanreijiho No 2221, p 71).

In the above case, regarding a contract for the design and maintenance of an order-receiving system on a website, the existence of contractual liability for default was a material issue because of the vulnerability of the application, produced by the defendant, which caused the leak of credit card information.

The court held that "Since the defendant entered into the System Ordering Agreement on February 4, 2009, and received the order for the System, it was implicitly agreed to provide a program with security measures in accordance with the technical level at that time".

On that basis, the court affirmed the defendant's responsibility for defaulting on the fact that it did not implement countermeasures against SQL injection attacks, which are a typical attack method announced by the Ministry of Economy, Trade and Industry and the Information-Technology Promotion Agency, Japan, etc.

Taking this case as a reference, it is conceivable that there is room to remedy a "defect" under the PLA when both security measures are not implemented in accordance with the technical level at the time of the delivery, and when, if safety is lacking, further damage is caused as a result.

In the event of an accident due to hacking of the autonomous operation system

Cybersecurity issues can also be an issue in autonomous systems.

For example, let us assume that an accident occurs when a vehicle is operated by a third party, who has hacked an autonomous driving system, and has no relationship with the driver or the vehicle owner.

In this case, an accident would not be due to the negligence of the owner or driver of the vehicle, and it would be difficult to hold them liable. For this reason, the MLIT study group has found that the situation would be the same as in the case of vehicle theft. In other words, in regard to accidents caused by stolen vehicles, the Automobile Liability Security Act prescribes that damages will be compensated for by the Government's Programme Guaranteeing Compensation for Automobile Accidents, and that the owner of the vehicle will not be held liable as a person that puts an automobile into operational use for their own benefit. Similarly, in the event of hacking, it is considered reasonable to deal with the situation through the Government's Programme Guaranteeing Compensation for Automobile Accidents. However, in the event of hacking caused by a defect in the autonomous operation system, the autonomous vehicle manufacturer, etc, may ultimately be responsible.

In addition, if the vehicle owner did not implement the necessary security measures, the owner may be responsible under the Automobile Liability Security Act.

Conclusion

In addition to what has been described in this article, the criteria for determining the existence of defects in the autonomous operation system

program and the concept of defects in instructions and warnings have also been discussed. As for the discussions in this report, there are points that can be referred to in products where products, software and digital services are closely related and linked.

NETHERLANDS

Law and Practice

Contributed by:
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Contents

JPR Advocaten (JPR) is a Dutch independent law firm founded in 1899. With around 55 professionals and offices in Utrecht, Deventer and Doetinchem, the firm is dedicated to providing the best expertise, knowledge and services for its clients. Its lawyers cover corporate law, M&A, construction, labour law, IP/ICT/privacy, and liability and insurance law. The liability and insurance team deals with claims, coverage disputes, compliance and crisis management. JPR offers expertise in a variety of insurance areas, such as casualty, product liability and recall, professional indemnity, property and construction, credit insurance, and accident & health. The team represents insurers as well as corporates, and is well respected for being service-minded and pragmatic. Its members are frequently asked to act as judges, arbitrators or mediators, and are part of several reputable international networks, which allows them to provide bespoke global cover.

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1. Product Safety

1.1 Product Safety Legal Framework

Product safety laws in the Netherlands are mainly based on European legislation. There are separate product safety regimes for medical devices, pharmaceuticals and food. In addition, harmonised legislation applies for sector-specific products, such as cosmetics, toys, radio equipment and motor vehicles. For consumer products that fall outside the scope of the sector-specific regime, the European General Product Safety Directive 2001/95/EC (GPSD) applies.

European legislation is implemented within the Dutch Commodities Act ("Warenwet"), the Commodities Act Decree on General Product Safety ("Warenwetbesluit algemene productveiligheid") and sector-specific Product Safety decrees, such as those applicable for cosmetics products, toys and machinery, etc. For food, the Dutch Commodities Act applies, as well as specific Commodities Act decrees.

Since 2021, Market Surveillance Regulation (EU) 2019/1020 ("Verordening Markttoezicht") has applied for non-food consumer products subject to the "Union harmonisation legislation" shown in Annex I of the Regulation, as there are no specific provisions with the same objective in the Union harmonisation legislation that more specifically regulate particular aspects of market surveillance and enforcement.

The current applicable GPSD has been replaced by the new European General Product Safety Regulation (EU) 2023/988 of 10 May 2023 ("the Regulation"). The Regulation aims to ensure an even higher level of consumer protection and improve the functioning of the internal European market with regards to products intended for consumers. The Regulation must be complied with for all non-food consumer products put on the market from 13 December 2024.

Sector-specific directives and regulations with the same objective remain in place. The new Regulation will only apply to those aspects and risks or categories of risks of products which are not covered by those sector-specific regulations.

1.2 Regulatory Authorities for Product Safety

There are several Regulatory Authorities in the Netherlands that are designated to supervise on product safety, as follows.

- *NVWA:* The Netherlands Food and Consumer Product Safety Authority ("Nederlandse Voedsel- en Warenautoriteit") is the main designated responsible authority for consumer products (including food).
- *RDI:* The Dutch Authority for Digital Infrastructure ("Rijksinspectie Digitale Infrastructuur") is the supervising Authority for products relating to telecom, radio equipment and 5G, and is responsible for obtaining and allocating frequency space and monitoring its use. The work of the agency covers the entire field of wireless and wired communication.
- *ILT*: The Dutch Human Environment and Transport Inspectorate ("Inspectie Leefomgeving en Transport") is responsible for transport, infrastructure, environment and living. Its task is to ensure that businesses, organisations and government agencies comply with laws and regulations regarding sustainable living, environment, physical safety, and the housing association sector.
- *"Nederlandse Arbeidsinspectie":* The Netherlands Labour Authority oversees machinery and tools at work to ensure compliance with laws and regulations with respect to working conditions.

- *IGJ*: The Health and Youth Care Inspectorate ("Inspectie Gezondheidszorg en Jeugd") handles safety on medical devices and medication.
- *ACM:* The Netherlands Authority for Consumers and Markets ("Autoriteit Consument & Markt") is the authority for fair sales of products to consumers to prevent misleading practices.

Scope of Power

The scope of power of the abovementioned Authorities is similar. They are authorised, among other things, to request information, carry out inspections and investigations, impose fines, and order corrective measures be implemented.

1.3 Obligations to Commence Corrective Action

Producers are obliged to place only safe products on the market and to monitor those products. If they become aware, or should be aware, of a safety risk, they need to perform a risk assessment and then take appropriate corrective measures. The corrective measures depend on the product, the nature and severity of the risk in question and (potential) damages, as well as the group of people for whom the product is intended (children or adults, for example). In case of a serious risk, a product recall might be required.

1.4 Obligations to Notify Regulatory Authorities

Notification

Based on the current applicable GPSD, where producers and distributors know or ought to know, on the basis of the information in their possession and as professionals, that a product they have placed on the market poses risks to the consumer that are incompatible with general safety requirements, they must immediately inform the competent authorities, giving details, in particular, of action taken to prevent risks to the consumer.

However, the flow of information must remain manageable. The guidelines of the Commission Decision of 14 December 2004 (2004/905/EC) ("the Guidelines") therefore include criteria for non-notification. Producers and distributors do not need to issue a notification, for example, on products for which the manufacturer has been able to take immediate corrective action and for all items concerned, if the defect is limited to well-identified items or batches of items, and if the manufacturer has withdrawn the items in question.

Time Limit

"Immediately" is interpreted as acting without undue delay. According to the Guidelines, this means as soon as the relevant information has become available, and, in all cases, within 10 days of the manufacturer or distributor having reportable information, even while investigations are continuing, indicating the existence of a dangerous product. When there is a serious risk, companies are required to inform the authorities immediately, and in no case later than three days after they have obtained notifiable information. In an emergency situation, such as when immediate action is taken by a company, the company should inform the authorities immediately and by the most expedient means.

Notification Process

Although notification can be carried out in person, the authorities in the Netherlands prefer electronic notification via the Product Safety Business Alert Gateway set up by the European Commission.

This application offers the advantage of simultaneously notifying all competent authorities in the affected Member States.

Formal Requirements

A template form for notifying authorities about dangerous products by manufacturers or distributors can be found in Annex I of the Commission Decision of 14 December 2004 (2004/905/EC). The notification should include details of the notifier, the product involved, the safety risk at hand and conclusions of the risk assessment, the jurisdictions where the product was put on the market, details of the supply chain (including the numbers sold) and the corrective measures taken to prevent or limit the risk.

1.5 Penalties for Breach of Product Safety Obligations

The authorities have recourse to various interventions in case of non-compliance. These depend on the type of violation (serious, medium or light). The more serious the violation in terms of product safety, or in the case of repeat violations, the heavier the penalty. Interventions include the following:

- an official warning;
- corrective measures;
- an administrative fine or criminal penalty;
- closure or shutdown of activities;
- suspension of accreditation; and
- criminal prosecution.

For non or late notification of a product safety issue, an administrative fine of EUR795 applies, or EUR1,590 for companies with more than 50 employees. These amounts also apply for putting unsafe products on the market. They may also may vary slightly, depending on product type. One can also be criminally prosecuted for non or late notification, leading to six months' imprisonment, community service or a criminal penalty of EUR25,750 (category 4).

Failure to cooperate with the authorities is regarded as a serious offence. It can lead to three months' imprisonment or a criminal fine of EUR5,150 (category 2).

In exceptional circumstances involving intent or gross negligence, large companies can be subject to an administrative fine related to annual turnover. This fine is capped at EUR900,000 per violation. According to the NVWA's intervention policy, in principle, a maximum of five violations will be fined per inspection. As a consequence, a total maximum fine of EUR4.5 million can be imposed.

In the Fipronil case, where millions of eggs were unlawfully infected with Fipronil, two board members were sentenced to one year of imprisonment by the Court of Overijssel. These board members neglected food safety, resulting in health risks, environmental damage, and significant economic loss (District Court Overijssel 12 April 2021, ECLI:NL:RBOVE:2021:1508).

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

In the Netherlands, the causes of action for product liability are based on the Dutch Civil Code (DCC):

Strict Liability

Article 6:185 of the DCC includes the lex specialis. Based on this article, a manufacturer can be held liable for damages resulting from a defective product. This strict liability is only applicable to cases involving death, personal injury or prop-

erty damage caused by the defective product to another item intended for private use or consumption. The injured party must have primarily obtained the product for their own private use or consumption. For this kind of property damage, a threshold of EUR500 applies. Articles 6:185 to 6:193 of the DCC align with European Product Liability Directive 85/374, incorporating its provisions into Dutch law.

Fault-based Liability (Tort)

Article 6:162 of the DCC is the lex generalis. It provides a general legal basis through which a manufacturer may be held liable for damages caused by a defective product. Fault on the part of the defendant needs to be established. This article imposes no limitations on the type of damages that can be pursued, and is therefore often utilised by companies. Consumers may also resort to these legal grounds when the long or short stop has expired, which is applicable for the strict liability regime.

Contractual Liability

Article 6:74 of the DCC is the legal basis for addressing breaches of contract related to defective products. Strict liability (Article 6:185 of the DCC) cannot be contractually excluded. This means that, even if a contract attempts to waive strict liability, these attempts would be legally invalid.

2.2 Standing to Bring Product Liability Claims

Consumers who are directly affected by the product defect and who claim to have suffered damages as a result of the defective product can bring a claim for product liability on the basis of Article 6:185 and Article 6:162 of the DCC. On behalf of a group of consumers, representative bodies, such as foundations and associations, can bring a collective product liability claim. Companies can rely on contractual liability and fault-based liability (Article 6:162 of the DCC).

2.3 Time Limits for Product Liability Claims

Two important limitation periods apply for a product liability claim against the manufacturer based on Article 6:185 of the DCC, as follows:

- short-stop term: this is three years from the day on which the injured person became aware, or reasonably should have become aware, of the damage, the defect and the identity of the manufacturer; this short term can easily be suspended by sending a letter to the defendant in which all rights are reserved; and
- long-stop term: this is 10 years from the date on which the manufacturer put the product that caused the damage into circulation; unless the injured person initiated legal proceedings within these 10 years, the right to claim damages expires.

A different limitation period applies for a fault-based liability claim based on tort: a five-year term applies from the day on which the injured person became aware, or reasonably should have become aware, of the damage and the identity of the manufacturer. This term can also easily be suspended by sending a letter to the defendant reserving all rights. No long-stop term applies for a claim based on tort.

2.4 Jurisdictional Requirements for Product Liability Claims

European Legislation

For product liability, international jurisdiction is, in principle, governed by European Council Regulation EU No 1215/2012, commonly referred to as the Brussels I Recast. One can be sued in court in another member state if the place where

a harmful event occurred, or could occur, falls within the competence of that court. The place where the product in question was manufactured and the place where the initial damage occurred are referred to *Handlungsort* and the *Erfolgsort*, respectively. Depending on the specifics of the case, there could be some special jurisdiction rules (eg, for liability insurers).

Lugano Convention 88/592/EEC governs the jurisdiction and the enforcement of judgments in civil and commercial matters, specifically between EU member states and Switzerland, Norway and Iceland.

The Convention on Choice of Court Agreements, established in The Hague in 2005 (2014/887/EU), is applicable to the exclusive choice of court agreements in commercial transactions involving parties from EU member states, as well as from other nations such as the United Kingdom.

DCCP

Where no international treaty is applicable, the Dutch Code of Civil Procedure (DCCP) determines international jurisdiction. The main rule according to Article 2 of the DCCP is that the Dutch court has jurisdiction if the defendant is domiciled or habitually resident in the Netherlands. The court may also have jurisdiction if jurisdiction has been agreed upon in a contract or if the contract that is the subject of the proceedings had to be performed in the Netherlands (Article 8 of the DCCP). However, if it is truly impossible for the claimant to start legal proceedings outside the Netherlands, the Dutch court may also assume jurisdiction, according to the forum of necessity doctrine (Article 9 of the DCCP).

Due to the complexity of the above-mentioned legislation, careful legal analysis must be carried out to ensure that the claim is brought before the competent court.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There are no pre-action procedures and requirements in the Netherlands for filing a lawsuit for product liability claims. The only exception is for collective action (Article 3:305a of the DCC). Failure to comply with these pre-action requirements can result in the claim becoming inadmissible. For more detailed information, please see **2.16. Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**.

2.6 Rules for Preservation of Evidence in Product Liability Claims

Except for the statutory retention period for technical files, etc, there are no further rules for the preservation of documents or other evidence. For an individual's own position, it would likely be advisable to preserve a number of products and documents relating to product compliance.

2.7 Rules for Disclosure of Documents in Product Liability Cases

There are no such rules in the Netherlands other than on the basis of Article 843a of the DCCP, which provides the Dutch version of a disclosure proceeding. However, before a party can be ordered to disclose specific documents, it must meet strict conditions.

New Product Liability Directive

This situation may change with the upcoming new Product Liability Directive ("new PLD"). EU institutions informally agreed on the proposal at the end of 2023 and the new PLD will replace the existing EU General Product Liability Directive, introducing a fresh disclosure regime. According to the new PLD, claimants only need to provide

"facts and evidence to support the plausibility of the claim for compensation" to obtain disclosure. When determining whether the disclosure is proportionate, the national courts will consider the legitimate interests of all parties in relation to the protection of confidential information and trade secrets.

2.8 Rules for Expert Evidence in Product Liability Cases

In order to support their arguments and position, the parties are allowed to present expert evidence. In addition, the court can appoint an expert, either upon request of one of the parties or upon its own authority. The court-appointed expert is regarded as fully independent. The expert is not permitted to have a role in the decision-making process alongside the judge.

2.9 Burden of Proof in Product Liability Cases

Burden of Proof

The burden of proof lies with the claimant. The injured party needs to prove the damage, the defect and the causal link between the damage suffered and the defect (Article 6:188 of the DCC). The same applies for a tort claim, based on Article 6:162 of the DCC, although proof of an attributable unlawful act is also required.

Res Ipsa Loquitur

For incidental production failure of one particular product, defectiveness can be assumed under this doctrine.

Batch Liability

In the Boston Scientific case of 5 March 2015 (ECLI:EU:C:2015:148) involving pacemakers and defibrillators implanted in patients, the European Court of Justice introduced the principle of "batch liability": "Where it is found that such products belonging to the same group, or forming part of the same production series, have a potential defect, products within that batch may be classified as defective without needing to prove the defect in the particular product in question". In the same judgement, the Court ruled that compensation of damages includes the costs relating to replacing the defective product, provided that such replacement is required to overcome the defect in the product in question.

Batch liability is adopted in the new PLD.

2.10 Courts in Which Product Liability Claims Are Brought

Civil Court

Product liability claims in the Netherlands are normally brought before one of the eleven District Courts. For claims with a maximum quantum of EUR25,000, the cantonal court is competent. The relative jurisdiction of a specific court depends on factors such as where the harmful event occurred or where the defendant is domiciled.

Judges

Cases are decided by judges. The Dutch legal system is not familiar with juries.

2.11 Appeal Mechanisms for Product Liability Claims

Parties are allowed to appeal within three months at the Court of Appeal. One can also appeal at the Supreme Court, for which a term of three months also applies. Shorter terms apply for interlocutory proceedings.

2.12 Defences to Product Liability Claims

According to Article 6:185 of the DCC, the following statutory defences regarding strict liability are available to the manufacturer:

- they did not put the product on the market;
- with regard to the circumstances, it is likely that the defect that caused the damage did not exist at the time the product was put on the market, or that the defect occurred afterwards;
- the product was neither manufactured by the manufacturer for sale or any form of distribution for economic purpose, nor manufactured or distributed by them in the course of their professional practice or business;
- the defect was due to compliance of the product with mandatory regulations issued by the public authorities;
- the state of scientific and technical knowledge at the time the product was put on the market was not such that the existence of a defect could be discovered ("state-of-the-art defense"); and
- in the case of a component, that the defect was attributable to the design of the product in which the component was fitted, or to the instructions given by the producer of the parts.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

According to Article 6:186 of the DCC, a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, particularly in terms of:

- its presentation;
- the use that could reasonably be expected to be made of the product; and
- the time when the product was put on the market.

These circumstances are not limitative. Non-compliance with product safety requirements will be taken into account when considering a defect.

On the other hand, full compliance with safety requirements does not automatically mean a product is not defective.

The proposal of the new Product Liability Directive states: "In order to reflect the relevance of product safety and market surveillance legislation for determining the level of safety that the public at large is entitled to expect, it should be clarified that safety requirements, including safety-relevant cybersecurity requirements, and interventions by regulatory authorities, such as issuing product recalls, or by economic operators themselves, should also be taken into account in that assessment. Such interventions should, however, not of themselves create a presumption of defectiveness".

2.14 Rules for Payment of Costs in Product Liability Claims

Court Fees

In the event of litigation, court fees are due by both parties. A fixed schedule applies, and the amount depends on the quantum of the claim. The minimum amount for companies is EUR688, and the maximum is EUR9,825.

Recoverable Costs

These include fixed court fees, expert fees, costs for hearing witnesses, bailiff fees and disbursements, and fixed expenses for having the judgment executed are recoverable costs for the successful party. Attorneys' fees will only be compensated according to a fixed liquidation schedule. In reality, these fees are much lower than the actual attorneys' fees incurred.

"Deelgeschil"

A product defect can cause personal injury. In personal injury cases, one could start a *deelgeschil*, in which the court is asked to rule a judgment on a particular issue of the case, such as liability, causation or quantum. A condition for admissibility of a deelgechil is that the judgment assists parties in reaching an out-of-court settlement. Contrary to normal litigation, in a deelgeschil the liable party will be ordered to pay for the actual attorneys' fees of the personal injury claimant.

2.15 Available Funding in Product Liability Claims

No Cure, No Pay

According to the Rules of Professional Conduct for lawyers ("de Gedragsregels voor advocaten"), lawyers are prohibited from making "no cure, no pay" arrangements. An exception is made for personal injury claims (based on a pilot, which is recently extended for another two years), but this is strictly regulated. Certain conditions need to be met, and the Dean of the Bar where the lawyer practices needs to be notified. Fixed or capped fees are permitted.

Third-party Funding

Third-party funding for court litigation is allowed in the Netherlands. The European Collective Redress Directive 2020/1828 includes provisions regulating third-party litigation funding for collective actions on behalf of consumers. These are incorporated in the WAMCA (see **2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**).

Previously, the so-called Claim Code 2019 served as a code of conduct for claim vehicles with principles governing the relationship between a claim vehicle and a third-party funder.

On 13 September 2022, the European Parliament adopted a resolution (2020/2130(INL)) including a proposal for a new directive on the regulation of third-party litigation funding (2023/C 125/01). This proposal is still under consideration.

Legal Aid

Individuals who have insufficient financial means to secure legal representation might be eligible for legal aid under the conditions outlined in the Legal Aid Act.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Two causes of collective action are available under Dutch law, as follows.

WCAM Procedure

The Dutch Act on the Collective Settlement of Mass Damage (WCAM), as laid down in Article 7:907 of the DCC, provides for a collective settlement to be approved as binding by the Amsterdam Court of Appeal, after which it can be enforced.

WAMCA

On 1 January 2020, the Dutch Collective Redress Act (WAMCA) came into force. A claim vehicle can initiate a collective damages action on an opt-out basis. The WAMCA is characterised by the following:

- it only applies to actions that relate to events that occurred on or after 15 November 2016;
- strict admissibility requirements apply for the claim vehicle;
- the so-called "scope rule" requires a claim to have sufficiently close connection to the Dutch jurisdiction before it can be brought under the WAMCA;

- collective claims must be registered in the Central Register, which is publicly accessible;
- if there are several claim vehicles for the same event, the Court will appoint an Exclusive Representative from among the claimants who shall act for the interests of all parties in the litigation;
- the Court classifies the individual claimants into groups for the purpose of damage awards, which is known as damage scheduling; and
- a final judgment on a collective action binds all people residing in the Netherlands who have not opted out, and on all non-Dutch residents who opted in.

Product Liability

Currently, there are two WAMCA class actions pending in the Netherlands:

District Court of Amsterdam 14 February 2024 (ECLI:NL:RBAMS:2024:745) – Allergan

On 12 December 2022, on behalf of thousands of women, the Foundation Bureau Clara Wichmann issued a WAMCA class action against Allergan, an American medical device manufacturer of breast implants. The women claim the breast implants to be defective, as a result of which they have suffered damages. On 14 February 2024, the Court of Amsterdam ruled that Bureau Clara Wichmann is admissible in its claim. As a consequence, the case will now be dealt with on its merits.

District Court of Midden-Nederland (ECLI:NL:RBMNE:2023:4132) – Bayer

On 3 April 2023, a WAMCA class action was issued by the Foundation Essure Claims (and others) against medical device manufacturer Bayer. The case concerns permanently implanted birth control devices for women (female sterilisation). The Foundation is holding Bayer liable for these allegedly defective products to which numerous attribute a variety of complaints. A first hearing on the preliminary issues is expected in September or October 2024.

2.17 Summary of Significant Recent Product Liability Claims

Please refer to **2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims**, in addition to:

Supreme Court 16 July 2021 (ECLI:NL:HR:2021:1172) – Long-stop term metal-on-metal hip implant

Metal-on-metal hip implants consist of various components, such as the ball, the stem and the cup. These components can be put on the market at different dates. During surgery, they are put together in order to replace the patient's original hip. When does the long-stop term of 10 years start for a hip implant? According to the Supreme Court, every component can be regarded as a separate product. The start of the long-stop term depends on when the particular component was put on the market.

Court of Appeal Arnhem-Leeuwarden 15 June 2021 (ECLI:NL:GHARL:2021:5818), confirmed by the Supreme Court 11 November 2022 (ECLI:NL:HR:2022:1602) – Seroxat

As a minor in 2001, the claimant was prescribed the antidepressant Seroxat. Fifteen years later, they held the manufacturer liable for failing to properly warn them about the suicide risk linked to drug. At the time, they used the medication for five months and attempted suicide several times. Unlike the Midden-Nederland Court, the Court of Appeal rejected liability. According to the Court of Appeal, the manufacturer did comply with its duty of care in properly warning users about this risk. Moreover, in terms of a conditio

sine qua non, a causal link between the damages and the use of the product or the alleged failure to warn was not established. The judgment was upheld by the Supreme Court.

District Court of Rotterdam 28 June 2023 (ECLI:NL:RBROT:2023:5214) – Biomet metal-on-metal hip implants

Following the extensive report of the Court-appointed experts, the Court was of the opinion that the metal-on-metal hip implants could not be regarded as defective in the relevant (2004–2009) period, when they were considered to be "state of the art". Liability was rejected.

District Court of Rotterdam 27 September 2023 (ECLI:NL:RBROT:2023:8987) – PFAS

This judgment is worth mentioning as it concerns PFAS, or manufactured chemicals used in consumer goods. In the judgement, the District Court of Rotterdam held manufacturer Chemours (a Dutch company previously known as DuPont) liable towards four Dutch Municipalities for environmental damage caused by PFAS from 1984 to 1998. This judgement could open the door for product liability claims from local residents against Chemours. In September 2023, around 3,600 people had already collectively filed a criminal complaint against Chemours and, in the meantime, the Public Prosecutor's Office opened a criminal investigation against Chemours and its directors.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

New Product Safety Regulation 2023/988

The European Product Safety Directive and the Food Imitating Product Directive are being replaced by new General Product Safety Regulation 2023/988. This increases the protection of EU consumers against dangerous non-food products sold both online and offline. The Regulation will be applicable by businesses and national market-surveillance authorities from 13 December 2024.

Compared with the current Directive, the main changes under the Regulation are as follows:

- a product includes software (and artificial intelligence);
- for all non-food consumer products, a responsible person needs to be established in the EU, and can be the fulfilment service provider;
- specific requirements for providers of online marketplaces will be introduced;
- manufacturers will be required to immediately report accidents with their products to the authorities in the event of severe injury or fatalities;
- specific rules will apply on how to handle product-safety recalls and a mandatory recall notice template must be used; and
- a Consumer Safety Network will be set up and a modernised Safety Gate will be the platform where all information comes together.

Revision of the EU Product Liability Directive

On 28 September 2022, the European Commission issued a proposal for a new Product Liability Directive. In December 2023, the EU reached a provisional agreement on the text of the new directive.

The main proposed changes under the new directive compared to the current directive, are as follows:

- the definition of a product should be expanded to include software;
- damages should include medically recognised damage to psychological health and the destruction or irreversible corruption of data;
- the threshold for property damage should be deleted;
- any person that substantially modifies the product outside the manufacturer's control and makes it available on the market thereafter will be considered a manufacturer;
- a disclosure obligation should be introduced;
- the burden of proof is eased for consumers; and
- the whole supply chain is exposed to strict liability.

The revised Directive, if accepted, will substantially improve the position of consumers, and all the more so due to European Collective Redress Directive 2020/1828, which became effective from 25 June 2023. As a result, consumers are more likely to issue a (collective) product liability claim, with an improved chance of success.

As the Netherlands is already familiar with class actions due to the popularity of the WAMCA, it will likely remain a leading forum for class actions. The class-action framework is well established, the court is geared up, extensive expertise is available, and the duration of the litigation process is attractive compared to other European countries.

3.2 Future Policy in Product Liability and Product Safety

Please refer to **3.1. Trends in Product Liability and Product Safety Policy**.

SOUTH KOREA

Law and Practice

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Contents

Shin & Kim is a leading law firm in Korea with over 700 professionals, including Korean and foreign attorneys, patent attorneys, tax attorneys, certified public accountants, customs specialists, and other advisers. Founded in 1983, the firm's vision has always been to offer practical and creative solutions whilst preserving its core values of integrity and excellence. Shin & Kim advises companies of all sizes across a broad variety of industries. The professionals work in close-knit teams to deliver client-focused results through offices in South Korea, including satellite offices in Beijing, Shanghai, Ho Chi Min, Hanoi, Jakarta and Singapore while leveraging an unrivalled network of leading international firms and consultants to collaborate on matters. The teams have demonstrated outstanding litigation capabilities and maintain a high success rate in significant domestic and international cases.

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1. Product Safety

1.1 Product Safety Legal Framework

The following laws may be applicable to a product safety case.

- The Product Liability Act – In the event of damage to life, body or property due to a defect in the manufacturing, design or indication of a product, a person suffering from such damage may file a claim for compensation for damages against the relevant manufacturer under this Act.
- The Framework Act on Consumers – This Act regulates general matters on the duties of consumers, the state and business operators to promote the rights and interests of consumers. Under this Act, the state has the duty to specify matters to be complied with in supplying consumers goods, obligations of indication/advertising, etc of business operators and may recommend or compel the removal, destruction, etc of goods that cause, or may cause, harm, to the lives, bodies and properties of consumers.
- The Framework Act on the Safety of Products – This Act provides for basic matters to ensure the safety of products supplied to consumers. Under this Act, a safety investigation into a product may be requested to ensure the safety of such product, and a product that causes, or may cause, harm to the lives, bodies and properties of consumers shall be recommended or compelled to be removed or destroyed.
- The Serious Accidents Punishment Act – This Act provides for punishment against business owners, responsible managing officers, public officials and corporations that cause casualties in breach of their obligations to take safety and health measures while handling materials or products harmful to human bodies.
- The Motor Vehicle Management Act, concerning motor vehicles.
- The Chemical Substances Control Act, concerning chemical substances.
- The Food Sanitation Act, concerning foods and food additives.
- The Electrical Appliances and Consumer Products Safety Control Act, concerning the safety management of electrical appliances and consumer products.

1.2 Regulatory Authorities for Product Safety

There are different regulators under different applicable laws, and the scope of authority that may be exercised under such law also varies.

- In relation to safety and consumer protection for general products, the Korea Fair Trade Commission (KFTC) and the Korea Consumer Agency (KCA) and the Ministry of Trade, Industry and Energy are the main regulatory bodies exercising their authorities under the Framework Act on Consumers and the Framework Act on the Safety of Products. For example, the regulatory bodies may decide to recall a product that causes, or may cause, harm to the lives, bodies and/or properties of consumers. KCA also provides dispute-mediation services for consumers.
- The Ministry of Land, Infrastructure and Transport is responsible for several motor vehicle-related duties under the Motor Vehicle Management Act. These include vehicle registration, imposing operational restrictions, setting safety standards, and certifying vehicles. The ministry also addresses manufacturing and pre-sale defects by taking corrective measures or issuing recalls.

- The Ministry of Environment oversees the designation and management of hazardous chemical substances and grants authorisation to businesses handling these substances in accordance with the Chemical Substances Control Act.
- The Ministry of Food and Drug Safety is tasked with establishing criteria and standards for foods and food additives. It authorises food-related businesses and can issue corrective orders, mandate destruction, suspend operations or cancel business permits for harmful foods under the Food Sanitation Act.
- The Ministry of Trade, Industry and Energy, under the Electrical Appliances and Consumer Products Safety Control Act, designates safety certification bodies for electrical appliances and consumer products. It manages products requiring safety verification and can order improvements, destruction, removal or suspension of sales for products lacking safety certification.

1.3 Obligations to Commence Corrective Action

Under various applicable laws, if a product is found to have safety defects, the government can order the business operator to take corrective actions, which must be complied with.

The Framework Act on Consumers stipulates that businesses must report defects in goods and voluntarily remove products that could harm consumers' lives, bodies or properties (Articles 47 and 48). The state can also recommend or mandate the removal or destruction of such goods, with businesses obligated to comply (Articles 49 and 50).

Specific laws governing motor vehicles, foods, electrical appliances and consumer products include provisions for the public announcement of defects and the implementation of corrective measures. Business operators are required to announce defects directly or, alternatively, the state will do so.

1.4 Obligations to Notify Regulatory Authorities

The Framework Act on Consumers and the Framework Act on the Safety of Products outline different reporting obligations for businesses concerning product defects.

The Framework Act on Consumers mandates businesses to report not only actual harm caused by defective products but also potential risks, adhering to a "risk-based report" principle. This obligation requires businesses to report any defects they become aware of, without a specified time limit. Under the act, businesses must report defects in manufactured, imported, sold or supplied goods to the relevant central administrative agency in the following scenarios, unless the goods are voluntarily removed:

- if the business discovers that the goods have serious defects in manufacturing, design, labelling, etc, which cause or could cause harm to consumers' lives, bodies or properties; or
- if the business takes measures because similar goods with defects have been found in a foreign country, or if it is discovered that a foreign business has taken such measures:
  - (a) removal, destruction, etc, under a recommendation or an order of removal, destruction, etc, from a foreign government; or
  - (b) voluntary removal, destruction, etc.

The Framework Act on the Safety of Products requires immediate reporting by business opera-

tors when a product distributed in the market causes specific types of accidents, regardless of whether the product has a significant defect. This "incident-based reporting" mandates that businesses report the product's name, accident details, sales quantity, and other relevant information to the head of a central administrative agency:

- fatal accident;
- accident that caused an injury requiring at least four weeks' medical treatment in a medical institution under the Medical Service Act;
- fire or explosion; or
- other accidents caused repeatedly by the same product.

1.5 Penalties for Breach of Product Safety Obligations

Business operators who fail to comply with their obligations under relevant consumer safety laws face various penalties, including criminal punishment (imprisonment and fines), fines for negligence, and administrative actions such as suspension or cancellation of business licences. However, in practice, non-compliant operators are typically subject to corrective orders or fines for negligence rather than the more severe penalties.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

In Korea, product liability claims can be raised under various laws, depending on the subject matter. They include the following:

- the Civil Act;
- the Commercial Act;
- the Product Liability Act (PLA);
- the Framework Act on Consumers;
- the Framework Act on the Safety of Products;
- the Motor Vehicle Management Act; and
- the Chemical Substances Control Act (K-REACH).

Most claims are filed under the PLA or the Civil Act's tort provisions.

The PLA predominantly governs product liability litigation, holding manufacturers liable for damages to life, persons and property caused by product defects, excluding damages to the product itself (Article 3(1)). Claims under the PLA are treated as strict liability offences, meaning the manufacturer is liable regardless of fault. In contrast, claims under the Civil Act or Commercial Act require proof of fault.

2.2 Standing to Bring Product Liability Claims

In Korea, product liability claims can be brought by parties who have suffered damages to life, persons or property due to a product defect. Heirs of a deceased individual can also file claims on behalf of the deceased. Additionally, regulations may grant third parties the right to seek indemnity, allowing them to bring claims on behalf of the injured party.

It is common for insurance companies to pay out claims to insured individuals and then seek indemnity from manufacturers. A notable example is an ongoing appellate court case where the National Health Insurance Service has filed an indemnity claim against tobacco manufacturers after covering medical expenses for smokers.

2.3 Time Limits for Product Liability Claims

The Product Liability Act (PLA) in Korea sets dual statutes of limitations for bringing product liability claims. A claim must be filed within the earlier of:

- ten years from the delivery of the defective product; or
- three years from the claimant's discovery of the damages and relevant liabilities.

For damages caused by harmful substances or those that become apparent after a latent period, the ten-year statute of limitations is calculated from the date the damage occurred. The statute of limitations expires when either of these periods lapses.

2.4 Jurisdictional Requirements for Product Liability Claims

In Korea, jurisdiction for lawsuits under the Product Liability Act is determined by the Civil Procedure Act, as the PLA does not specify jurisdictional rules. According to the Civil Procedure Act, a lawsuit falls under the jurisdiction of a court where the defendant's general forum is located (Article 2). Additionally, a lawsuit concerning a tort may be filed at the place where the tort occurred (Article 18(1)). Since a lawsuit under the Product Liability Act is considered a tort lawsuit, it can be filed either at the court where the defendant's general forum is located or at the place of the tort.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There are no procedures required to be completed prior to product liability claims in Korea. However, under the Framework Act on Consumers, individuals have the option to pursue remedies for damages caused by the use of goods through the Korea Consumer Agency (KCA). Additionally, disputes between consumers and business operators can be mediated through the Mediation Commission. These procedures, outlined in Articles 55 to 59 and Articles 65 to 68 of the Framework Act on Consumers, provide alternative avenues for resolving disputes before resorting to formal legal action.

2.6 Rules for Preservation of Evidence in Product Liability Claims

There are no rules for the preservation of evidence applicable only to product liability cases in Korea. However, under the Civil Procedure Act, provisions enable courts to conduct examinations of evidence when necessary. If a situation arises where evidence might become unusable without prior examination, the court has the authority to conduct such examinations either on its own initiative or upon request from a party (Articles 375 and 370). This applies to all types of evidence, including witness testimony, documentary evidence, expert opinions and examinations of parties involved. Thus, parties involved in public liability cases can utilise these provisions to ensure the preservation and examination of evidence critical to their claims or defences.

2.7 Rules for Disclosure of Documents in Product Liability Cases

Korea does not have a discovery system similar to the system in the US. It is, however, possible to make a request to the court to order the other party to produce specific documents or make an application for inquiry of facts. It is possible for a party possessing the requested documents to refuse to produce them, claiming that they contain trade secrets. In such cases, failure to comply with the court's order to produce documents without a justifiable cause could lead to the court

accepting the veracity of the other party's claims regarding the contents of the documents.

2.8 Rules for Expert Evidence in Product Liability Cases

There are no rules for expert evidence specific to product liability cases. Under the Civil Procedure Act in Korea, parties involved in legal proceedings have the option to apply for expert testimony to obtain opinions from individuals possessing necessary knowledge and experience.

Upon designation as an expert witness, the individual undergoes examination by the presiding judge. The presiding judge may then have the expert witness state their opinions either verbally or in writing. Additionally, parties can also file applications for expert witnesses regarding facts known from special knowledge and experience (Articles 333 to 342).

2.9 Burden of Proof in Product Liability Cases

In Korean product liability cases, claimants typically bear the burden of proving a product defect. However, if certain conditions are met – such as the accident occurring under normal product use, within the manufacturer's control and unlikely without the defect – the existence of the defect and its link to damages are presumed under the revised Product Liability Act, which became effective in 2018 (Article 3-2 of the PLA). This amendment lightens the claimant's burden, as previously they had to prove the defect, manufacturer negligence, damages and causation.

2.10 Courts in Which Product Liability Claims Are Brought

As stated in **2.4 Jurisdictional Requirements for Product Liability Claims**, a lawsuit may be brought to a court having jurisdiction under the Civil Procedure Act. As a trial by jury is not available in civil cases in Korea, a product liability case is decided by judges. A case with a claim amount of KRW500 million or smaller is decided by a single judge, while a case with a claim amount exceeding KRW500 million is decided by a three-judge panel.

Compensation for damages is determined according to Civil Act provisions, allowing for reimbursement of direct (eg, property damage, medical expenses), indirect (eg, loss of expected benefits, wages) and emotional distress damages.

Punitive damages are generally not recognised in Korea, except under specific circumstances outlined in the PLA. Courts may award exemplary damages, not exceeding three times the actual damages, if the manufacturer was aware of the defect but failed to prevent harm to life or serious bodily injury. Additionally, the Serious Accidents Punishment Act, effective from 27 January 2022, holds business operators liable for damages resulting from "Serious Civic Accidents", with compensation amounting potentially up to five times the actual damages incurred.

2.11 Appeal Mechanisms for Product Liability Claims

In Korea's legal system, the three-trial system allows for appeals against final judgments rendered in lower courts. An appeal (second trial) can be filed against a final and conclusive judgment from the first trial, and a final appeal (third trial) can be lodged against a final and conclusive judgment from the second trial.

During the first and second trials, both factual examination and legal judgments are conducted. However, in the third trial, the judgment is based on whether the decision from the second trial

violates the law, without revisiting facts or re-examining evidence.

According to the Civil Procedure Act, appeals or final appeals must be filed within two weeks of receiving the written judgment. For final appeals, a written statement of grounds must be submitted within 20 days of receiving notice of the litigation record from the court of final appeal.

2.12 Defences to Product Liability Claims

The Product Liability Act (PLA) in Korea outlines defences that manufacturers can utilise to counter product liability claims (Article 4(1) of the PLA).

- *Non-supply of the product* – Manufacturers can be relieved from responsibility by proving they did not supply the product in question.
- *Unidentifiable defect* – If the defect was not discoverable by the state of science or technical knowledge at the time of supply, manufacturers may be exempt from liability.
- *Compliance with regulations* – Manufacturers can argue that the defect arose from compliance with laws or regulations at the time of supply.
- *Defects in raw materials or components* – For raw materials or components, manufacturers can claim that the defect stemmed from the design of the final product or instructions provided by the manufacturer of the final product using these materials or components.

Additionally, manufacturers can defend against product liability claims by disproving the existence of a defect or the causation between the defect and the damage suffered. This entails demonstrating the following:

- the product was manufactured according to the intended design (for manufacturing defects);
- the product meets safety standards expected given current technology and economic feasibility (for design defects); or
- adequate explanations, instructions and warnings were provided to users, addressing anticipated dangers (for indication defects).

2.13 The Impact of Regulatory Compliance on Product Liability Claims

The court does consider adherence to regulatory requirements in relation to breach of a product safety regulation. However, such consideration will be limited to the breaches that are found to have causal relationship with the damages.

2.14 Rules for Payment of Costs in Product Liability Claims

In Korean litigation, the general principle dictates that the unsuccessful party bears the costs of the proceedings. If only a portion of a claim is recognised by the court, the distribution of costs is determined based on the ratio of the recognised claim. However, not all costs may be recoverable, as the amount of legal fees that can be reclaimed is subject to limitations set forth in court rules.

Lawyers may also charge a percentage uplift on their costs, though this is subject to negotiation and agreement between the lawyer and the client.

2.15 Available Funding in Product Liability Claims

In Korea, the claimant typically funds legal costs, but the court may grant legal aid to parties unable to pay upon request or at its discretion. To qualify, a party must demonstrate financial need, and legal aid can include deferred payment of

court and attorney fees, as well as exemption from court fee deposits.

The Korea Legal Aid Corporation offers legal assistance, including trial representation, at minimal fees or free of charge to financially disadvantaged individuals.

While there is no specific prohibition on third-party litigation funding, entrusting litigation to a third party in property disputes is generally not allowed unless under specific circumstances and in compliance with the Trust Act. Contingency or conditional fee arrangements are permitted without a maximum limit, and parties are not obligated to disclose such arrangements to the opposing party.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

While Korea lacks a general class action system in civil proceedings, the Securities-Related Class Action Act addresses specific illegal acts, such as false or insufficient securities filings, effective since January 2005.

Korea employs an "appointed-party" system, somewhat akin to class actions but with differences. Only those participating in the trial benefit from court findings and awards. While multiple persons can join a lawsuit if their rights and obligations are intertwined, the court's decision applies only to the involved parties, distinct from class actions. In product liability cases involving multiple victims, it is common for victims to appoint one legal representative to litigate on their behalf, streamlining legal proceedings.

2.17 Summary of Significant Recent Product Liability Claims

Significant recent product liability claims include the following.

- *Agent Orange Case* – Since early 2020, Vietnam War veterans and widows have refiled the Agent Orange case in Korean courts, with two additional cases filed in 2022. The cause of action remains similar to previous filings.
- *NHIS Tobacco Case* – The National Health Insurance Service (NHIS) filed a claim against tobacco companies, which was dismissed by the trial court on 20 November 2020. NHIS appealed this decision, citing a lack of legal basis for direct claims and insufficient evidence of causation between smoking and lung cancer. The court of appeal is currently deliberating, with contentious issues surrounding the hazards of additives.
- *Humidifier Disinfectant Case* – Victims who suffered lung-related injuries and deaths after using humidifier disinfectants filed claims against manufacturers in August 2014. Initially, the trial court held manufacturers liable but dismissed government liability. However, in February 2024, the court of appeal found the government accountable, criticising its handling of toxicity evaluations and neglect over nearly a decade. The case is pending review by the Supreme Court.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

In recent years, there has been a notable shift towards implementing more consumer-friendly regulations in Korea. This includes provisions such as the presumption of defect or easing

the burden to prove causation, which are also reflected in court decisions. The heightened concern for consumer safety is expected to drive further legislative changes and court rulings in this direction.

Future amendments to the Product Liability Act (PLA) may impose the burden to prove product defect on the manufacturer or introduce provisions allowing group action in product liability cases. While the burden to prove causation is likely to remain with the claimant, there is the potential for legislation or court decisions to accept presumptions of causation or statistical causation analysis in the future.

3.2 Future Policy in Product Liability and Product Safety

The Korea Department of Justice previously proposed a class action bill, which underwent review by the Ministry of Government Legislation in 2020. However, the bill was abolished with the constitution of a new National Assembly. Under the proposed bill, groups of 50 or more people would be eligible for class action regardless of industry. It aimed to ease victims' burden of proof and introduce a discovery system akin to that in the US, promising a more favourable legal environment for victims upon passage.

Similarly, a bill on the Framework Act on Artificial Intelligence (AI) was introduced to the National Assembly around July 2021 but failed to pass and was abolished by the new National Assembly. Despite this setback, there is the expectation of a new bill reflecting international trends and discussions on AI regulation, especially considering the establishment of the EU AI Act. The previous bill focused on restrictions on AI technology, products or services causing harm to public safety without addressing manufacturer liability. However, discussions on acknowledging product liability for AI or software suggest that a new bill may incorporate such provisions.

Trends and Developments

Contributed by:
Ghyo-Sun Park, Bong Joo Song, Sea Hee Bang and Da Yoon Shin
Shin & Kim

Shin & Kim is a leading law firm in Korea with over 700 professionals, including Korean and foreign attorneys, patent attorneys, tax attorneys, certified public accountants, customs specialists, and other advisers. Founded in 1983, the firm's vision has always been to offer practical and creative solutions whilst preserving its core values of integrity and excellence. Shin & Kim advises companies of all sizes across a broad variety of industries. The professionals work in close-knit teams to deliver client-focused results through offices in South Korea, including satellite offices in Beijing, Shanghai, Ho Chi Min, Hanoi, Jakarta and Singapore while leveraging an unrivalled network of leading international firms and consultants to collaborate on matters. The teams have demonstrated outstanding litigation capabilities and maintain a high success rate in significant domestic and international cases.

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Evolving Regulatory Framework

In recent years, the regulatory framework governing product liability and safety in Korea has undergone significant evolution, driven by a growing emphasis on consumer protection and the need to address emerging challenges in product safety. This trend is reflected in both legislative reforms and judicial decisions that increasingly prioritise the interests of consumers.

Legislative Reforms

One of the key developments in this regard is the ongoing strengthening of the Product Liability Act, which serves as the cornerstone of product liability law in Korea. Amendments made to this act in 2018 introduced several important provisions aimed at enhancing consumer safeguards. For instance, the introduction of a new provision allowed for the presumption of causal relationships between product defects and resulting damages in certain cases. Moreover, manufacturers found guilty of intentionally neglecting product defects can now face compensation claims of up to three times the actual damages incurred, providing a significant deterrent against such practices.

The Framework Act on Product Safety, serving as the fundamental legislation governing recalls, introduced several key provisions aimed at enhancing recall procedures and ensuring compliance. Specifically, it mandated that business operators who receive recall orders must prepare and submit detailed recall plans, a requirement implemented in 2019. Additionally, the act established explicit authorisation for authorities to inspect the status of recall compliance, providing oversight to ensure adherence to recall protocols. Moreover, it expanded and reinforced penalties for non-compliance with recall orders, reflecting a commitment to bolstering accountability and consumer protection in product safety matters.

Similarly, the enactment of the Act on the Punishment of Serious Accidents, etc in 2021 has reverberated profoundly throughout Korean society, particularly concerning major industrial accidents. This legislation encompasses provisions not only for serious industrial incidents but also for disasters affecting citizens. Where such events lead to at least one fatality or ten or more injuries or illnesses due to defects in design, manufacturing, installation or management of specific raw materials, products, public facilities or transportation means, they are classified as serious disasters. Under this act, business owners responsible for such incidents face criminal penalties, and compensation for damages, extending up to five times the actual damage incurred, is mandated.

Furthermore, there is a growing inclination to introduce specialised legislation aimed at determining causal relationships and quantifying damages based on epidemiological correlations, particularly in response to large-scale disasters that garner significant social attention. A notable example of this trend is the Special Act on Remedy for Damage Caused by Humidifier Disinfectants, which underscores the government's commitment to addressing public health concerns arising from widespread incidents involving consumer products.

Judicial Decisions

In tandem with legislative reforms, Korean courts have increasingly adopted a consumer-centric approach in adjudicating product liability cases. Courts now demonstrate a greater willingness to find causation even in instances where the link between product defects and resulting damages is not immediately clear. This approach is par-

ticularly evident in cases concerning defects in products related to occupational safety, worker health or environmental pollution, where courts actively review the causation issue. However, in matters of general product liability, evaluating how significantly the courts have shifted their stance on proving defects or causation compared to the past is challenging. Nonetheless, it appears that courts now prioritise fairness and equity in individual cases, indicating a subtle but noticeable change in their approach to product liability disputes.

Despite these advancements, challenges persist in certain areas of product safety regulation. Issues such as rapid technological advancements in automotive engineering, incidents of battery fires in electric vehicles, concerns regarding automobile exhaust emissions, and ongoing litigation related to tobacco products and chemical safety continue to pose significant challenges for regulators and industry stakeholders alike.

For example, instances of sudden acceleration in automobiles have been frequently raised, although no manufacturer has yet been held liable for such incidents in civil judgments. However, in criminal cases, some defendants have been acquitted based on claims of sudden acceleration rather than negligence. Although a bill requiring manufacturers to disprove defects in cases of sudden acceleration was proposed, it has not yet been passed.

Moreover, incidents related to battery fires, particularly in automobile batteries and Energy Storage Systems (ESS), have been on the rise. Parties involved in such cases often opt for settlement agreements rather than awaiting final court rulings. Regarding automobile exhaust gas and tobacco lawsuits, no definitive rulings have been made on illegal acts or causal relationships involving manufacturers.

Legislative response

In response to these challenges, policymakers are actively exploring measures to strengthen existing regulatory frameworks and enhance consumer protections. Efforts to bolster tobacco control measures, including the recent 2023 bill aimed at analysing and disclosing the ingredients of tobacco products, highlight the government's commitment to safeguarding public health in the face of evolving risks.

Furthermore, revisions to the Chemical Substances Control Act in 2015 underscore Korea's commitment to aligning its chemical safety regulations with international standards, particularly those set by the European Union. These efforts reflect a broader recognition of the importance of harmonising regulatory practices across global markets to ensure the safety and integrity of consumer products.

Conclusion

In conclusion, the evolving landscape of product liability and safety regulation in Korea reflects a concerted effort to adapt to changing consumer needs and emerging risks. While significant progress has been made in strengthening legal frameworks and enhancing consumer protections, ongoing challenges underscore the need for continued vigilance and proactive measures to safeguard public health and well-being. Through collaborative efforts between government, industry and civil society stakeholders, Korea aims to uphold the highest standards of product safety and accountability, ensuring that consumers can confidently access and use a wide range of products without compromising their safety or well-being.

SPAIN

Law and Practice

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Contents

Faus Moliner is a modern boutique law firm, specialising in legal matters typical of the pharmaceutical industry and of other companies that operate in the life sciences sector. The firm was founded in 1997 and focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. Since its foundation, Faus Moliner has been widely recognised as a market leader in the area of pharmaceutical law in Spain. The product liability and civil and commercial litigation space is one of the leading areas of expertise for the firm. The team is well known for assisting industrial and insurance companies in complex high-stakes cases regarding medicinal products, medical devices and other products of the life science sector.

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1. Product Safety

1.1 Product Safety Legal Framework

Royal Legislative Decree 1/2007 (RLD 1/2007) is the main law setting out the legal regimen for product safety in Spain. It approves the consolidated text of the General Law on the Protection of Consumers and Users and other complementary regulations.

RDL 1/2007 establishes the main rules and obligations that, in general, must be respected by companies that make products available on the market to guarantee the protection of the health and safety of consumers and users.

Other laws and regulations set forth additional rules and obligations depending on the type of product and its impact on the health and safety of consumers. This is the case with the following laws and regulations:

- Royal Legislative Decree 1/2015, which approved the consolidated text of the law on guarantees and rational use of medicinal products and medical devices;
- Law 17/2011, regarding food safety and nutrition;
- Law 14/1986, on general public health;
- Royal Decree 1801/2003, on general product safety;
- Royal Decree 1345/2007, which regulates the authorisation, registry and dispensation conditions of medicinal products for human use prepared industrially;
- Royal Decree 192/2023, which regulates medical devices; and
- Royal Decree 85/2018, which regulates cosmetic products.

1.2 Regulatory Authorities for Product Safety

The General Directorate for Consumer Affairs of the Ministry of Consumer Affairs and the competent consumer authorities of the autonomous regions of Spain are the main authorities responsible for ensuring that the products made available to consumers and users meet the requirements established to provide a high level of health and safety at the same time as they respond to demands related to quality.

Other key sector-specific regulators are also in charge of ensuring that the specific products made available to consumers and users meet the requirements established to provide a high level of health and safety at the same time as

they respond to demands related to quality. Such regulators include:

- the Spanish Agency for Medicinal Products and Medical Devices (AEMPS), which is the regulatory authority in charge of technical requirements and surveillance of medicinal products, medical devices, cosmetics and personal care products; and
- the Spanish Agency for Food Safety and Nutrition (AESAN), which is in charge of technical requirements and surveillance of food and nutritional products.

Regional authorities are also responsible for controlling advertising, performing inspections of manufacturing and distribution premises, and performing all necessary controls to ensure that products comply with the applicable regulations.

1.3 Obligations to Commence Corrective Action

According to the provisions of RLD 1/2007, any entity involved in placing a product at the disposal of consumers and users, within the limits of its activity, must withdraw from the market, suspend marketing or recover from the consumer or user, through effective procedures, any product that does not meet the conditions and requirements of RLD 1/2007 or which, for any other reason, represents a foreseeable risk to personal health or safety on any other grounds.

In addition, the competent authorities may adopt all measures as are necessary and proportionate to eliminate the risk, including direct intervention regarding the product and direct compulsion of the entity involved. In these cases, all the expenses incurred will be charged to the involved entity whose conduct gave rise to such measures, irrespective of the sanctions that may be imposed, if any. The levying of such expenses and penalties may be carried out through the administrative enforcement procedure. Taking into account the nature and severity of the risks detected, public authorities may also inform affected consumers and users through the most appropriate means about the existing risks or irregularities, the affected product, the measures adopted and the appropriate precautions, in order to protect themselves from the risk and to obtain their collaboration in the elimination of its causes.

1.4 Obligations to Notify Regulatory Authorities

The trigger for notification to authorities in respect of product safety issues may vary depending on the type of product at issue and the applicable regulations.

Medicinal Products

For instance, regarding medicinal products, applicable regulations establish that the holder of a marketing authorisation is obliged to:

- comply with its pharmacovigilance obligations;
- observe the conditions under which the marketing authorisation was granted, in addition to the general obligations established in the legislation;
- submit periodic safety reports established by regulation, in order to keep the safety file updated;
- make the results of clinical trials public, regardless of the favourable (or not) outcome of their conclusions; and
- collaborate in the control programmes, guarantee the suitability of the products on the market and report any possible withdrawal of batches from the market and notify the AEMPS, the autonomous regions and the authorities of all countries where it has been

distributed, with the appropriate speed for each case and stating the reasons and any action undertaken to withdraw a batch from the market.

Without prejudice to their own responsibility, all authorities and health professionals, as well as pharmaceutical companies and distribution entities, are obliged to collaborate diligently in the dissemination of knowledge of the safety of the product. Likewise, health professionals, pharmaceutical companies and distribution entities are obliged to notify any anomalies of which they have knowledge to the health authorities.

Medical Devices

With regard to medical devices, manufacturers of devices made available on the Union market shall report to the relevant competent authorities, in accordance with provisions of Regulation (EU) 2017/745, the following:

(a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting; and
(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.

In addition, healthcare professionals and authorities who, in the course of their activity, become aware of a serious incident must also notify it to the AEMPS, through the electronic site enabled for this purpose, who will transfer it to the manufacturer of the affected product. Patients and users are also allowed to notify serious incidents to the AEMPS using the electronic procedure enabled for this purpose, without prejudice to the notification they may have made to the manufacturer, or to another economic agent, or to the healthcare professional.

Food and Nutritional Products

In accordance with Article 19 of Regulation No 178/2002, if a food business operator considers or has reasons to believe that any of the food that it has imported, produced, processed, manufactured or distributed does not meet the safety requirements, it shall immediately withdraw that food from the market when the food is no longer subject to its immediate control and shall inform the competent authorities thereof. In the event that the product may have reached consumers, the operator will effectively and accurately inform consumers of the reasons for its withdrawal. Moreover, if the competent authorities deem it necessary, the operator will recover the products that have already been supplied to consumers when other measures are not sufficient to achieve a high level of health protection.

1.5 Penalties for Breach of Product Safety Obligations

The intentional or negligent breach of product safety obligations may be subject to administrative and criminal sanctions. Furthermore, any person responsible for such a breach can be also liable for damages.

The most notorious criminal case in this regard was the rapeseed oil case, in which more than 30 industrialists were prosecuted during the late 1980s due to their participation in the commercialisation of a supposedly edible oil that was adulterated with rapeseed oil (for industrial

use and forbidden for foodstuffs). The rapeseed oil contained a toxic chemical substance that caused the death of more than 300 people and left more than 25,000 affected. In 1992, the Supreme Court sentenced the industrialists responsible to significant convictions of imprisonment and to payment of the correspondent compensation to the affected persons. Because of the large compensation, some of the convicted industrialists became, and were declared, insolvent.

As a result, the affected persons started legal proceedings against the Spanish State to also declare its pecuniary responsibility due to the negligence of its officials in the process. The judicial battle ended in 1997 when the Supreme Court sentenced the State as a subsidiary liable party to pay compensation of more than 500 million pesetas to those affected.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

Liability Under RLD 1/2007

In Spain, the regime for general liability for defective products is established in RLD 1/2007, with Articles 128–146 setting the main rules on product liability. It is mainly of a strict nature.

Under this regime, the "producer" of a defective product will be liable for any damage caused by death or by personal injuries, and/or any damage to, or destruction of, any item of property other than the defective product itself, provided that the item of property is of a type ordinarily intended for private use or consumption and was used by the injured person mainly for their own private use or consumption. It is the responsibility of the claimant to prove that the product was defective, that damage occurred and that there was a causal link between the defective product and the damage suffered.

Under this regime of RLD 1/2007, a product is defective when it does not offer the safety that could legitimately be expected, considering all circumstances and, especially, its presentation, the reasonably foreseeable use of the product and the moment when the product was put into circulation. As established by the Spanish Supreme Court in its judgment 495/2018 of 14 September 2018, this concept of a "defective product" is a normative concept that must be interpreted in accordance with the criteria established by law. In this regard, simple modification of a product (eg, to introduce enhanced information on warnings, risks, or side effects according to the latest available data) does not cause the product to be defective, since the defect definition makes it clear that "a product shall not be considered defective for the sole reason that such product is subsequently put into circulation in a more improved version".

Therefore, within the framework of the regime for product liability outlined in RLD 1/2007, a defect is defined as "the lack of safety that could legitimately be expected from the product" – ie, based on the criterion of the "consumer's reasonable expectations".

For the purposes of this regime, "producer" means:

- the manufacturer or the importer in the European Union of a finished product, any raw material, or a component part of the finished product; and/or
- the "apparent producer" of the product – ie, any person who presents themselves as the producer of the product, by putting their

name, trade mark or other distinguishing feature along with the product, whether on the container, wrapping or any other protective or presentational component.

The "producers" responsible for the same damage by application of this regime will be jointly and severally liable before the injured party. However, the one who responded to the injured party will have the right to file an action for recovery against the other responsible "producers", according to their participation in the damage.

Where the "producer" of a product cannot be identified, each supplier of this product (ie, the distributor or the "retail" supplier) will be considered as its "producer", unless they inform the injured party of the identity of the "producer" or of the person who supplied them with the product, within a term of three months before they are required to give such information. This has been clarified, among other matters, by the judgment of the Court of Justice of the European Union (CJEU) of 2 January 2009 (case C-358/08) and the judgments of the Spanish Supreme Court of 21 January 2020 and of 20 July 2020.

It must also be noted that the suppliers of a defective product will be treated as if they were its "producer" if they supplied the product while being aware that the defects exist. In such a case, the supplier is also able to file an action for recovery against the producer.

Other Forms of Liability

This strict liability system set forth in RLD 1/2007 does not preclude other liability systems providing an injured party with greater protection, nor does it affect any other right to damages, including moral damages, to which the injured party may be entitled as a consequence of contractual liability, based on the lack of conformity of the goods or any other cause of non-performance or defective performance of the contract, or of any other non-contractual liability that may apply.

2.2 Standing to Bring Product Liability Claims

Every injured party has standing to bring a product liability claim based on RLD 1/2007.

2.3 Time Limits for Product Liability Claims

The statute of limitations for bringing a claim for product liability under the regime of RLD 1/2007 is three years from the date when the damages were incurred by the injured party, provided that the identity of the party liable for the damages is known to the injured party.

The limitation period may be interrupted by the injured party, by filing a claim before the courts or by means of an extrajudicial claim, or through any act of acknowledgment by the liable party.

Nevertheless, the right to claim the recovery of damages as provided in the product liability regime of RDL 1/2007 expires ten years after the defective product was placed on the market. The only way to stop this expiration date is to start legal proceedings.

2.4 Jurisdictional Requirements for Product Liability Claims

The requirements to invoke the jurisdiction of the courts of Spain for product liability claims will depend on whether the defendant is domiciled in an EU member state or in a third country (ie, a non-EU member state).

Domiciled in an EU Member State

If the defendant is domiciled in an EU member state, the provisions of Regulation (EU) 1215/2012, on jurisdiction and the recognition

and enforcement of judgments in civil and commercial matters, will be applicable.

According to the rules set forth in this Regulation, Spanish courts have jurisdiction over any dispute when the defendant is domiciled in Spain, regardless of the claimant's domicile. Therefore, if the producer of the defective product is domiciled in Spain, a claim may be brought against them before the Spanish courts.

Defendants not domiciled in Spain may also be sued before the Spanish courts on product liability claims if the events leading to the product defect occurred in Spain, or if the damage occurred in Spain.

In this regard, see the judgment of the CJEU, case C-45/13, of 16 January 2014, or the judgment of the Spanish Supreme Court of 21 January 2019.

Domiciled in a Non-EU Member State

If the defendant is domiciled in a non-EU member state that has subscribed to an international treaty with Spain, the jurisdiction of the Spanish courts will be governed by the provisions of that treaty.

In the absence of an international treaty, the jurisdiction of the Spanish courts will be governed by the internal rules of jurisdiction of Spain. In this regard, a defendant not domiciled in Spain may be sued before the Spanish courts in the following situations, among others:

- if the parties agree to do so, or if the defendant appears before a Spanish court (this shall not apply where appearance was entered to contest the jurisdiction);
- regarding non-contractual obligations, when the harmful event has occurred in Spain; and
- in matters related to consumers if the consumer has its habitual residence in Spain.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There are no mandatory steps that must be taken before a product liability proceeding can be commenced.

Nonetheless, prior to filing a lawsuit, it is common for the claimant to address an extrajudicial claim to the one who is intended to be sued, in order to try to resolve the dispute out of court.

2.6 Rules for Preservation of Evidence in Product Liability Claims

Before the initiation of any court proceeding, the one who intends to initiate it or any of the litigants during the course thereof may request the court to adopt, by means of an order, any useful measures to prevent the destruction of any evidence due to human conduct or natural events.

Among other things, the applicant for the adoption of any of these measures should prove that:

- the evidence to be insured is possible, pertinent and useful at the time of proposing its assurance/preservation;
- there are real reasons to fear that the use of said evidence may be impossible in the future if the preservation measures are not adopted; and
- the preservation measure proposed, or another measure that the court deems preferable for the same purpose, may be deemed conducive and carried out within a short time and without causing serious and disproportionate damage to the persons involved in the litigation or to any third parties.

2.7 Rules for Disclosure of Documents in Product Liability Cases

Under Spanish civil law, there is no general discovery obligation between the litigating parties – neither before court proceedings are commenced nor as part of the pre-trial procedures. The Spanish civil system is based on the principle of parties' own production of evidence (ie, each litigant shall obtain and present its own evidence to support its claims in court proceedings).

Exceptionally, and only in those cases in which they are unable to obtain by themselves certain data necessary to file a claim, the applicant may request the judge to provide access to certain sources of evidence specifically provided for, prior to filing the lawsuit by way of preliminary proceedings, in accordance with the Code of Civil Procedure 1/2000.

Among other preliminary proceedings provided in the law:

- any interested party may request a copy of the medical records from the health centre or professional with custody of said records; and
- an individual who considers themselves to have been damaged by an event that could be covered by civil liability insurance may request the exhibition of the insurance contract.

In addition, at the pre-trial hearing, any litigant may request the judge to order the other party, or third parties unrelated to the proceedings, to exhibit any document related to the subject of the dispute. In said request, the applicant must:

- prove that the document is not available to them and prove the impossibility of obtaining it;
- prove that the document refers to the subject of the process (because it is documentary evidence relevant to the case) or to the effectiveness of other means of proof (because it gives, or does not give, effectiveness to other evidence presented); and
- provide a photocopy or simple copy of the document or indicate its content in the most exact terms.

2.8 Rules for Expert Evidence in Product Liability Cases

In this type of proceeding, the litigants are responsible for proposing the examination of expert evidence. The only restriction regarding its nature and scope is that it must be necessary to have scientific, artistic, technical or practical knowledge to ascertain any facts or circumstances that are relevant to the matter or to acquire certainty about them.

The parties are allowed to present their own evidence and bring their own technical specialists, and/or request the court to appoint any technical specialist in order to assess the evidence presented by the parties or ascertain any facts or circumstances that are relevant to the matter of the case.

Generally, in this kind of proceeding, the court may not ex officio propose the examination of expert evidence nor appoint technical specialists in order to assess the evidence presented by the parties. However, in exceptional cases, once the proceedings have been concluded and before judgment is rendered, the court may ex officio order the examination of new evidence (including expert evidence) on relevant facts if the evidence already examined is found to be insufficient. In practice, this is very unusual.

2.9 Burden of Proof in Product Liability Cases

The product liability regime places the burden of proving the existence of the defect, the damage and the causal relationship between them upon the claimant. To establish such causal relationship, the claimant must provide solid and substantial evidence that supports such a link and proves that damages are an appropriate and sufficient result of the defect.

Proximate Causation

Nonetheless, occasionally, Spanish courts also accept that the causal relationship may be proven by means of presumption or circumstantial evidence.

In Spain, the principle of generic causation (ie, in order to prove the causal relationship, it would be enough to demonstrate that a product is capable of causing the alleged injury) is not applied. Spanish courts have ruled that the mere fact that a product can cause damage is not enough to determine the defective nature of that product; in order to prove that a product is defective, the claimant must prove that the damages suffered are effectively caused by the defective product. It is sufficient that the claimant proves the existence of a defect, but it is not strictly necessary that the claimant provides evidence of the specific defect of the product. It can, therefore, be concluded that the proximate causation principle operates in Spain.

Defective Batches/Series of Products

On 5 March 2015, the CJEU issued a ruling on joined cases C-503/13 and C-504/13, under which certain kinds of products can be considered defective under the proximate causation principle. In these particular cases, the CJEU concluded that Directive 85/374/CEE on damages caused by defective products shall be interpreted in a manner sensitive to the particular product in question. The security requirements that patients can expect from products such as pacemakers and cardioverter defibrillators are particularly high, considering their purpose and the vulnerability of patients who use them. Under these circumstances, as they are products of the same model and production series, after a defect has been detected in a unit, the other units of the same model or batch can be classified as defective without it being necessary to prove the existence of the defect in each particular unit.

Proving Liability When Medical Research Is Inconclusive

On 21 June 2017, the CJEU issued another decision (C-621/15) referring to the product liability of manufacturers whose products have a defect that poses a risk to the consumer. In these circumstances, the Court decided that European law does not preclude a national court from considering, when medical research does not establish or reject a relationship between the vaccine and the occurrence of a disease, that some facts alleged by the injured person constitute serious specific and consistent evidence, enabling the court to conclude that there is a defect in the vaccine and that there is a causal link between that defect and the disease.

On the other hand, the Court also ruled that judges should ensure they do not reverse the burden of proof when applying this evidence regime. According to the Court, the Directive precludes rules based on presumptions in which medical research neither establishes nor rules out the existence of a link between the vaccine and the disease. The existence of a causal link between the defect attributed to the vaccine and the damage suffered by the affected party will

always be considered determined if certain predetermined factual evidence is presented.

In the five judgments issued between 2017 and 2019 by the National High Court (AN) regarding different liability claims filed in connection with human papillomavirus (HPV) vaccines, the Court confirmed that the burden of proving the defect, the damage and the causal relationship lies with the claimant and, in the absence of evidence from the claimant, the Court absolved the Ministry of Health and the pharmaceutical company of all wrongdoings attributed to them. The AN rejected the evidence proposed by the claimants consisting of opinions which, according to the Court, did not undermine the studies and clinical trials that endorsed the efficacy of the product. With respect to the alleged lack of informed consent prior to its administration, the AN rejected the complaints because the claimants had not proven that the pathologies they were diagnosed with were a frequent adverse reaction, and therefore the obligation to inform did not include this risk since it was not known. Moreover, the AN considered that the causal relationship between the diagnosed diseases and the vaccines had not been proven, as the medical history did not point to the ailments and symptoms from which the claimants suffered being a consequence of the vaccine. Finally, the Court also rejected the liability of the pharmaceutical companies for defect of information in the summary of product characteristics and the leaflet on the basis that the claimants had not proven that their diseases were caused by the vaccine.

2.10 Courts in Which Product Liability Claims Are Brought

Product liability cases are usually brought before civil courts. These cases shall be resolved by a judge.

The amount of compensation will depend on the damage suffered by the injured party. However, the producer's civil liability for damages caused by defective products is subject to the following rules:

- EUR500 will be deducted from the amount of compensation for material damage; and
- the global civil liability of a producer for death and personal injury caused by identical products that present the same defect will be limited to approximately EUR63 million.

2.11 Appeal Mechanisms for Product Liability Claims

In legal proceedings on product liability, it is possible to file an appeal before the Court of Appeal against the judgment issued by the Court of First Instance.

Against judgments on appeal rendered by the Court of Appeal, it is possible to file a cassation appeal before the Supreme Court. This cassation appeal may be funded infringement of a procedural or substantive provision, provided that there is an interest in the cassation proceedings. The appeal will be considered to have a cassation interest when the decision appealed against in cassation opposes to the case law of the Supreme Court or resolves points and issues on which there is contradictory case law of the Appeal Courts or applies rules on which there is no case law of the Supreme Court. This cassation appeal cannot be grounded on the assessment of the evidence or the determination of facts, except on obvious and immediately verifiable errors of fact based on the proceedings themselves. When the appeal is based on an infringement of procedural rules, it is essential to prove that the infringement has been reported at all previous instances prior to the lodging of the appeal. If the procedural infringement has

produced a defect that can be remedied, it must have been requested to be remedied in the corresponding instances.

2.12 Defences to Product Liability Claims

The producer shall not be liable if they can prove that the product is not defective because it provides the safety that could legitimately be expected from it, taking all circumstances into account, including the time when the product was put into circulation, the presentation of the product and the use to which it could reasonably be expected that the product would be put.

The producer shall also not be liable if they can prove that:

- they did not put the product into circulation;
- it may be presumed that the defect did not exist when the product was put into circulation, given the circumstances of the case;
- the product had not been manufactured for sale or for any other form of distribution with an economic purpose, nor was it manufactured, imported, supplied or distributed within the context of a professional or entrepreneurial activity;
- the defect is due to the fact that the product was elaborated in accordance with existing mandatory rules; and/or
- the state of scientific and technical knowledge existing at the time the product was put into circulation did not allow for the discovery of the existence of the defect.

The producer of a part integrating a finished product shall not be liable if they prove that the defect is attributable to the design of the product into which the part was integrated, or to the instructions provided by the manufacturer of the finished product.

In addition, the doctrine points out that the apparent producer shall not be liable if they can prove that they were not the one who placed the sign, brand, logo or stamp that identifies them as the apparent producer into the defective product or its packaging.

In the case of medicinal products, foods or foodstuffs intended for human consumption, the producer shall not be able to invoke the state of scientific and technical knowledge defence referred to above.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Compliance with regulatory requirements relating to the development, manufacture, licensing, marketing and supply of a product can be used as a defence if such requirements oblige the producer to develop, manufacture, license, market and/or supply the product in strict compliance with such regulatory requirements. If this is the case, the manufacturer could invoke the ground for exoneration mentioned in the fourth bullet point of **2.12 Defences to Product Liability Claims**.

In addition, compliance with regulatory requirements can be considered in the context of assessing whether a product meets legitimate safety expectations, and, therefore, when determining whether a product is defective or not. These cases should be evaluated on a case-by-case basis.

2.14 Rules for Payment of Costs in Product Liability Claims

At the end of the proceedings, the costs of the proceedings are imposed on the party who has had all its pleas rejected, unless the court considers that the case posed serious de facto or de jure doubts.

When the payment of costs is imposed on the party who has lost the case, that party shall pay all court fees and other incidental expenses, the fees of experts who have intervened in the proceedings, as well as the attorneys' fees of the successful party, up to an amount that shall not exceed one third of the total claimed in the proceedings for each of the litigants who have obtained such an award. However, this limitation shall not apply if the court declares the recklessness of the losing party.

However, if the pleas were partially accepted or rejected, each party shall pay the costs generated on its behalf, and half of the common costs, except when there are reasons to impose the payment thereof upon one of the parties due to reckless litigation.

2.15 Available Funding in Product Liability Claims

Third-party funding is not forbidden in Spain. There is no specific provision that regulates this method, apart from Article 1255 of the Civil Code, which sets forth the following: "The contracting parties may establish any covenants, clauses and conditions deemed convenient, provided that they are not contrary to the laws, to the morals or to public policy". Therefore, if it is not contrary to the law, morals or public order, any agreement in this regard is valid.

Attorneys' professional fees shall be freely agreed upon between the client and the attorney in observance of the rules on ethics and free competition. Furthermore, lawyers are allowed to charge a success fee if they agree on such with their client. The form of payment of fees shall also be freely agreed upon, and may include payment of a percentage of the outcome of the claim. However, in any case, the client shall pay the minimum expenses that the lawyer may incur as a result of its designation.

Moreover, parties providing evidence that they lack sufficient economic resources to litigate may be beneficiaries of legal aid if they comply with the requirements established in Law 1/10 January 1996, on Legal Aid.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Article 11 of the Code of Civil Procedure 1/2000 foresees the possibility of bringing collective legal proceedings and sets out that legally constituted associations of consumers and users shall have standing in court to defend the rights and interests of their members and of the association, as well as the general interests of consumers and users, without prejudice to the individual legal standing of the persons who have suffered the damages.

When those damaged by a harmful event (eg, by a defective product) are a group of consumers or users that are perfectly determined or may be easily determined, the standing to apply for the protection of these collective interests corresponds to:

- associations of consumers and users;
- legally constituted entities whose purpose is the defence or protection of such consumers and users; or
- the affected groups themselves.

In contrast, when those damaged by a harmful event are an undetermined number of consumers or users, or if the number is difficult to determine, the standing to bring court proceedings in defence of these collective interests

shall correspond exclusively to the associations of consumers and users that form part of the Council of Consumers and Users. If the territorial scope of the conflict mainly affects one specific autonomous region, the specific legislation of that autonomous region shall apply.

The Attorney General's Office also has legal standing to bring any action in defence of the interests of consumers and users.

Despite these procedural provisions, collective actions and representative proceedings for product liability claims are not very common in Spain. Such claims are usually brought by individual plaintiffs.

2.17 Summary of Significant Recent Product Liability Claims

Regarding product liability of medicinal products and medical devices, the following judgments of the Spanish Supreme Court deserve special mention.

The Judgments of 21 December 2020, and 21 and 28 January 2021

In these cases, the Supreme Court has resolved different appeals for the unification of doctrine and case law, regarding whether a hospital that has used a product whose toxicity is discovered and alerted after it has been used shall be liable for the injuries caused to the patient or if such liability must only fall upon the "producer" and the competent authorities that authorised the medicinal product, if applicable. The Supreme Court has clarified that, in such cases, liability must lie solely with the "producer" and, if applicable, with the authorities that authorised the product. The Supreme Court rejected any liability of the hospital as the competence for monitoring the adequacy of such products relied on the competent authorities (not the hospital). The Supreme Court also pointed out that the hospital cannot be held liable for the risk created by allowing the use of the product, since that risk derives from the defective manufacture of the product.

The Judgment of 1 March 2021

In this case, the Supreme Court ruled on the concepts of "defective product" and "safety which may reasonably be expected" with regard to a hip prosthesis that, after being commercialised, showed a revision rate higher than expected. Its manufacturer issued a safety notice recommending that users of the affected prosthesis follow a specific monitoring and control plan, and several months later voluntarily withdrew the product from the market.

The Supreme Court pointed out that a manufacturer may be held liable under the product liability regime of RLD 1/2007 not only for damages caused by products infringing safety and quality regulations but also for damages caused by products that, despite having undergone safety and quality controls, remain "unsafe". The relevant time to determine whether a product is unsafe/defective is the time when the product is put into circulation. According to the Supreme Court, although the voluntary withdrawal of a product from the market does not necessarily mean that the product was defective at the time it was put into circulation, it may indeed constitute an indication that at that time the product did not comply with the safety standards which may reasonably be expected from it.

In the court proceeding, the manufacturer alleged that the prosthesis only had minor failures and that, in the majority of cases, it worked well in accordance with its purpose. Furthermore, the manufacturer alleged that there was no proof that the damages were caused by the prosthesis

itself and that the withdrawal of the product from the market had been entirely voluntary.

The Supreme Court did not accept these claims and considered that the fact that the prosthesis had an unexpectedly high rate of revisions must prevail. As per the Court, this high rate of revisions, which was neither identified nor disclosed by the manufacturer at the time the product was put into circulation (and, therefore, was not known by the medical community and the relevant notified bodies at that time), shows that the risks posed by the prosthesis were higher than expected. In these circumstances, the Supreme Court concluded that it falls on the manufacturer to prove why it was not possible to identify and disclose the true risks of the device (that ultimately caused the need to withdraw the product from the market) at the time the product was put into circulation.

The Judgment of 24 January 2022

In this judgment, the Supreme Court confirmed the doctrine set forth in the Judgment of 20 July 2020 regarding liability for damages in corporate groups.

The Supreme Court began by recalling that the general rule in Spain is to respect the concept of the separate legal personality of companies, meaning that:

- each company is only liable for the fulfilment of the obligations it assumed and those arising from its own actions; and
- belonging to a corporate group does not entail that a company may be held liable for acts carried out by other group companies.

Although the doctrine of veil piercing allows the plaintiff to sue a company other than that which performed the acts leading to the alleged damage, this is only possible on an exceptional basis. In order to apply such veil piercing, the plaintiff must prove that the company liable for the acts leading to the alleged damage was used abusively by another group company for the very purpose of impeding future claims. In these cases, the other group company may indeed be sued. In the remaining cases, suing a group company other than the one that performed the acts leading to the alleged damage will pose serious difficulties to the claimants.

The Supreme Court further stated that partially coinciding names between companies belonging to a corporate group is not a sufficient reason to sue a company for the acts carried out by another company of the same group.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

On 24 December 2020, Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers, and repealing Directive 2009/22/EC, entered into force.

The Spanish Government's first preliminary draft law to transpose this Directive was published on 9 January 2023. This has been followed by a period of public discussions. Once the final draft receives approval from the Council of Ministers, it will be debated and enacted by the Spanish Parliament. One of the developments of this Directive is to include a system of disclosure of evidence that allows qualified entities intending to bring a representative action to request that the defendant or a third party discloses certain

pieces of evidence under its control that are relevant for the action to be brought. This may lead to significant modifications of the structure of the Spanish civil procedure regarding representative actions for the protection of the collective interests of consumers related to product safety infringement and product liability, among others.

3.2 Future Policy in Product Liability and Product Safety

On 12 March 2024, the European Parliament approved the text of the proposal for the new Directive of the European Parliament and of the Council on liability for defective products.

This proposal for a new Directive on liability for defective products contains certain measures that may have a relevant impact on product liability litigation. These include the following:

- The more precise definition of defectiveness (which would continue to be based on the criteria of safety that a person is entitled to expect in accordance with the safety standards required under Union or national law) and the broader list of non-exhaustive circumstances to be considered when assessing defectiveness, including (i) the characteristics and presentation of the product (including its instructions for use); (ii) the reasonably foreseeable use and misuse of the product; (iii) the relevant product safety requirements; (iv) any recall of the product or any other relevant intervention by a competent authority or by an economic operator. As in the current regulation, the proposal provides that in no case shall a product be considered defective because a better product or an improved or upgraded version of the product is subsequently placed on the market.
- The new system of disclosure of evidence and presumptions, which aims to make it easier for the claimants to prove the defect and the causal link in complex cases.
- The new rules on limitation and expiry periods.
- The grounds that will allow the defendant to be exonerated from liability even if it is proven that the damage was caused by a product that is found to be defective. Among other grounds, the new proposal will allow defendants to invoke that "the objective state of scientific and technical knowledge at the time when the product was placed on the market, put into service or in the period in which the product was within the manufacturer's control was not such that the defectiveness could be discovered".

The new system of disclosure of evidence and presumptions will imply a big modification on the disclosure of evidence requirements existing in Spain.

SWITZERLAND

Law and Practice

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Contents

Walder Wyss Ltd is a Swiss commercial law firm with offices in Zurich, Geneva, Basel, Berne, Lausanne and Lugano. Its 280 legal experts specialise in corporate and commercial law, banking and finance law, intellectual property and competition law, industrial know-how, public and administrative law, dispute resolution and tax law. The firm's clients include national and international companies, publicly held corporations and family businesses as well as public law institutions and private clients. With regard to product regulatory and product liability matters, its experts advise and represent clients in administrative, civil and criminal proceedings, contract negotiations and regulatory compliance at all its locations.

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1. Product Safety

1.1 Product Safety Legal Framework

The Swiss product safety legal framework consists of regulations that fall into two broad categories: sector-specific and horizontal framing regulations.

Sector-Specific Federal Regulations

These regulations apply to specific product categories and include, for instance, the following.

- The Federal Act on Foodstuffs and Utility Articles and implementing ordinances, such as:
  (a) the Federal Council's Ordinance on Foodstuffs and Utility Articles;
  (b) the Federal Department of Home Affairs' Ordinance on the Safety of Toys; or
  (c) the Federal Department of Home Affairs' Ordinance on Cosmetic Products.
- The Federal Act on Medicinal Products and Medical Devices and implementing ordinances, such as the Federal Council's Ordinance on Medical Devices.
- The Federal Council's Ordinance on Machines.
- The Federal Act on Electrical Light and Heavy Current Installations and implementing ordinances, such as:
  (a) the Federal Council's Ordinance on Electrical Low Current Installations; or
  (b) the Federal Council's Ordinance on Electromagnetic Compatibility.
- The Federal Act on Construction Products.

Horizontal Framing Regulations

These are subsidiary, applicable and cross-sectoral to all products, and include the following.

- The Federal Product Safety Act and the implementing Federal Council's Ordinance on Product Safety – these regulations are applicable to the extent that a sector-specific regulation does not address product safety (eg, regarding post-market surveillance or competencies of the enforcement authorities).
- The Federal Act on Technical Barriers to Trade and the Federal Council's Ordinance on the Placing of Products on the Market according to Foreign Regulations – these regulations shall ensure free trade between Switzerland and its main trading partners by obliging the Swiss legislators to align product regulations with those of such partners, in particular with the European Union.
- The Federal Act on Product Liability, which provides for the strict liability (ie, not depending on the producer's fault) of a producer for its defective products.

1.2 Regulatory Authorities for Product Safety

The enforcement of product safety regulation in Switzerland is generally sector-specific. This means that the enforcement authorities that are competent in a specific product sector are likewise competent to enforce the specific product safety regulations for that sector. Depending on the sectoral law, the responsibility for enforcement lies with either the cantons or the federal government. The main regulators are the following.

- The State Secretariat for Economic Affairs (SECO) co-ordinates the enforcement of Swiss product safety legislation in agreement with the competent sector-specific enforcement bodies and is, additionally, the surveying regulatory enforcement authority in several product sectors; the SECO also operates a product safety reporting and information centre together with the Federal Consumer Affairs Bureau (FCAB).

- The Federal Inspectorate for Heavy Current Installations (ESTI) is responsible for the technical supervision and inspection of electrical installations and electronic devices.
- The Swiss Council for Accident Prevention (BFU) is competent for personal protective equipment, specifically with regard to traffic, sport and household needs, and for machines, though with regard to recreational use only.
- The Swiss Accident Insurance Institution (SUVA) is the competent enforcement body for personal protective equipment and machines, with regard to operational use.
- The Swiss Agency for Therapeutic Products (Swissmedic) is responsible for the market surveillance of therapeutic products and medical devices.
- The respective cantonal bodies – eg, cantonal inspectorates/laboratories – are generally competent to enforce the Swiss Foodstuffs and Utility Articles legislation (including with regard to toys, cosmetic products or food contact materials).
- The respective cantonal bodies – eg, cantonal inspectorates/laboratories – are generally competent to enforce Swiss chemical legislation.

1.3 Obligations to Commence Corrective Action

Generally, for consumer products (ie, products that are intended for consumers or likely to be used by consumers under reasonably foreseeable conditions), the Swiss Product Safety Act obliges the producer or any other distributor to take adequate measures (ie, corrective actions) in the course of its business to prevent potential dangers arising from those products.

A corrective action is deemed "adequate" if the disadvantages that arise for the producer or other distributor are not considered completely disproportionate in comparison with the advantages resulting for the affected consumers. Potential measures include the issuing of warnings, a sales stop, the withdrawal from the market or the recall of the product. The law does not provide for any fixed formal requirements. Therefore, any corrective action may be chosen if it ultimately serves to avert the danger emanating from the product. In practice, the competent enforcement bodies regularly require a producer/importer to issue a warning throughout the supply chain as well as towards consumers (provided that the product has already reached the consumer). Depending on the actual safety risk, the enforcement body may also require that the warning is made public – eg, on the producer's website and/or on the website of the Swiss Federal Consumer Affairs Bureau (regarding the role of the Bureau, please refer to **1.2 Regulatory Authorities for Product Safety**).

1.4 Obligations to Notify Regulatory Authorities

Switzerland follows a risk-based approach regarding the obligation to notify the regulatory authorities. Generally, the duty to notify the authorities in respect of a product safety issue is triggered – for consumer products – if a producer or any other person placing a product on the market knows or ought to know that the product in question presents a risk to the safety or health of users or third parties (Article 8, paragraph 5, Swiss Product Safety Act). The respective provision in the Product Safety Act corresponds to the producer's or other distributor's obligation to notify the authority according to Article 5, paragraph 3 of the EU General Product Safety Directive (2001/95/EC). Regulation (EU) 2023/988 on General Product Safety, which replaces the EU General Product Safety Directive by 13 December 2024, will use, however, the new wording

"considers or has reason to believe" (Article 9 paragraph 8, Article 11 paragraph 8 and Article 12 paragraph 4).The notification obligation of the Product Safety Act applies where the specific sectoral law does not provide for any separate notification obligation.

The notification must be made immediately. According to an FAQ guide published by the State Secretariat for Economic Affairs (SECO), "immediately" means no later than one to two days, depending on the associated safety risk. Swiss legal scholars advocate a longer period of a maximum of ten days pursuant to the European Commission's Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers and Distributors in accordance with Article 5, paragraph 3 of Directive 2001/95/EC.

The Swiss Product Safety Act defines the minimum content of the notification. There are no legal requirements as to the form of the notification. However, some regulatory bodies provide for voluntary notification templates on their websites but emphasise that the completion of the form should not delay the notification.

1.5 Penalties for Breach of Product Safety Obligations

Generally, whoever fails to timely notify the authorities of a dangerous or potentially dangerous consumer product according to Article 8, paragraph 5 of the Swiss Product Safety Act or whoever violates the duty to collaborate with the enforcement authorities (Article 11 Swiss Product Safety Act) is liable for a fine of up to CHF40,000 (in the case of wilfulness) or CHF20,000 (in the case of negligence). Further, any person who intentionally places a product on the market that does not meet the requirements of Article 3 paragraphs 1 and 2 of the Swiss Product Safety Act (general safety requirements) and thereby endangers the safety or health of users or third parties shall be liable to a custodial sentence not exceeding one year or to a monetary penalty (if the offender acts on a commercial basis, a custodial sentence up to three years or a monetary penalty). Further sanctions are possible if the person acted by negligence or in the case of false certifications, the unauthorised issuing of declarations of conformity or the use of labelling or warning and safety instructions that do not correspond to the specific hazard potential of a product. Sectoral law, however, sometimes provides for different criminal liability. In any case, the law sets forth that the person within the producer's organisation who is responsible for the offence should be punished. The principal is only punished if they wilfully or negligently, in breach of a legal obligation, failed to prevent the offence.

There are no publicly available examples of companies being prosecuted or fined for breaching these obligations. However, that does not mean that no such cases exist. Under Swiss criminal prosecution law, the courts may generally only publish a judgment if the publication is in the public's interest or in the interest of the injured party.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

Depending on the respondent of the action (eg, a producer, distributor or retailer), an injured party would likely base its claim for damages on the following grounds.

Against the Producer

The Federal Product Liability Act provides for the non-contractual strict liability (ie, not depending on fault) of a producer for damages if a defective product leads to the death or injury of a person or the damaging or destruction of property. "Producer" means the person who has manufactured the end product, a basic material or a partial product; any person who claims to be the producer by affixing its name, trade mark or other distinctive sign to the product ("quasi-producer") as well as any person importing the product for distribution purposes to Switzerland. The liability is only triggered if the product is deemed defective – ie, if it does not offer the safety that one may expect considering all circumstances (such as the get-up or overall appearance of the product, the expected use or the time of market placement). The Federal Product Liability Act, however, provides for several defences (please refer to **2.12 Defences to Product Liability Claims** for further details).

In addition, the injured party could base a damages claim on contract (if the producer is the seller and the injured party is the buyer) or general tort law. The latter, however, would require proof of fault. Given this obstacle, a claimant would generally invoke the respective tort claim only on a subsidiary basis.

Against the Seller

The Swiss Code of Obligations provides for the strict contractual liability of a seller for the direct damage suffered by a buyer due to a defective object purchased from that seller. "Direct damage" would also include any personal damage or damage to property which was directly caused (ie, without any additional causal link) by the product's defect. If the seller were also the producer of the defective product, the injured buyer could alternatively base its claim for damages on the Federal Product Liability Act as discussed above.

2.2 Standing to Bring Product Liability Claims

In Switzerland, the standing to bring claims for product liability is – such as with any other claim – a matter of substantive law – ie, it depends on the legal basis of a claim. A party has standing to sue if it (at least allegedly) has a substantive claim under a certain law or legal relationship.

In the context of product liability, claims are usually based on either the Federal Product Liability Act, a contract or tort law (as discussed in **2.1 Product Liability Causes of Action and Sources of Law**).

Under the Federal Product Liability Act, any person injured by a defective product or any person suffering property damage due to a defective product may bring a claim against the responsible producer.

For contractual claims, a party to a contract usually has standing to sue if it suffers damage following a violation of the contract by the other party (in the context of product liability – eg, in case of the delivery of a defective product).

Under general tort law, any person who has suffered damage following a civil wrong committed by another person – whether or not the injured party is linked to that person by a legal relationship, such as a contract (eg, as often in product liability cases: the consumer and the producer of a product) – has standing to sue.

Which of these legal bases is the most favourable for an injured party to bring claims related to a product depends largely on the underlying facts of the case. Whenever there is a con-

tractual relationship, an injured party will most probably bring claims under that contract given that, under Swiss law, there is a presumption of fault – ie, the burden of proof is on the breaching party causing damage, and in sales contracts there is even a strict liability without requirement of fault for direct damage. If there is no such contract – which is usually the case between an injured party and a producer – the injured party would generally try to sue a producer primarily under the Federal Product Liability Act because of its strict liability, whereas under tort law the producer can only be held liable in case of fault.

2.3 Time Limits for Product Liability Claims

The applicable time limit depends on the legal basis that the respective claim is based on. For claims based on the Federal Product Liability Act, the statute of limitations is three years, starting from the date on which the injured person became or should have become aware of the damage, the defect of the product and the identity of the producer (Article 9 of the Federal Product Liability Act).

For claims based on contract law (in the context of product liability, most likely a sales contract), the statute of limitations is two years, starting from the day the defective product was delivered (Article 210, Swiss Code of Obligations).

For claims based on tort law, the Swiss Code of Obligations provides for two different statutes of limitations: a relative and an absolute one (Article 60, Swiss Code of Obligations). The relative limitation period is three years, starting from the date on which the injured person became aware of the damage and the person liable for it. The absolute limitation period is ten years for damaged goods and 20 years for personal injuries, starting from the date on which the damaging event occurred or ended. This longer limitation period, under tort law with regard to personal damage, has the effect that a producer may be held liable by an injured party under tort law, even if the limitation period for claims under the Federal Product Liability Act has already lapsed. This absolute limitation period generally runs regardless of whether the injured person has any knowledge of the damage and even if the damage has not yet occurred. However, the European Court of Human Rights has recently ruled that Swiss courts need to reconsider the limitation period, taking into account the lengthy latency period of asbestos-related diseases and the realistic opportunity for victims to recognise the damage. It remains to be seen whether Switzerland will appeal against this decision and how the Swiss courts will implement this ruling.

2.4 Jurisdictional Requirements for Product Liability Claims

The Swiss Civil Procedure Code defines the locally competent court for a dispute in domestic matters, whereas the Swiss Federal Act on Private International Law or the Lugano Convention (applicable in civil and commercial matters involving parties from EU or European Free Trade Association (EFTA) states) deals with the question of territorial jurisdiction of a Swiss court in international, cross-border disputes.

Rules regarding the place of jurisdiction are quite comparable both in domestic and in international cases. As a general rule, proceedings can be initiated in the competent court at the domicile or seat of the respondent (eg, at the seat of the liable producer). Depending on the area of private law concerned, a claimant may also initiate proceedings at another forum – eg, in product liability cases, a consumer would be entitled to bring a claim at its own domicile.

With regard to subject-matter jurisdiction, it can be said that, generally speaking, all cantonal courts in Switzerland have jurisdiction in all areas of the law and apply both cantonal and federal law. There are no specific/specialised courts for product liability claims, which can therefore be brought before any locally competent court.

However, the Swiss Civil Procedure Code grants the cantons the option to establish specialised commercial courts, in which the panel of judges is mixed – ie, composed of regular judges and experts (so-called expert judges) in the economic sector relevant for the case. Four cantons – Zurich, Berne, Aargau and St Gallen – have established such a court, which is part of the cantonal supreme court and serves as a court of first instance for commercial matters. Such a commercial court has subject-matter jurisdiction if:

- a claim concerns the commercial activity of at least one of the parties to the dispute;
- the decision could be appealed to the Swiss Federal Supreme Court (which requires an amount in dispute of at least CHF30,000); and
- the parties to the dispute are registered in the Swiss commercial register or a similar foreign registry.

Where only the defendant is registered in the commercial register, a claimant can choose to initiate proceedings before either the commercial court or the locally competent ordinary court. If a producer has its registered seat in a canton with a commercial court, an injured party can thus choose to bring its product liability claim before either the commercial court or the ordinary court. Due to a revision of the Swiss Civil Procedure Code, coming into force on 1 January 2025, it will no longer be necessary that the decision can be appealed to the Swiss Federal Supreme Court; however, the amount of dispute must still be at least CHF30,000.

If a claiming party has the possibility to choose where to bring its claims, which court is the most favourable depends on the underlying facts and on the party's perspective. Commercial courts have the advantage that experts from the relevant sectors are part of the judges' panel, whereas judges of ordinary courts generally do not have expert knowledge in the specific product sector, but their decisions might be more consumer-friendly. Another difference to take into consideration is that there is only one legal remedy against decisions rendered by a commercial court, whereas decisions of the ordinary courts can be appealed against twice (see **2.11 Appeal Mechanisms for Product Liability Claims**).

2.5 Pre-action Procedures and Requirements for Product Liability Claims

Swiss procedural law provides for mandatory reconciliation proceedings. Before initiating the main proceedings, the claimant must submit a reconciliation request to the Conciliation Authority (the so-called justice of the peace), following which the Authority will schedule a conciliation hearing. If no agreement can be reached, the Conciliation Authority will issue an authorisation to proceed (ie, to file a claim before a court), which is valid for three months. If a claim is filed before a court without a valid authorisation to proceed, the court will not decide on the merits but dismiss the case for procedural reasons.

Despite the mandatory nature of the reconciliation proceeding, the Civil Procedure Code provides for a few exceptions which might be of relevance in product liability cases. A claimant may unilaterally waive conciliation if the respondent's registered domicile is outside Switzerland. The parties may mutually agree to waive rec-

onciliation if the amount in dispute is at least CHF100,000. In addition, and irrespective of the amount in dispute, the parties may agree to replace the reconciliation procedure with mediation pursuant to Article 213 of the Swiss Civil Procedure Code.

In addition, and as set out in **2.4 Jurisdictional Requirements for Product Liability Claims**, certain cantons have established commercial courts. If a producer has its registered seat in one of these cantons, an injured party may choose to bring its product liability claim either before the commercial court or the ordinary court, as long as the criteria as set out in **2.4 Jurisdictional Requirements for Product Liability Claims** are met. If a claimant decides to bring a claim before a commercial court, no reconciliation proceedings take place and the claim must be filed directly with the commercial court.

2.6 Rules for Preservation of Evidence in Product Liability Claims

There are no specific rules, under Swiss product liability law or Swiss procedural law, obliging a producer or other distributor to preserve any evidence in product liability cases.

There are, as in many other jurisdictions, general evidentiary risks in not preserving evidence. In a product liability case, the claimant is generally required to prove that the defendant's product is defective, and that the product defect is the cause of their injury or damage to property. Under Swiss product liability law, the defendant (producer or other distributor) has several defences (please refer to **2.12 Defences to Product Liability Claims** for further discussion of these). In this light, a producer or other distributor is well advised to preserve documentation (eg, random samples, technical documentation, consumer feedback, etc) and product samples for every batch so that such evidence can be readily produced if necessary. Furthermore, under some sectoral laws, producers may be required to preserve the conformity declaration or technical documentation.

2.7 Rules for Disclosure of Documents in Product Liability Cases

There are no specific rules on the taking of evidence in product liability cases, and the Swiss Civil Procedure Code does not provide for any pretrial or discovery mechanisms. Pursuant to the general rules on the taking of evidence in civil procedure, each party must indicate the evidence it wants to rely on in its briefs. To the extent that such evidence is already in its possession, the party must file the evidence together with its briefs. For product liability cases, in particular this holds true for:

- product samples;
- documentary evidence (such as technical documentation, risk assessment, customer feedback, etc);
- expert opinions; and
- digital or other data.

Court-Ordered Evidence

To the extent that it is the responsibility of the court to order the taking of evidence, parties must submit respective requests together with precise descriptions of the evidence. In particular, this holds true for:

- opinions to be submitted by a court-appointed expert (indication of the questions to be presented);
- inspections to be executed by the court (indication of the subject); and
- witness testimony (indication of the witnesses) – under Swiss law, witnesses will

be examined by the court and there are no cross-examinations.

If a party wants to rely on evidence in the possession of the opposing party or a third party (eg, a defective product, purchase receipt or medical reports), it has to precisely identify the evidence and request that the court order that the evidence be provided.

Preventative taking of evidence

If a potential claimant (ie, an injured person) has reason to believe that evidence is at risk, it may request the preventative taking of evidence by the court. This request can be filed at any time during the proceedings and even prior to the commencement of the proceedings.

The preventative taking of evidence is considered an interim measure. The request is usually granted if:

- a specific law or provision allows the preventative taking of evidence;
- the evidence is at risk (which is the case if the evidence may cease to exist or may alter before the ordinary evidentiary proceedings); or
- there is another interest worthy of protection.

In any case, the requesting party has to credibly demonstrate (but not prove) the grounds on which it bases its request. In case of imminent harm, the request can be granted ex parte.

2.8 Rules for Expert Evidence in Product Liability Cases

The court may seek an opinion from one or more experts at the request of a party or ex officio. However, the court will do so only if it considers an expert opinion necessary to prove relevant facts that are disputed by the parties. If such an opinion is sought, it is the court that appoints as well as instructs the experts and submits the relevant questions to them. Prior to this, the parties are given the opportunity to submit additional questions or to have the questions modified. The court can order that the experts submit their opinion in writing or present it orally. It may also summon the experts to the hearing to present and explain their written opinion. In that case, the parties will be given the opportunity to ask for explanations or to put additional questions to the expert. However, cross-examination of the expert is not permitted.

Furthermore, the court may put questions to a witness with expert knowledge in order to assess the merits of the case. The expert witness must have special expertise in the subject so that the court can examine the expert witness not only with regard to the merits, but also on its assessment thereof. However, an expert witness cannot replace an expert opinion. In contrast to an expert, the expert witness is not subject to an appointment procedure. Finally, an expert witness is liable to prosecution only for giving false testimony and not for giving a false expert opinion.

Parties are free to individually commission an expert opinion and to submit it in the proceedings. As opposed to an expert opinion that was produced by a court-appointed expert, the party expert opinion is not considered to be evidence but will only qualify as a party allegation.

2.9 Burden of Proof in Product Liability Cases

As a general rule under Swiss civil law, it is incumbent upon the party who wants to rely on a certain fact to establish and prove this fact. For product liability cases, this means that it is gen-

erally the injured person who bears the burden of proof for all facts underlying its claim.

This holds true for all claims (and the respective requirements) based on tort law and on the Federal Product Liability Act. For claims based on a contract there is one deviation from this rule: the burden of proof for fault is reversed. This means that, if all other requirements are met, it is assumed that the defendant was at fault and it will be upon the defendant (ie, the producer) to prove that this was not the case. From a procedural perspective, it may thus be favourable for an injured person to bring a claim based on contract rather than based on tort law. For claims based on a sales contract, provided that a direct nexus between the damage and the defect of the product can be established, fault is not a requirement at all. The same holds true for claims based on the Federal Product Liability Act.

The Federal Product Liability Act provides, however, for several exceptions to this strict liability (see **2.1 Product Liability Causes of Action and Sources of Law**). In accordance with the general rule as set out above, it is the producer who bears the burden of proof for any fact it wants to rely on in order to exonerate itself from liability.

As to the relevant standard of proof: the general threshold is full proof, meaning that the court has to be convinced beyond any reasonable doubt. Where this is not possible (eg, because the defective product has been destroyed or disposed of or the amount of damage suffered cannot reasonably be quantified), the courts may apply a less strict standard.

2.10 Courts in Which Product Liability Claims Are Brought

There are no specific or specialised courts for product liability cases in Switzerland. Therefore, such cases generally must be brought before ordinary courts (ie, the competent local court) or – in certain cantons and if the statutory prerequisites are fulfilled (see **2.4 Jurisdictional Requirements for Product Liability Claims**) – before the competent commercial court.

Depending on the value in dispute, the proceeding is held in a simplified proceeding (for claims below CHF30,000) or in an ordinary proceeding (for claims above CHF30,000 or claims without monetary value).

In Switzerland, cases are decided by judges and the exact composition of a bench depends on local, cantonal law. In simplified proceedings, the court is, however, often composed of a single judge (*Einzelrichter*), whereas there are usually three or more judges (*Kollegialgericht*) on the panel in ordinary proceedings.

There is usually no minimum threshold with regard to the damages that can be claimed. If claims are brought under the Swiss Product Liability Act, however, the claimant must bear a deductible of CHF900 in case of a claimed damage to property.

With regard to the damages that can be awarded to a claimant, there is no maximum in absolute numbers. However, a claimant can only be compensated for the damages it actually suffered. In other words, Swiss courts do not award so-called punitive damages that exceed the amount of the actual loss. Swiss law does not allow a damaged party to take monetary advantage (enrichment) from the event of damage. Accordingly, the claimant must prove each individual

damaged position (exact amount) and the causal link between the damaging event (in product liability cases: the defective product) and the respective position.

2.11 Appeal Mechanisms for Product Liability Claims

There are no specific rules governing the appeal mechanisms in product liability cases. The general procedural rules provide essentially for two appeal opportunities which are relevant for product liability cases: a first one to the high court of the respective canton and a second one to the Swiss Federal Supreme Court.

Appeal to the High Court of the Respective Canton

Final and interim decisions and decisions on interim measures of a court of first instance can be appealed if the amount in dispute is at least CHF10,000. The time limit for the filing of an appeal is 30 days in the case of an ordinary proceeding and ten days in that of a summary proceeding. The appellant may submit that the first-instance court has (i) applied the law incorrectly, and/or (ii) established the facts incorrectly. The conduct of the proceeding is, to a large extent, at the discretion of the appeal instance – ie, the court of second instance will decide whether to conduct a second round of written submissions or to hold an oral hearing. The appeal instance may conclude the proceedings either by confirming the challenged decision, by rendering a new decision or by remitting the case to the court of first instance.

Appeal to the Swiss Federal Supreme Court

The decision of the court of second instance may be appealed to the Swiss Federal Supreme Court if the amount in dispute is at least CHF30,000 or if a question of fundamental interest is to be decided. The time limit for filing the appeal is 30 days. The appellant may essentially claim that the previous instance has (i) violated federal law, and/or (ii) established the facts manifestly wrongly or in violation of the federal law, provided that such deficiency was relevant for the outcome of the case. The procedure will be conducted in writing and will usually be limited to two written submissions. As in the previous instance, the Swiss Federal Supreme Court may confirm the challenged decision, render a new decision or remit the case to the previous instance.

Exception: Decisions of the Commercial Courts

There is only one legal remedy against a decision rendered by a commercial court, which is the appeal to the Swiss Federal Supreme Court. The procedure will be the same as described above.

2.12 Defences to Product Liability Claims

The Federal Product Liability Act provides for the strict liability of a producer. The producer is, however, not liable under the Federal Product Liability Act if it can prove that:

- it has not placed the product on the market;
- there was no defect when the product was put into circulation;
- it did not manufacture the product for sale, or any other form of distribution with an economic purpose, or manufacture or distribute the product in the course of its professional activity;
- the defect is due to the fact that the product complies with binding regulations issued by public authorities; or
- the defect could not have been detected according to the state of the art in science and technology at the time the product was put into circulation.

Furthermore, the producer of a raw material or part product is not liable under the Act if it can prove that the product defect is due to the construction of the product or the instructions of the producer of the end product.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

A producer's failure to meet the regulatory requirements is considered a breach of the product user's justified safety expectations and can be decisive for the determination of the defectiveness of the product. Swiss courts, however, have repeatedly found that adherence to regulatory requirements is the minimum standard only when determining the justified safety expectations. The producer must assess, in each individual case, whether its product meets the user's safety expectations and may not rely on adherence to regulatory requirements or the conformity assessments of regulatory bodies.

2.14 Rules for Payment of Costs in Product Liability Claims

In Switzerland, the claiming party has to pay an advance on the court costs to initiate court proceedings. The payment of the advance is a procedural requirement for the action, meaning that if no payment is made the case will be declared inadmissible. This has been quite a threshold for claiming parties in general and in particular in product liability cases involving consumers, given that the amounts to be advanced are calculated based on the amount in dispute and are generally relatively high.

However, the claiming party may get reimbursement of the advance if it wins the case as, in Switzerland, the "loser pays" principle applies. Accordingly, the costs follow the event, which means that the losing party must bear the court costs and, on top of that, must compensate the successful party for its legal costs. Court costs are determined and allocated by the court ex officio, while party costs are awarded upon request.

Currently, the court does not directly reimburse an advance payment of court costs made by a successful party, but only grants this party a compensation claim against the unsuccessful party, so that the successful party bears the risk that the costs cannot be collected.

The compensation for legal costs is determined in accordance with a tariff that is primarily based on the amount in dispute. The tariffs vary between cantons, but in the majority of cases the compensation granted does not cover the real legal costs incurred by a party; depending on the amount at stake, the amount payable as compensation for legal fees can be higher or lower than the actual costs incurred.

If no party succeeds entirely, the costs are allocated in accordance with the outcome of the case and unnecessary costs are charged to the party that caused them, independently of whether it was the losing party.

The Swiss Civil Procedure Code is currently undergoing a revision which will affect the costs in civil proceedings. In particular, under the revised law, the advanced payments will be cut in half (as a general rule but with certain exceptions such as summary proceedings), which will lower the threshold to initiate proceedings. Furthermore, the law provides that the successful party will be directly reimbursed by the court for the advance it paid and will no longer have to reach out to the losing party to be reimbursed. The revised Civil Procedure Code will enter into force on 1 January 2025.

2.15 Available Funding in Product Liability Claims

Third-Party Funding

Third-party funding is permitted and exists, although it is not very common in Switzerland. In principle, there are no restrictions to it, as long as the funded party is still in control of the claim. If the funded party is represented by legal counsel, it is important to avoid any set-up that might impair the counsel's ability to act independently and to pursue only their client's interests. Otherwise, such a set-up might interfere with the counsel's obligations pursuant to the rules of professional conduct.

Contingency Fee Agreements

"No win, no fee" and contingency fee agreements are not permitted under Swiss law since they are considered to stand in contradiction to the counsel's obligations to act independently. According to the Swiss Federal Supreme Court, the attorney's rules of professional conduct require a base salary, which does not only cover the attorney's costs but must also guarantee a certain profit. Only if this precondition is met, may the parties agree on an additional success fee element in the sense of a top-up fee.

Legal Aid

Legal aid is available (mostly) for private individuals under the preconditions that (i) the requesting party does not have the funds to finance the proceedings itself, and (ii) the case is not devoid of any chance of success. The request must be placed with the same court that is also deciding on the merits. The court will decide on the request in a formal, preliminary proceeding, during which the requesting party must fully disclose its financials and state its position on the merits. If legal aid is granted, the applicant is relieved from the obligation to pay any court costs (including any advance on costs) and the state will cover any reasonable lawyer's fees. Legal aid does, however, not relieve the applicant from the obligation to pay party compensation to the opposing party in the case of defeat.

Legal Protection Insurance

Since the threshold for receiving legal aid is high and the costs for initiating proceedings are considerable, legal protection insurance is becoming more and more common amongst consumers. Even standard insurance packages include a legal protection policy. While the conditions of such policies vary significantly and most insurance policies tend to avoid litigation and to settle potential disputes, it is, however, difficult to quantify the impact of legal protection insurance on product liability claims.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

There are no real collective redress procedures in Switzerland. However, it is possible to jointly bring several claims (eg, by a number of claimants filing their claims together when there are similar facts and legal grounds) in one proceeding or by way of an assignment of the individual claims to a claimant party. However, since this is usually cumbersome, it is rare.

When the general revision of the Swiss Civil Procedure Code was initiated in 2018, it was envisaged that it would introduce certain collective redress mechanisms. However, the proposed amendments triggered so many debates that the Federal Council decided to split them off and to deal with them in a separate revision project in order not to jeopardise the revision as such.

2.17 Summary of Significant Recent Product Liability Claims

There are not many published decisions concerning product liability in Switzerland because most cases are settled. The following cases are noteworthy.

In its decision of 5 January 2015 (4A_365/2014; 4A_371/2014), the Federal Supreme Court held that in the case of prescription drugs, the justified safety expectations of the product need to be assessed with regard to the safety expectations of the patient, but also with regard to the knowledge of the prescribing physician. In the specific case (it concerned the contraceptive pill "Yasmin"), it was deemed sufficient that the warning of a possible increased risk of a thromboembolic event, compared to contraceptive pills of previous generation, was only included in the expert information, not in the patient information.

In its decision of 31 May 2019 (2C_60/2018), the Federal Supreme Court specified that missing expert information from a preparation label, which therefore does not warn of a preparation-specific risk, is not to be considered a product defect in every case.

Furthermore, the Swiss Federal Supreme Court clarified that the provisions of food law also apply to intermediaries. In the case at hand, the package leaflet was qualified as inadmissible, even though it was only directed at the sales staff of drugstores and pharmacies (Decision 2C_733/2020 of 15 March 2021).

In its decision of 9 September 2013 (2C_13/2013), the Federal Supreme Court held that the malfunction of a product is considered a product defect if the product's value is specifically based on its serviceability (ie, a fire extinguisher).

On 18 March 2011 (137 III 226), the Federal Supreme Court decided that a producer was not liable for any defects that were not detectable at the time of the market placement according to the then current state of science and technology (so-called development risks).

In its decision of 19 June 2010 (4A_255/2010), the Federal Supreme Court had to rule on a product liability claim relating to a defective window. The court held that the producer was not liable because the window was manipulated after it had been placed on the market, which was beyond the reasonable expectation of the producer.

On 4 October 2010, the Federal Supreme Court found that the compensation of an injured party is to be reduced if that party has failed to carefully study the product manual before using the product (4A_319/2010).

On 26 November 2021, the Higher Court of the Canton of Berne found in its decision (ZK 20 399) that the court of first instance had unjustifiably rejected a claim for product liability brought against Johnson & Johnson by a patient who had suffered from several complaints after the implant of a hip prosthesis. The prosthesis was finally removed. The Higher Court held that it was reasonable to conclude that a prosthesis which had caused a toxic reaction in half of the cases:

- had to be removed in more cases than expected;
- was the object of an "Urgent Field Safety Notice";
- was revoked from the Swiss market after five and a half years; and
- for which the producer had declared (thereby not accepting any liability) to cover all costs

for examinations, treatments and revision surgeries,

did not meet the user's justified safety expectations and was, therefore, faulty in the sense of Article 4 of the Federal Product Liability Act.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Medical Devices

Switzerland and the EU have gradually tightened the requirements for medical devices in recent years in order to improve the quality and safety of these products. In parallel, the chapter on medical devices in the MRA (Agreement between the Swiss Confederation and the European Community on mutual recognition in relation to conformity assessment) should have been completely updated. This agreement is intended to avoid barriers to trade between Switzerland and the EU and to ensure joint market surveillance by the enforcement authorities of Switzerland and the EU. The necessary update of the chapter in the MRA on medical devices has not yet been possible. After the Federal Council unilaterally decided in May 2021 not to sign the institutional framework agreement with the EU, the EU linked the updating of the agreement in the area of medical devices to institutional issues for political reasons. As long as there is no progress on the latter, no update will take place. As a result, medical device providers established in Switzerland can no longer benefit from the facilitation of the Swiss-EU MRA as of May 2021. At that time, an update of the MRA was necessary to take into account the application of the EU Medical Device Regulation (MDR) and the corresponding legislation in Switzerland. The European Commission also reiterated in 2022 that an update of the MRA can only be envisaged in the context of a resolution of the institutional issues. The same problem also applies to in vitro diagnostics since 26 May 2022, for which the EU has classified Switzerland as a third-party country, meaning that previously existing trade facilitations under the MRA are suspended.

Despite the institutional deadlock, Switzerland has embarked on a major legislative project in recent years to comprehensively revise Swiss legislation on medical devices and in-vitro diagnostics and bring it into line with the EU regulations on medical devices (MDR and In Vitro Diagnostic Medical Device Regulation (IVDR)). The latest changes in this field adopted the requirements on product groups without an intended medical purpose of the Implementing Regulations (EU) 2022/2346 and (EU) 2022/2347. Devices without an intended medical purpose are mainly cosmetic in nature but have a risk profile similar to that of medical devices. Therefore, devices without an intended medical purpose must be treated as medical devices subject to the Swiss Medical Devices Ordinance, in accordance with the transitional periods applicable in the EU.

Biocidal Products and Fertilisers

As of 1 January 2024, amendments to the Ordinance on Biocidal Products came into effect that aim to improve data interpretation in order to identify potential health and environmental risks caused by the use of biocidal products. The amendment introduces a new annual reporting requirement for biocidal products placed on the market. This reporting obligation applies to the person who first places a biocidal product on the market in Switzerland within the supply chain. Such notification must include information on the responsible party as well as information on

the biocidal products placed on the market (eg, the quantity of biocidal products distributed, the active ingredients in the biocidal products and their concentrations). Notifications must be made electronically. The first report, covering the data of 2024, is due by 31 May 2025. Additionally, indicators based on water measurements have been established to assess and reduce the risks posed by biocidal products. Repeated significant instances of exceeding the limits set in the Waters Protection Ordinance may lead to the modification or revocation of biocidal product authorisations.

Furthermore, following the entry into force of the new EU Regulation 2019/1009 with provisions for the making available on the market of EU fertiliser products, the Fertilisers Ordinance was completely revised in order to avoid technical barriers to trade, with effect from 1 January 2024. The content of the EU regulation was adopted as far as possible or adapted to the Swiss context. In particular, the approval system, the names of the fertilisers and the structure of the Ordinance have been harmonised with the EU Regulation.

Drop-Shippers are Considered Distributors

In a recent ruling, the Federal Administrative Court (A-4413/2021 of 20 September 2023) specified the definition of "placing on the market" according to the Ordinance on Low-Voltage Electrical Products (LVEO). The court ruled that an operator offering products for sale on its website while acting as a drop-shipper (ie, selling products to customers without delivering or storing the products itself but instead having them delivered to customers by a wholesaler or supplier) is considered to be a distributor placing a product on the market in accordance with the LVEO. By selling the product, the definition of making the product available on the market is fulfilled, whereby it is irrelevant whether the operator owned and stored the product itself. Drop-shippers are therefore obliged to comply with the regulations of the LVEO on market access and post-market surveillance of low-voltage electrical products. This ruling is presumably transferable to other sector-specific ordinances that use the term "placing on the market".

3.2 Future Policy in Product Liability and Product Safety

There are several areas of focus concerning future policy development in respect of product liability or product safety. The following developments are noteworthy.

Partial Revision of the Swiss Product Safety Act

With the enactment of the Regulation (EU) 2023/988 on General Product Safety in December 2024, a partial revision of the Swiss Product Safety Act will be expected pursuant to the State Secretariat for Economic Affairs, the responsible Swiss authority. The Regulation provides for a new EU framework for general product safety in the context of digitalisation and e-commerce. It can be assumed that the partial revision of the Swiss Product Safety Act not only serves to update the law to these developments but also to maintain existing harmonisation with EU law.

Swiss Product Liability Act – Mandate for Revision is Still Missing

The European Commission issued a proposal for a Directive of the European Parliament and the Council on liability for defective products (COM/2022/495) to adapt the current system on product liability to developments linked to transition towards a circular and digital economy and artificial intelligence (AI). Since the Swiss Product Liability Act has been in line with the current Directive 85/374/EEC, an adaption of Swiss law to such new developments seems conceivable.

However, the competent Swiss authority has not yet received a mandate to initiate any revision of the Swiss Product Liability Act (as of publication of this chapter of the guide in June 2024).

Partial Revision of the Swiss Therapeutic Products Act

In the context of new technologies and legal development in the EU, Switzerland is currently revising the Swiss Therapeutic Products Act, inter alia, in relation to drug safety for patients and drug safety in paediatrics, namely by creating a legal basis for a mandatory electronic medication plan or with an obligation to use electronic systems to calculate drug dosage of medicines for children respectively. In light of Regulation (EC) No 2007/1394, new regulations in relation to advanced therapy medicinal products (ATMPs) shall also be implemented in order to grant access to new products and create a comparable level of safety to that in the EU. In relation to veterinary medicinal products, the partial revision aims to ensure equivalence of the Swiss law with EU law and to guarantee market access to novel and innovative therapies.

Tobacco Regulation

Parliament passed a new Federal Act on Tobacco Products and Electronic Cigarettes (the "Tobacco Products Act") on 1 October 2021. In addition to tobacco products, it also regulates electronic cigarettes and herbal smoking products, especially low-THC hemp cigarettes with CBD. With regard to the protection of minors, advertising for tobacco products and electronic cigarettes that is directed at minors or that may reach minors is prohibited. As a result, the Tobacco Products Act prohibits the advertising of tobacco products and electronic cigarettes on posters, in cinemas, on sports fields, in and on public buildings, and in and on public transport. It also prohibits the sponsorship of events for minors or events of an international character. Currently, the implementing ordinance to the Tobacco Products Act is being drafted (publication of this chapter of the guide, June 2024). Both the Federal Act and its implementing ordinance are expected to enter into force in autumn 2024.

Plant Protection Ordinance

A comprehensive revision of the Plant Protection Ordinance is planned, aiming to align the ordinance with EU legislation (Regulation (EC) 1107/2009). Under the proposed draft, active ingredients approved in the EU will be considered approved in Switzerland, though exceptions may apply. The draft also simplifies the authorisation of plant protection products already approved in EU member states and includes provisions for environmental organisations' involvement in the approval process. Additionally, a new digital system for submitting and processing authorisation applications and recording sales volumes of plant protection products will be introduced. Authorisation fees will significantly increase to cover the related costs. The legislative process for these amendments is currently in progress (June 2024).

Trends and Developments

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Walder Wyss Ltd is a Swiss commercial law firm with offices in Zurich, Geneva, Basel, Berne, Lausanne and Lugano. Its 280 legal experts specialise in corporate and commercial law, banking and finance law, intellectual property and competition law, industrial know-how, public and administrative law, dispute resolution and tax law. The firm's clients include national and international companies, publicly held corporations and family businesses as well as public law institutions and private clients. With regard to product regulatory and product liability matters, its experts advise and represent clients in administrative, civil and criminal proceedings, contract negotiations and regulatory compliance at all its locations.

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New Legal Frameworks on Product Safety, Product Liability and Green Advertising

In the context of digitalisation, new technologies and environmental governance aspects, legislators have enacted or are about to enact new laws. In the EU, a new regulation on general product safety, a proposal for a directive on liability for defective products and a directive against misleading environmental advertising have been issued. While Switzerland is not a member of the EU, it has adapted (and may continue to do so) its legislation to new legal developments in the EU. The following will discuss the developments in the EU from a Swiss law perspective and its implications for Switzerland. In the context of green advertising claims, an overview of the current legal situation in Switzerland will be provided.

GPSR and its implications for Switzerland

On 13 December 2024, the Regulation (EU) 2023/988 on General Product Safety (the "Regulation on General Product Safety" or GPSR) will enter into force. It replaces the general product safety directive from 2001 and provides for a new EU framework for general product safety in the context of digitalisation and e-commerce. The State Secretariat for Economic Affairs, ie, the responsible Swiss authority, is currently analysing the GPSR and will partially revise the Swiss Product Safety Act (PSA) and the Swiss Product Safety Ordinance (PSO) accordingly. However, no public documents or information regarding this partial revision are available as of the time of publication of this guide (June 2024). Since the PSA transposed the former Directive 2001/95/EC on general product safety into Swiss law in order to reduce technical barriers to trade by harmonising legislation with the rules of the EU, it can be assumed that the partial revision of the PSA is also designed to maintain existing harmonisation to facilitate trade and secure continued access to the European market. Even though the PSA has not been revised yet, Swiss companies doing business in the EU or in Switzerland should get prepared since the GPSR will be relevant for them, either directly because of their EU business or indirectly due to the anticipated change of Swiss law.

Scope of application of the GPSR

The GPSR applies to products that are placed or made available on the (EU) market unless there are specific EU provisions with the same objective regulating the safety of the products concerned. "Product" means any item which is intended for consumers or is likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them. This also includes products sold online or through other means of distance sales if the offer is targeted at consumers in the EU. An offer for sale shall be considered to be targeted at consumers in the EU if the relevant economic operator directs, by any means, its activities to one or more member states (Article 2 and 4 GPSR). Whether an offer is targeted at consumers in the EU is to be determined on a case-by-case basis, taking into account factors such as the geographical areas to which dispatch is possible, the languages available, the use of currency of the member state or a domain name registered in one of the member states. Thus, companies located in Switzerland selling products in the EU will fall under the scope of the GPSR.

In terms of personal scope of application, the GPSR applies to economic operators. "Economic operators" means the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products or making them available on the mar-

ket in accordance with the GPSR. As specific obligations for providers of online marketplaces are listed in the GPSR, they also fall under its scope of application. The GPSR provides for various obligations for economic operators, such as the obligations to set up internal processes for product safety. New information obligations apply for distance sales, such as the clear and visible indication of the manufacturer details, information allowing the identification of products and any warnings or safety information in a language easily understood by consumers of the relevant member state in which the product is made available on the market. Therefore, Swiss providers of online marketplaces targeting consumers in the EU should be aware of such new obligations.

Responsible person for products placed on the EU market

A product covered by the GPSR may only be placed on the EU market if an EU-based economic operator fulfils the obligations set out in Article 4(3) of Regulation (EU) 2019/1020 (such as verification obligations in relation to the declaration of conformity or performance and technical documentation). Thus, Swiss companies with no economic operator located in the EU should designate in due time a responsible person to secure market access for their products in the EU.

Providers of online marketplaces

The GPSR provides for a set of obligations for providers of online marketplaces. "Provider of an online marketplace" means a provider of an intermediary service using an online interface, ie, any software, including a website, part of a website or an application, including mobile applications, which allows consumers to conclude distance contracts with traders for the sale of products. Providers of online marketplaces have to fulfil various obligations, such as the following:

- to designate a single point of contact allowing for direct communication, by electronic means, with member states' market surveillance authorities and consumers in relation to product safety issues;
- to register with the Safety Gate Portal;
- to have internal processes for product safety in place;
- to take without undue delay the necessary measures to handle orders of a market surveillance authority (orders may include removing content referring to an offer of a dangerous product from their online interface, to disable access to it or to display an explicit warning);
- to design and organise their online interface in a way that enables traders offering the products to provide some minimum information for each product offered and that ensures that the information is displayed or otherwise made easily accessible by consumers on the product listing; and
- to co-operate with market surveillance authorities, traders and relevant economic operators, in particular, to allow access to their interfaces for the online tools operated by market surveillance authorities to identify dangerous products.

Thus, providers of online marketplaces located in Switzerland with an international scope should carefully review and implement their new obligations under the GPSR, particularly considering that providers of online marketplaces are also subject to penalties in case of infringement of their obligations under the GPSR (Article 44 GPSR).

Product safety recalls and recall notice

In the case of a product safety recall or a safety warning, economic operators and providers of online marketplaces shall ensure that all identifiable consumers affected are notified directly and without undue delay. If they have product registration systems or customer loyalty programmes in place, they shall offer the possibility to their customers to provide separate contact details only for safety-related purposes. If not all affected consumers can be contacted by such means, they have to be informed through other appropriate channels, including newsletters and retail outlets, mass media and other communication channels. Regarding the recall notice, the GPSR defines the required information to be included (Article 36 GPSR).

While some rules provide for new requirements (eg, possibility of customers to provide contact details or the extension of the obligation to providers of online marketplaces), the basic tone of these GPSR obligations has been general practice under Swiss law. However, the GPSR provides for explicit information to be included in a recall notice to consumers and prohibits the use of terms and expressions such as "voluntary", "precautionary", "discretionary", "in rare situations" or "in specific situations" that could decrease consumers' perception of risk. In contrast, the PSA currently provides for a list of mandatory information only in the notice to the surveillance authority, not in a recall notice to consumers. Thus, even though it is not explicitly prohibited to use expressions such as "voluntarily" in any recall notice under Swiss law as of now, wording chosen in any recall notice that could conceal a product safety risk will not be accepted.

Remedies in the event of a product safety recall

Pursuant to the GPSR, economic operators responsible for a product safety recall shall offer consumers effective, cost-free and timely remedies. Remedies shall not entail significant inconvenience for consumers such as bearing the costs of returning the product (eg, shipping costs). Without prejudice to any other remedies that the economic operator responsible for the recall may offer the consumer, the economic operator shall offer the consumer the choice between at least two of the following remedies:

- the repair of the recalled product;
- a replacement of the recalled product with a safe one of the same type and at least the same value and quality; or
- an adequate refund of the value of the recalled product, provided that the amount of the refund shall be at least equal to the price paid by the consumer.

These new remedy obligations under the GPSR are more far-reaching than existing Swiss law. Generally, Swiss product safety law on its own does not provide for any consumer remedies in case of a recall or other corrective action, with the exception of some sector-specific provisions that provide for more far-reaching after-market obligations. Generally, the Swiss Code of Obligations (CO) contains several material warranty claims that buyers can assert towards sellers (eg, the manufacturers) in case of a recall (eg, rescission of the contract, repair of the product or reduction of the sales price).

Safety Gate Rapid Alert System and Safety Business Gateway

The former "Rapid Exchange of Information System" (RAPEX) will be changed to "Safety Gate", which comprises three elements:

- Safety Gate Rapid Alert System – a rapid alert system on dangerous non-food products through which national authorities and the European Commission can exchange information on such products;
- Safety Gate Portal – a web portal to inform and enable the public to submit complaints; and
- Safety Business Gateway – a web portal to enable businesses to comply with their obligation to inform authorities and consumers of dangerous products and accidents.

Switzerland is currently not a member of the RAPEX reporting system. However, under the GPSR, the European Commission can co-operate with authorities of third countries in order to improve the overall level of safety of products made available on the market, including through the exchange of information. Full participation of third countries in the Safety Gate Rapid Alert System requires full alignment with EU law, participation in the European Standardisation System and a respective agreement with the EU. While Switzerland may adapt its legislation to the EU, it remains to been seen whether full harmonisation with EU legislation is achieved and whether participation in the Safety Gate Rapid Alert System will be considered. Until then, companies doing business in the EU and Switzerland should be aware that product compliance must be assessed for each of their products for both markets. Corrective measures (including recalls if necessary) must be separately co-ordinated with the respective surveillance authorities in the EU and Switzerland.

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

On 28 September 2022, the European Commission issued a proposal for a Directive of the European Parliament and the Council on liability for defective products (COM/2022/495; adopted by the European Parliament in its first reading on 12 March 2024, the "Proposal") to adapt the current system on product liability under which producers compensate consumers for damage caused by defective products to developments linked to transition towards a circular and digital economy and artificial intelligence (AI).

The Proposal provides for the following.

- The inclusion of software in the definition of "product", excluding, however, free and open-source software that is developed or supplied outside the course of a commercial activity.
- The enlargement of potentially liable parties: for example, liability of online platforms for defective products under certain circumstances. In addition to the manufacturer of a defective product, the manufacturer of a defective component can also be held liable. Since "component" means any item, whether tangible or intangible, or raw material or any related service, that is integrated into, or interconnected with, a product, liability can also extend to service providers such as data providers. For defective products manufactured outside the EU, the importer, the authorised representative of the manufacturer or the fulfilment service providers can be held liable.
- In terms of damages, compensation for the destruction or corruption of data that are not used for professional purposes.
- Further relief for the plaintiff in relation to the disclosure of evidence by the defendant and the burden of proof of the defectiveness of the product if the plaintiff faces excessive difficulties.

Since the Swiss Product Liability Act has been in line with the current Directive 86/374/EEC, an adaption of Swiss law to such new developments seems conceivable, in particular as the problems in relation to new technologies and the respective liability questions are the same in Switzerland. However, the competent Swiss authority has not yet received a mandate to implement any changes of the EU revision into Swiss law. In the context of civil law, there is no "harmonisation" automatism so that a revision may only be initiated by a political decision. At the time of publication of this guide (June 2024), such a decision has not yet been made. However, companies are well advised to monitor any developments in this area.

Green advertising

On 26 March 2024, the EU's "Anti-Greenwashing Directive" entered into force (Directive (EU) 2024/825 as regards empowering consumers for the green transition through better protection against unfair practices and through better information). With this Directive, the EU aims to better protect consumers from misleading advertising regarding the sustainability and eco-friendliness of products (so-called green claims). In specific terms, all green claims and environmental labels must in future be correctly, fully and transparently documented, comparable and verifiable. Companies can be held liable for false or misleading green claims.

It remains to be seen whether Switzerland will adopt the EU's Anti-Greenwashing Directive as a model for similar Swiss provisions. While not explicitly addressing green claims, current Swiss laws already have measures to prevent and penalise companies spreading false or deceptive information regarding product sustainability, as illustrated by the following examples.

Contractual claims

Liability towards customers for false or misleading green claims could arise from a contractual claim. For the enforcement of contractual claims, it is relevant whether the misleading statement has become a contractual component. This may occur, in most cases, either because the statement has become a warranty of the product's quality, or because the lack of the advertised characteristic is considered a material defect of the product.

- Advertising claims may constitute a warranty of quality, provided that these claims can objectively be seen as a serious representation of a specific, verifiable quality that a buyer can reasonably rely on when entering into a contract.
- If an eco-friendly claim does not reach the threshold of a warranty of quality, the absence of such claimed attributes can lead to a contractual claim if such absence is considered a product defect, ie, if the actual characteristics of the product significantly fall short of the agreed-upon standard, thereby substantially reducing or nullifying its value or fitness for the intended purpose. However, typically, the usability of products remains unchanged, regardless of their sustainability characteristics (eg, produced in an eco-friendly manner or made of recycled material). Thus, customers would have to prove that the misinformation significantly influenced their decision to the extent that they would not have purchased the product or would have negotiated different terms. Swiss legal authors commonly agree that a defect exists where customers paid a surcharge for the claimed characteristics of the products, eg, a premium for sustainability features. Such hurdle of proof can be challenging for customers

— price differentiation could also stem from other factors, such as brand reputation.

Nevertheless, depending on the specific form of the incorrect product information and the other circumstances of the situation, customers may have a contractual claim against sellers due to the incorrect statements. Potential claims include rescission of the purchase contract, reduction of the purchase price, or substitute performance (Article 205 CO).

If customers seek compensation (Article 97 CO), they must, in addition to a breach of contract, demonstrate the resultant damage. In the context of misleading claims, a claim for damages would be justified if customers can demonstrate that the misinformation led to an actual economic loss. Claims for disappointed expectations, lost opportunities for use, and wasted expenditure are not recognised as compensable damages. This requirement makes it challenging for customers to successfully claim damages based on false advertising information. Furthermore, for a claim for damages to be enforced, the opposing party must be at fault. While, for contractual claims, the seller is presumed to be at fault for the breach of contract, exculpation is possible in the case of sellers that carry out their business activities independently of the misleading claim or are neither intentionally nor negligently responsible for the misleading claim or its falsity (eg, distributors selling products unaware of other distributors' misleading advertising).

Tort law

Customers in their role as injured parties may also claim compensation under tort law as specified in Article 41 CO, provided they can demonstrate actual damages incurred – with the same challenges as set out above for contractual claims. Additionally, injured parties would have to prove that the potentially liable person's conduct was unlawful. In the case of purely financial losses, this would require a breach of a "protective provision", ie, the violation of a provision that is intended to protect buyers from this financial loss. According to Swiss legal authors, Article 152 of the Swiss Criminal Code (CC) constitutes such a protective norm. Article 152 CC prohibits false or incomplete statements of considerable importance by founders, authorised representatives and other persons of similar position in public announcements, communications, reports, etc, that could cause another person to dispose of their own assets in such a way that they suffer financial loss. However, it remains to be seen whether Article 152 CC will be recognised by the courts as a protective provision allowing a claim for damages under tort law based on misleading green claims.

Unfair competition

Alternatively, it would also be conceivable to base a claim on a violation of the Unfair Competition Act (UCA), prohibiting any false or misleading green claims or even for seeking damages (Articles 10 et seq UCA and Article 41 CO). Article 3(1)(b) UCA defines incorrect or misleading information about (inter alia) a company's goods, works or services as an unfair act, encompassing false or misleading statements by companies concerning the sustainability of their products.

In November 2023, the privately organised Swiss Commission for Fair Trading (FTC) issued guidelines on commercial communication with environmental references/arguments. These guidelines require, for example, that environmental representations adhere to the principles of clarity and truthfulness and that all green claims must be based on widely acknowledged scientific facts and be objectively verifiable, which must be substantiated within the commercial com-

munication itself. For instance, claims of CO_2 net neutrality should specify whether the CO_2 offsetting pertains to emission reductions or the removal of greenhouse gases, with phrases like "CO_2-neutral due to compensation through CO_2 storage". Additional information on the explanation of such claims should be accessible via web link or QR code. Further, advertising must not use self-evident statements that are standard or even mandatory in the industry. In this regard, it is worth noting that international claims used in Switzerland must also hold true in Switzerland and reflect local conditions, considering factors like recycling or manufacturing capabilities for claims on recyclability and local manufacturing.

Although the FTC cannot issue binding judgments but only recommendations, its guidelines provide important points of reference for courts and other authorities when deciding on unfair competitive practices. In the event of violations of the UCA, a court can prohibit the infringing act, order the elimination of an existing violation and declare the unlawfulness of the violation (Article 9(1) UCA). Furthermore, competitors and customers can file an action for damages and satisfaction in accordance with the CO (Article 9(3), Article 10(1) UCA). In addition, criminal sanctions of up to three years' imprisonment or a monetary penalty can be imposed (Article 23(1) UCA).

Sector-specific regulations

In addition to such general provisions, sector-specific regulations may prohibit misleading information for certain products, which would also cover any false or misleading environmental claims. For example, the Ordinance on Foodstuffs and Utility Articles requires that product information be truthful and not mislead consumers regarding certain aspects such as composition, nature, production method, and origin of ingredients (Section 12(1)). Similar provisions can be found in many other product-specific areas: eg, in the legislative framework on medicinal products (Articles 31 et seq and 51 Therapeutic Products Act and the corresponding ordinances).

THAILAND

Law and Practice

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Baker McKenzie is the largest and most prominent international law firm in Thailand. For over 40 years, it has been at the forefront of legal excellence in Thailand. Its extensive experience makes it the go-to firm for Fortune 500 companies doing business in the country, and it has an unrivalled reputation for guiding local businesses in expanding their global reach. Baker McKenzie's Bangkok office has helped companies navigate complex legal challenges across practice areas and has worked on some of the most innovative transactions and largest projects in the country. The team of 65 partners and 250 legal professionals works closely with colleagues across offices in Asia-Pacific and the rest of the world to help clients overcome their business challenges. The healthcare and life sciences team has deep understanding and experience in local regulatory processes and laws affecting pharmaceutical, medical device and biotechnology businesses, and the firm's dispute resolution lawyers represent clients in domestic and international litigation and arbitration.

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1. Product Safety

1.1 Product Safety Legal Framework

General

The Consumer Protection Act, B.E. 2522 (1979) (the "Consumer Protection Act") is the main law in Thailand which seeks to provide protection to consumers from unfair practices, including in matters relating to advertising, labelling and contracts. One of the specific matters governed by the Consumer Protection Act is product safety.

Under the Consumer Protection Act, products which are sold, offered or marketed by business operators must be safe. Various matters may be considered in relation to how to make the product safe, including:

- the type of product;
- the product's design;
- the product's label; and
- the generally accepted safety standards for such product.

The business operator must also not manufacture, import for sale or advertise any product which is unsafe.

Sector-Specific Criteria

Other specific criteria may also be issued for certain products in order for the business operator to provide additional safeguards to prevent possible harm for consumers (eg, products which contain asbestos or melamine). Certain products may be banned from selling due to safety concerns (eg, baraku and e-cigarette).

In addition to the Consumer Protection Act, there are other laws which may govern safety issues around other specific types of products, including:

- the Drug Act, B.E. 2510 (1967), which governs the safety of drugs;
- the Food Act, B.E. 2522 (1979), which governs the safety of foods;
- the Medical Device Act, B.E. 2551 (2008), which governs the safety of medical devices;
- the Cosmetics Act, B.E. 2558 (2015), which governs the safety of cosmetics;
- the Hazardous Substance Act, B.E. 2535 (1992), which provides the requirements for controlling the use of substances which are deemed to be hazardous; and
- the Industrial Product Standard Act, B.E. 2511 (1968), which prescribes safety standard for certain industrial products.

1.2 Regulatory Authorities for Product Safety

The Consumer Protection Act established the Consumer Protection Committee to oversee and regulate adherence to the Consumer Protection Act.

Additionally, the Consumer Protection Act established other subcommittees to oversee and regulate the specific matters which are controlled under the Consumer Protection Act, including the Products and Services Safety Committee.

The Products and Services Safety Committee has the authority to issue specific regulations to regulate product safety matters. For example, under the Consumer Protection Act, the Products and Services Safety Committee is empowered to set out the criteria and methods for notifying the Office of the Consumer Protection Board (OCPB) when a business operator finds that its product is a dangerous one.

Although the Consumer Protection Act empowers the aforementioned committees, the main regulator, which handles product safety issues

on a day-to-day basis, is the OCPB. As the primary regulator, the OCPB also handles product complaints and investigations.

Furthermore, as noted in **1.1 Product Safety Legal Framework**, certain products are controlled under specific laws and such laws may have a specific regulator. For example, the Food and Drug Administration (FDA) oversees and regulates safety issues which specifically relate to food, drugs, medical devices and cosmetic products.

1.3 Obligations to Commence Corrective Action

Under the Consumer Protection Act, in the event that a business operator finds out, or is informed that, a product which it manufactures, imports or sells is dangerous, the business operator is required to carry out corrective measures to prevent or eliminate the danger. These include rectifying the safety issue, changing the product or undertaking a product recall.

The business operator must also inform the OCPB in writing of the corrective measures that it is taking without delay (no more than five days from the date on which it starts to undertake the corrective measures).

In the event that there is reason to suspect that a product may be dangerous, the Products and Services Safety Committee also has the authority to issue orders to the business operator. These include orders for the business operator to undertake tests to prove the product's safety or orders for the business operator to stop manufacturing, importing or selling the product.

Where the Products and Services Safety Committee issues an order for the business operator to stop selling the product, the business operator is required to, amongst other matters, recall the product and notify/advertise the measures that it is taking to consumers. The business operator is also required to submit its corrective plans, including the plans related to the product recall and the remediation measures for consumers, to the Products and Services Safety Committee. Such plans are subject to the Products and Services Safety Committee's review and approval, and must also be notified/advertised to consumers.

The methods for notifying/advertising to consumers regarding the aforementioned issues may be subject to the OCPB's specific guidelines.

In addition to the requirements under the Consumer Protection Act, other laws may contain obligations regarding the corrective measures which must be undertaken by business operators (eg, the laws which the FDA is empowered to enforce).

1.4 Obligations to Notify Regulatory Authorities

In addition to the issues highlighted in **1.3 Obligations to Commence Corrective Action**, the business operator is required to notify the OCPB without delay where a product is found to be dangerous, or where a product causes death or injury (including injury to the mind and the properties of others).

The specific criteria and methods for making the notification will be as prescribed by the Products and Services Safety Committee.

In addition to the requirements under the Consumer Protection Act, other laws may contain notification obligations that must be undertaken

by business operators (eg, the laws which the FDA is empowered to enforce).

1.5 Penalties for Breach of Product Safety Obligations

The penalties for breaching the product safety requirements under the Consumer Protection Act will depend on the specific offence that may have been committed. The penalties include criminal fines and/or imprisonment.

Where the offence is committed by a juristic entity (legal person), the directors, managers or other persons responsible for the operation of that juristic entity may also be held liable if they were involved in the commission of the offence through their actions or inactions.

As the product safety requirements under the Consumer Protection Act were only recently introduced in 2019, at present there are no specific examples of companies which have been prosecuted or fined for breaching these obligations.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

There are two specific laws which relate to product liability, namely: the Liability for Injuries from Unsafe Products Act, B.E. 2551 (2008) (the "Product Liability Act"), and the Consumer Case Procedure Act, B.E. 2551 (2008) (the "Consumer Case Procedure Act").

The main cause of action for a product liability claim is that the injured party suffers damages from an unsafe product, where that product has been sold to the consumer, irrespective of whether such damages are a result of a wilful or a negligent act of the relevant business operators. In such cases, the relevant business operators will be held jointly liable.

The term "business operator" means the manufacturer (or the hirer of the manufacturer) or importer of the products (or the seller of the products where the manufacturer or importer cannot be identified). Persons who use a name, tradename, trademark or other marks which lead to the understanding that they are the manufacturer (or the hirer of the manufacturer) or importer of the products may also be held liable.

The term "unsafe" means a product which causes (or may cause) damages as a result of a manufacturing or design defect; or because the appropriate instructions for using or storing the products, warnings or other information regarding the product were not provided (or where it was provided but the information was inaccurate or insufficient). Consideration must also be given to the specific conditions of the products, as well as the way that the products may be used or stored under normal and expected conditions.

The term "product" covers all types of movable property, including agricultural products and electricity, but excluding certain products specified in subsequent Ministerial Regulations.

Types of products that have been exempted so far include agricultural products created by nature, agricultural produce grown by farmers that originated in Thailand, as well as drugs and medical devices manufactured by public healthcare service providers specifically to treat individual patients or animals, or those manufactured pursuant to the public healthcare service provider's orders.

2.2 Standing to Bring Product Liability Claims

The person (or the legal representative of that person) who suffers damages from an unsafe product can bring a claim.

The OCPB (as well as associations or foundations that have been certified by the OCPB) also has the authority to bring a claim on behalf of the consumer.

2.3 Time Limits for Product Liability Claims

The time limit to exercise a claim for a product liability case is three years from the date the injured person becomes aware of the damage and the business operator that is responsible, or ten years from the date on which the product was sold.

In the event of damages that are caused by substances that build up in the body of the injured person, or where it may take time for the symptoms to show, the time limit to exercise a claim is three years from the date of becoming aware of the damage and the business operator that is responsible, but not more than ten years from the date of first becoming aware of the damage.

2.4 Jurisdictional Requirements for Product Liability Claims

The Product Liability Act and the Consumer Case Procedure Act do not provide any specific jurisdictional requirements.

The general provisions of the jurisdiction of Thai courts will therefore be applied. Generally, if the injured person or business operator resides in Thailand, or if the damage arises in Thailand, or if the business operator has property that may be enforced by a judgment in Thailand, then the Thai courts may have jurisdiction.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There are no specific mandatory steps that must be taken before proceedings can be commenced formally for product liability cases.

2.6 Rules for Preservation of Evidence in Product Liability Claims

Under the Consumer Case Procedure Act, specific rules regarding the preservation of evidence may be applied.

If a person, or a party to a case, fears that evidence on which they may rely might be lost or prove difficult to produce at a later time, that person or party may file a claim before the court requesting that it hear such evidence immediately.

In the case of an emergency, the claimant may also ask the court to order the seizure of evidence, under conditions set by the court.

Any person who fails to comply with an order of the court may also be held liable for a criminal offence (which may include criminal fines and/or imprisonment terms).

2.7 Rules for Disclosure of Documents in Product Liability Cases

There are no specific rules relating to the disclosure of documents or other evidence in product liability cases.

However, under the Consumer Case Procedure Act, the court will be responsible for asking the witnesses questions while parties to the case (or their lawyers) can only do so with the court's permission. To this end, the court is empowered to ask the witnesses about any facts which it considers to be connected with the case, even if these issues are not raised by one of the parties.

In the interest of justice, the courts themselves may also order other evidence to be produced.

2.8 Rules for Expert Evidence in Product Liability Cases

There are no specific rules relating to expert evidence in product liability cases.

However, under the Consumer Case Procedure Act, the courts themselves may ask expert witnesses to provide testimony in a case. In such cases, the courts must provide the parties to the case with the appropriate opportunity to call their own expert witnesses to provide counter-arguments or additional testimony.

Furthermore, the general provisions relating to expert evidence (which allow both parties to request expert evidence) also apply to product liability cases.

2.9 Burden of Proof in Product Liability Cases

In order to make a claim in relation to an unsafe product, the injured party needs to prove that they received the damage from the business operators' product, and that the product was used or stored in its normal state. However, the injured party does not have to prove which business operator actually caused the damage.

The burden of proof is on the business operator to prove that it should not be liable for the damage that was caused by the product. To do so, the business operator must prove that:

- the product is not an unsafe product;
- the injured party knew that the product was an unsafe product; or
- the damage was caused because the injured party did not use or store the products in accordance with the instructions for using or storing the products, warnings or other information regarding the products, which had been accurately and sufficiently provided by the business operator.

Additionally, under the Consumer Case Procedure Act, where there are any arguments regarding the facts related to the manufacture, design or composition of the product, if the court is of the view that such facts are known specifically by the party which is the business operator then the burden of proof in relation to such matters will fall on the business operator.

2.10 Courts in Which Product Liability Claims Are Brought

Product liability cases will be filed with the civil courts and these cases will be decided by judges. There are no specific thresholds of awards in these courts. However, it should be noted that the Thai courts will generally only provide awards for actual damages which have been proven to the satisfaction of the court.

However, in the case of claims for liability under the Product Liability Act, the courts may also award additional compensation for mental damages arising from damage to the body or wellbeing of the injured party. Punitive damages not exceeding two times the compensation granted may also be awarded where the business operators have produced, imported or sold the products knowing that the products are unsafe, or fail to be aware of such facts due to gross negligence.

Under the Consumer Case Procedure Act, if the actual damages do not exceed THB50,000 (approximately USD1,480; this is based on the exchange rate at the time of writing and may be subject to change (this applies wherever an approximate USD amount is provided through-

out this guide)), the courts are empowered to award punitive damages in amounts not exceeding five times the amount of the actual damages.

The consumer case procedure described in the Consumer Case Procedure Act will apply to product liability cases.

2.11 Appeal Mechanisms for Product Liability Claims

The appeal mechanisms for a product liability case are stipulated in the Consumer Case Procedure Act. A product liability case can be appealed within one month from the day the court read the judgment or order.

However, a product liability case with the value of not more than THB50,000 (approximately USD1,480) may not be appealed on issues related to the facts of the case.

2.12 Defences to Product Liability Claims

As noted in **2.9 Burden of Proof in Product Liability Cases**, the main defences available to business operators in product liability cases are that:

- the product is not an unsafe product;
- the injured party knew that the product was an unsafe product; or
- the damage was caused because the injured party did not use or store the products in accordance with the instructions for using or storing the products, warnings or other information regarding the products, which had been accurately and sufficiently provided by the business operator.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Adherence to regulatory requirements may be one of the relevant considerations in product liability cases.

More specifically, it is possible that this issue may be a factor in determining whether or not the product was in fact unsafe (eg, was the product manufactured in accordance with the required regulatory standards or was the product labelled correctly in accordance with the requirements which are applicable to the specific product).

This is not, however, to say that adherence to regulatory requirements in itself will automatically mean that the product is not an unsafe one. Again, the business operator would still be required to provide the defences as mentioned in **2.9 Burden of Proof in Product Liability Cases** and **2.12 Defences to Product Liability Claims**.

2.14 Rules for Payment of Costs in Product Liability Claims

Under the Consumer Case Procedure Act, the court fees will generally be exempted for the consumer (or the legal representative of the consumer).

However, the court may also order the consumer to pay all or any part of the exempted fees, for the reasons stipulated in the Consumer Case Procedure Act. These include the court finding that the consumer filed the claim without any appropriate reason or seeks inappropriate amounts of damages. If the consumer fails to pay the fees as ordered by the court, the court may order the case to be dismissed.

The court may also, at its discretion, order the business operator to pay the court fees for the injured person.

Generally, the successful party may also seek to recover costs associated with the litigation by including those costs in its request for awards. However, any such award would be subject to the discretion of the court.

2.15 Available Funding in Product Liability Claims

There is no litigation funding provided by third parties in Thailand. Contingency fee and "no win, no fee" arrangements are not permissible.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

As noted in **2.2 Standing to Bring Product Liability Claims**, the Consumer Protection Committee (or the OCPB), as well as associations or foundations which have been certified by the OCPB, also have the authority to bring a claim on behalf of the consumer.

Class actions are also available in product liability cases and have started to be used in practice. To file a class action suit, the plaintiffs must have the same legal claims arising from the same facts and legal grounds, and must fulfil the specific condition of being of the same group.

2.17 Summary of Significant Recent Product Liability Claims

There is one significant recent product liability claim in Thailand, which is a class action case between car business operators and nine consumers. Even though currently this is only the decision of the court of first instance, and the court's interpretation and decision may be changed by higher courts, interesting interpretations of the Product Liability Act are provided in this case.

The nine consumers filed a claim to the court against three defendants that they suffered damages from cars that they had purchased. The cases involved (i) the owner of the cars' trademark, (ii) the manufacturer of the cars' parts sold to the owner of the cars' trademark, and (iii) the company that assembled cars on behalf of the owner of the cars' trademark. The problems faced by the consumers included engine shaking, the motor oil level abruptly rising, incorrect cylinders firing, strange diesel particles in the filter system, the car's incapacity to operate and overconsumption of gasoline.

It appears that the court interpreted the term "business operator" under the Product Liability Act to mean a person who utilises a trademark to give customers the impression that they are the manufacturer. Based on the court's decision, because the defendants in (ii) and (iii) exclusively produced and assembled automobiles for the owner of the cars' brand, the court determined that the sole "business operator" under the Product Liability Act in this case is the owner of the cars' trademark.

This court's view also demonstrates that mental injury compensation is practically enforceable. That is, the court determined that the existence of these car problems had injured the consumers' mental health since the customers would have been anxious that their vehicles might be unsafe, even if they did not suffer any physical harm. As a result, the court ruled that these cars are unsafe products under the Product Liability Act and ordered the owner of the cars' trademark to compensate each purchaser THB30,000 (about USD850) plus the cost of any necessary repairs.

However, for punitive damages, the owner of the cars' trademark was able to demonstrate in

court that it took appropriate attempt to identify and resolve problems with the cars as soon as it became aware of them. Ultimately, the court did not order the owner of the cars' trademark to be liable for punitive damages. This could become one of a precedence for punitive damages in the future.

The key interesting interpretations of the Product Liability Act from this case may be summarised as follows:

- the damage was considered to be caused though there was merely damage to the mental health (and not physical health);
- damages for mental health can be awarded in practice;
- a person or company that uses a trademark that leads to the understanding that it is the manufacturer would be regarded as a business operator under the Product Liability Act; and
- putting appropriate and best effort to address issues and repair unsafe products could reduce the possibility of punitive damages.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Thailand has started to see an increase in class actions that relate to product liability claims (eg, the use of class actions for products in the automotive industry). However, such cases are still limited. The aforementioned increase may have more to do with a rise in consumer awareness (as opposed to any significant changes to product liability and safety laws). For further discussion, please refer to the Thailand Trends and Developments article in this Global Practice Guide.

3.2 Future Policy in Product Liability and Product Safety

Although there have been no recent significant developments in Thailand's product liability laws themselves, there has been an update with respect to the law governing defective products, ie the draft Defective Product Liability Bill. For further discussion, please refer to the Thailand Trends and Developments article in this Global Practice Guide.

Trends and Developments

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Baker McKenzie is the largest and most prominent international law firm in Thailand. For over 40 years, it has been at the forefront of legal excellence in Thailand. Its extensive experience makes it the go-to firm for Fortune 500 companies doing business in the country, and it has an unrivalled reputation for guiding local businesses in expanding their global reach. Baker McKenzie's Bangkok office has helped companies navigate complex legal challenges across practice areas and has worked on some of the most innovative transactions and largest projects in the country. The team of 65 partners and 250 legal professionals works closely with colleagues across offices in Asia-Pacific and the rest of the world to help clients overcome their business challenges. The healthcare and life sciences team has deep understanding and experience in local regulatory processes and laws affecting pharmaceutical, medical device and biotechnology businesses, and the firm's dispute resolution lawyers represent clients in domestic and international litigation and arbitration.

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We continue to see trends of increased public awareness in general regarding their rights in relation to product safety and product liability, which may have stemmed from the fact that there have been a number of cases relating to consumer products that have received wide coverage in the media, both traditional and social media. However, the majority of these cases may usually be settled or ended outside the court and did not create a significant development in terms of legal consumer protection or precedents interpreting terms in the Liability for Injuries from Unsafe Products Act, B.E. 2551 (2008) (the "Product Liability Act"). This may be because one of the key concerns of the business operator is their reputation which may be ruined if there is any court case or court decision. Having said that, a recent Supreme Court judgment was rendered last year on a product liability case, which helps provide a basis and clarity on how the court applies several provisions within the Product Liability Act.

In terms of legal development, although there have been no recent significant developments in Thailand's product liability laws themselves, there has been an update with respect to the law governing the defective products, ie the draft Defective Product Liability Bill (the "Lemon Law Bill").

These developments are outlined further below.

Recent Product Liability Case

A recent Supreme Court judgment was rendered on a case involving failure of airbags to deploy in a car accident. Although this case does not involve high award or public attention, the judgment, which overturns the judgments of the lower courts, provides a notable example on the extent of the burden of proof imposed on the business operators under the Product Liability Act and how the act interplays with other laws on consumer protection.

Background

In this case, a plaintiff claimed that she and her husband suffered major injuries in the car accident when another vehicle rammed into them side on, and these severe injuries resulted from the airbags at the steering wheel and the dashboard of their vehicle failing to deploy properly. The plaintiff filed a case against the distributor and dealer on the grounds of wrongful act as well as breach of contracts. As the case developed, the manufacturer was also summoned into the case as a co-defendant.

Business operators under the product liability act

This case involves three business operators, two of which could be interpreted as the distributor and the dealer of the vehicle, and one as a manufacturer of the vehicle in dispute. In terms of Product Liability Act, the manufacturer would be considered as the business operator liable under the act, while the sellers (distributor or dealer in this case), would only be considered as the business operator who must be liable for any injury from an unsafe product in the case that the manufacturer cannot be identified.

Therefore, since the co-defendant has been identified as the manufacturer, based on the court ruling, the co-defendant would be liable to the plaintiff on the basis of wrongful act under the Product Liability Act, while the two defendants are not. They, however, would be liable on a different ground, as discussed below.

Unsafe product

As per the Product Liability Act, the term "unsafe product" means a product that causes or may cause damages as a result of a manufactur-

ing or design defect; or because the appropriate instructions for using or storing the products, warnings or other information regarding the product were not provided (or where it was provided but the information was inaccurate or insufficient). The question in this case, as highlighted by the judgment, was whether the airbags deployed during the accident, and if they did not, the vehicle would be deemed as an unsafe product as a result of a manufacturing defect, causing damage to the plaintiff and her husband.

Burden of proof

Under the Product Liability Act, the consumer must prove how the consumer suffers damage as a result of the products of the business operators but do not have to prove which business operator caused the damage, how the product is deemed an unsafe product or how the product caused the damage. On the other hand, in order not to be liable, the business operators had the burden of proof to demonstrate to the court that the product is not unsafe.

In proving to the court, the co-defendant presented a witness who was an employee of the co-defendant who testified on the process of the manufacturing and installation of the airbags, and the inspection performed on the airbags and the airbag control box after the accident. Based on the testimony, the witness found no abnormalities in terms of the manufacturing or installation of the airbags and found that the airbag control box showed that the airbags were working properly.

On the other hand, the plaintiff had claimed in their complaint that when the accident happened, the airbag on the driver's side at the steering wheel only deployed slightly and improperly, while the airbag on the passenger side at the dashboard did not deploy at all. The plaintiff presented witnesses, including a policeman and a tow truck driver who were at the scene of the accident, who confirmed that they noticed the airbags did not deploy properly. The plaintiff's argument is based on the ground that as a result of the failure of the airbags to deploy upon occurrence of the accident, the plaintiff and her husband suffered more severe injuries than they would have if the airbags had deployed properly.

In the end, the Supreme Court ruled the product unsafe as the co-defendant was not able to demonstrate to the court that the product is not an unsafe product. Based on the judgment, the co-defendant failed to provide sufficient proof, including presenting more impartial and credible witnesses than an employee, such as a third-party independent expert, or demonstrating that credible tests and examinations have been performed after the incident by an external expert.

Liabilities under other laws

Apart from the ground of wrongful act under the Product Liability Act, the plaintiff also filed a complaint against the defendants on the ground of breach of contract, by breaching their claims that their vehicle are very safe. The court applied similar interpretation on the safety of the product and ruled that the two defendants breached their claims on safety, and that they would be liable to the plaintiff on the ground of breach of contract.

Therefore, although, the distributor and the dealer are not considered as business operators under the Product Liability Act in this case, the defendants ended up being liable for the damages under a separate ground. This ruling also highlights the provision in the Product Liability Act, which provides that the provisions under the act do not deny the damaged party the right

to seek compensation for damages under other laws.

Damages

In light of the damage caused to the plaintiffs discussed above, the court ordered the three defendants to jointly be liable for compensation of THB500,000 (approximately USD13,500) to the plaintiff.

Apart from actual damages, the Product Liability Act also authorises the court to award punitive damages based on certain grounds, including the case where the business operators were already aware that the products were unsafe or that they were not aware of such fact due to gross negligence. In this particular case, the court did not impose punitive damages on the co-defendant. The judgment provided the rationale that it is not apparent to the court that the co-defendant was already aware that the product was unsafe or such unawareness was a result of gross negligence. This is consistent with the provision on punitive damages under the Product Liability Act.

To summarise, this case helps highlight the application of the Product Liability Act in action, as follows:

- It is the business operator's burden to prove to the satisfaction of the court that the products are not unsafe, in order not to be liable.
- The proof may need to involve external and impartial experts (even though an employee may in practice be the party that knows the facts the best).
- The sellers are not considered business operators who need to be liable under the Product Liability Act unless the manufacturer cannot be identified.
- Although a defendant may not be considered as a business operator under the Product Liability Act, it could still be liable to the consumer under other laws.

Recent Development of Draft Defective Product Liability Bill

Following the approval in principle of the draft Lemon Law Bill by the Thai Cabinet in 2022 and subsequent review by the Office of the Council of State and the House of Representatives, the Lemon Law Bill has been revised once more to reflect changes in market conditions. The updated draft was made available for public hearings by the Office of Consumer Protection Board in December 2023.

The Lemon Law Bill is one of the most recent significant developments for consumer protection legislation that indicates the aim of the government to enhance consumer protection in Thailand.

Generally, the Lemon Law Bill is considered to be part of the consumer protection law in terms of product safety as it protects buyers against defective or unsafe products purchased from sellers and provides a remedy to buyers for those defects.

It is worth noting that the Lemon Law Bill and the Product Liability Act have distinct legal implications. The Product Liability Act stipulates liability for damages or injuries caused by an unsafe product, whether to life, body, health, wellbeing, emotions or property, but excludes damage to the unsafe product itself, whereas the Lemon Law Bill stipulates liability for defects in the products itself, not damages or injuries.

For example, a buyer purchases a motorcycle from a dealer's shop. If the buyer later detects

that the engine parts do not operate properly, causing the engine to shake and the overconsumption of gasoline, the dealer will be liable to remedy those defects in accordance with the Lemon Law Bill, which could be repair or replacement. However, if this engine part issue is a manufacturing defect that the buyer was not aware of at the time of purchase and the buyer is later injured by the defective engine exploding, the motorcycle manufacturer will be liable to the consumer for the injuries in accordance with the Product Liability Act.

The following key updates are made to the previous draft Lemon Law Bill prepared by the Office of Consumer Protection Board:

Definition

The previous Lemon Law Bill specifically defined the terms "Business Operator" and "Consumer". These definitions were not included in the current Lemon Law Bill. The current Lemon Law Bill instead provides broader definitions using the terms "Seller" and "Buyer". That is, the term "Seller" means distributors of products in their ordinary course, and the term "Buyer" includes transferees or successors of rights to the products from such buyers.

Applicability

All provisions set out in the previous Lemon Law Bill were intended to apply specifically to the purchase or hire-purchase of electronic devices, personal cars, personal motorcycles and other products to be stipulated later. On the other hand, the current Bill includes general provisions for general products and specific provisions for cars, motorcycles, electronic devices and engines.

Scope

The previous Lemon Law Bill expressly did not apply to the purchase or hire-purchase of used products, products that are sold 'as is', or products purchased at an auction, whereas the current Lemon Law Bill only excludes used products and live animals.

Presumed liability

The current Lemon Law Bill applies the principle of presumed liability for defects in products found within six months of delivery, contrasting with the one-year period of the previous draft.

Claim Period

The previous Lemon Law Bill limited the period for claiming defects in a product to two years from the date a consumer detects the defects or a business operator refuses to perform duties as requested by the entitled consumer. However, the current Lemon Law Bill generally limits the period to one year from the date a buyer detects the defects in a product, or the date a seller agrees to repair or provide a replacement for a product or provide the buyer with a discount for the product. Nevertheless, a two-year period may apply for certain products.

TÜRKIYE

Law and Practice

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Contents

Akin Legal is a boutique law firm with offices in Istanbul and Ankara, boasting a legacy of nearly 40 years since its establishment in 1986 by Ibrahim Akin. The firm has seven senior partners, each with over two decades of hands-on experience in their respective fields. Integrity, ethical behaviour, and a commitment to environmental responsibility are fundamental principles at Akin Legal. The partners emphasise personal involvement in their clients' strategic projects, positioning themselves as business enablers. To maintain high-quality service, the firm focuses on selected industry sectors and legal areas where they possess deep expertise. Akin Legal is committed to empowering young women through scholarships and mentoring programmes. At Akin Legal, success is viewed as an ongoing journey achieved through teamwork, diversity, trust, and respect.

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1. Product Safety

1.1 Product Safety Legal Framework

Turkish product safety legislation is underpinned by three fundamental pillars, complemented by specific regulations for certain industries and products:

- The main body is the Turkish Code of Obligations, No 6098 (TCO), which is the backbone of civil law, together with Turkish Civil Code and Turkish Code of Commerce. Product safety matters are generally based on the tort law and contract law provisions of the TCO, or are interpreted in its context.
- Whenever a product safety matter is connected with consumers, the terms of the Consumer Protection Law No 6502 ("Consumer Protection Law" or the CPL) would be applicable as a specific regulation. The CPL is an adapted version of EU's Acquis Communautaire.
- Law No 7223 on Technical Regulations and Product Safety ("Product Safety Law") covers the product safety terms as a legislative text, which again closely mirrors the EU acquis.

These three pillars collectively establish the framework for Turkish product safety law, encompassing contractual, tortious, and strict liability. Courts apply these principles based on the specific circumstances of each claimant's case.

Contractual liability, the most prevalent form, typically arises from a contractual relationship between parties, such as a manufacturer and a customer. It requires a breach of contract terms, such as non-compliance with agreed-upon specifications or objective technical regulations. Notably, contractual liability is fault-based, necessitating proof of negligence or wrongdoing.

The Turkish Code of Obligations extends strict liability to employers, animal/pet owners, and building owners for damages caused by their employees, animals/pets, and buildings, respectively. Additionally, operators and owners of high-risk businesses are subject to strict liability for damages resulting from their operations, regardless of prudent behaviour.

Product liability claims may also be based on tort law, especially if there is no contractual relationship between the manufacturer and the claimant. This generally applies if a product causes damage to a property, or death or injury to persons. In this case, the claimant may make a claim against the manufacturer (or, as the case may be, the importer) for damages suffered due to the faulty product. The burden of proof rests with the claimant, and liability is fault-based.

If a natural or legal person has acquired a product or service for non-profit purposes, then they would be considered a consumer and therefore be subject to the terms of the Consumer Protection Law. Even though the liabilities under the Consumer Protection Law are still fault-based, it offers certain advantages to consumers, such as shifting the burden of proof to the vendor/manufacturer for defects occurring within the first six months after purchase and holding the manufacturer/importer liable for the faults of their authorised sellers or service providers.

The terms of the Product Safety Law would always be applicable for any product safety claim, whether there is a contractual relationship between the claimant and the manufacturer/importer/seller, or the claimant is a consumer or merchant. When applying the Product Safety

Law rules, the claimant must prove the existence of a production or design defect in the product that caused the damages. The manufacturer or the importer would then be held liable for all damages due to product defects.

Liability exclusion, or indemnification provided before damage occurs, is prohibited.

For food, pharmaceuticals and automotive products, specific secondary regulations are in place that establish strict liability conditions.

In recent years, the Court of Appeals has significantly broadened the scope of product liability in favour of consumers/customers. Notably, the court ruled that the statute of limitations does not apply to hidden defects, effectively extending the limitation period to ten years from the product's delivery. Moreover, the court shifted the burden of proof to the manufacturer once the claimant establishes that the damage resulted from the defective product. This means that the manufacturer must prove they were not negligent.

1.2 Regulatory Authorities for Product Safety

Generally, the Ministry of Industry and Ministry of Commerce are the two main regulators (authorities) for product safety matters.

While the Ministry of Industry focuses on the manufacturing aspect, ensuring compliance with the technical regulations and initiating recalls for serial defects. Conversely, the Ministry of Trade concentrates on the market side, preventing the entry of defective goods into the market and restricting their marketing. In essence, the Ministry of Industry adopts a bottom-up approach, while the Ministry of Trade regulates with a top-down approach.

Apart from the two main authorities, specific ministries or semi-independent agencies have their own surveillance and regulatory responsibilities. The key regulatory bodies and their respective legislation include the following:

- The Ministry of Commerce has a series of communiques for import inspection and market surveillance of almost all types of products, including medical, agricultural, textile, etc (Communiques 2023/01 to 2023/27 on Product Safety and Inspection).
- The Ministry of Industry implements extensive regulations for the inspection of industry goods (General inspection and market surveillance regulation and Special inspection and market surveillance regulation for automotive products).
- The Pharmaceuticals Law No 1262 establishes specific rules for pharmaceuticals and vaccines, serving as the basis for detailed secondary legislation and authorising the Ministry of Health and its semi-autonomous agencies.
- The General Directorate of Customs has the authority to test all products imported to Turkey for homologation and standardisation compliance.
- The Ministry of Agriculture and Forestry conducts inspections on foods, substances and materials intended to come into contact with foodstuffs.

The authority of those government bodies varies depending on the nature of the product.

For strictly regulated products like pharmaceuticals, food, or automotive products, the relevant authority acts as the approval agency. Manufacturing or importing these products necessitates homologation and approval from these authorities.

The second tier of the regulators' authority involves monitoring and surveillance of the market. In this capacity, they collect samples from the market and conduct tests to ensure compliance with product safety requirements.

In the event of a product safety issue, these government bodies have the power to order the suspension of marketing of such products, the correction of defects, and the withdrawal of defective products from the market, including both voluntary and compulsory recalls.

The final level of regulatory intervention includes the cancellation of homologation, type/product approvals, orders to cease manufacturing, and the issuance of monetary fines. These government bodies also hold the authority to bring matters before consumer courts to protect the overall interests of consumers and even involve public prosecutors in cases of criminal allegations.

1.3 Obligations to Commence Corrective Action

The Product Safety Law requires that manufacturers, importers and distributors (collectively referred to as the "Enterprise(s)") continuously test and monitor their products.

Manufacturers are obligated to continuously monitor, inspect, and test products introduced to the market, maintain records of complaints and non-compliant or recalled products, and inform their distributors and customers accordingly. They must also take corrective measures to bring the product into conformity and, if necessary, stop placing it on the market, withdraw it, or initiate a recall.

Manufacturers are required to inform end customers of identified defects, the recall process, and intended corrective measures (replacement, sales contract rescission, or free repair) and submit bi-monthly reports to the Ministry. Informing stakeholders in the supply chain alone is insufficient.

The learned intermediary principle is not applicable.

If the Ministry identifies potential risks, it will warn the Enterprise to take necessary precautions, including a recall. If the Enterprise fails to take action or initiate a voluntary recall, the Ministry can implement compulsory recalls and remove the products from the market. For products marketed under a specific license or permission from the Ministry, the Ministry may also suspend such license or permission, effectively banning the product's marketing.

Therefore, a recall can be initiated by the manufacturer, importer, distributor, or the authority, either automatically or upon an individual's claim.

A recall also necessitates that the Enterprise announce the campaign on its website's front page, directly notify known customers via registered mail, and in some cases, through mandatory advertising.

Initiating a recall does not absolve the manufacturer/importer from liability for damages suffered. They remain liable for compensation, provided the claimant proves a causal link between the damage and the defect. Thus, a recall alone does not automatically trigger liability; the existence of damage due to the defect is also required.

1.4 Obligations to Notify Regulatory Authorities

Under the Product Safety Law, the manufacturer (or its authorised representative), the importer and the distributor (collectively referred to as the "Enterprise(s)") are obliged to immediately inform the competent market surveillance regulator once it is identified that a product poses a risk to health and safety or is not compliant with regulatory standards. This notification requirement is risk-based, meaning it does not necessitate an incident to occur before precautions are taken.

The Enterprise is obliged to include in its notification to the regulator:

- the precise identification of the concerned product;
- a comprehensive description of the identified risk;
- available information pertaining to the traceability of the product; and
- the measures that are necessary to prevent the occurrence of the identified risks.

Under the regulations, the Enterprises are expected to take all necessary actions and precautions immediately. Although the definition of "immediate" is not explicitly stated, Enterprises are expected to act in accordance with the severity of the risks, akin to the response of a diligent and prudent businessperson.

While there are no formal requirements for reporting to authorities, the government has digitised most of its services. In practice, this necessitates Enterprises and individuals to initiate and track all proceedings through the relevant regulatory bodies' dedicated websites or databases. These platforms are designed with a step-by-step approach, guiding Enterprises through the notification process.

1.5 Penalties for Breach of Product Safety Obligations

The Product Safety Law provides for several types and levels of administrative fines and penalties due to breach of product safety obligations. A manufacturer, importer or distributor is subject to administrative fines and penalties if it has breached product safety obligations, unless they can prove they took all necessary precautions before regulatory intervention and rectified the failure.

Even though there is no provision that clearly addresses criminal liability due to defective products, the case law refers to a number of criminal offences relating to product liability for specific matters.

For instance, defective food and drug products may be interpreted as selling, supplying, or keeping food materials or drugs that endanger human health and life (Turkish Criminal Code (TCC) 186) or producing, providing and selling poisonous products without obtaining necessary permissions (TCC 193).

Additionally, several criminal allegations have been raised, though without successful outcomes to our knowledge, regarding smuggling and fraud. These allegations are based on the argument that product defects indicate false declarations in product conformity documents, leading to smuggling during customs clearance (for imported goods) and forgery of private documents.

It should be noted that such allegations may prompt authorities to take stricter measures during market surveillance activities, including

mandatory recalls or suspension of marketing activities.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

The Product Safety Law is the main legislation governing product liability. However, extensive case law exists for product liability matters resolved under the tort law provisions of the TCO. Therefore, the terms of the Product Safety Law and the TCO can be taken as the main causes of action for product liability claims.

Apart from general provisions, specific legislation for certain industries, such as pharmaceuticals, agriculture, or food products, may also be applicable.

Liability under the Product Safety Law is triggered when a defective product causes death, injury, or harm to a person's health, or damage to property. Claims may be brought against the manufacturer, those representing themselves as the manufacturer, importer, distributor, or seller.

As a general principle, the claimant bears the burden of proving the defect, damage, and causation. Both the TCO and the Product Safety Law adhere to this approach.

The Consumer Protection Law, however, shifts the burden of proof to the vendor, service provider, importer, or manufacturer for claims raised within the first six months of product or service delivery.

In specific cases, such as under the Pharmaceuticals Law or in situations involving strict liability for the supply of dangerous goods, courts may presume liability on the manufacturer's part.

These rules, particularly those under the Pharmaceuticals Law or concerning dangerous goods like petroleum gas or electricity, which are subject to strict liability according to case law, may require the manufacturer/vendor to prove they acted with due care and that the product complied with all relevant standards.

2.2 Standing to Bring Product Liability Claims

Any person, natural or legal, that suffers damage due to a defective product may bring a claim under the Product Safety Law or the TCO.

Each claimant must initiate a separate lawsuit, as class action lawsuits are not recognised within the Turkish judicial system.

However, while class actions are not available, the Consumer Protection Law empowers consumer associations and foundations to file determination cases or seek preliminary injunctions to safeguard the interests of their members or the groups they represent.

Also, the Ministry of Commerce, relevant authorities and consumer associations may file lawsuits for declaratory judgment actions or preliminary injunction for prohibition or suspension of unlawful consumer-related matters under the Consumer Protection Law.

2.3 Time Limits for Product Liability Claims

Under the TCO, the time limit for contractual obligations is ten years.

For damages arising from tortious acts, the limitation period is two years, commencing when

the claimant becomes aware of (i) the damage; and (ii) the identity of the responsible person. This period expires five years after the incident under the tortious act, unless the act also constitutes a crime, in which case criminal statute of limitations rules apply (typically longer than civil limitation periods).

The Consumer Protection Law establishes a two-year limitation period for consumer rights related to product defects.

The Product Safety Law provides a three-year time limit for seeking reimbursement for damages suffered due to unsafe products.

However, jurisprudence is evolving towards an understanding that the statute of limitations does not apply to hidden defects, thereby extending the general period to a ten-year limit in accordance with general principles.

2.4 Jurisdictional Requirements for Product Liability Claims

Under civil procedural law, the courts of first instance within the defendant's domicile have jurisdiction.

The TCO, however, allows the claimant to choose the competent court either at the defendant's domicile or the place where the tortious act occurred.

Furthermore, if the claimant is a consumer, they may elect to file their claim in the court of their own domicile.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

For all consumer and commercial disputes, a mediation process is compulsory.

The mediation period is limited to three weeks for consumer matters and six weeks for commercial matters. The parties may mutually extend this period by one-third.

While the defendant is not obligated to participate in the mediation process, failure to do so may result in them being liable for the mediation costs incurred if the dispute proceeds to litigation.

2.6 Rules for Preservation of Evidence in Product Liability Claims

The Product Safety Law does not provide for any particular rules for preservation of evidence (save for market surveillance activities of the regulators).

The Turkish system also does not have pre-trial deposition. The preliminary objections, as well as the evidence, are tried during the suit proceedings.

However, the CPL, which outlines general civil litigation procedures, does provide a specific mechanism for "determination of evidence". If circumstances suggest that evidence may be lost or destroyed before it can be collected during regular litigation proceedings, the relevant party can apply to the nearest competent court to secure the evidence, with or without the opposing party's presence.

The court will then decide whether there is sufficient time to notify the opposing party and obtain their statements, or if necessary, secure the evidence immediately and inform the opposing party afterward.

However, the Court of Appeals expects the lower courts to collect additional evidence that supports the findings of this "determination of evi-

dence" process if such evidence is collected in the absence of the opposing party.

2.7 Rules for Disclosure of Documents in Product Liability Cases

Under general principles of civil judgment in Turkey, the burden of proof lies with the claimant (Article 7 of the Civil Code), and each party is responsible for presenting the evidence they rely on. Courts do not automatically collect evidence without the parties' initiative in civil proceedings.

If a party asserts that the evidence supporting their claims or defences is in the possession of the other party or a third party, they can request a court order compelling them to produce the evidence. If the opposing party withholds such evidence, defying court assessment, the burden of proof may shift following the court's order. In the case of a third-party custodian, they must present the evidence to the court (upon compensation for any losses incurred) by court order.

In recent years, there has been a judicial trend towards expanding the application of Article 31 of the Civil Procedural Law, which mandates judges to clarify cases. This article requires judges to order parties to address legally ambiguous or contradictory matters or to introduce any additional evidence crucial for resolving the case. If a party hesitates to comply with such an order to produce evidence, the court may decide to shift the burden of proof, as described above.

2.8 Rules for Expert Evidence in Product Liability Cases

Under the Civil Procedural Law, the parties may request the court to appoint expert witnesses to analyse and comment on the technical aspects. This appointment commences with a specific discovery session with the participation of the parties, the judge and the experts. The judges also have the authority to appoint expert witnesses if they require any technical assistance to resolve specific matters.

The costs of the expert witness are borne by the party bearing the burden of proof, to be later reimbursed by the losing party at the conclusion of the proceedings.

Under the Expert Witnesses Act, a list of qualified sworn expert witnesses is annually announced in each judicial area.

If the expert opinion is deemed insufficient, parties may request, or the judge may independently decide to, request further details from the experts, appoint a different expert or a committee of experts, or summon the expert witness(es) to clarify their technical opinion.

In product liability and product safety cases, the Court of Appeals often expects the lower courts to appoint expert witnesses.

While the Civil Procedural Law allows parties to utilise their own expert opinions, these opinions do not carry the same weight as those of court-appointed experts.

2.9 Burden of Proof in Product Liability Cases

While the general principle places the burden of proof on the claimant, the Turkish Civil Procedural Law stipulates that both parties are responsible for proving their allegations or defences with sufficient evidence.

In principle, the establishment of a fact should be beyond doubt. The Civil Code requires evidence to reasonably prove the alleged incident or situation. If the alleging party fails to provide sufficient evidence reasonably indicating the

alleged fact, the courts will conclude that they have not met their burden of proof.

In product liability cases, this principle often hinges on court-appointed expert reports. In the absence of sufficient evidence, experts may draw conclusions based on the balance of probabilities, and courts may tend to rely on such reports. However, if the appealing party insists on the strict application of the burden of proof, appellate courts may remand the case due to insufficient evidence.

An exception to the reasonable proof burden exists in cases involving general life expectations or presumptions. If a party's claims contradict common sense or general expectations, the burden of proof shifts, and the court may require them to substantiate their allegations.

It is important to note that in strict liability cases, the burden of proof rests with the defendant.

2.10 Courts in Which Product Liability Claims Are Brought

Generally, product liability cases in Turkey are heard by civil courts of first instance, presided over by a first-class judge.

However, if the claimant is a consumer, they must file their claim in a consumer court, which is also presided over by a first-class judge.

When both parties are merchants or the dispute is commercial in nature, the case falls under the jurisdiction of a commercial court. Commercial courts typically consist of a panel of three first-class judges, but commercial disputes with a value below an annually adjusted threshold are heard by a single judge of commerce. Due to high inflation, this threshold must be reviewed and adjusted each calendar year.

The Turkish legal system does not employ trial by jury. All judicial review and decision-making are exclusively conducted by judges.

2.11 Appeal Mechanisms for Product Liability Claims

First-instance court decisions in Turkey can be challenged before the Court of Cassation. This can involve either objecting to preliminary injunction orders or seeking cassation (annulment) of the verdict. The Court of Cassation has the authority to either retry the case from the beginning or simply remand it back to the court of first instance for reconsideration.

The Court of Cassation decisions may be appealed before the Supreme Court (Court of Appeals) if the value of dispute is above certain thresholds. Due to high inflation in Turkey, the monetary thresholds should be reviewed annually for each calendar year.

As a general principle, the time limit for filing a demand for cassation or appeal is two weeks. This is a statutory period beginning once the written award with the legal grounds is served upon the relevant party.

2.12 Defences to Product Liability Claims

Under the general provisions of the TCO, a seller is not liable for defects that were readily apparent to the buyer at the time of contract formation. This principle also applies if the buyer fails to inspect the product or notify the seller of the defect, unless the defect is latent or hidden.

In tort law cases, the defendant may argue that they were not at fault or that there is no causal link between the alleged defect and the damage.

In contract law disputes, the defendant may contend that they did not breach their contractual obligations.

A common defence strategy is to argue that the product conforms to the technical standards that were in effect at the time of marketing of the product.

The manufacturer/seller may argue and attempt to prove that the defect was not discoverable given the state of scientific and technical knowledge at the time of the delivery. However, this defence is often rejected in Court of Appeals jurisprudence, as it requires the manufacturer/seller to prove that the defect was not only undiscoverable but also unavoidable.

Defendants can assert a third party's fault and issue a third-party notice under the CPL. Third parties have the option to participate in the proceedings and support the defendant. If the third party ignores the notice, they cannot then object to the findings in the noticed case file. If they do participate, their defence is limited to the designated defendant's defences.

Due to the limited intervention rights of third parties, the verdict does not have a binding effect on them. Therefore, if the defendant loses the case, they must seek recourse against the relevant third party for reimbursement of the costs incurred due to the judgment. There is no specific time limit for such recourse; the general statute of limitations applies.

Since a sound judgment requires determining causality, the impact of the claimant's actions will be considered. If the claimant's actions caused or contributed to the damage, the court may reduce or even eliminate the manufacturer's liability.

It is important to note that special regulations for pharmaceutical products, food, or dangerous goods may have additional or specific provisions that should be analysed separately.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Compliance with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of a product is the initial burden that the manufacturer must satisfy. However, case law also imposes an additional burden on the manufacturer to take further measures to resolve any non-compliance if it was foreseeable and preventable.

2.14 Rules for Payment of Costs in Product Liability Claims

The successful party can recover all court fees, including court levies and charges, court-appointed expert costs, etc, to be compensated by the losing party.

The costs of proceedings are determined in accordance with the Civil Procedural Law, Attorneys' Law and Levies' Law, and are dependent on the value in dispute, with no apparent excess costs.

The losing party is required to reimburse the successful party's lawyer fees, with the limits defined in the tariff for legal works announced annually by the Union of Turkish Bars. The lawyers' fees vary between fixed rates (from approximately EUR500) and 25% of the value of the dispute.

2.15 Available Funding in Product Liability Claims

Parties may be granted legal aid by the courts if they can demonstrate that they lack the financial resources to cover the costs of proceedings and have a reasonable prospect of success in

their case. However, public funding of proceedings and pro bono legal aid by an attorney are generally not permitted unless authorised by the relevant Bar Association.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Class action is not recognised in the Turkish judicial system.

However, while class actions are not available, the Consumer Protection Law empowers consumer associations and foundations to file determination cases or seek preliminary injunctions to safeguard the interests of their members or the groups they represent.

Also, the Ministry of Commerce, relevant authorities and consumer associations may file lawsuits for declaratory judgment actions or preliminary injunction for prohibition or suspension of unlawful consumer-related matters under the Consumer Protection Law.

Co-ordinated proceedings are not recognised as each claimant is expected to file a separate lawsuit.

However, in practice, courts may informally co-ordinate several cases if the defendant and the cause of action are the same across a series of lawsuits. This may involve running parallel judgment procedures or designating one case as a pilot case for the remaining ones to follow.

2.17 Summary of Significant Recent Product Liability Claims

A recent comprehensive summary of product liability law by the Trabzon Court of Cassation (4th Chamber) provides insight into the evolving legal landscape in Turkey. This case involved a toddler's tragic suffocation after crawling into a washing machine. Expert investigation revealed that the machine's cover easily locked with minimal pressure, deviating from general expectations for similar products.

The court ruled that the manufacturer's liability should be based on the Product Safety Law, a departure from the previous reliance on tort law principles under the TCO. The court referenced a 1996 ruling by the General Chamber of the Court of Appeals, which established fault-based liability for manufacturers. However, the court emphasised that fault should not be interpreted strictly, as manufacturers also bear the burden of showing diligent care as required by law. A manufacturer must prudently assess potential risks and dangers likely to occur during product use. Failing to take precautions to avoid such potential risks should be classified as a faulty act.

In light of recent jurisprudence, it can be summarised that (i) the courts tend to apply the terms of the Product Safety Law more frequently than the tort law principles of the Code of Obligations, and more importantly, (ii) there is a shift in the judiciary's evaluation of manufacturer (product) liability from fault-based liability towards strict liability. This shift involves heightened care and diligence expectations in the design and manufacturing of products.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

The EU adopted the General Safety Regulation (GSR) in 2019, which will come into force in

stages starting in July 2024. The GSR introduces additional safety features for homologation and type approval of automotive products marketed in the EU.

Turkey has a customs union with the EU, and Turkey's automotive industry is fully integrated with the EU market. Turkey ranks 15th in the world and 5th in Europe in terms of automotive production, and Europe is the biggest market for Turkish automotive manufacturers.

Recognising this integration, Turkish automotive legislation is closely aligned with the EU acquis, ensuring consistency with European standards and regulations.

Turkish policymakers typically monitor legislative developments in the EU, evaluate their market impact in relation to Turkey's economic needs, and subsequently adapt them into local legislation with minor modifications.

Therefore, it is anticipated that a replication or slightly modified version of the GSR will be introduced in Turkish legislation following the full implementation of the EU GSR.

3.2 Future Policy in Product Liability and Product Safety

Given the customs union between Turkey and the EU, with the EU being Turkey's largest import and export partner, a significant flow of products exists between the two markets. To maintain this flow of goods, Turkey closely monitors and often aligns its regulations with the EU acquis.

In recent years, the EU has introduced cutting-edge regulations concerning artificial intelligence, personal data, mobility, and sustainable and circular economy, either through legislative implementation or in draft form.

The EU's draft product liability directive aims to adapt liability and safety expectations to the technological advancements of recent decades. This adaptation will involve redefining concepts related to products and the burden of proof, resulting in the expansion of manufacturers' product liability towards strict liability, along with significant procedural changes.

It is expected that Turkey will follow the EU approach with a short delay, after observing the implementation and initial impact of the EU legislation.

UK

Law and Practice

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Contents

Ashurst has a reputation for successfully managing large and complex multi-jurisdictional transactions, disputes and projects and delivering outstanding outcomes for clients. Ashurst acts as a global team, with 31 offices in 18 countries, and offers the reach and insight of a global network of legal, new law and risk professionals, combined with the knowledge and understanding of local markets. With over 490 partners and a further 2,000 lawyers working across 11 different time zones, the firm is able to respond to clients wherever and whenever required.

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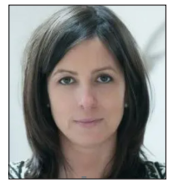

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1. Product Safety

1.1 Product Safety Legal Framework

The UK's product safety legal regime seeks to balance the rights of consumers with those of business, aiming for the highest level of public safety that does not stifle innovation.

Regulated Products

The product safety regimes apply to consumer products, including:

- products that are newly manufactured and, in certain instances, that are used and second-hand;
- products marketed through all modes of sale, including traditional bricks-and-mortar stores or via e-commerce;
- products that enter the UK for the first time after being imported from a third country (including the EU, post-Brexit); and
- products that have been subjected to significant changes that modify their function or safety profile.

Legislation

The system consists of the following fundamental legislative pillars.

General product safety requirements

These are contained within the General Product Safety Regulations 2005 (GPSR). This legislation contains fundamental, overarching concepts of product safety, including the following:

- only "safe" products are marketed in the UK;
- various actors within the supply chain are responsible for product safety and compliance, or aspects thereof;
- conformity assessments that analyse the risks and features of products are necessary before marketing a product;
- compliance with relevant safety legislation is usually denoted by appropriate marking, including the new UKCA mark or, in certain circumstances, the EU CE mark and/or Northern Ireland UKNI mark, as underpinned by relevant declarations of conformity or similar;
- the trigger for most significant regulatory obligations is "placing on the market" and/or "making available on the market";
- post-market surveillance obligations exist after the initial sale of products;
- corrective actions are required in certain circumstances; and
- reports to regulators are required in certain circumstances.

Supplementary product-specific safety requirements

These are contained within sector-specific legislation, to more specifically address unique or specific risks associated with certain types of products. Where they exist, such requirements take precedence over the above-mentioned general requirements contained in the GPSR. Otherwise, these product-specific requirements apply where the GPSR are silent. Sector-specific laws exist in respect of the following, for example:

- chemicals;
- cosmetics;
- construction products;
- low-voltage electrical equipment;
- machinery;
- motor vehicles;
- personal protective equipment; and
- toys.

Separate product-specific safety regimes

Separate product safety regimes aim to address the unique and quite separate risks of products that are not considered "industrial products" (which are addressed by the above-mentioned legislation). These operate separately from the GPSR and include the following, for example:

- food;
- pharmaceuticals; and
- medical devices.

Enforcement and Monitoring of Obligations Imposed by Regulators

Market surveillance activities are carried out by regulators, who are empowered to monitor and enforce compliance with the above-mentioned product safety laws. Please refer to **1.2 Regulatory Authorities for Product Safety** for further detail.

The Role of Technical Standards

In practice, compliance with the above legal requirements is often achieved through adherence to technical standards specific to each product type/category/feature, which provides a benefit of conformity under the relevant legislation. Technical standards are developed by relevant standardisation organisations, and are designated under appropriate legislation by the Secretary of State who is empowered to do so in the UK.

The Effect of Brexit on the UK Product Safety Law Regime

The above UK product safety laws derive largely from EU legislation (the GPSR give effect to EU Directive 2001/95/EC on general product safety, for example). Given the implementation of local UK laws to enact EU-level obligations prior to Brexit and/or the direct effect of EU laws in the UK at the time of initial pre-Brexit implementation, much of the legislative framework for product safety in the UK remains substantively unchanged post-Brexit. However, the Retained EU Law (Revocation and Reform) Act 2023 received Royal Assent in June 2023, introducing further divergence between the EU and UK law with the revocation of almost 600 pieces of legislation by 31 December 2023.

Further, various UK legislation, such as, most relevantly, the Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2019, was enacted to amend EU-based legislation to make correct references to the UK rather than the EU, and to ensure the continued applicability of the legislation in the UK. Supplementary legislation was also required to be enacted in some sectors to empower the relevant UK law-makers to implement future changes to UK legislation. In some specific areas, including medical devices, the EU and UK positions already deviated

significantly because of legislative changes in the EU that did not take effect prior to Brexit. Please refer to **3.1 Trends in Product Liability and Product Safety Policy** for further detail.

1.2 Regulatory Authorities for Product Safety

Oversight of the UK product safety regimes is undertaken by several regulators in the UK, at various levels.

Local Authorities

Local authorities have day-to-day responsibility for the enforcement of product safety legislation in the UK, which is carried out through local Trading Standards (TS) offices. Through the GPSR and Consumer Rights Act 2015 (CRA), such authorities have a wide range of powers, including the ability to:

- issue recall/withdrawal notices;
- issue requirements to warn;
- issue product recall enforcement notices;
- enter and search premises;
- seize documents and goods;
- require information;
- test equipment;
- observe the carrying on of business;
- inspect products;
- issue statutory notices;
- issue cautions;
- seek the imposition of civil sanctions; and
- commence criminal prosecutions.

Overarching Product Safety-Specific Regulator

The Department for Business, Energy and Industrial Strategy (BEIS) is responsible for high-level oversight of policy and strategy in the area of product safety regulation. In January 2018, the Office for Product Safety and Standards (OPSS) was developed within BEIS to address an apparent need for a technical, centralised resource to assist localised regulatory enforcement around product safety issues. The OPSS carries out the following functions:

- supports the work of TS, by providing advice and access to technical and scientific assistance, including product testing and risk assessments;
- co-ordinates national responses to safety issues by providing an incident management capability and working with TS to collate intelligence and identify emerging trends;
- works with industry to inform the approach to regulation and enforcement; and
- administers the Primary Authority scheme where companies work with specific authorities.

The OPSS is empowered with many of the aforementioned enforcement powers of TS.

Product-Specific Regulators

There are product-specific regulators for the following product categories:

- food;
- vehicles;
- medicines and medical devices; and
- workplace equipment (including PPE).

1.3 Obligations to Commence Corrective Action

Product producers in the UK are required to conduct corrective actions to address product safety issues that make a product unsafe (GPSR Regulation 7), in contravention of the GPSR safety requirements or other relevant product safety laws. The actions taken by producers must be "commensurate with the characteristics of the product" and there are a range of corrective actions that can be taken, including withdrawal

from the supply chain, additional warnings to consumers, in-market repairs or alterations, and a consumer-facing recall. Generally, consumer-facing recalls are considered a last resort. The nature of the corrective action undertaken is determined by the results of a risk assessment.

In March 2018, the OPSS co-operated with the UK's standards institution, the British Standards Institution (BSI), to launch a Code of Practice for Product Safety Recalls (PAS 7100:2018). The Code has two parts.

- Part 1 provides guidance to manufacturers, importers and distributors (of non-food products) on planning and managing corrective actions, establishing mechanisms to monitor product safety, investigating potential product safety issues and reviewing corrective action programmes.
- Part 2 provides guidance to market surveillance authorities, such as TS, regarding their roles.

EU-level guidance on topics of risk assessments (RAPEX methodology, 2019) and guidelines (European Commission and PROSAFE guides) may still be useful, given the basis of the laws, notwithstanding the event of Brexit, but will not necessarily be held in the same regard without further changes being implemented to preserve their position as official guidance in the UK.

There are no mandatory requirements for advertisements or other form-specific requirements for the advertising of product safety recalls in the UK. However, the above-mentioned Code provides detailed guidance on the form and content of corrective action announcements.

1.4 Obligations to Notify Regulatory Authorities

Under Regulation 9 of the GPSR, or equivalent sector-specific regimes, there is a mandatory obligation on producers or distributors to report to authorities where they know that a product they supply is "incompatible with the general safety requirement" under the GPSR.

The GPSR requires the report to be in writing and to contain certain mandatory information – namely, the action taken to prevent risk to consumers and the location of supplied products, as well as further identifying information if the product is thought to pose a serious risk.

There is no mandatory procedure to follow to make these reports, and the practices of TS offices can differ greatly in practice, including requiring completion of specific forms. There is also sometimes interaction between the OPSS and TS; for example, where a report to both entities is requested, or warranted for certain more significant issues.

Post-Brexit, the UK is no longer part of the European Commission's rapid alert system, Safety Gate (formerly RAPEX), which assists with Europe-wide information sharing regarding non-food product safety risks. Reports to UK market surveillance regulators will be recorded, in certain circumstances, on the OPSS' Product Safety Database, which covers consumer products under the ambit of the OPSS' work.

Although there are no specific timeframes under statute regarding these reports (the legislation simply states that obliged entities should "forthwith notify an enforcement authority"), the recommended timeframe for reporting, provided in guidance documents only, is generally dictated

by the assessed risk of the safety matter to consumers who use the affected products.

1.5 Penalties for Breach of Product Safety Obligations

It is a criminal offence to fail to report to authorities under Regulation 20(3) of the GPSR, punishable with an unlimited fine or imprisonment for a term not exceeding three months.

In practice, companies and regulators work to resolve issues before there is a need to prosecute formally. Regulators are likely to employ the wide range of powers available to them under relevant legislation prior to commencing formal prosecution; please refer to **1.2 Regulatory Authorities for Product Safety** for details. There are a few isolated examples of companies being prosecuted, particularly toy or children's product manufacturers where the risk to vulnerable users is considered particularly egregious, or where there has been a significant delay in reporting to authorities. Generally, companies plead guilty in short hearings in UK Magistrates' Courts, and fines have also historically been small.

A recent illustrative example is the fining of a toy manufacturer following a prosecution by Thurrock Council Trading Standards in April 2021. The company pleaded guilty to the import and supply of unsafe toys at a hearing in Southend Magistrates' Court on 14 April 2021. Initial raiding of the premises by TS uncovered toys without relevant safety documents, and further testing confirmed that the toys presented risks of choking asphyxiation. The company was ordered to pay approximately GBP4,100. The prosecution was said by the Council to be brought after "repeated attempts" to encourage the company to comply with its legal obligations.

Another, more serious, example of a penalty for breaching product safety standards is the imprisonment of a supplier of electrical goods following a prosecution by Havering Council Trading Standards in May 2022. A three-month prison sentence was handed down by Snaresbrook Crown Court to a company director for failing to comply with requirements of product safety regulations and unauthorised use of a trade mark. The online business sold electrical chargers, adapters, plugs, cables and earphones. Following a raid of the storage premises by TS, a large quantity of the items, with a retail value of GPB54,000, were found to be contravening UK safety regulations or counterfeit.

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

There are three main causes of action typically employed by claimants pursuing product liability claims in the UK. Each suit offers certain strategic advantages that might make it preferable to certain claimants in certain circumstances; however, claimants often elect to pursue more than one of the causes of action in parallel, in respect of the same facts, to increase the likelihood of success and overcome some of the limitations of certain causes of action.

"Strict Liability" Statutory Regime Under the Consumer Protection Act 1987 (CPA)

The CPA creates a no-fault liability scheme in respect of defective products that have caused personal injury or damage to private property, excluding damage to the product itself.

Under the regime, the following entities have joint and several liability:

- the manufacturer of the product, or an entity that holds itself out as such by having the product designed/manufactured on its behalf and marketing the product under this trade mark/name;
- the importer of the product into the UK (post-Brexit, there are significant changes to liability exposure and responsibility under product safety regulations in respect of former distributors within the UK now being considered importers); and
- the distributor/supplier, in rare circumstances where the above-listed entities cannot be identified by the distributor within a reasonable timeframe when that information is requested or a claim is made against the supplier/distributor.

The following three key elements of the cause of action must be established by the claimant.

Defect

Section 3 of the CPA establishes there is a defect in the product "if the safety of the product is not such as persons generally are entitled to expect". The court will take into account all of the circumstances when assessing the safety of the product, including:

- product marketing;
- date of supply;
- any safety mark;
- warnings;
- what might reasonably be expected to be done with the product; and
- the time when the product was supplied by its producer to another.

The landmark case of Colin Gee & Others v DePuy International Limited [2018] EWHC 1208 (QB) ("Gee") provides the following guidance on the application of this statutory test:

- the test is objective (what persons generally are entitled to expect) and not subjective (what the individual claimant expected);
- hindsight is not relevant in determining entitled expectation – entitled expectation must be assessed as at the date of supply of the product; and
- a court can take into account all of the circumstances it considers factually and legally relevant to the evaluation of safety, on a case-by-case basis.

Damage

Generally, death, personal injury or any property loss (property for private use, occupation or consumptions) are damages for which claimants can seek compensation under the CPA.

Damage to the product is excluded from the scope of recoverable heads of damage. There is also a minimum monetary value of GBP275 that the property damage suffered must exceed in order to be entitled to pursue a claim under the CPA.

Causal link

There must be a causal link between the product defect and the damage/injury sustained. The traditional English law tests for causation apply to product liability cases.

Tortious Liability – Negligence

Manufacturers or other actors in the supply chain (mostly where a manufacturer cannot be identified) can be liable in common law negligence in respect of a defective product.

To bring a successful claim in negligence, a claimant must prove, on the balance of probabilities, that:

- the defendant owed the claimant a duty of care;
- the defendant breached that duty of care;
- the breach caused the claimant's loss or damage; and
- the loss was reasonably foreseeable.

The key distinguishing feature of such actions is that the claimant must establish fault on the part of the defendant. For this reason, this claim is generally considered to be more difficult to bring than that under the no fault mechanism of the CPA.

Breach of Contract – Express or Implied Statutory Term

Consumers that are party to a contract with a seller or supplier of products can pursue a breach of contract claim if a product supplied is defective or otherwise fails to conform to the contract of sale.

The seller may be exposed in respect of breach of either express terms, or those implied by the Consumer Rights Act 2015 (CRA) in respect of:

- the fitness for purpose of the product;
- it being as described; and
- it being of satisfactory quality.

To bring a claim in contract, a claimant must prove the following on the balance of probabilities.

- A contract is in place – ie:
  (a) there is a mutual intention to create a contract;
  (b) an offer has been made;
  (c) that offer has been accepted; and
  (d) there has been "consideration" (value) exchanged between the parties.
- The contract has been breached.
- The breach of contract has led to loss.

2.2 Standing to Bring Product Liability Claims

There are different requirements to bring the three causes of action mentioned in **2.1 Product Liability Causes of Action and Sources of Law** in relation to product liability claims in the UK, as follows.

CPA

Consumers ("any person who purchases or uses the product in question for private use") have legal standing to bring product liability claims. Persons who purchase or use goods for the purpose of resale or commercial use are expressly excluded from the definition of consumers. In order to have a right of action under the CPA, the consumer must have suffered damage of a kind covered by Part 1 of the CPA.

Negligence

Any person to whom a duty of care is owed can bring a negligence claim in circumstances where that duty is breached and they sustain a reasonably foreseeable loss or damage caused by a defective product.

A claimant need not know the defendant in order to bring a successful claim in negligence. A claim may be brought by a consumer/purchaser of the product, a person who uses the product, or a third-party bystander who is injured by the product.

Contract

Generally, because of the doctrine of "privity of contract", only the parties to a contract can enforce the terms of that contract. However, in certain circumstances a third party may seek enforcement under the Contract (Rights of Third

Parties) Act 1999, unless these rights have been expressly excluded.

2.3 Time Limits for Product Liability Claims

There are strict time limits for bringing civil claims in England and Wales, including product liability claims.

Negligence and Contract

Under the Limitation Act 1980, claims involving personal injury must be brought within three years from the date that the damage occurred or the date that the claimant knew, or reasonably ought to have known, that they had a cause of action ("the date of knowledge"). Knowledge can be acquired from the date that the claimant knew the identity of the defendant or realised the significance of their injury.

For non-personal injury claims, the claim must be brought within six years from the date on which the damage or loss occurred, or three years from the date of knowledge for claims concerning latent damage. The three-year limitation period can be extended at the court's discretion.

CPA

Working in tandem with these time limits, the CPA contains a ten-year long-stop provision, allowing claims under it to be brought within ten years from the date on which the product was put into circulation. Absent the issuing of court proceedings within that timeframe, rights under the CPA are extinguished and cannot be extended by the court.

2.4 Jurisdictional Requirements for Product Liability Claims

Prior to Brexit, the jurisdiction of UK courts, as opposed to other EU member state courts, was determined by the operation of EU-level laws. Post-Brexit the situation is as follows.

CPA

Generally, UK courts, as with other European-based courts, will assume jurisdiction to try a case where either the injury, loss or damage occurs, or where both parties are domiciled, in that country.

Prior to the UK leaving the EU, where a defendant was domiciled in England, the English court had jurisdiction and could not decline jurisdiction, pursuant to Owusu v Jackson (Case C-281/02) [2005] ECR I-1383. This no longer applies now that the UK has left the EU, and UK-domiciled defendants are able to challenge the English court's jurisdiction on grounds of it not being the appropriate forum.

Negligence

In order to invoke the jurisdiction of English courts in respect of negligence claims, it is sufficient for a defendant to be physically present in England and Wales to enable the claimant to serve proceedings on that defendant.

Contract

Contractual terms agreed by both parties ordinarily determine the applicable law, jurisdiction and location of proceedings in respect of contractual breaches.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

There are mandatory pre-action protocols applicable in respect of product liability claims, under the Civil Procedure Rules Practice Direction on Pre-Action Conduct and Protocols, that must be complied with prior to the commencement of formal claims.

The following Pre-Action Protocols may typically be applicable to product liability claims:

- the Pre-Action Protocol for Personal Injury (Employers' Liability and Public Liability) Claims; and
- the Pre-Action Protocol for Low Value Personal Injury (Employers' Liability and Public Liability) Claims.

These Pre-Action Protocols ordinarily dictate the following pre-action procedural steps:

- exchanges of correspondence, including, for example, a brief outline of each party's case, in the form of either a letter or a prescribed form; and
- the exchange of evidence in some circumstances, including, for example, high-level medical evidence in respect of personal injury claims.

Breach of these protocols can have a substantive impact on the ability to commence formal proceedings and/or can have negative costs consequences for the defaulting party, with the court potentially taking the following actions:

- requiring explanation for any breach or variation of protocols, particularly in circumstances where both parties have departed from their prescriptive requirements;
- awarding costs, taking into account any breaches or defaults under the protocols;
- applying sanctions against the offending party; and
- staying proceedings entirely until there is pre-action compliance.

2.6 Rules for Preservation of Evidence in Product Liability Claims

Broad document preservation obligations are imposed on parties to proceedings in England and Wales, including product liability matters. These rules work in tandem with rules regarding document disclosure; please refer to **2.7 Rules for Disclosure of Documents in Product Liability Cases** for further detail.

Under Civil Procedure Rules (CPR) Practice Direction 31B (paragraph 7), once litigation is contemplated, parties must ensure that all potentially disclosable documents are preserved, including any relevant products, devices, design files, testing information, etc. Please refer to **2.7 Rules for Disclosure of Documents in Product Liability Cases** for further detail.

Under this provision, past, present and future documents must be preserved.

Failure to comply with these requirements – including by interfering with evidence by deleting, overwriting, updating or destroying documents – has far-reaching consequences, including the following measures which the courts can and do impose:

- penalties for interference with evidence;
- satellite litigation regarding affected documents;
- costs sanctions;
- striking out a party's particulars of claim or defence; and
- the drawing of adverse inferences as to the contents of those documents (Earles v Barclays Bank Plc [2009] EWHC 1) – it is likely that the court will order a party to provide an explanation as to why the documents have not been preserved before drawing adverse inferences or making further orders.

2.7 Rules for Disclosure of Documents in Product Liability Cases

There are far-reaching disclosure requirements in respect of product liability cases in the UK.

CPR Part 31 sets out the parties' responsibilities. Generally, as part of "standard disclosure", parties to an action are required to disclose the following:

- those documents that are or have been in their control;
- documents on which they rely; o
- documents that may adversely affect their own or another party's case; or
- documents that support another party's case (standard disclosure).

The court, in its discretion, may limit or dispose of the above requirements (CPR 31.5). CPR 31 does not apply to claims entering the small claims track (see **2.10 Courts in Which Product Liability Claims Are Brought**). However, a court will ordinarily order standard disclosure, requiring each party to file and serve on the court and all parties copies of all documents upon which they intend to rely.

Parties are required to conduct a reasonable and proportionate search for the above-mentioned disclosable documents. Disclosure obligations are ongoing – ie, continual disclosure is required until the cessation of the matter, including in respect of documents created during the proceedings.

Electronic Document Disclosure

Given the prevalence of electronic documents and sources in modern litigation, specific rules apply to electronic documents. An electronic document is defined as any document held in electronic form – eg, emails, text messages, voicemails, word processed documents, social media messages and databases. CPR 31, Practice Direction 31A and 31B set out the rules of disclosure of electronic documents in multi-track claims (though a court can also apply these rules to small or fast-track claims), and provide for the following, amongst other things.

A party requesting the specific disclosure of electronic documents that are not reasonably accessible must demonstrate the relevance of those documents in order to justify the costs and burden of retrieving them.

The parties must advise the court before the first scheduled case management conference (CMC) if an agreement has been reached concerning electronic disclosure. If an agreement has not been reached before the first scheduled CMC, the parties will be required to identify issues to put before the court for directions. It may be considered reasonable for a party to search for relevant documents using "key word searches" if a full review of every document would be considered unreasonable or disproportionate in terms of costs and review time involved.

2.8 Rules for Expert Evidence in Product Liability Cases

There are prescriptive requirements for expert evidence in respect of product liability claims in England and Wales courts, as set out in the following CPR provisions:

- Annex C of the CPR Practice Direction on Pre-Action Conduct, outlining the general procedure for the use of expert evidence;
- CPR Part 35, which sets out the control and use of experts in proceedings;
- Practice Direction 35;
- the Protocol for the Instructions of Experts to give Evidence in Civil Claims; and

- Part 7 of the Pre-Action Protocol for Personal Injury Claims (where applicable).

Generally, the above provisions provide that parties' use of experts is limited to:

- circumstances where such evidence is reasonably required to resolve the proceedings; and/or
- those cases where the court grants express permission.

Other requirements include the following.

- Form:
  (a) expert evidence must generally be in written form (written report), unless the court directs otherwise;
  (b) with the court's permission only, in certain circumstances parties can put forward written questions to the experts, including to other parties' experts; and
  (c) oral evidence can be relied upon, but subject to permission from the court (CPR 35.4).
- Expert duties:
  (a) expert witnesses are impartial in their analysis and must acknowledge their duty to act independently when preparing their own expert report, with their overriding duty being owed to the court and not the party instructing or paying them; and
  (b) experts must verify their report by including a statement of truth. CPR Practice Direction 35 paragraph 3.3 sets out the recommended template for statements of truth for experts to include in their reports.

Costs

Courts are increasingly limiting the use of experts in cases in an attempt to control costs. Accordingly, if an expert is instructed, it is important that parties manage costs carefully, including by the following means.

- In lower-value claims, using a single joint expert to address both parties' positions may be the most cost-effective solution.
- In respect of small claims or fast-track matters, experts will generally be directed not to attend the hearing, except in limited circumstances where the court deems that necessary.
- In high-value claims where parties instruct their own experts, the court may direct a joint discussion between experts for the purpose of identifying and discussing the issues in the proceedings and, where possible, direct the experts to reach an agreed opinion on those issues. The court may direct that, following the discussion, the experts prepare a joint statement for the court setting out the issues on which they agree and disagree (with reasoning).

2.9 Burden of Proof in Product Liability Cases

In respect of each cause of action in product liability claims, the claimant bears the onus of proof. The standard of proof required, in respect of each discrete action, is to prove the case against the defendant on the balance of probabilities (civil standard).

2.10 Courts in Which Product Liability Claims Are Brought

The forum in which a product liability is heard is dictated by the value and/or complexity of the claim. Claims all commence, in the first instance, in either the High Court or the County Court. Thereafter, courts allocate these defended claims to one of three procedural tracks, at an early stage:

- small claims track – claims with a value of no more than GBP10,000 or where personal injury damages is valued up to GBP1,000 only;
- fast-track – claims with a value over the small claims track limit, but less than GBP25,000; and
- multi-track claims – claims valued over GBP25,000.

Multi-track claims can be heard at either the High Court or County Court. Claims with a value of less than GBP50,000 which are commenced in the High Court are generally transferred to a County Court unless there is a specific reason for them to be heard at the High Court (for example, where the case concerns particularly difficult questions of law or where it might attract significant public interest).

In general, in the first instance, product liability cases are heard by a single judge who will generally be alive to the potential complexity of such claims and will allow evidence from a range of expert disciplines and lay witnesses where required. On appeal in the Court of Appeal or Supreme Court, cases may be heard by three or five judges. Jury trials do not take place in civil product liability cases.

Damages Available

There is no upper threshold for the award of damages in product liability cases generally.

Claimants that succeed with an action in negligence are entitled to an award of damages, the aim of which is generally to place that claimant in the position they would have been had the negligence not occurred.

2.11 Appeal Mechanisms for Product Liability Claims

Appeals in respect of product liability claims follow the general rules applicable to appeals for all civil claims in England and Wales, as follows.

- Standing – the court's permission must be obtained before an appeal can be lodged by way of an application.
- Time limits – a party ordinarily has only 21 days following a judgment to make a request for an appeal against a County Court or High Court decision.
- Application for permission to appeal – the courts only grant such permission in circumstances where the appeal appears to have a real prospect of success or there are other compelling reasons why it should be heard; the application process is usually "on the papers" (rather than by way of oral hearing) only, unless the court deems the application exceptionally requires an oral hearing.
- Scope of appeal – an appeal is usually limited to a review of the lower court's decision; however, the court can apply its discretion to order a re-hearing if the interests of justice would be served by doing so.
- Grounds for an appeal – an appeal will be allowed where the decision of the lower court was wrong (eg, where the court made an error of law, or of fact, or in the exercise of its discretion) or if the decision was unjust because of a serious procedural or other irregularity of the lower court; in practice, the courts rarely interfere with findings of fact made by lower courts, on the basis the judgments were made with the benefit of hearing witness and expert evidence first-hand.
- Effect of appeal decision – an appeal court may affirm, vary or set aside any order or judgment made by the lower court, order a

new trial or hearing, or make any other appropriate order.
- Forum of appeal – the Court of Appeal hears appeals against decisions made in a County Court or in the High Court; these are heard at the Royal Courts of Justice in London. The Supreme Court in London is the final appellate court, which hears appeals on arguable points of law of general public importance.

2.12 Defences to Product Liability Claims

The nature of available defences depends on the cause of action pursued.

CPA

Given the statutory nature of the CPA, the defences available are limited to those provided under the legislation, as follows:

- the defect is attributable to compliance with any requirement of UK or retained EU law post-Brexit;
- the defendant did not at any time supply the product;
- the product was not supplied in the course of the defendant's business or with a view to profit;
- the defect did not exist in the product at the time of supply;
- the state of scientific and technical knowledge at the time the product was put into circulation was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in their products while they were under their control (known as "state of the art" or "development risks" defence); and
- the defect was not in the component supplied but in the finished product in total, for which the defendant should not be responsible.

Negligence

In practice, negligence claims are most often defended on the basis that the requisite elements of the cause of action have not been established – eg, there was no duty of care owed, there was no breach of said duty and/or there was insufficient evidence to establish causation.

Other common defences to claims in negligence are as follows.

- Contributory negligence – a claimant contributed, at least to some extent, to their damage and/or injury; the liability of the defendant is reduced by the contribution of the claimant.
- Voluntary assumption of risk – the claimant consented to the risk that resulted in injury/loss.
- Establishing that the injury was caused by the claimant's participation in a criminal enterprise.

Contract

Again, contractual claims are often defended in practice on the basis that not all elements of the claim are made out – eg, there was no contract in place or the contractual terms did not include the term allegedly breached.

Otherwise, the following defences may be available in contract claims:

- the breach of contract was waived and the claimant did not act on the breach within a reasonable time (or at all);
- the contract terms were varied; and
- promissory estoppel.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

Under the CPA, it is a statutory defence to allege that the fact of compliance with mandatory reg-

ulatory standards introduced a product defect (see **2.12 Defences to Product Liability Claims**).

Furthermore, although it is still considered an area of development for judicial consideration, it is generally accepted that whilst compliance or lack thereof with regulatory obligations is a persuasive factor in determining whether or not a product is defective, it is by no means decisive.

Wilkes v DePuy International Limited [2016] EWHC 3096 (QB) made it clear that compliance with appropriate mandatory regulatory standards and/or the grant of regulatory approval are appropriate circumstances to take into account under the CPA statutory test for whether a product is defective. It was said by the court that, whilst these factors are not complete defences to a claim under the CPA, they would be "powerful evidence" to indicate that the level of safety contemplated by the CPA had been reached, and that against that backdrop "it may be challenging" for the claimant to make out a case that a higher level was expected. Compliance with the manufacturer's own specification and standards could also be persuasive on the same basis.

However, by comparison, the court took a firmer line in Pollard v Tesco Stores [2006] EWCA Civ 393, finding that a dishwasher powder bottle was defective on the basis that the toddler-resistant bottle cap did not conform to the relevant British Design Standard. The claimant was a toddler who opened the bottle and swallowed the dishwasher powder.

Non-adherence to regulatory requirements is a separate cause of action, which can attract criminal liability; please refer to **1.5 Penalties for Breach of Product Safety Obligations**.

2.14 Rules for Payment of Costs in Product Liability Claims

The general principle for the payment of costs in English law applies to product liability cases: the losing party pays the costs of the successful party, including fees, court fees and disbursements (including expert fees).

The court can award costs on two bases.

- Standard basis, under CPR 44.3(2) – the court will only award costs that are considered to be both reasonably and necessarily incurred by the party seeking recovery; any costs considered to be disproportionate may be disallowed or reduced, even if they were reasonably and necessarily incurred.
- Indemnity basis, under CPR 44.3(1)(b) – where the court orders costs to be assessed on an indemnity basis, costs need not be incurred by necessity and there is no requirement for costs to be proportionate to the issue in dispute. They need only be reasonable; essentially, a party that has an indemnity costs order made in their favour is more likely to recover a sum that reflects the actual costs incurred in the proceedings.

In product liability claims involving damages for personal injury or death, the regime of qualified one-way costs shifting (QOCS) applies. In practice, this means that the claimant will not be responsible for the defendant's costs in most claims where a claimant is unsuccessful. However, the QOCS provisions may not apply if the claim is struck out, or if the court determines that the claimant was fundamentally dishonest. If the claimant's claim is successful, they may recover their costs from the defendant, subject to a "set-off" of any (interlocutory) costs orders made in the defendant's favour. However, the QOCS regime was recently subject to change

following a consultation initiated by the UK government on 9 May 2022. Amendments to CPR 44.14, which came into force on 6 April 2023, allow defendants to enforce up to the extent of orders or agreements for damages, costs and interest.

Costs are subject to a formal assessment procedure if they are not or cannot be agreed between the parties. The court has wide discretion to vary any of the above general positions regarding costs, however.

2.15 Available Funding in Product Liability Claims

As with all civil claims in England and Wales, there are many litigation funding options regularly used by product liability claimants to fund their litigation. The following are common mechanisms used in product liability cases:

- conditional fee agreements (CFAs), whereby the legal fees of legal representatives are contingent upon a certain event taking place (usually the client "winning" the case); and
- damages-based agreements (DBAs), whereby the lawyer's fees are contingent on success in the case, determined as a percentage of the compensation received by the successful party.

Lawyers can charge success fees, and third-party funding is permissible.

Notably, for the above agreements entered into after 1 April 2013, successful claimants can no longer recover success fees, after the event (ATE) premiums or other arrangement costs from the defendant.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Several mechanisms, both formal and informal, exist in respect of group actions in England and Wales, as set out below.

Formal Mechanisms

Group litigation orders (GLOs)

Under CPR 19 Section III, a GLO allows the management of multiple claims that give rise to common or similar issues of fact or law. Claimants to these actions must "opt in". In the process of GLO proceedings, there will be a trial of issues that are common to all underlying claims. Lead cases that are considered the most appropriate can be chosen, and they are used to allow the parties to put common issues into context. Decisions made in respect of these lead cases are binding on all parties to the GLO. This is the most commonly used formal mechanism in respect of product liability claims.

Representative actions

Representative actions, under CPR 19 Section II, can be brought by one or more claimants on behalf of a group considered to have the "same interest". The UK Supreme Court (UKSC) judgment in Lloyd v Google LLC [2021] UKSC 50 provided clarity on the interpretation of the "same interest" requirement in the context of a large-scale data privacy action. In this action, the UKSC held that, to bring a claim for compensatory damages for a breach of the Data Protection Act 1998, a claimant must establish that there has been a breach, and that damage has been suffered as a result, in the form of material damage or distress. As this would involve an assessment of individual damages and loss, the claim could not proceed as a representative

action under CPR 19.6 as the "same interest" requirement had not been met.

In cases requiring an individual assessment of damages, the UKSC suggested that the representative action procedure could still be used to determine common issues of fact or law, leaving issues that require individual determination to be dealt with subsequently.

Representative actions operate on an "opt-out" basis, such that all group members will be automatically included in the group and represented in the action, and a judgment will be binding on all those represented unless they expressly state that they wish to be excluded. Such actions are rare, although there are signs they may become more widely used.

Informal Mechanisms

The courts can also manage group litigation informally, including by hearing one or more representative test cases at trial while staying remaining cases. The test case decision is not binding on parties to the other claims; however, the decision is intended to determine common issues relevant to the subsequent cases to assist parties to resolve remaining claims without further litigation.

2.17 Summary of Significant Recent Product Liability Claims

Product liability cases do not commonly reach trial in England and Wales. Claims that do reach trial are often in respect of medical devices or pharmaceutical products rather than general consumer products.

A small body of cases have assisted in interpreting statutory tests under the no-fault mechanism of the CPA. Of these, the Gee judgment remains the seminal decision in product liability. That case related to the metal-on-metal hip prosthesis group litigation in England in Wales. The court found in favour of the defendant manufacturer in concluding that the claimant's argument that the products had a "tendency" to cause soft tissue reactions (adverse reaction to metal debris – ARMD) was "untenable" on the basis it would render all similar hip prostheses defective and is "directly contrary to the spirit and objectives" of the CPA. Based on a lack of evidence, even though it accepted the approach, the court also rejected the claimant's alternative argument that the products had "an abnormal potential for damage".

Gee adopted much of the reasoning of an earlier seminal product liability case, Wilkes v DePuy International Limited [2016] EWHC 3096 (QB), but departed from A v National Blood Authority [2001] 3 All ER 289, a somewhat controversial case that previously provided guidance on how to approach the question of "defect" in product liability cases. The Wilkes method of "abnormal potential for damage" was considered favourably, but no finding was made on the basis of that test due to a lack of claimant evidence. In doing so, the A v NBA approach, of first identifying "the harmful characteristic which caused the injury", was discredited.

The court in Gee:

- recognised the inherent flexibility of the no fault mechanism under the CPA;
- promoted assessing defect under the CPA in a holistic manner, whereby the court is entitled to take into account all relevant factors, including legal and factual circumstances, when evaluating product safety;
- determined that hindsight has no place in the formulation of the "entitled expectation" of safety, the test for defect under the CPA; and

- found that a known and inherently harmful, or potentially harmful, consequence of the ordinary use of a product did not amount to a defect.

The above position taken in Gee was largely approved in another case involving a metal-on-metal hip prosthesis: Hastings v Finsbury Orthopaedics Limited and Stryker UK Limited [2019] CSOH 96. In this Scottish matter, the court found for the defendant manufacturers. That finding was upheld on appeal ([2021] CSIH 6) and a further appeal was brought by the pursuer, which was heard before the UKSC in April 2022. The UKSC's judgment, which was handed down on 29 June 2022, unanimously dismissed the appeal brought against the respondent manufacturers, thereby maintaining the finding of the lower courts that the appellant failed to prove that the metal-on-metal hip product in question is defective under the CPA. The UKSC's ruling reinforces the approach to the question of defect under the CPA, as determined in Wilkes and Gee.

Further, the UKSC held that the appeal was "no more than an attempt to appeal against the… findings of fact". In the circumstances, it declined the appellant's invitation to overturn the factual findings made by the judge at first instance as they were findings the lower court had been entitled to make on the evidence. The appellant had suggested that the UKSC examine such findings through a different prism that introduced principles such as a benevolent approach to the application of the Act.

The appellant further argued that the lower court was not entitled to find against him on defect because the evidence before the court raised a presumption of defect that was not capable of being rebutted by the manufacturers. The UKSC rejected this argument, holding the following.

- Expressions of professional concern in the surgical community regarding metal-on-metal hip prostheses generally did not help to establish that the product in question was defective, given that revision rates for the metal-on-metal class of hip prostheses varied from product to product.
- The lower court was entitled to find that the product was withdrawn from the market based on commercial considerations, and therefore the fact of the withdrawal did not assist a case on defect.
- Product safety alerts and notices issued by a regulator and/or manufacturer cannot of themselves be determinative of product defect. In the appellant's case, his reliance on the issued Medical Device Alert and Field Safety Notices was undermined by the accepted evidence on the unreliability of the underlying statistics on which the alert/notices were based.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Divergence of UK Laws From EU Position

Alongside parallel legislative developments at EU and UK levels, Brexit has resulted in the increasing divergence of product safety laws across the region. The timing has meant the immediate divergence of UK laws from EU laws in some instances, such as medical devices. Otherwise, the UK looks poised to make a decision to actively depart from the EU in other instances by the creation of new legislation – eg, as foreshadowed by consultations in respect of

UK product safety laws generally, and genetically modified organism (GMO) legislation.

Multiplication of Product Compliance Obligations Across Europe

The above phenomenon also means that there are now separate and distinct requirements across the region, including, by way of example, the requirement for UK and/or EU-based notified bodies and/or UKCA, UKNI and CE marking on products. Such multiple requirements are a departure from the prior Europe-wide product safety regime, which operated on the basis of maximum harmonisation and single market principles. There are strict timelines and rules attached to these new UK-only requirements, of which companies need to be aware. However, the government has recently published legislation to continue the recognition of current EU requirements, as well as CE marking indefinitely in respect of a range of products. The legislation, entitled the Product Safety and Metrology etc (Amendment) Regulations 2024 will allow businesses to choose either the UKCA or CE marking when selling their products. There are 21 product regulations listed to which continued recognition of the EU requirements will apply.

The new Regulations, which are due to come into force on 1st October 2024, will allow businesses with greater flexibility whereby they can choose to comply with regulations by following either EU requirements and use the CE mark or UK requirements and use the UKCA mark in respect of the product regulations listed in the Statutory Instrument.

Furthermore, UK-based companies continuing to sell in the EU must be aware of ongoing EU obligations. Generally, EU compliance practices are more accepted in the UK post-Brexit – during some ongoing transition periods allowed in some instances – than UK compliance practices will be in the EU.

New Enforcement Practices

In line with a Europe-wide ramp up of product safety enforcement, there is an increased focus on market surveillance and increased empowerment of regulators, including by way of the implementation of new legislation regarding the same.

Focus on Online Selling

In line with the general principles of UK product liability laws, which expose companies to liability notwithstanding the mode of sale (ie, online sales are included), there is now an increased focus on properly ascribing responsibility to online sellers in respect of product safety compliance obligations and breaches thereof, including by way of a requirement to have a local entity in place to nominally be responsible for these issues. The EU-led "Product Safety Pledge" practices may yet be implemented in the UK also.

Similarly, the UK government's anticipated reform of its product safety framework is expected to strengthen the current framework, including in relation to online and marketplace sales. A number of proposals were advanced in the consultation on the UK product safety regime which opened in August 2023, including defining activities carried out by businesses that would qualify them as an "online marketplace" and thereby subject them to certain duties as well as setting out due care requirements in relation to unsafe product listings.

The EU has already taken steps to regulate online marketplaces by virtue of the Market Surveillance Regulation (EU) 2019/120, which came into force in July 2021 to bring online platforms within the remit of the EU's product safety frame-

work, including online marketplaces. Given the further growth of online sales during the COVID-19 pandemic and beyond, this is an area of particular focus for regulators and law-makers alike.

Development of Collective Redress Regime

The much-discussed collective redress regimes to bring about US-style "class actions", including in respect of consumer law issues specifically, are poised to change the product liability landscape across Europe, with the EU Directive on representative actions having now come into force and which took effect in EU member states in June 2023.

Not having adopted the EU laws prior to Brexit, the UK will be able to take its own stance in respect of this developing area of law. The UKSC's decision in Mastercard Incorporated and Others v Walter Hugh Merricks CBE [2020] UKSC 51 ("Merricks"), as delivered on 11 December 2020, demonstrates that, in the right circumstances, an English court will not stand in the way of a group action. Following the UKSC's decision, the Competition Appeals Tribunal (CAT) certified Mr Merrick's application for an opt-out Collective Proceedings Order (CPO), in which he represents a class of more than 46.2 million consumers in respect of a GBP7.2 billion action concerning allegedly unlawful bank charges. The CAT has since certified several more CPOs, indicating a growing trend towards large consumer class actions.

In this vein, there have been calls for a generic opt-out class action regime beyond the scope of the CAT, driven by claimant law firms and consumer groups who share the view that the burden of proof is too high in product liability actions, particularly those concerning allegedly defective medical devices and pharmaceutical products, compared to actions brought in the competition sphere.

In addition to the CPO regime in the CAT, the UK's representative actions procedure, which has been seldom used owing to the court's historically narrow interpretation of the "same interest" test under CPR 19.6, also provides for an opt-out group action regime. CPR 19.6 provides for representative actions where one claimant can represent other claimants in a group action providing they all have the "same interest" in the claim. Whilst the UKSC's ruling in Lloyd v Google [2021] UKSC 50 affirmed the limited scope of the "same interest" test, the recent decision in Commission Recovery Ltd v Marks & Clerk [2023] suggests the court may approach the test more flexibly than had been assumed in Lloyd. The CRL decision also indicates that the court is becoming more amenable to allowing the opt-out representative actions procedure to be used more generally, particularly as (i) the opt-out collective regime in the CAT is available for competition claims only; and (ii) the modern digitalised world is increasingly likely to give rise to mass harms, resulting in affected claimants seeking legal redress.

Convergence of Multi-sector Product Safety Laws

Whilst there is a divergence of product safety laws from a geographical perspective, there is, in parallel, a convergence of laws in terms of product safety issues in the UK. For example, issues formerly considered primarily privacy concerns are now increasingly being considered product safety issues. This is particularly the case in respect of radio equipment and medical devices, and there is an increasing reliance on parallel or potentially relevant separate product safety regimes across other sectors. For example, the food contact materials laws are now being relied

upon for cosmetics packaging in certain circumstances.

Corporate Social Responsibility and Environmental Sustainability

There has been a broadening of product compliance obligations to incorporate concepts of corporate social responsibility, environment and sustainability, and increased focus on these areas. In line with EU-based initiatives in which the UK participated prior to Brexit, including the EU Green Deal and Circular Economy practices, there is now an increased focus on product compliance requirements, contemplating this broadened scope. For example, in January 2023, the UK government consulted on a proposal to increase the minimum energy performance standard for lighting products placed on the Great Britain market from 2023 and again from 2027.

Modernisation of Product Safety and Liability Regimes

As part of an ongoing review at EU level in respect of the fitness of product liability laws to respond to issues created by modern technologies, there is currently a debate regarding the application of the CPA to new technologies – eg, in software supplied over-the-air (OTA). This type of software is updated wirelessly (and used in products such as smart pacemakers) and several questions are currently being debated, including:

- whether software can be considered a product under the CPA;
- if software is considered a product under the CPA, who will have the responsibility (and associated potential liability) to update the OTA software;
- how the state-of-the-art defence and limitation will apply to updated OTA software (see **2.12 Defences to Product Liability Claims**); and
- whether a data breach can be considered a defect under the CPA if the data breach causes injury such as psychological damage.

If the CPA is updated to adapt to new technologies, there may be a proliferation of product liability group actions where there has been a data breach in relation to smart consumer products.

3.2 Future Policy in Product Liability and Product Safety

There are wide-ranging imminent policy developments in respect of product liability and safety in the UK, including as a result of Brexit but also in response to long-standing issues that were being grappled with for some time at an EU level.

Product Safety Law

In August 2023, the UK government launched its consultation on the UK's product safety regime with the goal of creating a clearer, smarter and more proportionate regime while remaining responsive to consumer and business needs. The consultation, which closed in October 2023, advanced 13 proposals under three headings aimed at modernising the UK's product safety framework. These included:

- bringing products to market;
- online supply chains; and
- compliance and enforcement.

The proposals on bringing products to market aimed to ease the burden on businesses by proposing a hazard-focused approach whereby products are categorised by their hazards and consequent risks, thereby falling into one of several defined risk levels. The aim behind the proposal is to lower the regulatory burden and compliance costs for lower-risk products and

unlock innovation while simultaneously maintaining high levels of protection for other higher-risk products.

Optional e-labelling was also proposed for certain marking and compliance labelling such as the UKCA conformity marking and manufacturers' details.

As noted above, proposals were put forward in respect of online market places such as defining activities carried out by a business which would qualify them as an "online marketplace".

A number of proposals were also put forward to strengthen enforcement and compliance. These included enhancing the leadership of the OPSS and requiring all notification of recalls and serious product safety incidents and other corrective action by a manufacturer or distributor to be sent to OPSS, rather than the local authority, as soon as the economic operator has knowledge of an unsafe product.

The result of the consultation, and any hard or soft laws created on the basis thereof, would mark a significant development in UK product safety laws, which are more than 30 years old.

The review is in parallel to a similar review held at EU level, which has resulted in the EU General Product Safety Regulation which will take effect on 13 December 2024. Once the UK has concluded its review, it is likely to result in a significant departure of the two sets of product safety laws and further onerous requirements for companies operating in both markets.

Connected Products and Cybersecurity

In April 2021, the UK government published a policy paper providing an overview of the government's updated intentions for proposed legislation to regulate the cybersecurity of connected consumer products. The government's aim is to implement a new robust scheme of regulation to protect consumers from insecure connected products, mandating base requirements and disclosures for those selling such products.

The UK government also launched its National Cyber Strategy in January 2022, setting out its plan to protect its citizens in cyberspace, including the Product Security and Telecommunications Infrastructure (PSTI) Act, which was enacted in December 2022, to enable enforcement of minimum security standards in all new connectable products sold in the UK. The PSTI Act came into effect on 29 April 2024. Its provisions will:

- ensure that consumer connectable products defined as "products that are able to connect to the internet or other networks and can transmit and receive digital data" (eg, smart TVs, and security cameras) are more secure against cyber-attacks, protecting individual privacy and security;
- require the relevant persons (ie, manufacturers, importers and distributors) to comply with their applicable duties relating to consumer connectable products – applicable duties include requiring statements of compliance to accompany a consumer connectable product before making them available in the UK market, investigating a potential compliance failure by a relevant person, and taking corresponding action to remedy such failure; and
- create an enforcement regime with civil and criminal sanctions aimed at preventing insecure products being made available on the UK market.

The Regulations underpinning the Act on security requirements for relevant connectable products

came into force on 29 April 2024 and establish security requirements for relevant connectable products and prescribe conditions to be met for deemed compliance of security requirements. Schedule 1 to the Regulations sets out the specific requirements that must be complied with in relation to relevant connectable products. These include the following.

- Passwords – passwords must be unique per product; or capable of being defined by the user of the product.
- Information on how to report security issues – the manufacturer must provide information on how to report to them security issues about their product. They must also provide information on the timescales within which an acknowledgement of the receipt of the report and status updates until the resolution of the issue can be expected.
- Information on minimum security update periods – Information on minimum security update periods must be published and made available to consumers in a clear, accessible and transparent manner.

Medical Devices

In January this year, the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) published its much-anticipated roadmap on the future regulatory framework for medical devices. This plan details the timescales for the implementation of the UK's future medical device regulations, which will be implemented through four statutory instruments. Key measures to enhance post-market surveillance will be the first component and will be put in place in 2024. Further core elements of the new framework will follow in 2025.

The MHRA will run stakeholder discussions for the provision of information on these future core regulations, which are expected to involve a range of measures, such as the following:

- up-classifying implantable medical devices so that more stringent pre- and postmarket requirements apply;
- ensuring devices have an unique device identifier (UDI); and
- requiring manufacturers to provide implant cards to enable patients to know which device they have had implanted.

Additionally, the UK government, in order to minimise disruption to the availability of medical devices in Great Britain, has amended the Medical Device Regulations 2002 (SI 2002 No 618, as amended) (UK MDR) to extend the acceptance of EU conformity assessment-marked (CE-marked) medical devices on the Great Britain market for a limited period.

Artificial Intelligence

The EU's Artificial Intelligence Act (the "AI Act") came into being in 2024 and is the first ever legal framework on AI to address the risks and trustworthiness thereof. Building upon the UK's National AI Strategy published in September 2021, in March 2023, the Department for Science, Innovation and Technology published a White Paper titled "AI Regulation: A pro-innovation approach", which set out the government's proposals to regulate AI in a pro-innovation manner. It addressed the potential benefits and risks of AI. The government intended to "take an adaptable approach to regulating AI", allowing regulators to use their expertise to modify the implementation of the principles to suit the specific context of AI in their respective sectors. The UK government, in February 2024, provided its long-anticipated response to the White Paper consultation on regulating Artificial Intelligence (AI).

The approach is one of "pro-innovation" but with safety at its core and is largely non-prescriptive compared to other jurisdictions. The UK's approach is intended to focus on promoting innovation and experimentation, whilst maintaining a light touch in terms of regulation. The difference in approach between the UK and EU may present challenges for companies that operate in both markets, and those looking to expand from one market into the other.

Sustainability and Environment

Following several related initiatives, the UK government undertook a consultation on waste prevention proposals for products: the "Waste Prevention Programme for England". This UK-led initiative mirrored a parallel EU initiative of a similar nature, called the Sustainable Products Initiative, and addressed topics such as end of life, repair, reuse and remanufacturing, and extended producer responsibility. Following the consultation, the government has published the waste prevention programme for England entitled "Maximising Resources, Minimising Waste", which sets out the government's priorities for managing resources and waste, aiming to move to a more circular economy in the UK.

The introduction of the Environment Act 2021, described by the UK government as "world-leading legislation", empowers the government to make targets, plans and policies for improving the national environment, including addressing waste and resource efficiency, air and water quality, and nature and biodiversity, with cross-sector impact. National authorities will be empowered to introduce regulation that aims to eliminate avoidable waste by 2050 by introducing robust measures such as making producers responsible for the disposal of waste products and charges.

As of 1 April 2022, manufacturers or importers of plastic packaging products into the UK may be liable under Part 2 of the Finance Act 2021 to pay a tax on those products, known as PPT. The introduction of PPT follows the EU's introduction of a levy on non-recycled plastic packaging waste in July 2020 and reflects the growing trend toward sustainable practices across industries and the demand for greater corporate responsibility by large-scale manufacturers, importers and their insurers. It aims to incentivise manufacturers and importers to incorporate more recycled plastic into their packaging.

Food Technological Practices

Following an EU initiative of the same nature, the UK government is currently considering the scope of GMO legislation. Following a public consultation in 2021 on gene-edited organisms, the Genetically Modified Organisms (Deliberate Release) (Amendments) (England) Regulations 2022 came into force in April 2022. This was followed by the Genetic Technology (Precision Breeding) Act 2023, which came into force on 23 March 2023.

Trends and Developments

Contributed by:
Sarah-Jane Dobson and Louise Forrest
Ashurst

Ashurst has a reputation for successfully managing large and complex multi-jurisdictional transactions, disputes and projects and delivering outstanding outcomes for clients. Ashurst acts as a global team, with 31 offices in 18 countries, and offers the reach and insight of a global network of legal, new law and risk professionals, combined with the knowledge and understanding of local markets. With over 490 partners and a further 2,000 lawyers working across 11 different time zones, the firm is able to respond to clients wherever and whenever required.

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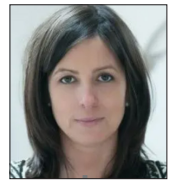
Sarah-Jane Dobson leads the global product litigation and product risk (safety and regulatory) practice at Ashurst. She acts on regulatory, litigious and policy matters across the full product life cycle in respect of product safety, compliance and product liability and consumer litigation matters. Her corporate clients are from a broad range of sectors including automotive, chemicals, consumer goods, cosmetics, food (including novel foods) and beverages, industrial and life sciences products (medical devices and pharmaceuticals, and advice regarding clinical trials). Sarah-Jane holds prominent leadership positions – including as a member of the Board of Directors for ICPHSO and as a Chair of International Legal Issues for DRI's Product Liability Committee.



Louise Forrest is a consultant in Ashurst's global product litigation and product risk (safety and regulatory) practice, advising on matters across all stages of the life cycle of the product, from product launches to product recalls and ongoing regulatory compliance. Her work crosses many sectors, including consumer products, cosmetics, apparel, and chemicals. Previously leading a team of international product regulatory consultants for a global provider of market access and product compliance to world-leading brands, she gained in-depth knowledge of the changing product regulatory landscape across areas including safety, chemicals, design, energy efficiency, batteries, packaging, labelling, waste, cybersecurity, artificial intelligence, food contact materials and ESG. Louise is a qualified Irish barrister.

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The Changing UK Product Safety and Liability Landscape

Introduction

The UK has always regarded itself as a leader in product safety and, keen to maintain this reputation and keep apace with developments, particularly against the backdrop of developments in the EU, it took significant steps in this space last year.

As the EU introduced the General Product Safety Regulation (GPSR) came into force in June 2023, the UK's national product safety regulator the Office of Product Safety and Standards (OPSS) launched its much-anticipated consultation on the UK product safety regime. The consultation, which forms part of the UK's wider Smarter Regulation Review, was targeted to update the UK product safety regime in line with developments and advancements in technology.

Another significant development, similarly, targeted to update the UK product regulatory framework, was the entry into force of the UK's product security and telecommunications regime. This saw significant requirements being introduced to ensure the security of connected products and had significant impact across the manufacturing world as manufacturers sought to ensure that they were ready for the new requirements which came into effect in April 2024.

Of course, Brexit also had its part to play in the development of product safety policy. In this context, the Retained EU Law (Revocation and Reform) Act received royal assent. This initiative moved away from the initial "sunset clause" approach, which called for all retained EU law (REUL) that had not been preserved or replaced to be automatically revoked at the end of the sunset period. Instead, the Act took the approach of publishing a list of retained EU laws (consisting of 600 pieces of legislation – known as the "revocation schedule") which were revoked at the end of 2023. Those not listed were automatically retained. This approach is thought to have provided more certainty for business, helping to allay their fears of a cliff-edge effect with all legislation removed in one fell swoop.

Another effect of Brexit was the approach to product marking in the UK. In a bid to smooth the path for product manufacturers and remove uncertainty, the UK government laid down legislation to continue the recognition of the current EU requirements and CE marking. Draft legislation was advanced in the form of the Product Safety and Metrology etc (Amendment) Regula-

tions 2024. The legislation will apply indefinitely in respect of a range of product regulations.

Overhaul of product safety regime

On 2 August 2023, the UK government's consultation on the UK's product safety regime was launched, which set out to examine the fundamental tenets on which it is built with a view to reforming and future-proofing the regime. The aim is to make it fit for the 21st century, noting that the way products are sold and used has undergone significant changes in a short period of time.

The goal of the consultation, which closed on 24 October 2023, was to create a clearer, smarter and more proportionate regime while remaining responsive to consumer needs. The framework the UK government is seeking to establish is one that fosters business innovation while simultaneously protecting consumers. In this regard, it aims to revolutionise how it will use and share data with businesses and the public in a bid to support targeted enforcement and an agile evidence-based product safety framework.

The consultation advanced 13 proposals in total under three headings aimed at ensuring the UK's product safety framework is future-proof and a global exemplar. These included:

- bringing products to market;
- online supply chains; and
- compliance and enforcement.

Bringing products to market

The proposals linked with bringing products to market aimed to ease the burden on businesses by proposing a hazard-focused approach whereby products are categorised by their hazards and consequent risks, thereby falling into one of several defined risk levels. The hope behind the proposal is to lower the regulatory burden and compliance costs for lower-risk products and unlock innovation while simultaneously maintaining high levels of protection for other higher-risk products.

Optional e-labelling was also proposed for certain marking and compliance labelling such as the UKCA conformity marking and manufacturers' details. Removing the need to always apply physical labels, it is hoped, will lower business costs, allow information to be easily updated and produce less waste.

Online supply chain

Recognition of the exponential growth in online sales and the concomitant challenges to the product safety regime which pre-existed this expansion was also recognised in the consultation. The UK product safety regime has been grappling with different challenges such as increased volume of non-compliant products and the absence of responsible economic operators in the UK, thereby making corrective action difficult, with confusion as to where responsibilities lay, as well as a lack of product safety or seller information.

To combat these challenges, several proposals were put forward, such as defining those activities carried out by a business that would qualify them as an "online marketplace" and thereby subject them to certain specified duties. Yet to be crystallised, they are likely to include duties (i) to co-operate with enforcement authorities, such as providing information or taking appropriate action if products are unsafe or non-compliant, and (ii) to have a compliance function established in the UK.

Another measure proposed is to set out specific due care requirements about the identification

and removal of unsafe product listings, which online marketplaces will be required to meet. For example:

- collecting information about third-party sellers for high-risk products;
- monitoring for products that look very similar to products subject to recalls and taking appropriate action; and
- gathering information about products and sellers and using this alongside information from enforcement authorities to provide more targeted monitoring and intervention.

For higher risk products, increased consumer-facing information on online product listings is proposed to support informed purchasing decisions. This proposal addresses the anomaly whereby requirements to display certain product safety and traceability information are not replicated for online product listings. It also seeks to make it clear when a consumer is purchasing from a third-party seller.

Information could include:

- warnings;
- clear indication when the seller is a third-party;
- details of checks carried out on products or sellers; and
- key product safety information which is already on the product, packaging or accompanying documents.

Compliance and enforcement

A number of proposals were put forward to strengthen enforcement and bolster compliance in the UK. This included enhancing the leadership of the OPSS and requiring all notification of recalls and serious product safety incidents and other corrective action by a manufacturer or distributor to be sent to OPSS, rather than the local authority, as soon as the economic operator has knowledge of an unsafe product.

Product security

Connected products bring many benefits to the modern world, making many aspects of day-to-day life easier and more convenient. In tandem with these benefits come some drawbacks, in particular threats to the security of data. An IOT product, due to its inherent nature of being connected, may be susceptible to external manipulation and hacking resulting in, for example, a data breach or it being used for surveillance.

The Product Security and Telecommunications Infrastructure (PSTI) Regime aims to address these risks, as part of the government's plan to tackle cybersecurity risks and aims to create a regime setting a baseline in cybersecurity for connected products.

The main content of the security provisions are found in the Product Security and Telecommunications Infrastructure (Security Requirements for Relevant Connectable Products) Regulations, SI 2023 No 1007, which came into force on 29 April 2024 and establish security requirements for relevant connectable products and prescribe conditions to be met for deemed compliance with security requirements.

Connected products

The PSTI Act applies to "relevant connectable products", defined as either products which are internet connectable or network connectable and are not an excepted product.

Excepted products in the Security Requirements Regulations include:

- charging points for electric vehicles to which the Electric Vehicles (Smart Charge Points) Regulations 2021 apply;
- medical devices to which the Medical Devices Regulations 2002 apply;
- smart meters installed under the Gas Act 1986 or Electricity Act 1989;
- desktop or laptop computers;
- tablet computers which do not have cellular network connectivity; and
- products for supply in Northern Ireland under free movement rules.

Obligations apply to economic operators where they supply what are termed "UK consumer connectable products", defined as a relevant connectable product that either:

- has been made available to consumers in the UK and has not been supplied to any customer by an economic operator at any time before that; or
- has been made available to customers in the UK who are not consumers and has not been supplied to any person by a relevant person at any time before that and is identical to the products which have been made available to consumers.

Security requirements

Schedule 1 to the Regulations sets out the specific requirements that must be complied with in relation to relevant connectable products.

- Passwords – passwords must be unique per product; or capable of being defined by the user of the product.
- Information on how to report security issues – the manufacturer must provide information on how to report to them security issues about their product. They must also provide information on the timescales within which an acknowledgement of the receipt of the report and status updates until the resolution of the issue can be expected.
- Information on minimum security update periods – information on minimum security update periods must be published and made available to consumers in a clear, accessible and transparent manner.

Other obligations of economic operators

Manufacturers are also required to create a statement of compliance for UK consumer connectable products, declaring compliance with the security requirements, which must be retained for 10 years. For an importer and distributor, they must check one is included with the product rather than create one, but the rest of the obligation is the same.

Economic operators must also act on compliance failures in respect of UK consumer connectable products, including taking all reasonable steps to prevent the product from being made available and to remedy the non-compliance. There is a strict duty to inform the enforcement authority, any other manufacturer, any importer or distributor the product was supplied to, and, if specific conditions are met (which have not yet been created), consumers who have been supplied with the product.

Manufacturers and importers are further required to do the following.

- Investigate potential non-compliance relating to UK consumer connectable products (taking all reasonable steps to do so) when informed.
- Maintain records of both compliance failures and investigations into the same (actual or suspected) for 10 years from the creation of the record.

Artificial intelligence

Artificial intelligence (AI) is very much at the forefront of the UK policy agenda. The UK government, in February 2024, provided its long-anticipated response to the 2023 White Paper consultation on regulating Artificial Intelligence (AI).

The approach the government has adopted is "pro-innovation" but with safety at its core, as highlighted in the Prime Minister's landmark speech in October 2023, where he said: "the future of AI is safe AI. And by making the UK a global leader in safe AI, we will attract even more of the new jobs and investment that will come from this new wave of technology."

The approach advocated by the UK is largely non-prescriptive compared to other jurisdictions.

Product liability

Given developments in the EU on product liability, in particular the EU Product Liability Directive (PLD) which has been passed and is awaiting signature, it is still not clear whether the UK will be prompted to make similar changes to the Consumer Protection Act 1987 (CPA).

It is worth noting that proposal number 13 of the OPSS product safety consultation provided for reviewing the civil product liability regime in light of technological developments. It can be taken from this that there is a widespread recognition that, similar to the product safety regime context, the product liability regime in the UK is in need of updating and modernising. Therefore, the door has most certainly been left open for future development and change in this regard, which, no doubt, will be seen in the coming years.

USA

Law and Practice

Contributed by:
Trevor Keenan, Michelle Byers and Curtis Berglund
Campbell Conroy & O'Neil, P.C.

Contents

Campbell Conroy & O'Neil, P.C. is a nationally and internationally recognised law firm that has successfully tried hundreds of large-value, high-exposure, technically complex cases to verdict in state and federal courts throughout the United States. The firm provides advice, counselling and representation during all stages of a dispute from pre-litigation matters through trial and appeal. The defence of product liability claims has been a mainstay of the firm's practice since its inception in 1983, and it has represented clients in industries that include pharmaceuticals, medical devices, aviation, chemicals, automotive, heavy equipment, toxic torts and material handling. In addition to product liability defence, the firm's lawyers represent clients in professional liability claims, legal and medical malpractice claims, construction defect claims, environmental litigation, business and commercial litigation, fraud/bad faith claims, premises liability claims, personal injury and negligence claims, mass torts defence and class actions.

Authors

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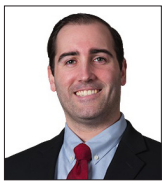

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1. Product Safety

1.1 Product Safety Legal Framework

The legal framework governing product safety in the US is discussed below.

Overarching Federal Laws and Regulations

Consumer Product Safety Act of 1972 (CPSA), 15 USC section 2051 et seq

This legislation established the Consumer Product Safety Commission (CPSC), the independent federal regulatory agency charged with protecting the public from unreasonable risks of harm from consumer products. CPSC is authorised to develop standards, issue recalls, and ban products in the US under certain circumstances.

Consumer Product Safety Improvement Act of 2008 (CPSIA), Pub. L. 110-314, 122 Stat. 3016

The CPSIA amended the CPSA. It provided new regulatory and enforcement tools, and authorised CPSC to create SaferProducts.gov, a website database where the public can file and read complaints about products under CPSC's jurisdiction.

Amendment to Consumer Product Safety Improvement Act of 2008, Pub. L. 112-28, 125 Stat. 273 (2011)

The CPSIA was amended in 2011 to add requirements for SaferProducts.gov, including expanding the information collected in product reports, defining the timing for posting the reports to the database, and expanding CPSC's authority and discretion to enforce product safety laws.

In addition, certain federal statutes impose safety and labelling requirements for particular products, such as:

- Flammable Fabrics Act, 15 USC section 1191 et seq;
- Labeling of Hazardous Art Materials Act, 15 USC section 1277;
- Refrigerator Safety Act, 15 USC section 1211
- Virginia Graeme Baker Pool and Spa Safety Act, 15 USC section 8001 et seq;
- Drywall Safety Act of 2012, 5 USC section 553, 15 USC sections 2058, 2063;
- Portable Fuel Container Act of 2020, 15 USC section 2056d.

Industry-Specific Laws

Food and drugs

Federal Food, Drug, and Cosmetic Act of 1938 (FD&C), 21 USC section 301 et seq

This law charges the Food and Drug Administration (FDA) with ensuring the safety of the US food supply; cosmetics; and the safety, efficacy and security of drugs, biological products and medical devices. The law protects the public from adulterated and misbranded products manufactured and sold in the US.

Food and Drug Modernization Act of 1997, Pub. Law 105-115

The regulation of food, drugs, medical devices and cosmetics was reformed to include off-label use of drugs and medical devices, risk-based regulation of medical devices, elimination of premarket approval for food packaging, and monitoring healthcare claims for foods.

Family Smoking Prevention and Tobacco Control Act of 2009 (TCA), Pub. L. 111-31, 123 Stat. 1776

This law authorises the FDA to regulate the manufacture, distribution and marketing of tobacco products in the US.

Transportation

Federal Aviation Act of 1958, 49 USC section 40101 et seq (repealed and recodified in 1994)

The Federal Aviation Act of 1958 established the Federal Aviation Agency (FAA) to provide for the safe and efficient use of national airspace and regulate safety in the aviation industry.

National Traffic and Motor Vehicle Safety Act (VSA) of 1966, Pub. L. 89–563, 80 Stat. 718

This law establishes federal motor vehicle safety standards (FMVSS) for all new domestic and imported vehicles, addresses concerns about tyre safety, and requires manufacturers to notify consumers of safety-related defects and pay for the repairs.

Highway Safety Act of 1970, 23 USC section 401 et seq

This law established the National Highway Traffic Safety Administration (NHTSA) and charged it with setting and enforcing safety performance standards for motor vehicles and related equipment and investigating safety defects in motor vehicles.

Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act, 49 USC sections 30101-30170

The TREAD Act requires vehicle and equipment manufacturers to periodically report to NHTSA safety recalls in the US and safety campaigns in foreign countries, and report information that could indicate the existence of a potential safety defect, and imposes criminal liability on vehicle manufacturers that intentionally violate reporting requirements.

Toxic substances

Toxic Substances Control Act of 1976 (TSCA), 15 USC section 2601 et seq

The TSCA granted the Environmental Protection Agency (EPA) the power to impose reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and mixtures. The TSCA addresses the production, importation, use and disposal of specific chemicals. Food, drugs, cosmetics and pesticides are excluded from the TSCA.

Lautenberg Chemical Safety Act, Pub. L. 114-182, 130 Stat. 448 (2016)

The Lautenberg Act revised the TSCA to permit more rigorous vetting of chemicals before they are allowed on the market and updated the EPA's risk analysis for chemicals already on the market, including a risk-based safety standard that excludes cost considerations.

Asbestos Information Act of 1988, 15 USC section 2607(f), Pub. L. 100-577, 102 Stat. 2901

This law requires companies that make certain asbestos-containing products to report production to the EPA.

Children's safety

Several federal statutes address safety measures for products dangerous to children:

- Federal Hazardous Substances Act of 1960, 15 USC section 1261 et seq;
- Poison Prevention Packaging Act of 1970, 15 USC section 1471 et seq;
- Child Safety Protection Act, Pub. L. 103-267, 108 Stat. 722 (1994);
- The Children's Gasoline Burn Prevention Act, 5 USC section 553, 15 USC section 2058 (2008);

- Child Nicotine Poisoning Prevention Action of 2015, 15 USC section 1471 et seq;
- Safe Sleep for Babies Act of 2021, Pub. L. 117-126, 136 Stat. 1208;
- Reese's Law, Pub. L. 117-171, 136 Stat. 2094 (2022) (mandating federal safety requirements for button cell or coin batteries);
- Stop Tip-overs of Unstable, Risky Dressers on Youth (STURDY) Act, HR 2617 (2022) (imposing mandatory furniture tip-over standards).

Consumer protection

Federal Trade Commission Act (FTCA), 15 USC section 41 et seq

The FTCA established the Federal Trade Commission (FTC) and empowered it to prevent unfair methods of competition or unfair and deceptive acts and practices affecting commerce, to seek relief for conduct that harms the public, and to prescribe rules defining and preventing unfair or deceptive acts or practices.

State laws

Product safety laws at the state level can vary widely and may be enforceable both by private action and through state attorneys general.

1.2 Regulatory Authorities for Product Safety

The main regulators of product safety in the US are: CPSC, FAA, FDA, NHTSA, FTC and EPA. Their authority to regulate product and consumer safety is defined by statute.

CPSC

CPSC regulates consumer products by developing standards and issuing recalls and bans on products in the US under certain circumstances. Its regulations are set forth in the Code of Federal Regulations (CFR), Title 16.

FAA

The FAA regulates airworthiness standards for aircraft and aircraft equipment. Its regulations can be found in CFR, Title 14.

FDA

The FDA regulates and safeguard food, cosmetics, drugs, biological products, medical devices and tobacco products. The FDA's regulations are set forth in CFR, Title 21.

NHTSA

NHTSA regulates highway and vehicle safety, establishes and enforces FMVSS, and issues motor vehicle and component part recalls. NHTSA regulations can be found in CFR, Title 49.

FTC

The FTC investigates violations and enforces consumer protection laws and federal antitrust laws. FTC rules are published in CFR, Title 16.

EPA

The EPA regulates chemical products, pesticides, airline emissions, and air and water quality standards. The EPA's regulations are set forth in CFR, Title 40.

1.3 Obligations to Commence Corrective Action

Corrective action, such as product recalls, can be requested or required by CPSC, the FDA and NHTSA.

CPSC

If CPSC makes a preliminary determination that a product defect creates a substantial risk of injury, corrective action is required. It classifies product dangers depending on the likelihood and severity of death, injury or illness as either Class A, Class B or Class C Hazards. Each Hazard Class requires corrective action, which may

include a recall, public notice and remedies for consumers. Corrective action may also include steps to mitigate a potential hazard, such as changes to design, manufacturing materials, quality control, warnings or marketing, or discontinuing a product.

Companies must work with CPSC to prepare a plan for communicating a recall to consumers. Requirements for recall notices are set forth in CFR Title 16, section 1115.27. CPSC has established the Fast-Track Product Recall Program, under which a company may avoid a preliminary determination by CPSC that a product creates a substantial risk of injury if it reports the potential defect, meets other requirements for a timely recall, and works with CPSC to implement a corrective action plan.

FDA

FDA corrective action is largely voluntary and consists of either correction or recall. The FDA evaluates a potential health hazard based on factors set forth in CFR Title 21, section 7.41, and assigns a recall classification (Class I, II or III) indicating the product's relative degree of health hazard. Classes are assigned based on the likelihood and seriousness of a product's adverse health impact. The company then submits a proposed recall strategy to the FDA consistent with the requirements set forth in CFR Title 21, section 7.42, and communicates the correction or recall to consumers consistent with the requirements set forth in CFR Title 21, section 7.49. The FDA will notify the public through its weekly Enforcement Report. CFR Title 21, section 7.50.

NHTSA

NHTSA requires manufacturers to recall motor vehicles and component parts that fail to comply with FMVSS or that contain safety-related defects that pose an unreasonable risk to motor vehicle safety. Manufacturers have three options for correcting a defect: repair, replace or refund. If a recall is required, manufacturers must notify by first-class mail all registered owners and purchasers of the affected vehicles or components. The requirements for notification are set forth in CFR Title 49, section 577.5.

1.4 Obligations to Notify Regulatory Authorities

The notification requirements concerning potential protect safety issues vary by agency.

CPSC

CPSC mandates risk-based and incident-based reporting. Section 15 of the CPSA requires manufacturers, importers, distributors and retailers to notify CPSC immediately if they receive information that reasonably supports the conclusion that a product: fails to comply with an applicable CPSC safety rule or law enforced by CPSC; contains a defect which could create a substantial product hazard; or creates an unreasonable risk of serious injury or death. Section 15 report requirements are found in CFR Title 16, section 1115. Section 102 of the Child Safety Protection Act requires companies to report certain choking incidents involving children. Code of Federal Regulations Title 16, section 1117 details the information the manufacturer, distributor, retailer and importer should include in the report. Reports under either section must be made within 24 hours of receiving reportable information. If uncertain about whether information is reportable, an entity can conduct an investigation not to exceed ten working days, with some exceptions. Section 37 of the CPSA requires manufacturers of consumer products to report information about settled or adjudicated civil actions after the third such action is terminated. Section 37 report requirements are found in CFR Title 16, section 1116.

FDA

The FDA's reporting requirements depend upon the product at issue.

Drugs and Biologics

Manufacturers, packagers and distributors of marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application are required to report all serious and unexpected adverse drug experiences (as defined by CFR) associated with the use of their products within 15 days of receipt of this information. Reporting requirements are found at CFR Title 21, section 310.305.

Biologic manufacturers must report serious and unexpected adverse events within 15 days of learning about the event. Requirements for the report are set forth in CFR Title 21, section 600.80.

Devices

Manufacturers must report to the FDA within 30 days when they learn a device has malfunctioned and would likely cause or contribute to causing serious injury or death if the malfunction reoccurs. CFR Title 21, section 803.50(a). Device importers are required to report to the manufacturer of the imported device within 30 days a malfunction that would likely cause or contribute to causing serious injury or death. CFR Title 21, section 803.40(b). Reporting requirements are set forth in CFR Title 21, sections 803.42, 803.52. Manufacturers are also required to report within five days events requiring remedial action to prevent an unreasonable risk of substantial harm to public health. CFR Title 21, section 803.53.

NHTSA

NHTSA requires risk-based and incident-based reporting.

Vehicle and equipment manufacturers must submit a Defect and Noncompliance Information Report to NHTSA within five working days of concluding the equipment or vehicle poses a danger or fails to comply with FMVSS. Information required in the report is set forth in CFR Title 49, section 573.6. Pursuant to CFR Title 49, section 579.11, manufacturers must inform NHTSA of safety recalls or campaigns in foreign countries within five days of deciding to conduct the recall or receiving notice from a foreign government that action is required.

The TREAD Act requires vehicle and equipment manufacturers to report periodically to NHTSA on a variety of information that could indicate the existence of a potential product safety defect and advise NHTSA of safety recalls or campaigns in foreign countries. Pursuant to 49 USC section 30166(f), manufacturers are required to submit to NHTSA copies of their communications about defects and noncompliance with FMVSS.

1.5 Penalties for Breach of Product Safety Obligations

Penalties are set by law and imposed by agency or the US Department of Justice.

CPSC

Civil penalties are available if a company violates laws enforced by CPSC. The maximum amounts allowed are USD120,000 for each violation, and USD17.15 million for any related series of violations. In January 2023, CPSC unanimously approved a USD19.065 million penalty against an exercise equipment manufacturer for keeping vital safety information secret and distributing recalled products with a lethal defect. In May 2023, CPSC announced a USD15.8 million civil penalty against a portable generator manufacturer for failing to report finger injuries to consumers.

FAA

The FAA may assess civil penalties up to USD400,000 against persons other than individuals and small businesses, and up to USD50,000 against individuals and small businesses, for violation of a law or statute enforced by the FAA. 49 USC section 46301; CFR Title 14, section 13.18. Generally, the penalty for each violation ranges from USD1,100 to USD27,500, depending on the provision violated and the category of the alleged violator.

FDA

Civil and criminal penalties can be imposed upon anyone who violates the FD&C. Civil penalties include warning letters, injunctions, seizure and civil fines. 21 USC sections 332, 334, 335b. Criminal penalties include imprisonment up to one year, a fine of USD1,000, or both. 21 USC section 333(a). The FD&C also imposes enhanced criminal penalties for prescription drug marketing violations, violations related to medical devices, and distribution of human growth hormone. 21 USC sections 333(b), 333(e), 333(f). Civil penalties can also be imposed by the FDA pursuant to CFR Title 21, section 17 et seq, for failing to submit clinical trial information or submitting false or misleading information. The FDA is also authorised to impose civil penalties for violating the TCA. In February 2023, the FDA filed civil complaints against four tobacco product manufacturers for manufacturing and selling e-liquids without marketing authorisation, seeking USD19,192 per violation, the maximum amount allowed by law.

NHTSA

The VSA provides for civil penalties up to USD21,000 per violation, and up to USD105 million for a related series of violations. 49 USC section 30165. Submitting false or misleading reports exposes companies to civil penalties of USD5,000 per day, up to USD1 million for a related series of violations. Criminal penalties for falsifying or withholding information include fines or imprisonment up to 15 years, or both. In January 2023, NHTSA imposed a USD130 million penalty against a vehicle manufacturer for untimely recalls, inaccurate reports and failing to notify owners of a recall. In March 2022, NHTSA imposed a USD75,000 penalty against a vehicle importer for submitting improper certificates of conformance, selling or releasing imported vehicles during the waiting period, and changing the location of its operations without informing NHTSA.

EPA

The EPA can impose civil penalties up to USD37,500 for violating the TSCA, criminal fines and injunctions. 15 USC section 2615. Criminal penalties can include fines ranging from USD50,000 per day for individuals, up to USD1 million per corporate violation of the TSCA; restitution; or incarceration ranging from one to 15 years (15 USC section 2615).

FTC

The FTC can impose civil penalties for knowing rule violations, including injunctions and fines up to USD10,000 per violation (15 USC section 45).

2. Product Liability

2.1 Product Liability Causes of Action and Sources of Law

Product liability is derived from state rather than federal law. There can be significant differences among product liability law of individual states.

The primary causes of action in product liability cases are negligence, strict liability and breach of warranty. Other legal claims that may be applica-

ble to product liability lawsuits include consumer protection, fraud and negligent misrepresentation. Claims can generally be asserted against anyone in the chain of commerce including a manufacturer, seller, distributor or retailer, even if a defendant was unaware of the defect at the time it left its control.

Negligence

A negligence claim focuses on the reasonableness of the defendant's conduct and whether there was a breach of the duty of care. A defendant owes a duty of reasonable care in its design and manufacturing processes and in its provision of adequate product warnings.

The elements of a negligence claim are the following:

1. The defendant owed a duty of care to the plaintiff;
2. The defendant breached that duty;
3. The breach caused the plaintiff's injury; and
4. The plaintiff sustained injuries or damages.

Strict Liability

Strict liability focuses on the product itself and not on the defendant's intent or level of care. As such, even if a manufacturer is found to have exercised reasonable care, it may still be found liable under strict liability. Strict liability generally requires a showing that:

1. The product was sold in an unreasonably dangerous condition when it left the possession and control of the manufacturer, seller, distributor or retailer;
2. The product was materially in the same condition when it reached the plaintiff as it was when it left the defendant's control; and
3. The defect caused the plaintiff's injury.

Breach of Warranty

Warranty claims may be based on express affirmations of fact or promises made to buyers or lessees relating to the product, descriptions or samples of goods, or implied warranties of merchantability and for fitness for a particular purpose.

A breach of express warranty arises when a seller makes an express promise to a purchaser that the product will meet a certain standard and it fails to do so. The promises are often found in sales contracts but may exist when there are assurances or descriptions of product quality made to the purchaser.

A breach of implied warranty of merchantability occurs when the product is not fit for the purpose for which it is typically used. The plaintiff typically must prove that the defect in the product rendered it unfit for its ordinary and intended use.

An implied warranty of fitness for a particular purpose may arise where: (1) the seller has reason to know of the particular purpose for which the goods are provided; (2) the seller has reason to know that the buyer is relying upon its skill or judgement to furnish the appropriate goods; and (3) the buyer does in fact rely on the seller's skill or judgement.

Consumer Protection

Consumer protection statutes are often broad and encompass such business practices as false or misleading advertising or labelling, breach of implied warranties, misrepresentations and safety violations. The statute will typically set forth the standard of proof. Many statutes require proof of intent and reliance on the misleading information or misrepresentation.

Fraud

To establish fraud or intentional misrepresentation claim, a plaintiff must prove that:

- The defendant knowingly made a false or misleading representation about the product to induce the plaintiff to purchase it;
- The plaintiff relied upon the misrepresentation when purchasing the product; and
- The plaintiff was damaged by the representation.
- A finding of fraud or intentional misrepresentation may provide a basis for awarding punitive damages.

Negligent Misrepresentation

To prove a claim of negligent misrepresentation, the plaintiff must prove that:

1. There was a false or misleading representation made about the product;
2. The defendant should have known that the information was false or misleading;
3. The plaintiff relied upon the false or misleading representation; and
4. The plaintiff was damaged as a result.

Negligent misrepresentation, unlike fraud, does not require the plaintiff to prove the defendant intended to mislead.

Types of Product Defect

Defects in manufacturing, design, packaging and product warnings can all give rise to liability. A manufacturing defect exists where the product differs from its intended design. A design defect exists where the product's design is defective, such that all products manufactured and sold with the design are defective and foreseeable risks could have been limited or eliminated by a reasonable alternative design. A defective warning involves the failure to disclose foreseeable risks of the product or the failure to adequately warn of the product's dangers. Failure to warn claims are typically asserted as negligence or strict liability claims.

The test for whether a product is defective varies among the states. Typically states use the consumer-expectations test, the risk-utility test, or a combination of both. Under the consumer-expectations test, a defect exists if the product is unreasonably dangerous, and the danger exceeds what an ordinary consumer would expect (Restatement (Second) of Torts: Product Liability section 402(a)). Under the risk-utility test, the product is defective if the utility of the product is outweighed by the risk of injury (Id.).

2.2 Standing to Bring Product Liability Claims

A person claiming injury resulting from a defective product has standing to bring a product liability claim. The original purchaser of the product is not typically the only one with standing. In a "tort based" warranty action (ie, for personal injuries or property damage other than to the product itself), the plaintiff need not have bought or leased the product directly from the defendant, so long as the plaintiff is a person whom the defendant might reasonably have expected to use, consume or be affected by the product. Theos & Sons, Inc. v Mack Trucks, Inc., 431 Mass. 736 (2000).

Whether a plaintiff can bring derivative damage claims in a product liability action typically depends on the law of the state where the action is filed. For example, a spouse or child may be permitted to bring a loss of consortium claim (for loss of care, guidance and comfort) in certain states. Wrongful death or survivor statutes, which also vary by state law, define when heirs or administrators can bring actions on behalf

of the decedent's estate. Certain states permit claims for emotional distress for individuals who were not physically injured by a product if they were in the "zone of danger" and witnessed someone else being injured.

2.3 Time Limits for Product Liability Claims

The time limits within which an action may be brought depends on the cause of action and jurisdiction. Statutes of limitations can range from one to six years. Some states have specific statutes for bringing a product liability action. In the absence of such a statute, the time limit for the cause of action controls.

Most states have adopted the discovery rule, which means that the statute of limitations will not begin to run until the plaintiff discovers, or reasonably should have discovered, the injury, cause, and/or wrongful conduct of the defendant. There is variation in the application of the discovery rule among the states that have adopted it. Many states require discovery of the injury and cause to trigger the statute. Other states require only that the plaintiff discover the injury. Certain states require the plaintiff discover the facts essential to prove each element of the cause of action.

2.4 Jurisdictional Requirements for Product Liability Claims

State Court Jurisdiction

To maintain a suit against the defendant, the court in which the case is brought must have personal jurisdiction over the defendant. Personal jurisdiction includes both general and specific jurisdiction.

General jurisdiction

A state court has general jurisdiction to hear all claims over a party where it is incorporated or has its principal place of business in that state. In 2023, the US Supreme Court in Mallory v Norfolk Southern Railway Co, 600 US 122 (2023), held that state statutes requiring consent to general jurisdiction as a condition for doing business in that state do not violate due process. The court's ruling opens up the potential for corporations to be sued in any state in which they conduct business.

Specific jurisdiction

Specific jurisdiction only allows a court to hear a particular case against a party. The US Supreme Court in Bristol-Myers Squibb Co v Superior Court of California, 582 US 255 (2017) clarified the scope of specific jurisdiction. Specific jurisdiction requires "an affiliation between the forum and the underlying controversy, principally, [an] activity or an occurrence that takes place in the forum State" (Id. at 264). Multi-plaintiff product actions with non-resident plaintiffs face jurisdictional hurdles when they are brought in courts of states where the defendant is not headquartered or incorporated and where the alleged incident did not occur.

In 2021, the US Supreme Court further delineated where lawsuits can be filed under the doctrine of personal jurisdiction. The court held that plaintiffs could file suit against a defendant where the defendant had cultivated and served a market in a state, even if there was no direct link between the product causing the injury and the forum state (Ford Motor Company v Montana Eighth Judicial District Court et al, 592 US 351, 362 (2021)).

Federal Court Jurisdiction

Federal courts have "federal question" jurisdiction over cases arising under the US Constitution, federal laws or treaties (28 USC section 1331). Federal courts also have "diversity jurisdiction"

in cases where each plaintiff is from a different state or foreign country than each defendant and the amount in controversy exceeds USD75,000 (28 USC section 1332(d)). In diversity jurisdiction, the federal court where the suit is filed must have specific jurisdiction over at least one party.

If federal jurisdiction prerequisites are not met, claims must be brought in the state court that has jurisdiction.

2.5 Pre-action Procedures and Requirements for Product Liability Claims

In general, there are no pre-action requirements to bring a product liability claim. Many jurisdictions, however, require a party asserting a warranty claim to provide the opposing party reasonable notice of the breach of warranty upon discovering the breach (UCC section 2-607). The notice requirement exists to provide the allegedly breaching party an opportunity to cure the breach. The notice requirement is typically not a prerequisite for bringing a breach of warranty claim, but the failure to provide reasonable notice may be asserted as an affirmative defence to the claim. In some jurisdictions, the filing of the lawsuit is sufficient notice to the defendant.

2.6 Rules for Preservation of Evidence in Product Liability Claims

Once an entity "reasonably anticipates" becoming party to a litigation or the target of a governmental investigation, it has a common law duty to preserve all potentially relevant documents and tangible things, including electronically stored information, that may be discoverable in that litigation or investigation.

This duty extends to materials within a party's possession, custody or control, and materials it created, revised, sent, received or changed; and applies regardless of where the party has physical custody of the materials. In product liability cases, parties may also be required to preserve tangible things such as the allegedly defective product.

The standards for appropriate preservation of evidence include reasonableness, proportionality and accessibility. A legal hold should be promptly implemented if it could be credibly argued that either an investigation or litigation involving the materials at issue is likely. Fed. R. Civ. P 37(e) governs the potential consequences if a legal hold is not properly implemented or adhered to.

2.7 Rules for Disclosure of Documents in Product Liability Cases

The scope and timing of discovery in federal court is governed by Fed. R. Civ. P. 26. State court discovery rules and practice are similar to the federal rules but often have their own nuances. Rule 26(b)(1) defines the scope of discovery as "any non-privileged matter that is relevant to any party's claim or defence and proportional to the needs of the case". Proportionality requires an assessment of "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit".

Fed. R. Civ. P. 34 governs the production of documents and tangible things, whether in physical documents, electronic records and data, records of communications (physical, email, text, recordings, etc), or physical objects such as the product itself. Fed. R. Civ. P. 45 addresses the procedures for obtaining documents from a non-party through the service of subpoenas. In a product case, typical non-parties include the

plaintiff's employer, prior owners of the product, and healthcare providers.

2.8 Rules for Expert Evidence in Product Liability Cases

Expert witness testimony in federal court is governed by Federal Rules of Evidence 702 and 703. Amendments to Rule 702 that went into effect on 1 December 2023 clarify the standard for the admissibility of expert testimony. The Amended Rule 702 states:

"A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise *if the proponent demonstrates to the court that it is more likely than not that*:

- the expert's scientific, technical or specialised knowledge to help the trier of fact understand the evidence or determine a fact at issue;
- the testimony be based on sufficient facts or data;
- the testimony be the product of reliable principle and methods; and
- the "*expert's opinion reflects a reliable application of* the principles and methods to facts of the case." (emphasis added)"

Rule 703 provides that an expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed.

While certain information that an expert relies on in forming his or her opinions may not need to be admissible, if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.

Federal Standard for Admissibility of Expert Testimony

Amended Rule 702 emphasises the judge's role as gatekeeper for expert testimony and articulates the standard for admission of expert testimony. The amendment clarifies that the party offering expert testimony must establish all criteria by a preponderance of the evidence. In other words, an expert's methods must be "more likely than not" reliable.

The new language also emphasises the judge's role in limiting an expert's opinion to that which reflects a reliable application of the principles and methods to the facts of the case because jurors may lack the specialised knowledge to make that determination.

Courts assess several factors in determining reliability of an expert's methodology, including:

1. Whether the theory is testable;
2. Whether the theory is subject to peer review and publication;
3. Whether there is a known or potential error rate; and
4. Whether the theory is generally accepted in the field.

Courts applying the Daubert standard typically apply additional factors identified by the Ninth Circuit Court of Appeals in Daubert on remand: "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying because the former provides important, objective proof that the research comports with the dictates of good science" (Daubert v Merrell Dow Pharm. Inc., 43 F.3d 1311, 1313 (9th Cir. 1995)).

Frye Standard

Some state courts apply the Frye standard rather than Daubert when assessing the admissibility of expert testimony. Expert testimony is admissible under Frye if the expert's methodology is generally accepted by experts in that particular field. Frye v United States, 293 F. 1013 (DC Cir. 1923). Experimental methodology or methodology that is not well recognised is generally not admissible.

2.9 Burden of Proof in Product Liability Cases

The plaintiff who asserts a product liability action bears the burden of proving his or her claims against defendant(s). Each element of the claim must be proven by a preponderance of the evidence. The failure to prove any element of a cause of action by a preponderance of the evidence is fatal to the claim. In some states, there is a heightened burden of proof for establishing punitive damages including "clear and convincing evidence" and "beyond a reasonable doubt". A defendant bears the burden of proving the affirmative defences he or she raises during the lawsuit.

In some states, plaintiffs are required to prove the existence of a feasible alternative design. Evans v Daikin North Am., LLC (D. Mass. 2019).

2.10 Courts in Which Product Liability Claims Are Brought

Product liability cases are typically brought in district court in the federal system and the state trial courts. Product liability cases are most often tried before juries; however, the parties can agree to proceed with a bench trial before a judge. Some states require the plaintiff to affirmatively as claim for jury trial, and the failure to do so may waive the party's right to a jury trial.

In a jury trial, the judge will preside over the trial and rule on all motions, including those for a directed verdict. A directed verdict motion asserts that the plaintiff has failed to meet his or her burden of proof at trial.

2.11 Appeal Mechanisms for Product Liability Claims

There are no unique appellate procedures for product liability cases. In federal court cases, a party may appeal a final decision to a regional Circuit Court of Appeal. A decision is final when the court enters a final judgment (either through ruling on a dispositive motion or following a verdict). Fed. R. Civ. P. 58. In some instances, a party may appeal a district court's ruling through an interlocutory appeal. The Federal Rules of Appellate Procedure and local rules of individual Circuit Courts of Appeal govern the appeal process. The appellate court will issue a ruling based on its review of the record, the parties' appellate briefs, and oral argument.

To challenge an appellate court ruling (or a state supreme court's ruling if there is a federal question), a party can file a writ of certiorari to the US Supreme Court. The Supreme Court has discretion to grant or deny such petitions.

In state court, there is typically a trial court, intermediate appellate court and high court. The appellate procedure is governed by the individual state's rules of appellate procedure.

2.12 Defences to Product Liability Claims

Affirmative defences to product liability claims are typically governed by state law and vary among jurisdictions. The defendant's burden of proving an affirmative defence is by a preponderance of the evidence. The following are

among the most common affirmative defences to product liability claims:

Comparative/Contributory Negligence

Most states follow comparative negligence principles, which means that the damages awarded will be apportioned based on the parties' respective percentages of fault. The most common comparative negligence schemes are the pure and modified approaches. Under the pure comparative negligence rule, the plaintiff's recovery is reduced by his or her percentage of fault. For example, if the plaintiff is 70% responsible for his or her damages, his or her recovery will be reduced by 70%. Under the modified comparative negligence rule, the plaintiff is barred from recovery if he or she is found more than 50% at fault. A small number of states follow the contributory negligence rule, which means that the plaintiff cannot recover if he or she is found any amount at fault.

Many states have rules or statutes that further define the scope of the comparative negligence defence. For example, in Massachusetts, the plaintiff's comparative negligence is not a defence to a breach of implied warranty claim unless the plaintiff voluntarily and unreasonably proceeded to encounter the defect.

Assumption of the Risk

The assumption of the risk defence precludes recovery where a plaintiff voluntarily used a product when he or she was aware, or should have been aware, of a defect or other risk of harm, and nevertheless proceeded despite having that knowledge.

Material Alteration

The plaintiff is barred from recovery under this defence when it is established the product was not in materially the same condition at the time of the incident as when it left the control of the defendant, and the alteration or modifications caused the injury.

Unforeseeable Misuse

The plaintiff is barred from recovery when he or she misuses the product in a manner unforeseeable to the manufacturer or seller, and the misuse causes the injury.

Sophisticated User/Learned Intermediary

The sophisticated user defence protects a manufacturer or product seller from liability for failure to warn when the end user knows or reasonably should know of the product's risks.

Under the learned intermediary doctrine, a product manufacturer may in some circumstances rely on the knowledge of a "learned intermediary" who has received an appropriate warning. This doctrine is most applicable in the prescription drug and medical device context.

Federal Pre-emption

Certain state law claims may be pre-empted and barred by a federal statute governing a particular product. Federal law pre-empts state law if (1) it is expressly stated by Congress, (2) the state law conflicts with federal law; or (3) Congress has indicated that a certain area is not subject to state law. Product cases in which the defence is typically raised are prescription drug and motor vehicle defect cases.

2.13 The Impact of Regulatory Compliance on Product Liability Claims

While compliance with regulatory standards is typically something the jury can consider in assessing the conduct of the defendant, it does not preclude a finding of negligence when reasonable conduct would suggest additional precautions were warranted. The failure of a

manufacturer to comply with applicable federal standards can be evidence of a breach of duty or negligence per se.

Compliance with regulatory standards is relevant to rebut a claim that the manufacturer's conduct warrants the imposition of exemplary or punitive damages.

2.14 Rules for Payment of Costs in Product Liability Claims

Under the "American Rule", each party is typically responsible for bearing its own litigation costs. There are exceptions to this rule, many of which vary by state. Many state rules allow recovery of certain litigation costs from the losing party. Certain state statutes may allow for recovery of attorney's fees and litigation costs if a plaintiff prevails in a particular type of claim. For example, under the Massachusetts consumer protection statute (M.G.L. c. 93A), a breach of implied warranty is a per se violation of the statute entitling the plaintiff to his or her attorney's fees and costs.

The availability of "offers of judgment" under both the federal rules and certain state rules and statutes provides a potential avenue to recovering litigation expenses. Under Fed. R. Civ. P. 68, a party can make an offer of judgment to the other party at least 14 days before trial. If the opposing party rejects the offer and the final judgment is less than the offer, the opposing party must pay the litigation costs incurred by the party making the offer incurred after the date of the offer.

2.15 Available Funding in Product Liability Claims

Contingency fee arrangements are the typical manner in which injured plaintiffs pursue product liability claims. In these arrangements, the plaintiff's counsel will receive a percentage of the award or settlement in addition to litigation expenses if there is a recovery. When there is no recovery, the lawyer receives no fee or reimbursement for expenses.

Third-party litigation funding arrangements in which a non-party funds the lawsuit in exchange for a portion of any recovery continues to be a growing trend in personal injury litigation.

2.16 Existence of Class Actions, Representative Proceedings or Co-ordinated Proceedings in Product Liability Claims

Multidistrict litigation (MDL) was created by statute and has as its primary purpose establishing a centralised forum where related cases pending in federal court are consolidated so that coordinated pretrial proceedings can proceed in an efficient and effective manner. Pretrial proceedings include pretrial motions and discovery. The objectives for an MDL proceeding are many, including reducing litigation costs through more efficient discovery, avoiding conflicting rulings and schedules among court proceedings, streamlining key issues, and moving cases towards a resolution – either through trial, motions or settlement. State courts may permit consolidated proceedings involving similar claims of product defect.

Class action proceedings are available in federal court if the prerequisites of Fed. R. Civ. P. 23 are met. Product liability and personal injury actions are rarely appropriate for class action proceedings because they require an individualised assessment of causation and injury, making it difficult to satisfy the requirements of Fed. R. Civ. P. 23.

2.17 Summary of Significant Recent Product Liability Claims

In re: Social Media Adolescent Addiction/ Personal Injury Products Liability Litigation, MDL No. 3047 (pending matter)

This ongoing case continues to exemplify a recent trend in which traditional product liability theories are applied to personal injuries alleged to have resulted from an intangible product. In this matter, the product defect and failure to warn claims are asserted against social media platforms, alleging that platform algorithms are products that can lead to addiction and poor mental health outcomes in adolescents. Certain claims survived dispositive motion practice and the parties are proceeding through discovery. The case has implications for how courts will allow product claims to be utilised in new contexts and relative to new technologies.

Garland v Blackhawk Manufacturing Grp., 144 S.Ct. 338 (2023), and Garland v VanDerStok, 23-852 (pending matter)

The US Supreme Court is taking up the regulation of "ghost guns," firearms without serial numbers that are unregulated and untraceable. In October 2023, the court vacated an injunction entered by the US District Court for the Northern District of Texas that prohibited the Bureau of Alcohol, Tobacco, Firearms, and Explosives from enforcing a rule against two gun manufacturers that would require ghost guns to be traceable, allowing the rule to go into effect and apply to all manufacturers (Blackhawk Manufacturing, 144 S.Ct. 338). In April 2024, the US Supreme Court agreed to hear the federal government's challenge to the decision of the Fifth Circuit Court of Appeals concluding that the rule "flouts clear statutory text and exceeds the legislatively imposed limits on agency authority in the name of public policy." This case will have implications beyond the constitutionality of the law as lawmakers seek new ways to combat gun violence.

3. Recent Policy Changes and Outlook

3.1 Trends in Product Liability and Product Safety Policy

Artificial Intelligence

2023 saw a significant increase in the use of generative artificial intelligence (AI) globally and across industries, which has highlighted numerous legal and ethical considerations. Law firms and businesses are currently navigating how to utilise the enormous potential of AI while appropriately implementing it to address concerns over professional ethics compliance and the adequate safeguarding of private client data. The use of AI without such safeguards has led to court sanctions against attorneys for ethical violations where AI-generated briefs were filed that cited non-existent case law.

Two overarching concerns relative to AI with policy implications pertain to privacy laws and security. Executive Order 14110 on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence was signed on 30 October 2023 to promote a coordinated approach across the federal government to capture the benefits and mitigate the risk of AI. The order applies to the federal government but affects developers and users of AI systems. Federal agencies are prompted to evaluate AI use in their sector and establish guidelines or best practices to minimise AI-related risks. The deadlines for many agencies to implement the order's requirements will occur in 2024. Given the breadth of the order's directive to provide AI-specific guidance and enforcement across agencies and

industries, private sector companies utilising AI should monitor these regulatory developments.

Public-Health-Related Litigation and Settlements

Lawsuits relating to public health issues continue to be a significant source of litigation across the US. Litigation involving opioids, for example, has been initiated by each state and settlements are often in the eight- to nine-figure range. As of February 2024, over USD4.3 billion has been awarded in litigation settlements to state and local governments from companies that manufactured, distributed, or sold opioids. Companies are expected to pay out over USD50 billion over the next two decades.

Another example is PFAS (so-called forever chemicals) litigation, for which billions of dollars in settlements have been paid through the end of 2023 and also involves state-actor litigants. The scope of these settlements and role of state actors reflect the trend of litigation directed against product makers associated with public health issues impacting significant populations.

Right-to-Repair Laws

In recent years at least 40 states have passed or introduced "right-to-repair" legislation. These laws seek to increase access to the means to perform repairs to certain automobile systems that may include software, electronics, or other components that automakers have not made publicly available. A number of legal concerns are raised by the required disclosure of this type information, such as data privacy, intellectual property rights, or public safety. These laws will present new issues in product liability litigation in the coming years.

3.2 Future Policy in Product Liability and Product Safety

Future policy issues with the potential for significant implications in the product liability legal landscape include: CPCS's goals and priorities relative to product safety under its current Strategic Plan, legal challenges to the discretion of federal agencies, and implementation of data privacy laws.

Policy Development – CPSC 2023-2026 Strategic Plan

CPSC published its 2023-2026 Strategic Plan, setting forth key priorities through 2026 (www.cpsc.gov/s3fs-public/Strategic-Plan-2023-2026.pdf?VersionId=Y6434PE4JIewh 2ns7YynofecxqNIv1B). The goals set forth in the Strategic Plan include: preventing hazardous products from reaching the market and addressing those that do; improved and timely consumer product safety; and increasing efficiency in operational support, technology, governance and management.

To help achieve these goals, CPSC intends to enhance its data analysis and research capabilities to identify existing and potential emerging product hazards that pose the greatest risks; address product hazards associated with changes in traditional manufacturing methods; evaluate safety implications of e-commerce sales and evolving distribution options; help develop voluntary standards and adopt mandatory regulations; identify, research and inform the public about chemical and chronic hazards in consumer products; and increase the ability to interdict potentially non-compliant de minimis shipments of e-commerce products.

Another major component of CPSC's prevention approach is identification and interception of hazardous consumer products through import

surveillance and inspection programmes. CPSC conducts establishment inspections of manufacturers, importers and retailers; monitors internet and resale markets; responds to industry-generated reports about potentially hazardous products; and tests products for compliance with specific standards and mandatory regulations.

Legal Challenges to Federal Agency Discretion under the Chevron case

On 28 June 2024, the US Supreme Court overturned Chevron USA Inc v Natural Resources Defense Council Inc, a 40-year-old precedent under which courts generally deferred to federal agency interpretations of ambiguous statutes under their purview, so long as the interpretation was reasonable. This approach was discarded in Loper Bright v Raimondo and Relentless v Dept of Commerce. Going forward, courts shall exercise their independent judgment when deciding whether a federal agency has appropriately exercised its authority and shall no longer defer to an agency's interpretation of an ambiguous statute. This ruling does not call into question past decisions that relied on the Chevron framework.

The policy implications of removing the "interpretive methodology" of Chevron are significant. Federal agencies will face more challenges to their statutory interpretations and challengers will have a better chance of prevailing without courts affording deference to an agency's interpretation. The abrogation of Chevron will impact regulatory issues and their adjudication across industries and expand the role of the courts in this process.

Data Privacy Laws

There is no comprehensive federal law governing data privacy in the US. Draft legislation, the American Privacy Rights Act, has been introduced in Congress but to date data privacy laws have only been advanced by state legislatures. Sixteen states have data privacy laws in effect or that will become effective as of 1 January 2026. Several states model their privacy legislation on the European Union's General Data Protection Regulation, under which individuals own their personal data and have a presumptive right to control it. This marks a shift in the approach to data privacy in the US with implications for product makers that rely on data.

Trends and Developments

Contributed by:
Michael Mallow, Amir Nassihi and Rachel Straus
Shook, Hardy & Bacon

Shook, Hardy & Bacon has defended clients for more than a century in some of the most contentious national and international litigations. Corporate giants turn to Shook to defend class actions, no matter the industry. Shook's clients include leaders in the automotive, energy, pharmaceutical/medical device, cybersecurity and consumer goods sectors. Having handled 870+ class actions since 2010, Shook has persuaded courts to deny or otherwise throw out class actions in every jurisdiction in the United States in cases spanning an array of theories of recovery. Shook attorneys, located in 19 cities in the United States and London, offer creative solutions that withstand judicial scrutiny when class settlement is the goal. In one recent success, Shook attorneys defeated class certification and obtained a defence verdict at trial in a consumer class action under the Washington Consumer Protection Act. The verdict was upheld in appellate court and Washington State Supreme Court.

Authors

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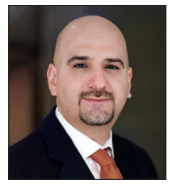

Amir Nassihi is the co-chair of Shook, Hardy & Bacon's class action and appellate litigation practice. His practice is dedicated to defending companies in class actions and aggregated litigation. Amir is recognised as one of the leading products class action lawyers in the United States, and regularly speaks on strategies to defend high-stakes class actions. Amir has led the defence of over 150 class actions throughout the United States, including successfully leading the defence of class actions with multibillion-dollar exposure. He has defended national and international class actions in the United States and abroad. Amir is a member of the Defense Research Institute.

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Equitable Claims and the Sonner/Guzman Quagmire: Much Ado About Nothing

In 2020, the Ninth Circuit decided Sonner v Premier Nutrition, 971 F.3d 834 (9th Cir. 2020) ("Sonner 1"), affirming dismissal of a consumer fraud class action seeking restitution under California's Unfair Competition Law (UCL) because the plaintiff failed to show she lacked an adequate legal remedy. In Sonner, the Ninth Circuit held that federal courts sitting in diversity must apply federal equitable principles to claims for equitable restitution brought under California law and that, under such principles, dismissal was appropriate because Sonner could not show that she lacked an adequate remedy at law (Sonner I, 971 F.3d at 837, 839–44).

Since that time, defendants in California consumer fraud class actions have been successful in arguing that plaintiffs' equitable claims (primarily UCL and False Advertising Law (FAL) claims) should be dismissed at the pleading stage if they cannot demonstrate an inadequate remedy at law. It is an advantage for defendants to have equitable claims dismissed because it eliminates certain remedies, reduces plaintiffs' ability to certify certain classes, and often shortens the limitations period from four to three years.

In Guzman v Polaris Industries, Inc, 49 F.4th 1308 (9th Cir. 2022), in addition to clarifying a number of issues related to the applicability of Sonner, the Ninth Circuit also confirmed that equitable jurisdiction is separate from subject matter jurisdiction (Guzman, 49 F.4th at 1314). As a result, a motion to dismiss for lack of equitable jurisdiction should be brought for failure to state a claim upon which relief can be granted under FRCP 12(b)(6), not for lack of subject matter jurisdiction under Rule 12(b)(1). In other words, "because the district court lacked equitable jurisdiction over [the] UCL claim, it could not, and did not, make a merits determination as to liability," which makes the decision binding on other federal courts "but not on courts outside the federal system." As Guzman explained, "[t]he possibility that federal and state courts would reach different results on the same claim is itself a consequence of Sonner's rule that federal courts sitting in diversity may exercise equitable jurisdiction only to the extent federal equitable principles allow them to do so. But where federal law bars [federal courts] from considering the merits of state-law claims, [federal courts] also lack authority to prevent state courts from doing so." On the same day the Ninth Circuit decided Guzman, a separate Ninth Circuit panel reaffirmed this in Sonner v Premier Nutrition Corp, 49 F.4th 1300, 1304-05 (9th Cir. 2022) (Sonner II). In Sonner II, the Sonner plaintiffs refiled their case in state court, the federal district court refused to enjoin the state case, and the Ninth Circuit affirmed, holding that even if the district court could have enjoined the state case, it did not abuse its discretion in declining to do so.

The Ninth Circuit's decisions in Guzman and Sonner II have led to a bit of a quagmire. Some district courts presented with a Sonner motion to dismiss equitable claims are splitting equitable claims from legal claims, allowing plaintiffs to pursue equitable claims in state court. There are three problems with this. Harkening back to the days when there were separate courts of equity and courts of law, the first problem is the clear inefficiencies in requiring that the same exact parties litigate the same exact factual issues regarding the same exact dispute separately in state and federal court. The second problem is that it puts the parties in a perpetual loop of removal and remanding. The final problem is that this type of claim-splitting appears to be a direct affront to the Class Action Fairness Act (CAFA), which was enacted to curb perceived abuse of

the class action device – an issue not raised in Guzman or Sonner II.

Clevenger v Welch Foods, Inc is a good example of how this problem is playing out in district courts. In that case, plaintiffs filed the original case in California state court alleging that defendant included nonfunctional "slack-fill" in boxes in violation of California's Unfair Competition Law (UCL), Cal Bus & Prof Code sections 17200-17210. The defendants removed the case to federal district court pursuant to CAFA, then moved for judgment on the pleadings on the plaintiffs' UCL claim due to lack of equitable jurisdiction. The district court agreed with the defendants and dismissed the plaintiffs' UCL claim without prejudice. The plaintiffs then refiled their UCL claim in the state court, and the defendants once again removed it to federal court pursuant to CAFA and moved to dismiss the claim. In response, the plaintiffs moved to remand the UCL claim to state court. Despite determining that CAFA conferred subject matter jurisdiction, the Clevenger court ruled it could remand the UCL claim to state court because it had "the power to dismiss or remand cases based on abstention principles where the relief being sought is equitable". In other words, the Clevenger court abstained based on lack of equitable jurisdiction and sent the equitable action back to state court. Beyond remanding the equitable claims to state court, the Clevenger court did not take kindly to the defendant removing the equitable action after the judge dismissed the equitable claims, calling it "forum shopping" and "judicial gamesmanship" to try to "extinguish claims which could properly be litigated only in state court."

Was the Clevenger court's perception that the defendant was engaging in judicial gamesmanship fair or correct? To be sure, the defendant wanted to get the equitable claims dismissed and was using Sonner to achieve that goal. But the "miss" in Clevenger is the implication that anything would have been different in state court.

Under California law, just like under federal law, if the plaintiff does not allege an inadequate remedy at law, the plaintiff cannot pursue equitable claims: see, for example, Prudential Home Mortgage Co v Superior Court 66 Cal App 4th 1236 (1998). Indeed, this principle is already so enshrined in California law that it has been cited as a reason not to publish more recent cases applying the same principle: see, for example, Consumer Advocates v Daimlerchrysler Corp, 2005 WL 327053, a unanimous decision applying adequate remedy at law not published because, as noted by the justices, "[t]he opinion follows established law and does not meet any of the standards for publication". Indeed, it is often forgotten that the original Sonner district court decision itself applied California state law principles in dismissing Sonner's UCL claim based on the adequate remedy at law doctrine, and scores of district courts in California similarly analysed and applied the adequate remedy at law doctrine based on California state law. In fact, a prior Ninth Circuit panel previously recognised this fact, ie, under California law if a plaintiff fails to allege an inadequate remedy at law, their equitable claims must be dismissed. Philips v Ford Motor Co, 726 Fed Appx 608 (9th Cir. 2018). It is unclear why the Ninth Circuit did not look to state law in Guzman and Sonner II as an additional basis to sustain dismissal of equitable claims.

So how can a defendant avoid the Sonner/Guzman quagmire? A possible solution is to challenge a plaintiff's failure to allege an inadequate remedy at law pursuant to both Sonner and Cali-

fornia state law. Beyond arguing for dismissal, it is advisable to head off a potential remand (or language from the court inviting a subsequent filing of equitable claims in state court) by noting that a plaintiff could not achieve a different result in state court. This is because state law also requires a plaintiff to establish an inadequate remedy at law to pursue equitable claims and state trial courts routinely apply the same doctrine to bar equitable claims under the UCL and other statutes: see, for example, Brantley v Nissan, 2017 WL 11679957 (Cal Super 9 February 2017).

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