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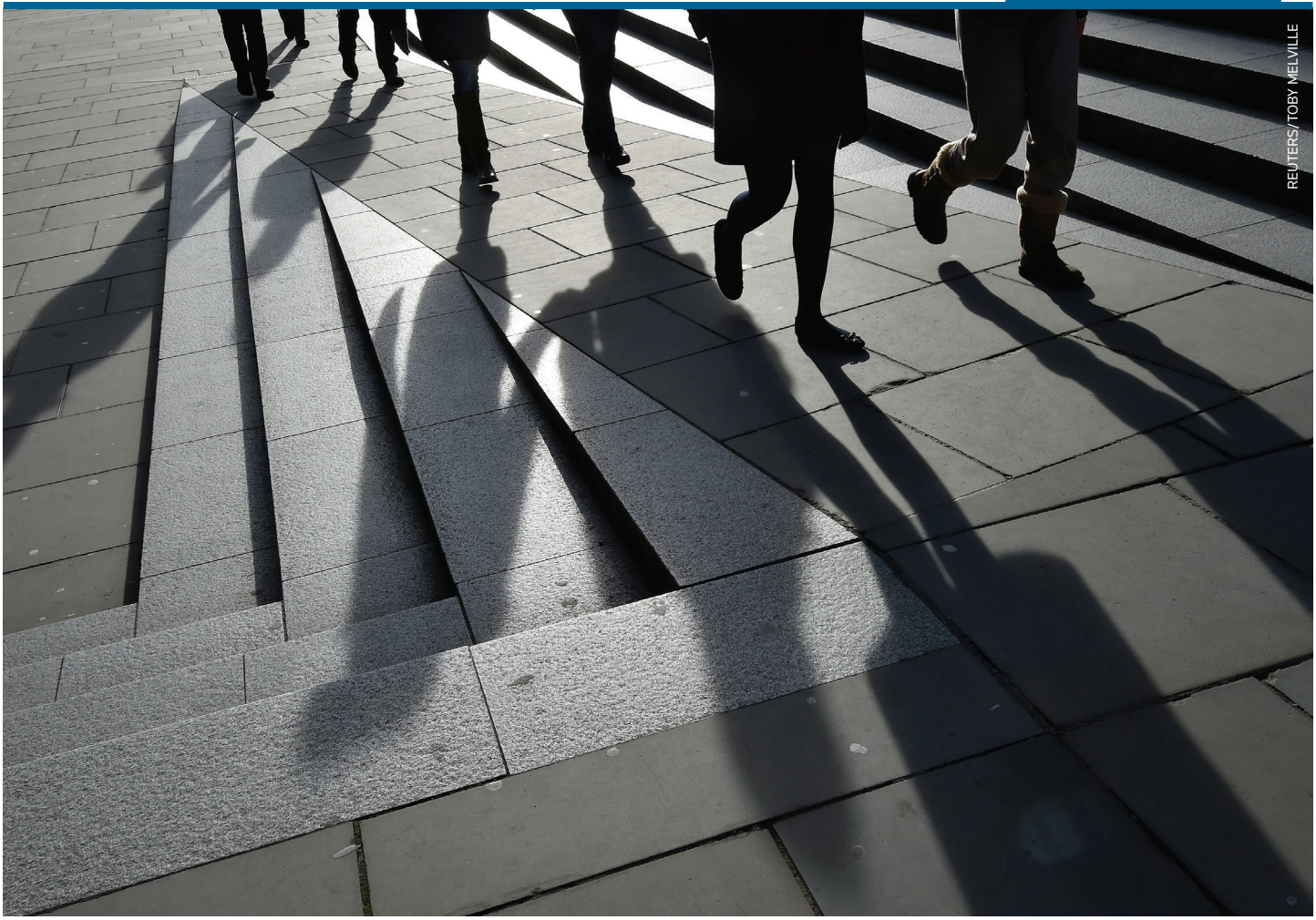
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PRODUCT LIABILITY AND SAFETY

in China, EU, United Arab Emirates, UK (England and Wales) and United States

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Product liability and safety in China: overview

Honghuan Liu and Xi Zhou
FenXun Partners

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SOURCES OF LAW

1. What are the main areas of law and regulation relating to product liability?

In China, the major laws and regulations governing product liability are:

Civil liability (this includes both tort liability such as the obligation to compensate damages and penalties imposed by administrative agencies:

- General laws and regulations, including the:
  - General Principles of the Civil Law (*Article 122*);
  - Tort Liability Law;
  - Product Quality Law;
  - Consumer Rights Protection Law.
- Laws and regulations for specific product areas, for example the (among many others):
  - Food Safety Law (specifically providing for product liability in the food industry);
  - Seed Law (specifically providing for product liability in the agricultural seeds industry).

The above provisions are based on, respectively, tort liability in civil law, such as the obligation to compensate for damages, and administrative liability, that is, penalties imposed by administrative agencies.

Criminal liability

- Laws and regulations for criminal product liability, for example:
  - Article 140, Crime of Producing or Selling Fake and Inferior Product;
  - Article 146, Crime of Producing or Selling Product Not Satisfying Safety Standard.

The Consumer Rights Protection Law specifically governs the consumption of products. This law defines products as those purchased and used for the need of consumption for living purposes (*Article 2*).

Consumers are not limited to the contractual party that directly signed the contract with business sellers, but include anyone that purchases or uses the goods or services.

The definition of "products" in Article 2 of the Product Quality Law refers to products "processed and manufactured for the purpose of marketing, not including construction projects".

"Consumer" is a legal subject who purchases and uses commodities or receives services for daily living needs and is limited to natural individuals in principle (*Article 2, Consumer Protection Law*). Consumers include the party who directly contracts with the product dealers, as well as family members of the purchasers and donees of the product who use the defective products.

2. What is required to establish liability under the most common causes of action? When is a product defective? Does strict liability apply in certain circumstances?

Elements of product liability under the law in China include:

- Defects.
- Loss.
- Causation between the defect and the loss.

A defect is one that unreasonably endangers personal safety or the safety of property (*Article 46*).

If a national safety or industrial standard for a specific product cannot be met by that product, the product can be treated as having defects. On the other hand, the fact that a product or service satisfies a national or industrial standard does not necessarily mean the product has no defects. If the product is unreasonably dangerous, it can still be treated as having defects.

In determining whether there are defects, the following principles are applied:

- The claimant does not need to show fault as the offence is one of strict liability (that is, in relation to the duty owed by the tortfeasor to the damaged party).
- However, "fault" is relevant to the question of allocating liability between defendants (for example, among several producers and sellers) for the purpose of indemnification. For example, when determining how to allocate the damage between sellers and producers, the sellers will only be liable if it can be proven that their conduct was at fault.

Claimants in product liability litigation are not limited to the direct users of the product. Any party that suffers damage due to a defect in the product can claim compensation.

3. Who is potentially liable for a defective product? What obligations or duties do they owe and to whom?

Parties that could be liable for a defective product are:

- The producer: this is generally believed to include the manufacturer of both the final products and the components and raw materials.
- The seller: this includes sellers involved in all the various channels of commerce.
- Transporters and warehouse operators will not be directly liable to damaged parties, but to producers and sellers (*Article 122, General Principles of Civil Law*).

The above parties are directly liable to anyone harmed by the product including any party that suffers damage due to the defect.

- Certain parties who are liable under specific provisions of law, for example:
  - business operators and distributors of advertisements which damage the legal rights of a consumer (for example, for misleading food advertising). (*Part II of Article 140, Food Safety Law*) are jointly liable with the food manufacturer (*see Question 20, Joint tortious liability*).

Allocation of liability

After the liable parties have paid compensation to the claimants, they will allocate their costs between any other directly or indirectly liable parties, for example, between producers and sellers. Under the Product Quality Law and Tort Liability Law, if the defect was caused by the producer of the defective goods, a seller who has compensated damaged parties has a right to claim an indemnity from that producer. If the seller caused the defects, the producer has a right to claim an indemnity from the seller after compensation has been paid to the claimants.

Defences

4. What are the defences to a product liability claim? Is there a time limit in which proceedings can be brought?

Statutory exemptions and grounds of defence include:

- The product was not put on the market.
- At the time when the product was put on the market, the defect that caused the damage did not exist.
- Under the Tort Liability Law, a defendant in a product liability case can also use specific defences such as fault or intent by the claimant (for example, incorrect use of the product by the claimant or the damaged party knew of the defect but still continued to use the product).

Claims for product liability are limited under the Statute of Limitation and other laws as follows:

- The time limit for claims for damage caused by defective products is two years from the date the claimant knew or should have known damage was caused (*Article 45, clause 1, Product Quality Law*).
- The general limitation period under the Statute of Limitation was extended from two to three years by Article 188 of the General Provisions of Civil Law (effective 1 October 2017). However, it is believed that the provisions of the Product Quality Law, that is, the two-year period, should apply in product liability cases, but this issue is not yet settled in Chinese legal practice.
- In addition to the above, there is an " absolute" limitation period of ten years after the defective product that caused the damage was put into the hands of the earliest consumers (unless the express " safe use" period indicated by producers is longer(*Article 45, Product Quality Law*).

Excluding/limiting liability

5. Can a supplier limit its liability for defective products and are there statutory restrictions on a supplier doing this? Do consumer protection laws apply? Are guarantees or warranties as to quality implied by law? Is there a mandatory or minimum warranty period for consumer products?

Limiting liability

Any restriction made by suppliers regarding compensation is invalid, including for liability under consumer protection laws.

Product suppliers and product sellers can agree to divide/allocate liability for defective products between themselves through contractual terms (*Article 40, Product Quality Law*). However, such terms could be invalid where the product causes (*Article 53, Contract Law*):

- Personal injuries.
- Property damage where intention or serious negligence is present.

Warranties

Requirements about product quality are as follows:

- Products must comply with quality including that they do not contain any unreasonable dangers (see *Question 2*) (*Articles 26 to 32, Product Quality Law*).
- Consumers have the right to enjoy products in safety when purchasing/using goods or services and to ask whether the sold goods/service comply with personal and property safety requirements (*Article 7, Consumer Protection Law*).

Minimum warranty periods.

There is no universal requirement for minimum warranty or guarantee periods. However, there is a minimum safe use period requirement for specific types of products, for example, for flat panel TVs it must be at least seven years.

Where contractual liability for failure to comply with a quality requirement has been agreed, the parties can fix the length of the period within which a complaint can be lodged (*Article 158, Contract Law*). If they did not specify the length, it is deemed to be a reasonable length of time up to a maximum of two years after receipt of the product. After this period has lapsed with no complaint, the product is deemed to comply with the contractual quality requirements.

If the parties do set up a quality warranty period, the purchaser has the right to ask the seller to perform its warranted promise within this period.

PRODUCT LIABILITY LITIGATION

6. In which courts are product liability cases brought? Are product liability disputes generally decided by a judge or a panel of judges? Are juries used in certain circumstances?

There are no specific courts dealing with product liability cases.

The jurisdiction of courts in product liability litigation is as follows:

- District jurisdiction: courts in the location where the product was manufactured or sold, where the service was provided, the tortious conduct occurred or where the defendant resides (*Article 26, Supreme People's Court Interpretation of the Civil Procedural Law*).
- Hierarchical jurisdiction: the level of first instance court which will hear a product liability case mainly depends on the disputed amount. Detailed rules for this are set out in a public notice issued by the Supreme 'People's Court in 2015', as well as in public notices issued by each High People's Court. Another factor in the choice of court is whether there is a foreign element in the case (including whether related to Taiwan, Hong Kong or Macau).

Product liability cases can be heard by one judge (simplified procedure) or a panel of judges (normal procedure) depending on the complexity of this case:

- Normal procedure generally applies, by which, a panel of judges (normally three) will hear and decide the case. Product liability cases are usually contentious and complex, involving technical evidence, therefore this procedure is widely applied.
- Simplified procedure is used for cases where the facts are clear, relationships between rights and obligations are clear and disputes between the parties are not contentious or many (*Article 157, Civil Procedural Law*). Cases are heard by one judge of a "basic level" court at the relevant local court branch If during the proceedings, the judge discovers that the facts of the case are complex and so needs to be converted into normal procedure, the court can order it to be heard by a panel of judges.

There is no jury system comparable with that of the UK or the US, but there is a "People's Juror" system, by which a non-judge (lay) citizen can participate in the hearing panel in a normal procedure case with the same power as a judge. The juror can participate in fact finding, in the application of law and the decision-making process but since product liability cases usually need high level legal expertise, the lay juror's opinion may not significantly impact the final decision.

7. How are proceedings started?

Proceedings are conducted as follows:

- The claimant files the claim (under the jurisdiction rules referred to in *Question 6)*, which includes:
  - statement of civil claims.
  - preliminary evidence to support the filing, and certain procedural materials.
- The court decides within seven days whether to accept the filing.
- If it accepts the case, the court must serve due process within five days by sending the filed legal documents to the defendant and any other third party. If the defendant resides outside China, a specified overseas delivery procedure is followed. China is a member of the New York Convention, as well as other international treaties and follows these as well as its own legal rules and regulations for court procedure.
- When service has been effected on all relevant parties, the court sets a timetable for filing evidence, exchanging evidence, pre-hearing meetings, formal court hearing and other proceedings.

8. Who has the burden of proof and to what standard?

The burden of proof is as follows:

- The claimant bears the burden for proving defect, damage, and causation between the defect and the damage (but see *Question 27*).
- The defendant bears the burden for statutory defences (see *Question 4*) once the claimant has discharged its burden of proof establishing the elements of product liability (see above).
- If the products in dispute are motor vehicles, computers, or other electrical appliances or durable products or the service in dispute is a decorating service, the business provider bears the burden of proof if the consumer discovered the defects within six months of purchasing the goods or accepting the services (*Article 23, Consumer Protection Law*).
- Once a party has satisfied its burden, the other party wishing to rebut those claims bears the burden of proof for their rebuttal (shifting of burdens).

The standard of proof is as follows:

- A party with the burden of proof must show its evidence is highly probable. (*Article 108, clause 1, Supreme People's Court's judicial interpretation of the Civil Procedural Law*). High probability is not defined in law or judicial interpretation but the normal practice is that evidence must be at least 75% probable.
- Evidence of parties submitting rebuttals must be good enough to persuade the presiding judge that the opposing party did not reach the high probability standard (*Article 108, clause 2, Supreme People's Court's judicial interpretation of the Civil Procedural Law*).
- In product liability cases, where there may be great disparity between the technical knowledge and weight of evidence between the parties, the court is more likely than in other cases to exercise its power to lower the standard of proof for the claimant. For example, if normal use of the product would not usually cause this type of accident, the court might presume the existence of defects and of damage (where neither has been proven to the required standard) if this type of defect will normally result in this kind of damage.

9. How is evidence given in proceedings and are witnesses cross-examined?

Evidence is submitted as follows:

- The types of evidence admissible in civil litigation are set out in Article 63 of the Civil Procedural Law. Standards and procedural requirements of submission of evidence are governed by Articles 69 to 80 of the Civil Procedural Law and Articles 90 to 123 of the Supreme People's Court Judicial Interpretation of the Civil Procedural Law.
- The court can order pre-hearing evidence exchange before the formal court hearing, either at its own discretion or through application by the parties. How many times evidence is exchanged depends on how complex the case is, but normally can be no more than twice. The evidence exchange is supervised by the court which can also conduct preliminary cross-examination of evidence or witnesses.
- After cross-exchange, both parties can submit supplementary evidence, the timing for which is determined by the court.

Witness evidence is dealt with as follows

- Witness testimony is one of the eight statutory evidence formats allowed under Article 63 of the Civil Procedural Law.
- Evidence must be presented in court and be subject to cross-examination by both parties (*Article 68, Civil Procedural Law*). If a major piece of evidence relied on by the court to make its decision was not cross-examined, this can be a statutory ground for a party to file a retrial petition to overturn the final or interim decision or judgment. The witness has a duty to testify in court and be cross-examined (*Article 72, Civil Procedural Law*).
- The normal procedure is for the witness to give the evidence he or she wants to prove, then be questioned by his/her own party, followed by the opposing party, then be questioned by other parties (such as a third party), and finally by the court.
- If a witness refuses to testify, the court usually refuses to admit the testimony, but will not normally take compulsory action or penalise that witness.

10. Are parties able to rely on expert opinion evidence and are there special rules or procedures for it?

In civil litigation generally, expert opinion to resolve technical issues in a case can be presented in several forms:

Expert forensic report

- A forensic report is one of the eight statutory forms of evidence allowed under Article 63 of the Civil Procedural Law and other Chinese laws.
- It is a written expert opinion issued by specialised institutes appointed either by a party or by the court offering scientific conclusions on technical or specialist issues by testing, analysing and investigating specific subjects/questions submitted by the party or court.
- All appraisal works must be conducted and completed by experts, who sign the report and are accountable for their opinions provided in the report.
- The report must be presented, cross-examined and verified in court proceedings. If a party raises objections or the court deems it necessary, appraisal experts must attend court and be cross-examined by the parties (*Civil Procedure Law and relevant judicial interpretations*). If the experts refuse to testify on notice by the court, the forensic report will be excluded.

Professional opinion by expert assistants

- A party can apply to the People's Court for an expert to give an opinion on a forensic report (*see above*) or on a specialist issue (*Civil Procedure Law, 2013 Revision*).
- Statements by expert assistants are categorised as parties' statements in evidence. The main function of an expert assistant is to state professional opinions, cross-examine forensic reports (including cross-examining experts), and cross-examine the expert witnesses of the other party.

Opinion from the court's own experts

Court investigation officer for technology: the three Intellectual Property Courts (located in Beijing, Shanghai and Guangzhou) each have investigation officers, who advise on technology-related issues and submit their technical opinions.

- Technical opinions by the court's team of external experts: courts usually hire experts to provide technical opinions on an ongoing basis courts at any time on specific issues. These experts do not participate in the proceedings and their opinions are not accessible to the parties. Their advice may influence the judgment on the facts but the parties 'cannot question these experts.

The Civil Procedure Law and judicial interpretations issued by the Supreme People's Court provide rules of procedure for expert evidence/advice as follows:

- The forensic report is the most common method for investigating technical issues and is governed by rules including on the:
  - timeframe and process for requesting reports;
  - decision on whether the report is necessary;
  - choosing specialist institutions and qualifications of experts;
  - procedure and requirements of the content and format of the expert report;
  - experts' attendance in court; and
  - cross-examination and circumstances for re-appraisal.
- Expert assistants:
  - parties must make a request to court in advance, with details of the experts, their expertise and proposed issues to be raised with them. If approved by the court, the experts can attend the trial.
  - expert assistants can only participate in the part of the trial related to the technical questions they intend to explain, and cannot attend or audit other parts of the trial.
- Court investigation officer for technology:
  - where a court decides to add an investigation officer into the proceedings, it usually informs the parties in writing. The rules applicable to judges also apply to investigation officers. This means parties have the right to request disqualification of an investigation officer on the grounds that, among others, he or

she is a party to a case, a close relative of a party or a litigation representative of, an interested party, or there are other circumstances which may affect the impartial trial of the case.

- The name of the investigation officer must be stated in the written judgment of the case.

- Opinions of the court expert database: since they are internal court opinions, there are no special procedure rules involved.

11. Is pre-trial disclosure/discovery required and which rules apply? If not, are there other ways to obtain evidence from a party or a third party?

There is no discovery system as such, but the "evidence presumption" rule means that if a party refuses to release evidence when requested to do so by the opposing party, the court can presume that the facts to be proven by that evidence do not exist. However this rule is not widely applied, and depends on the circumstances of the case and the discretion of the judge.

Other than submission of evidence by the parties, there are other means of adducing evidence.

When a party has difficulty in collecting evidence, it can apply to the court to use judicial power to obtain that evidence, subject to the following restrictions:

- The court has discretion whether to grant the application.
- Even if the court exercises its power to collect the evidence, in practice the evidence holding party might still refuse to provide it. It is rare for a court to impose compulsory action or penalties against a party, particularly if the party is a third party not directly involved in the litigation. If the holding party is an opposing party to the litigation, the court might exercise the evidence presumption rule (*see above*).
- In recent years, certain local courts on application by a party have started issuing investigation orders, under which attorneys of that party can enforce the order on a third party to release evidence on behalf of the court. However, this does not resolve the situation where a party refuses to release the evidence.

For evidence which may be lost or hard to obtain, a party can ask the court for an evidence preservation measure. This includes making copies, seals or other actions to preserve evidence, depending on its format and location.

12. Is there liability for spoliation of evidence/a remedy for destruction of or failure to preserve evidence (in particular, the product)?

Liability for evidence destruction applies as follows:

- Anti-evidence impediment rule. If a party with a burden of proof cannot meet this burden because the opposing party destroyed the evidence (including failure to properly preserve the evidence), the opposing party incurs a negative result against its own interest and the burden of proof is deemed to have been discharged. In practice, some courts have applied this Anti-Evidence-Impediment Rule in product liability cases. The court can penalise any party to the litigation or any third party who forfeits or destroys important evidence by imposing fines or detaining that person, depending on the seriousness of the circumstances (*Civil Procedural Law*).
- If the destruction of evidence including litigation documents is in breach of court orders and the circumstances are serious, this may result in criminal liability (*Article 309, Criminal Law*).

Where evidence is in danger of being destroyed or later on might become hard to obtain, a party can ask the court (before case filing or during the proceedings) to take evidence preservation actions (*see Question 11*). The court can also issue such measures on its own initiative.

13. What types of interim relief are available before a full trial and in what circumstances?

Interim relief and remedies include:

- Property preservation: before the court delivers final and effective judgment, the most common interim relief is a property preservation order, under which the court can, on its own initiative or on application of one of the parties, 'possess and control the defendant's property and restrict the defendant from disposing of the property, to ensure the effective enforcement of a future judgment.
- Temporary injunction: the court can order the defendant to perform certain specific conduct, or prohibit him or her from certain specific conduct (*revised Civil Procedural Law (2012)*).
- The above orders can only be granted if additional damage will be caused to the parties or judgment will be difficult to enforce without them. The application should be filed after the litigation procedure is formally triggered, but in urgent circumstances it can also be submitted before the case is filed. Interim reliefs usually require a monetary guarantee from the petitioning party.
- Execution in advance: the court can, on an application of the claimant, order the defendant to immediately give the claimant money or property, or cease and desist from certain conduct, in specific urgent circumstances (*Civil Procedural Law*).

14. Can the successful party recover its costs associated with the litigation, such as legal fees and experts' costs and to what extent?

A court fee must be paid in all cases (including product liability cases) to the court hearing the case, calculated in proportion to the amount of the claim. This fee is pre-paid to the court by the claimant but the court will decide which party ultimately pays it when the final judgment is given. The losing party usually pays the whole fee. If each party succeeds in different parts of the claim, the court will usually allocate the fee between the parties based on how much of the claim the claimant has won, but it can also allocate the fee in a different way.

It is rare for the losing party to pay the winning party's legal costs in litigation, but it is very common in arbitrations.

Allocation of other fees such as expert witness and forensic report fees are determined by the court. The losing party generally pays such fees.

15. What types of appeal are available?

Parties in all cases (including product liability cases) have various grounds to appeal, including:

- Fault of first instance court in fact-finding.
- Procedural error.
- Error in the application of laws.

The general rule is that only one appeal is permitted. Retrials are only allowed in a discretionary higher court supervisory procedure based on grounds such as the discovery of new evidence, forged evidence, the erroneous application of law or a severe procedural defect in the original procedure.

Class actions/representative proceedings

16. Are class actions, representative proceedings or co-ordinated proceedings available? If so, what are the basic requirements? Are they commonly used?

There are two types of class actions in China:

- Public welfare litigation (formally established by the Supreme People's Court in its judicial interpretation of 2016) is brought by claimants who are public welfare institutions, organisations or the state procuratorate. In these cases, the claimant asks the defendant to accept liability and, for example, cease and desist the infringement, remove the defect, eliminate the dangers created, compensate or apologise. During the procedure, the court determines the key facts related to product quality issues. After judgment becomes effective, any injured individual consumer can rely on this existing judgment to file his/her own private interest protection litigation obtain compensation. There have been some cases showing that public welfare litigation can apply to product liability claims. For example in one case, the state prosecutor filed public welfare litigation to stop the infringing activity of a party that had incurred product liability and require that party to compensate and apologise. The court eventually accepted the filing and continued to hear the case.
- A class action/representative litigation can be brought when there are a number of injured claimants, including in a product liability case. The court publishes an announcement, explains the case merits and claims, and notifies potential claimants register as claimants in with the court. The registered claimants can nominate co-claimants to be their representatives, who will participate in the litigation on their behalf. Once the judgment becomes effective, it binds all registered claimants. If unregistered parties file additional claims, this judgment will apply and bind the unregistered parties in those claims.

Litigation funding

17. Is litigation funding by third parties allowed? Is it common? Are contingency fee or no win no fee arrangements allowed?

Litigation funding

There is no statutory litigation funding system in China. In practice, however, specific state-supported funding is available for public welfare litigation (*see Question 16*) for parties who cannot afford the costs of this litigation.

By law, a court can decide to exempt, reduce or delay the court fee (*see Question 14*) if the court investigates and finds that a party is financially disadvantaged and meets certain conditions, for example, disabled people without steady incomes, citizens on minimal welfare benefits, people affected by natural disasters and other types of *force majeure*, or by business difficulties.

Lawyers' fees

Parties in specific types of cases can get *pro bono* legal aid services, including consultancy, representation and criminal defence. Although legal aid is not generally available for product liability cases, several local provinces have started to offer it for product liability cases, for example Beijing city, Anhui and Shanxi.

Contingency fees

In civil cases involving property, a contingency fee can be agreed between attorneys and clients. However this can legally be no higher than 30% of the total amount of the claim in the retainer agreement between the attorney and the client. Contingency fees are prohibited in:

- Property related cases arising under marriage, family and employment relationships.
- Criminal, administrative and state compensation cases.

Remedies

18. What remedies are available to a successful party in a product liability claim?

Remedies include:

- Damages for personal injury, such as:
  - medical treatment expenses, nursing fees and income losses;
  - disability assistance devices for living, assistance for costs of living, disability indemnity, and necessary living costs for persons to be raised by the victim;
  - funeral expenses, a one-off payment for the accident, and living expenses of persons who were being raised by the victim.
- Damages for mental distress (*Article 22, Tort Liability Law*)
- Damages for property loss do not cover damages to the defective product itself under the Product Quality Law. However, under the Tort Liability Law, according to discussion by legislators, recoverable damage can include the defective product itself.
- Punitive damages: only applicable under specific circumstances and in specific fields, such as:
  - where a manufacturer or seller knew of the defect in a product but still continued to manufacture or sell the product, and the defect caused 'death or serious injuries (*Article 47, Tort Liability Law*);
  - a victim can require a producer of food failing to meet food safety standards or a trader knowingly selling such food to pay an indemnity of ten times the price paid or three times the loss. The minimum amount payable is RMB1,000 (*Article 148, Food Safety Law*);

- where business operators fraudulently provide commodities or services, consumers can ask for an increase in compensation for their losses of three times the payment made by the consumer for the commodity purchased or the service received. RMB500 is the minimum amount payable (*Article 55, Consumer Protection Law*).

19. How are damages calculated and are there limitations on them? Are punitive or exemplary damages available and in what circumstances?

There is no limitation in Chinese law on the total damages a claimant can obtain. Except punitive damages, courts normally calculate the damages based on actual loss as follows:

- Personal injury: in general, these are calculated by actual loss, but for certain items, for example for disability indemnity, compensation for death, living costs of dependants, and funeral costs, a multiplier related to income is used.
- Property loss: includes direct loss and indirect loss, that is, the loss of obtainable profits.
- Psychological injury: the amount of damages is determined on the facts of the case, including the degree of fault of the tortfeasor, consequences caused by the tortious acts, earnings gained by the tortfeasor through the tortious acts and so on.
- Punitive damages:
  - for awards under Article 47 of Tort Law, the multiple is usually considered to be around three (see also *Question 18)*.
- Standards of damages for personal injury:
  - the standards to calculate damages for personal injury may vary for different victims. The calculation basis is the standard at the locality of the court dealing with the case (*Interpretation of the Supreme People's Court of Some Issues concerning the Application of Law for the Trial of Cases on Compensation for Personal Injury*). In practice, the economic status of regions varies widely and therefore the amount for damages may differ.
  - for death compensation: where the same tort (including in product liability cases) causes the deaths of several persons, a uniform amount of death compensation will be determined (*Article 17, Tort Law, see Question 27*).

20. Is liability joint and several/how is liability apportioned, including where a partially responsible entity is not a party to the proceedings?

Joint and several liability between manufacturers and sellers is as follows:

- Where any harm is caused by a defective product, the victim can request compensation from either the manufacturer or the seller of the product ("intermediate liability") (*Product Quality Law and the Tort Liability Law*).
- There are two interpretations of this rule: "optional indictment", where the victim chooses one or the other and cannot sue them together or "unreal joint and several liability", which means the aggrieved party can sue either the manufacturer or the seller and claim for full liability, but also can sue the manufacturer and the seller together and claim for joint and several liability.

Internal indemnity

- If the defect of the product is caused by the manufacturer while the seller compensated the damage and victim, the seller has the legal right to seek for indemnification by the manufacturer (*Tort Liability Law*); *vice versa*, if a defect is caused by seller's fault but the manufacturer compensated for the defect, the manufacturer has the right to seek for seller's indemnification. ("ultimate liability").

Joint tortious liability

Besides the indemnification rules, manufacturers and sellers may also bear joint and several liability if they committed a joint intentional tort or joint negligence for causing the product defects.

Specific laws make other parties jointly and severally liable with above liable manufacturers and sellers as follows:

- An agent/publisher of advertisement who designs, produces, or publishes any falsely stated advertisement about a defective/problematic food which causes any damage to the lawful rights and interests of consumers has joint and several liability with the defective food producer or trader (*Article 140, Food Safety Law*).
- A social group, any other organisation or an individual who recommends food to consumers through any false advertisement or other false publicity, and the food causes any damage to the lawful rights and interests of consumers, has joint and several liability with the problematic food producer or trader.

PRODUCT SAFETY

21. What are the main laws and regulations for product safety?

Articles 26 to 32 of the Product Quality Law set out regulations for product safety.

Government departments also issue national and industry standards related to product safety, including the National Food Safety Standards, Organic Product Standards and the Pharmacopeia of China.

There are also regulations on specific products, such as the:

- Food Safety Law, which applies to food, food additives and food-related products (including packing materials, containers, detergents, and disinfectants for food and utensils and equipment for food production and trade) and edible farm products (*Article 2, Food Safety Law*).
- Pharmaceutical Administration Law, which applies to the research, production, trade, use, supervision and management of pharmaceuticals (*Article 2, Pharmaceutical Administration Law*).
- Agricultural Product Quality Safety Law, which applies to plants, animals, microbes and their products, which are obtained from agricultural activities (*Article 2, Agricultural Product Quality Safety Law*)
- Special Equipment Safety Law, which applies to boilers, pressure vessels (including gas cylinders), pressure pipelines, elevators, lifting machinery, passenger ropeways, large-scale amusement devices, and non-road motor vehicles, among others (*Article 2, Special Equipment Safety Law*).

22. Are there general regulators of product safety issues? Are there specific regulators for particular goods or services? Briefly outline their role and powers.

General regulators of product safety include:

- State product quality supervision and administration departments include the:
  - General Administration of Quality Supervision;
  - Inspection and Quarantine for central government (*www.aqsiq.gov.cn/*);
  - regional product quality supervision and administration departments.
- Main functions include to:
  - supervise and administer quality of commodities and the safety of food in circulation;
  - punish illegal activities in production of counterfeit and substandard commodities (*see Notice of the General Office of the State Council on Issuing the Provisions on the Main Functions, Internal Bodies and Staffing of the General Administration of Quality Supervision, Inspection and Quarantine (No. 69 [2008] of the General Office of the State Council*).
- Industry and commerce administration departments, including:
  - State Administration for Industry and Commerce (*www.saic.gov.cn/*) for central government;
  - regional industry and commerce administration departments.
- Main functions include to:
  - supervise product quality and safety;
  - punish illegal activities related to product quality, inspect conduct health quarantine on exit-entry commodities (*see Notice of the General Office of the State Council on Issuing the Provisions on the Main Functions, Internal Bodies and Staffing of the State Administration for Industry and Commerce (No. 88 [2008] of the General Office of the State Council*).

There are specific government departments responsible for administration for some specific products such as:

- Food and drugs: China Food and Drug Administration (*www.sda.gov.cn/WS01/CL0001/*) and regional food and drug supervision and administration departments (*see Notice of the General Office of the State Council on Issuing the Provisions on the Main Functions, Internal Bodies and Staffing of the China Food and Drug Administration (No. 24 [2013] of the General Office of the State Council*).
- Pesticides: Ministry of Agriculture (*www.moa.gov.cn/*) and regional agriculture administration departments (*see Notice of the General Office of the State Council on Issuing the Provisions on the Main Functions, Internal Bodies and Staffing of the Ministry of Agriculture (No.76 [2008] of the General Office of the State Council*).

National standards on product safety are issued by the Standardization Administration governed by General Administration of Quality Supervision, Inspection and Quarantine.

Industrial standards on product safety are drafted by the related departments of the State Council.

Product recall

23. Do rules or regulations specify when a product recall is required or how companies should make decisions regarding product recalls and other corrective actions? Are any criteria specified?

Where a defect of a product is found after the product is put into circulation, the manufacturer or seller must take remedial measures such as warning and recall in a timely manner (*Article 46, Tort Law*). There are no other general conditions and standards applicable to recall of products. However, there are specific regulations relating to specific products, where product recalls are divided into voluntary and compulsory recall.

Under the Measures for the Administration of the Recall of Defective Consumer Goods:

- Voluntary recall: manufacturers must establish the defect information collection, analysis and processing system. If they confirm that there are defects in consumer goods, they shall immediately take measures to stop manufacturing, selling and importing defective consumer goods, and implement a recall in accordance with the law.
- Compulsory recall: where a related quality inspection department deems that there is any defect in any consumer goods, it must notify the manufacturer to implement a recall.

There are similar administrative regulations regarding other products, such as defective auto products and medical devices.

The purpose of recall is to eliminate or reduce the hazard of defective products. Under the Tort Liability Law, the manufacturer or seller who fails to recall defective products in a timely manner or recall them sufficiently and effectively and has caused harm assumes the tort liability. A manufacturer is not exempt from the corresponding liability due even if it recalls its defective consumer goods (*Measures for the Administration of the Recall of Defective Consumer Goods*).

State product quality supervision and administration departments are responsible for the implementation of recalls for general consumer products and auto products.

Relevant government departments are responsible for recalls of some specific products, for example, food, drugs and medical devices.

24. Are there mandatory advertising requirements for product recalls? Are there other rules governing how a product recall should be conducted?

As stated in *Question 23*, there are no general recall regulations applicable to all products, but under the regulations on specific products, manufacturers must:

- Implement recalls.
- Prepare a recall plan in accordance with related regulations.
- File the plan with the related government departments.
- Immediately notify other dealers.
- Publish information in a well-known manner which makes it easy for the public to inform owners.

- Related government departments must also publish information about the recall.

Well-known publication means (for example) newspapers and periodicals, websites, radio, television and other means accessible to the public (*Measures for the Administration of the Recall of Defective Consumer Goods*). Manufacturers must also set up public consultation through telephone hotlines, network platforms or other channels.

Detailed recall procedures for specific products are found in the various sets of regulations for those products.

25. Is there a mandatory obligation to report dangerous products or safety issues to the regulatory authorities?

There are no uniform regulations regarding the obligation to report dangerous products or safety issues. However, this obligation is widely required by a number of specific recall regulations for specific products, for example:

Under the Measures for the Administration of the Recall of Defective Consumer Goods:

- Manufacturers must report the defect investigation and analysis results to the provincial quality inspection departments at the places where manufacturers are located.
- Sellers, lessees, repairers, parts and components suppliers and other relevant operators must immediately notify the manufacturers and report to the provincial quality inspection departments at the places where they are located, once known that there might be defects in consumer goods.

Under the Special Rules of the State Council on Strengthening the Supervision and Management of the Safety of Food and Other Products, where manufactures and sellers do not fulfil the report obligation regarding products related to human health and life safety, they are liable to a fine and cancellation of the licence.

During a special operation on *ginkgo biloba* medicine in 2015by the China Food and Drug Administration, food and drug supervision bodies in various regions investigated more than 60 manufactures and gave administrative penalties to more than 50 enterprises. Enterprises that failed to report and concealed the defects were given heavier penalties, while enterprises which reported the defects and implemented recalls voluntarily were given lesser penalties.

Under the Measures for the Administration of Medical Device Recalls:

- Medical device manufacturers must immediately report to the related food and drug supervision and administration department if defects are found.
- Medical device operation enterprises and use entities must immediately notify the manufacturer or supplier of defects and report to the related food and drug supervision and administration department. Where the user is a medical institution, it must report to the related health administrative department.

If the manufacturer fails to submit a report for the medical device recall event or other related reports, it will be warned and ordered to take corrective action within a prescribed time limit; or where it fails to take corrective action within the prescribed time limit, it will be fined up to RMB30,000.

26. Is there a specific requirement to provide progress reports and/or keep the authorities updated about the progress of corrective actions? In practice, do authorities expect periodic update reports?

There is no general regulation on periodic update reports of product recalls. However, there are usually provisions in recall regulations for certain specific products.

For example, in the Measures for the Administration of the Recall of Defective Consumer Goods, a manufacturer must submit recall reports to the related quality inspection department in accordance with the provisions of the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).

In some regulations for specific products, there are more detailed requirements for periodic update reports, such as for recalls of defective auto products, and defective medical devices.

RECENT TRENDS AND REFORM

27. Are there any recent trends in product liability and safety law? Have there been any recent significant changes or important cases? Are there any legal or procedural issues that are attracting particular interest in your jurisdiction?

Following the promulgation of the Tort Liability Law, the general trend for product liability and safety laws and regulations is:

- Stricter liabilities for dealers in product liability and duty of care.
- A wider range of products to which the recall mechanism is applicable.
- A more favourable product liability litigation system for claimants.

There is a trend for heavier damage liabilities on dealers, especially after the establishment of the punitive damages mechanism (*see Question 18: Punitive damages*).

In addition, the following points apply:

- Where the same tort causes the deaths of several persons, a uniform amount of death compensation can be determined (*Article 17, Tort Liability Law*). The aim of this is to:
  - Avoid difficulties in raising evidence by the claimants.
  - Avoid subsequent delays in proceedings.
  - Ensure that claimants will get damages in a timely and sufficient manner.
- A food manufacturer or seller bears the burden of proof for compliance with food quality standards (*Article 6, Provisions of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Cases Involving Food and Drug Disputes*). This reverses the normal burden of proof for the product defect which is normally borne by consumers.

- For durable commodities such as motor vehicles, computers, televisions, refrigerators, air conditioners and washing machines and services such as decoration and remodelling, if consumers discover any defects within six months of receiving commodities or services and disputes arise, business operators bear the burden of proof for the defect(s) (*Article 23, Law on the Protection of Consumer Rights and Interests*).

There are also many recall administration measures which have expanded the scope of recalling products and refined the recall mechanism, including:

- Measures for the Administration of the Recall of Defective Consumer Goods (1 January 2016).
- Announcement on Acceptance of Recalls of Defective Imported Consumer Products (1 January 2016).
- Measures for the Administration of Medical Device Recalls (5 January 2017).
- Measures for the Implementation of the Regulation on the Administration of the Recall of Defective Auto Products (1 January 2016).
- Measures for the Administration of the Recall of Defective Railway Special Equipment Products (1 January 2016).
- Safety of motor vehicle products-Guidelines for risk assessment and risk control (GB/T 34402-2017 (1 April 2018).
- Consumer product recall—Guidelines for manufacturers (GB/T 34400-2017| 1 May 2018).

28. Are there any proposals for reform and when are they likely to come into force?

On 1 October 2017, the General Provisions of the Civil Law became effective. The legislature plans to continue to reform other aspects of the Civil Law Code, including tort liability. The general tendency in product liability, as outlined in *Question 27*, is to enlarge protection to consumers.

In addition, legal academics want to:

- Unify the standard for determining whether there is a defect. Currently, "unreasonable danger" and "national or industrial technology standard" are both applied. Some jurists argue that this dual-track standard is ambiguous and hard to apply, particularly as regards the meaning of "unreasonable danger".
- Increase the use and function of punitive damages in product liability litigation.
- Expand the use and application of mental distress damage in product liability litigation.
- Adjust the burden of proof rules in product liability (see *Question 27*). Some jurists argue that as modern products become increasingly complex, it is too difficult for claimants to prove defects.

The topics of artificial intelligence, driverless vehicles, cross-border e-commerce and others are also being discussed in the context of new legislation.

Contributor Profiles

Honghuan Liu, Partner
FenXun Partners
T + 86 10 5649 6018
F + 86 10 6505 9422
E liuhonghuan@fenxunlaw.com
W www.fenxunlaw.com

Professional qualifications. China, National Bar since 1993

Areas of practice. Product liability litigation and product recall, trade secret and competition law litigation, patent, trademark and copyright confirmation and infringement litigation, bank and financial institution litigation, compliance, anti-commercial bribery and FCPA government investigation, shareholder dispute litigation and arbitration, antitrust government investigation and litigation, construction litigation and arbitration, international sale of goods and letter of credit litigation and arbitration.

Non-professional qualifications. LLB, China University of Political Science and Law ,1986

Languages. Chinese (Mandarin), English

Recent transactions

- Assisting in complicated and influential cases
- Training expert witnesses in civil proceedings,
- Handling complicated litigation.
- Helping multinationals in PR aspects of litigation and practical crisis management advice.

Professional associations/memberships. Arbitrator, China International Economic and Trade Arbitration Commission (CIETAC), Beijing Arbitration Commission (BAC), Shanghai International Economic and Trade Arbitration Commission (SHIAC)

Xi Zhou, Partner
FenXun Partners
T + 86 10 5649 6019
F + 86 10 6505 9422
E zhouxi@fenxunlaw.com
W www.fenxunlaw.com

Professional qualifications. China, National Bar since 2003

Areas of practice. Dispute Resolution specialising in trade secrets, product liabilities, contracts equities, construction projects, financial derivatives, administrative litigation and anti-commercial bribery investigations.

Non-professional qualifications. LLB, Peking University (2002); LLM in Administrative Law, Peking University (2005)

Recent litigation and transactions

- Acting as leading trial lawyer for multinationals and large PRC state-owned companies in complex commercial litigations and arbitrations. Languages. Chinese (Mandarin, Shanghainese), English

Product liability and safety in the EU: overview

Rod Freeman, Sarah-Jane Dobson and Carol Roberts
Cooley LLP

global.practicallaw.com/w-013-0379

SOURCES OF LAW

1. What are the main areas of law and regulation relating to product liability?

The main legislative instrument relating to product liability at an EU level is Directive 85/374/EEC on liability for defective products (Product Liability Directive). The Product Liability Directive was adopted in 1985 and sets out the EU-wide no-fault liability regime for defective products. As a directive, it has been implemented by member states of the EU and their national courts enforce the directive in line with the relevant domestic laws that implement it.

The introduction of this directive was controversial at the time. It was the culmination of some ten years of deliberation and debate and ultimately in its application it has been relatively well accepted by all stakeholders.

The development of jurisprudence under this important measure is still ongoing. Nevertheless, it is now generally the case that product liability claims in the EU, for the most part, rely on the provisions of this EU initiative.

Unlike many EU-level legislative measures in this area, the Product Liability Directive is not a maximum harmonisation directive. As such, it does not exclude the scope for national law to provide for product liability by other causes of action, provided such is not inconsistent with the operation of the Product Liability Directive. The judgment by the Court of Justice of the European Union in *Novo Nordisk Pharma GmbH* (*Case C-310/13*) reaffirms previous case law that the Product Liability Directive does not aim to exclude national legislation that is beyond the scope of the directive, and that covers areas that are not regulated by the directive. Where such national legislation does not undermine or conflict with the supremacy of EU law, it will remain effective and can be used in the sphere of product liability. However, any such domestic legislation must always be interpreted and applied by national courts in light of the spirit of the relevant directive, here the Product Liability Directive (*Von Colson and Kamann v Land Nordrhein-Westfalen (Case 14/83)*).

Consumers in the EU will also have rights under national laws implementing the Consumer Sales and Guarantees Directive (*1999/44/EEC*). This provides that a seller that is "any natural or legal person who, under a contract, sells consumer goods in the course of his trade, business or profession" will be liable if the product in question does not conform to the contract of sale.

Conformity is presumed where the product:

- Complies with the description given by the seller.
- Possesses the quality of the goods that the seller has held out as a sample.
- Is fit for the particular purpose; or
- Is fit for the general purpose that products of that type are put to use.

Where a product does not conform, the consumer can have that product brought into conformity (either by repair or replacement) by the seller or can have a reduction in price of that product. This right exists for a minimum of two years under Article 5 of the Consumer Sales and Guarantees Directive. The Consumer Sales and Guarantees Directive also provides that member states can provide that, to benefit from their rights, consumers must inform sellers of the lack of conformity within two months of detecting it.

2. What is required to establish liability under the most common causes of action? When is a product defective? Does strict liability apply in certain circumstances?

To establish liability under Directive 85/374/EEC on liability for defective products (Product Liability Directive), the injured person must prove the defect, the damage and the causal link between the two.

Under the Product Liability Directive, a producer is liable for damages caused by a defect in their product. For these purposes, a product is defined as "all movables even if incorporated into another movable or into an immovable", and this definition includes electricity (*Article 2, Product Liability Directive*).

Therefore, at the heart of liability is the concept of defect. A product is considered defective for these purposes when it does not provide the level of safety that a person is entitled to expect, taking all the circumstances into account, including (*Article 6(1), Product Liability Directive*):

- Presentation of the product.
- Use to which it can reasonably be expected that the product will be put.
- Time the product was put into circulation.

It was held by the Court of Justice of the European Union (CJEU) in *Boston Scientific*(*Case ECJ 015/4*) that for certain products, the safety level that the consumer is entitled to expect is to be considered particularly high. This can be due to the inherent function of the product, the vulnerability of the typical user or the abnormal potential for damage that the product presents. In *Boston Scientific*, the products in question were a pacemaker and cardioverter defibrillator.

In the same matter, the CJEU confirmed that where products belonging to the same group or forming part of the same production series are found to have a potential defect, any product belonging to that group can be classified as defective without having to prove the product in question actually has such a defect.

It remains a controversial point in the EU as to whether a product that is subject to strict requirements under EU safety regulations can be considered defective if it complies with those regulations. It seems relatively clear that regulatory compliance will rarely be a complete defence and there is no concept of pre-emption in the EU in this context. However, it must still be the case that the requirements of product safety regulations must be an important consideration when trying to assess what a person's legitimate expectations as to safety must be for the purposes of liability under the Product Liability Directive. This is an area ripe for further consideration in Europe.

Under Article 4 of the Product Liability Directive, the claimant must establish the causal link between the defect and the damage. It was held in *NW et Al v Sanofi Pasteur*(*Case C-621/15*) that the standard of proof required is to be determined at a national level. Each member state can determine the most just standard themselves as long as the various national standards are all in line with the EU-wide principles of effectiveness and equivalence.

Under Directive 1999/44/EC on consumer rights (Consumer Sales and Guarantees Directive), the seller is liable if it can be proved that the product did not conform with the contract for sale at the time (*see Question 1*).

3. Who is potentially liable for a defective product? What obligations or duties do they owe and to whom?

It is the producer who is potentially liable for the defect in a product under Directive 85/374/EEC on liability for defective products (Product Liability Directive). A producer is defined as "the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer" (*Article 3(1), Product Liability Directive*).

This definition is extended to also include the EU-importer of the product as well as, potentially, a supplier who does not disclose, within a reasonable time, the identity of the person who supplied the product to them. It was held in *Commission v France* (*Case C-52/00 [2002]*) that a supplier will be free from liability under the no-fault liability regime where they identify the producer or upstream supplier, and that member states cannot restrict this defence through any provisions of domestic law.

Liability is joint and several where two or more producers are held liable for the same damage, without prejudice to the provisions of national law concerning the rights of civil liability contributions.

The producer will be liable if they fail to deliver products that provide the levels of safety to which a person is reasonably entitled to expect, and damages result as a consequence of that failure. This level of safety required is dependent on several factors, including the inherent nature of the product and the product's intended use.

Under the Consumer Sales and Guarantees Directive (1999/44/EC) the liable party will be the seller to the consumer of the non-conforming product. Usually, this will be the retailer of the product.

There are certain additional rights consumers have under Directive 2011/83/EU (Consumer Rights Directive). Before a consumer can be legally bound by a contract of sale, they must have been provided with certain prescribed information in a clear and comprehensible manner. Such information includes, but is not limited to:

- The main characteristics of the goods or services, to the extent appropriate to the medium and to the goods or services, and the identity of the trader, such as his trading name, the geographical address at which he is established and his telephone number.
- The total price of the goods or services inclusive of taxes; and
- Where applicable, the arrangements for payment, delivery, performance, the time by which the trader undertakes to deliver the goods or to perform the service, and the trader's complaint handling policy.

Defences

4. What are the defences to a product liability claim? Is there a time limit in which proceedings can be brought?

A producer will not be liable under Directive 85/374/EEC on liability for defective products (Product Liability Directive) if they can prove any of the following:

- They did not put the product into circulation.
- That, having regard to the circumstances, it is probable that the defect that caused the damage did not exist at the time when they put the product into circulation or that the defect came into being afterwards.
- That they did not manufacture the product for sale or any form of distribution for economic purposes, or manufacture or distribute the product in the course of their business.
- That the defect is due to compliance with mandatory regulations issued by public authorities.
- That the state of scientific and technical knowledge at the time when they put the product into circulation was not such as to enable the discovery of a defect (development risks defence).
- That 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 manufacturer of the product.

For the development risks defence, a member state can derogate from this and provide in its national legislation that a producer can still be liable even if they can prove that the state of scientific and technical knowledge at the time was not such as to enable the discovery of the existence of a defect (*Article 15(1)(b), Product Liability Directive*).

ONLINE RESOURCES

European Commission Guidance on EU general risk assessment methodology

W http://ec.europa.eu/DocsRoom/documents/17107/attachments/1/translations/en/renditions/pdf

Description. This website has the European Commission guidance on risk assessment methodology.

PROSAFE Consumer Product Safety in Europe Corrective Action Guide: Guidelines for Businesses to manage Product Recalls & Other Corrective (November 2011)

W www.prosafe.org/images/Documents/EMARS/Corrective_Action_Guide_Final-published.pdf

Description. This document is written by PROSAFE, a professional organisation of the product safety enforcement authorities in Europe. The document is supported by the European Commission. The guide is not legally binding. However, it represents a synthesis of the information and experience available to the Commission.

Product Liability Directive

W http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1515879089467&uri=CELEX:31999L0034

Description. This website has the full text of the Product Liability Directive.

General Product Safety Directive

W http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1515879323994&uri=CELEX:32001L0095

Description. This website has the full text of the General Product Safety Directive.

Consumer Rights Directive

W http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1515879390524&uri=CELEX:32011L0083

Description. This website has the full text of the Consumer Rights Directive.

The development risks defence has been especially controversial in the history of the Product Liability Directive (*see Commission v United Kingdom (Case C-300/95)*). Historically, the scope of the defence has been interpreted narrowly, however, in recent times national courts have shown a willingness to potentially extend its scope. Typically, this defence will be sought to be deployed in a complex case involving pharmaceutical products. It remains controversial as to whether it can apply in cases involving less complex defects or damages situations. Some member states have derogated from this particular defence and it will therefore be ineffective before their national courts.

If the producer can show that the damage or injury was caused in part by the negligence of the consumer, then this can mitigate any potential liability exposure.

A three-year limitation period applies to claims under the Product Liability Directive. This period begins from the earlier of either the day on which the party becomes aware, or ought to have been aware, of the damage, the defect and the identity of the producer. There is also a long-stop provision that states that any rights exercisable under the Product Liability Directive are extinguished ten years after the producer has put the product into circulation. Put into circulation is understood to mean the moment at which the product left the manufacturing process and entered the marketing process in the final form it is to be offered to the end user (*see O'Byrne v Aventis Pasteur MSD and Another (Case C-127/04)*).

Under Directive 1999/33/EC on consumer rights (Consumer Sales and Guarantees Directive), the product will be presumed to have been non-conforming at the time of delivery if the lack of conformity becomes apparent within six months of delivery. Time limits for bringing claims are subject to national law, but cannot be less than two years from the date of delivery.

Excluding/limiting liability

5. Can a supplier limit its liability for defective products and are there statutory restrictions on a supplier doing this? Do consumer protection laws apply? Are guarantees or warranties as to quality implied by law? Is there a mandatory or minimum warranty period for consumer products?

Under Directive 85/374/EEC on liability for defective products (Product Liability Directive), a producer is prohibited from limiting or excluding its liability entirely in relation to personal injury (*Article 12, Product Liability Directive*). Member states can enforce stricter requirements within their jurisdiction.

Sellers cannot limit their liability to consumers under Article 7(1) of the Consumer Sales and Guarantees Directive (*see Question 4*).

PRODUCT LIABILITY LITIGATION

6. In which courts are product liability cases brought? Are product liability disputes generally decided by a judge or a panel of judges? Are juries used in certain circumstances?

Claims under Directive 85/374/EEC on liability for defective products (Product Liability Directive) are brought in the national courts of each member state. The ultimate arbiter of questions of interpretation of the directive is the Court of Justice of the European Union (CJEU).

Each member state implements their own rules regarding the procedural aspects of the commencement of product liability litigation. Article 267 of the Treaty on the Functioning of the European Union authorises courts within each member state, and where that court is one of final jurisdiction, obligates them, to refer any questions regarding the interpretation of EU treaties or other EU legislative instruments for the CJEU's preliminary ruling on the matter. This stays proceedings in the relevant member state until such a time as the CJEU ruling is handed down.

7. How are proceedings started?

See *Question 6*.

8. Who has the burden of proof and to what standard?

The burden of proof in relation to the elements of liability is on the injured person. That person must prove the damage, the defect and the causal relationship between the defect and the damage. They do not have to prove the negligence or fault of the relevant producer or importer.

The producer against whom the claim is brought bears the burden of establishing any of the defences on which they will seek to rely.

The relevant standard of proof is determined at national law level.

9. How is evidence given in proceedings and are witnesses cross-examined?

There is significant variation in how evidence is received and assessed by courts across the member states of the EU. This can have a significant impact on the way in which cases are dealt with in the EU.

10. Are parties able to rely on expert opinion evidence and are there special rules or procedures for it?

See *Question 9*.

11. Is pre-trial disclosure/discovery required and which rules apply? If not, are there other ways to obtain evidence from a party or a third party?

See *Question 9*.

12. Is there liability for spoliation of evidence/a remedy for destruction of or failure to preserve evidence (in particular, the product)?

See *Question 9*.

13. What types of interim relief are available before a full trial and in what circumstances?

Questions of interim relief are subject to the procedural rules applicable in each jurisdiction.

14. Can the successful party recover its costs associated with the litigation, such as legal fees and experts costs and to what extent?

In some EU countries, significant costs are recoverable by the successful party. In others, they are not, or are significantly more limited.

15. What types of appeal are available?

Rights of appeal are governed by national procedural rules.

Class actions/representative proceedings

16. Are class actions, representative proceedings or co-ordinated proceedings available? If so, what are the basic requirements? Are they commonly used?

This has been a controversial area in the EU and has been in the spotlight of the European Commission for many years. The availability of such procedural mechanisms is subject to national rules in each jurisdiction.

In 2013, the European Commission made a non-binding recommendation calling for member states to adopt, by 26 July 2015, collective action procedures with common features in all areas where EU law grants rights. This was followed up in 2017 with a call for evidence on the implementation of the recommendation, including gathering information from interested stakeholders about practical experience with collective actions, identifying actual collective actions initiated after the recommendation was adopted and collecting quantitative and qualitative data on those actions (*http://ec.europa.eu/newsroom/just/item-detail.cfm?item_id=59539*).

Litigation funding

17. Is litigation funding by third parties allowed? Is it common? Are contingency fee or no win no fee arrangements allowed?

The regulation of litigation funding is dealt with at member state level.

Remedies

18. What remedies are available to a successful party in a product liability claim?

Damages are left to be determined at a national level. This is an important point, as it can lead to very different outcomes for consumers in product liability claims across the EU.

In *Boston Scientific*(*Case ECJ 2015/4*), which applied to products that have peculiar functions used by vulnerable individuals where the potential for damage is abnormally high, it was held that the remedy to such product liability claims is to determine what is necessary to diminish the harmful consequences that the relevant defect caused, and restore the consumer to the position they would have been in had the product conformed to the level of safety that was reasonably expected. Here, that meant the cost of surgically removing the defective pacemakers and replacing the product with a conforming alternative.

19. How are damages calculated and are there limitations on them? Are punitive or exemplary damages available and in what circumstances?

See *Question 18*.

20. Is liability joint and several/how is liability apportioned, including where a partially responsible entity is not a party to the proceedings?

Under Directive 85/374/EEC on liability for defective products (Product Liability Directive), where "two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse" (*Article 5, Product Liability Directive*).

PRODUCT SAFETY

21. What are the main laws and regulations for product safety?

Product safety is extensively governed by EU-level legislation. It is a complex regime that operates at a number of levels.

Some product categories are governed by sector-specific (vertical) measures. To the extent that consumer products are not covered by vertical measures, they will be subject to horizontal measures under Directive 2001/95/EC on general product safety (General Product Safety Directive).

Under the General Product Safety Directive, a product is any product, including in the context of providing a service, that is (*Article 1(2), General Product Safety Directive*):

- Intended for consumers, or that it is reasonably foreseeable that consumers will use it, whether intended for them or not.
- Supplied or made available, for free or not, in the course of a commercial activity.
- New, used or reconditioned.

Examples of vertical sector-specific measures include directives and regulations governing the safety of toys, low voltage electrical equipment, cosmetics, personal protective equipment, machinery, radio equipment, motor vehicles, medical devices, medicines and equipment for use in explosive atmospheres.

Other relevant horizontal measures include:

- Regulation (EC) 1907/2006 on the registration, evaluation, authorisation and restriction of chemicals (REACH), which addresses the production and use of chemical substances in the EU.
- Regulation (EC) 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP regulation), which incorporates the classification and labelling criteria agreed at the UN. This regulation requires manufacturers to appropriately classify, label and pack products that contain dangerous substances and mixtures before placing them into the consumer market.
- Directive 2012/19/EU on waste electrical and electronic equipment (recast WEEE Directive), which regulates waste electrical and electronic equipment (WEEE) and provides for the creation of collection schemes where consumers return their WEEE free of charge.
- Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast RoHS Directive), which governs the restriction on use of certain hazardous substances in electrical and electronic equipment.
- Regulation (EU) 1007/2011 on textile fibre names and related labelling and marking of the fibre composition of textile products (Textiles Regulation), which regulates fibre names and related labelling requirements for textile products.

22. Are there general regulators of product safety issues? Are there specific regulators for particular goods or services? Briefly outline their role and powers.

There is no EU-level regulator for general product safety or most product categories. Enforcement takes place at a national level. This complexity creates particular challenges for companies when dealing with compliance and product safety issues, and requires careful management.

In certain circumstances the European Commission can adopt a formal temporary decision that requires member states to ban the marketing of a product that poses a serious risk, to recall that product from consumers or to withdraw it from the market.

EU-level agencies exist that have some regulatory functions for medicines and chemicals.

Product recall

23. Do rules or regulations specify when a product recall is required or how companies should make decisions regarding product recalls and other corrective actions? Are any criteria specified?

EU law contains some provisions dealing with recalls, however, in practice much of it is vague and left to the exercise of appropriate judgement by companies and, ultimately, by the authorities. This is a rapidly developing area in the EU, as it is in much of the world.

Under Directive 2001/95/EC on general product safety (General Product Safety Directive), producers must take appropriate measures to deal with risks, including, as a last resort conducting a recall from consumers. In less serious cases, other corrective measures may suffice (including, for example, withdrawal from the supply chain or providing warnings to consumers). The measures taken to deal with a product safety issue should be commensurate to the risk posed. A risk assessment is used to assess what corrective action is necessary.

The General Product Safety Directive does not set out precisely how a risk assessment should be conducted. However, the European Commission has published guidance, which sets out a methodology that is routinely adopted for this purpose (*see Commission Decision 2010/15/EU*), and the EU general risk assessment methodology (*COM(2013)76*).

Under the European risk assessment methodology, the risk can be assessed as low, medium, high and serious.

A guide published by PROSAFE, the professional organisation for market surveillance authorities in Europe, provides guidance on what action may be needed to deal with the various categories of risk:

- Low risk: normally not requiring action for products on the market.
- Medium risk: normally requiring some action.

- High risk: normally requiring rapid action.
- Serious risk: normally requiring rapid action.

Ultimately, it is a matter for judgement, guided by appropriately-experienced experts, as to whether a particular risk scenario requires a company to undertake a product recall.

24. Are there mandatory advertising requirements for product recalls? Are there other rules governing how a product recall should be conducted?

There are no mandatory advertising requirements or other specific requirements for conducting product recalls at an EU level.

Responsibility for supervising the conduct of product recalls falls to national authorities in each country. This is a rapidly changing area. One of the key challenges for companies is to ensure consistency across the affected jurisdictions. This requires careful management, supported if necessary by experts experienced in managing regulators across the various jurisdictions.

25. Is there a mandatory obligation to report dangerous products or safety issues to the regulatory authorities?

Under Directive 2001/95/EC on general product safety (General Product Safety Directive), if a producer or distributor knows or ought to have known, on the basis of information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they mustimmediately inform the competent authorities of the member states in which the products in question are, or have been, marketed or otherwise supplied to consumers (*Article 5(3), General Product Safety Directive*). The European Commission has made available an online form (Business Application) to assist in making notifications. There are risks associated with using this form and it is recommended to obtain appropriate advice.

26. Is there a specific requirement to provide progress reports and/or keep the authorities updated about the progress of corrective actions? In practice, do authorities expect periodic update reports?

See *Question 24*.

RECENT TRENDS AND REFORM

27. Are there any recent trends in product liability and safety law? Have there been any recent significant changes or important cases? Are there any legal or procedural issues that are attracting particular interest in your jurisdiction?

Overall, there appears to be a general increasing trend in the prevalence of product liability claims and risks across the EU. There will be variations from country to country, for a variety of reasons, however, the overall trend appears to be increasing.

Product safety regulation is a rapidly developing area, both from the perspective of new regulation and from an enforcement perspective. Over recent years, economic pressures have led to a reduction in resources for market surveillance authorities in many countries, which is seen to have had a detrimental effect on the level of enforcement of product safety laws. As the issue of lack of resources comes to be addressed, by various means, it is expected that risks of non-compliance for companies will increase significantly. These trends are also impacted by the increasing levels of international co-operation between market surveillance authorities.

28. Are there any proposals for reform and when are they likely to come into force?

In 2013, the European Commission proposed replacing Directive 2001/95/EC on general product safety (General Product Safety Directive) with a new General Product Safety Regulation and a new Regulation on Market Surveillance.

The progress of this package through the legislative process has stumbled due to disagreement regarding the proposed country of origin requirements that would be imposed under the proposals.

On 19 December 2017, the European Commission published the new Goods Package, made up of two proposed regulations: one on mutual recognition of goods, and the other covering compliance and enforcement of EU harmonised legislation on products. The draft text includes various new proposals including a mutual recognition declaration, a requirement for a person responsible for compliance information and new information sharing provisions. The proposals aim to secure a more level playing field for legitimate suppliers of products in the EU market, however, the cost of this is a significant increase in enforcement power and more onerous obligations for almost all product sectors.

Article 21 of Directive 85/374/EEC on liability for defective products (Product Liability Directive) requires the European Commission to prepare a report of the application of the directive every five years. In September 2016, the European Commission published their Evaluation and Fitness Check Roadmap for the Product Liability Directive, which launched the latest review of the Product Liability Directive that would cover the period 2011 to 2015. The review is particularly concerned with the fitness of the directive in light of new technologies and whether the directive can keep up with the proliferation of technologies such as the internet of things, artificial intelligence and associated smart devices. The preliminary conclusions from the consultation were that the Product Liability Directive remains fit for purpose for the most part and continues to strike a good balance between all stakeholders. However, at a subsequent workshop to discuss those preliminary conclusions, concerns were raised by some stakeholders, primarily those representing claimants, that aspects of the Product Liability Directive are not fit for purpose. Interestingly, these concerns were more focused on traditional questions about defect, the burden of proof and access to resources than on the challenges of new technologies.

Contributor Profiles

Rod Freeman, Partner
Cooley (UK) LLP
T +44 20 7556 4429
E rfreeman@cooley.com
W www.cooley.com

Professional qualifications. England and Wales, Solicitor

Areas of practice. Product liability, product safety, product compliance, investigations, commercial litigation, consumer products, life sciences, cosmetics, new technologies including IoT and Artificial Intelligence, automotive, sporting goods, machinery, electrical and electronics, chemicals, and asbestos

Recent litigation and transactions

- Representing a Core Participant in a Public Inquiry arising from the Grenfell Tower Fire tragedy in the UK.
- Co-ordinated one of the largest ever global consumer product recalls, involving more than 150 million products across some 60 countries.
- Co-ordinated international defence of product liability claims arising out of the supply of contaminated products used in the pharmaceutical industry.
- Retained as advisor to OECD Consumer Policy Committee on liability issues arising from new technologies.

Professional associations/memberships:

- International Consumer Products Health and Safety Organization (Director).
- Product Liability Advisory Council (US).
- International Association of Defense Counsel.
- Defense Research Institute.
- Product Liability Forum – British Institute of International and Comparative Law.

Sarah-Jane Dobson, Associate
Cooley (UK) LLP
T +44 20 7556 4432
E sdobson@cooley.com
W www.cooley.com

Professional qualifications. Queensland, Australia, Solicitor

Areas of practice. Product liability, product compliance, investigations, commercial litigation, life sciences, cosmetics, medical devices, new technologies (IoT, artificial intelligence), automotive, sporting goods, machinery, electrical and electronics, chemicals.

Recent litigation and transactions

- Representing a Core Participant in a Public Inquiry arising from the Grenfell Tower Fire tragedy in the UK.
- Manages international portfolios of consumer claims against pre-eminent global manufacturers.
- Representing a pre-eminent manufacturer in respect of criminal investigations into alleged product safety issues under UK product safety legislation.
- Co-ordinates some of the largest international product recalls in the world, including those involving consumer electronics, cosmetics and toys.

Languages. French, German

Professional associations/memberships:

- International Association of Defense Counsel.
- International Bar Association.
- Defense Research Institute.
- Product Liability Forum – British Institute of International and Comparative Law.
- International Consumer Products Health and Safety Organisation.

Publications. Monthly product safety article in the *Product Safety Letter* publication since May 2016.

Contributor Profiles

Carol Roberts, Associate
Cooley (UK) LLP
T +44 20 7556 4226
E croberts@cooley.com
W www.cooley.com

Professional qualifications. England and Wales, Solicitor

Areas of practice. Product compliance, product liability, commercial litigation, retail and consumer products

Recent litigation and transactions

- Advising a number of leading companies with the launch of innovative consumer-electronic products.
- Advising a global company on international product compliance requirements in respect of a new product roll-out.
- Advising a number of global companies on multi-jurisdictional product recalls.
- Advising a global company on the impact of new European proposals for market surveillance and enforcement.

Languages. French

Professional associations/memberships. British Institute of International and Comparative Law.

Product liability and safety in the United Arab Emirates: overview

Zisha Rizvi and Fatima Al Sakkaf
STA Law Firm

global.practicallaw.com/w-013-1095

SOURCES OF LAW

1. What are the main areas of law and regulation relating to product liability?

The main areas of law and regulation relating to product liability are:

- Federal Law No. 24 of 2006 on Consumer Protection (Consumer Protection Law), as amended by Federal Law No. 7 of 2011, is the main piece of legislation relating to product liability. The Consumer Protection Law sets up Consumer Protection Departments on a local level in each emirate which supervise and carry out policies relating to consumer protection, the regulation of competition and the management of consumer complaints (*Article 4*). Part Four lists the obligations suppliers must comply with and the standards of safety and quality expected of products. This law defines a consumer as a person who obtains a commodity or service for a price or otherwise for his/her own or another person's needs.
- Cabinet of Ministers' Resolution No. 12 of 2007 and the Cabinet of Ministers' Resolution No. 207/16 of 2006 provide further guidance on consumers' rights, such as their right to be provided with the facts necessary to conduct proper purchases and the right to select from a number of alternative goods at competitive prices. Resolution No. 12 of 2007 defines a "consumer" as "any natural or juridical person receiving any goods or service, with or without consideration, to satisfy his personal needs or the needs of others". This definition of a "consumer" is similar to that of Federal Law Number 24 of 2006.

  The above two laws are referred to as the Consumer Protection Laws in this chapter.
- Article 282 of Federal Law No. 8 of 1985 on Civil Transactions states that a provider who provides a defective or damaged product is liable to make good the harm. Each Emirate has a Consumer Protection Department, and the Supreme Committee for Consumer Protection regulates matters relating to consumer complaints.

2. What is required to establish liability under the most common causes of action? When is a product defective? Does strict liability apply in certain circumstances?

To establish liability, the consumer(s) must file the case before the courts on the grounds of tortious liability, contractual liability and breach of the Consumer Protection Law.

The following must be established to prove liability in tort:

- A duty of care from the supplier or the manufacturer to the consumer.
- A breach of that duty of care due to defective design, manufacture or warnings or instructions (failure to instruct the consumer how to properly use the product).
- Causation must be established between the defect in the product and the individual's harm, determining the defendant's responsibility in the matter.

There is no option to bring class actions suits (*see Question 16*).

Under Regulation No. 12 of 2007, "defective" is defined as:

- Any fault in the designing, processing, or manufacturing of goods.
- Non-suitability, deformation, or damage emerging before, during, or as a result of use,or due to non-conformity or non-compliance sufficiently with the standard specifications, the warranty, or specifications declared by the provider; or any acknowledgement or advertisement relating to or posted on the goods

Product liability claims are generally based on strict liability and therefore manufacturers can be liable regardless of whether they were negligent or not.

3. Who is potentially liable for a defective product? What obligations or duties do they owe and to whom?

Manufacturers and suppliers are both potentially liable for defective products. Under the Consumer Protection Law, providers can be liable for defective products. **"**Providers**"** include local agents, distributors, manufacturers and anyone involved in the circulation of the product or service.

Suppliers must not display or offer defective goods (*Article 6, Federal Law No 24 of 2006*) and will be liable if a defective product is sold.

A supplier will also be liable for not respecting labelling requirements, and for matters relating to warranties and after-sales service. Producers (or manufacturers) are also liable for providing defective products (*Article 9, Federal Law No 24 of 2006*).

Defences

4. What are the defences to a product liability claim? Is there a time limit in which proceedings can be brought?

In the UAE, a seller can rely on exclusions or limitations of liability except in cases of personal harm which are void (*Article 296, Federal Law No. 5 of 1985 on Civil Transactions*), in cases of criminal liability, where providers have a guilty intention, and in cases where the standards the Federal Consumer Protection Department are not met.

There are time limitations in which product liability proceedings can be brought.

Under the provisions of the Civil Code, tort based liability claims (such as product liability claims) will be time-barred and will not be heard after the lapse of three years from the date of discovery of the damage.

The Civil Code creates a distinction between contractual liability and tortious liability. The time limit for filing a civil suit is 15 years from the date of damage in contract claims.

A tortious claim cannot be invoked where the parties have a legally binding agreement. However, exceptions to this rule are where the claim involves misrepresentation and/or breach of obligation as these claims arise irrespective of a contractual agreement between parties.

Excluding/limiting liability

5. Can a supplier limit its liability for defective products and are there statutory restrictions on a supplier doing this? Do consumer protection laws apply? Are guarantees or warranties as to quality implied by law? Is there a mandatory or minimum warranty period for consumer products?

See *Question 4*. A supplier can attempt to limit its liability for defective products by inserting relevant warnings on products for example but this will not necessarily protect it. The Consumer Protection Departments and the courts are rather pro-consumer when it comes to consumer complaints. The UAE laws do not extensively set out the quality or safety standards expected of a product.

Where goods are recalled, the provider of a defective product must replace the product regardless of the warranty period (*Article 12, Resolution No. 12 of 2007*). In the case of repair, a warranty for electronic and electric goods cannot be less than three months and for durable goods not less than six months from the date of delivery of the repaired goods (*Article 25*). In this case, improper use of the goods is not covered by the warranty. Service providers must provide warranties for a specific period in accordance with the nature of the service (*Article 32*).

PRODUCT LIABILITY LITIGATION

6. In which courts are product liability cases brought? Are product liability disputes generally decided by a judge or a panel of judges? Are juries used in certain circumstances?

Product Liability cases are brought before the Consumer Protection Departments of the relevant Emirate, which have been set up in the Ministry of Economy and the Economic Departments of each Emirate. The consumer does not require the help of a lawyer, nor do they need to pay any fees. The Consumer Protection Department has the authority to take the decision in relation to the complaint. Decisions are generally made by judges and not juries.

7. How are proceedings started?

Complaints against defective products are received by the Consumer Protection Department. The Department has the power to investigate all matters relating to the case. Despite this, consumers have the option of filing their cases directly with the courts of the United Arab Emirates. In this case, hearings are public and should have the effect of pressurising the provider into meeting the consumer's demands. For criminal law matters and matters involving the breach of intellectual property, the claimant or their lawyers in Dubai or UAE may also institute criminal action by filing a complaint before the police. For matters involving forgery, counterfeit, violation of commercial agency, a complaint can be filed before the Ministry of Economy.

8. Who has the burden of proof and to what standard?

The claimant has the burden of proof, and must prove that:

- The defendant breached his/her duty of care.
- The breach caused harm to the claimant.

In product liability matters, defendants have strict liability. The defendant's intention is not relevant.

9. How is evidence given in proceedings and are witnesses cross-examined?

The Abu Dhabi Quality and Conformity Council and the Dubai Municipality have the power to take samples of products and have them checked by the Emirates Authority for Standardization and Metrology. If the product is found to be defective, the supplier is notified and can conduct their own checks. Hearing witnesses is not a general procedure in UAE courts, although the courts can request to call and hear a witness if they consider it necessary (usually if the case is referred to an investigator or expert). A party can also request to have a witness called and heard The categories of admissible evidence are (*Article 112, UAE 2/87 of Civil Code*):

- Writing.
- Testimony.
- Circumstantial evidence.
- Eye-witness and·expert evidence.
- Admissions.
- Evidence on oath

10. Are parties able to rely on expert opinion evidence and are there special rules or procedures for it?

Parties can rely on expert opinion evidence and consumers generally appoint technical court experts to assist them with their claim.

ONLINE RESOURCES

Consumer rights, Department of Economic Development, UAE

W www.consumerrights.ae/en/Pages/default.aspx

Description. The main website governing consumer and retailer rights.

Consumer Protection Department, Abu Dhabi

W ded.abudhabi.ae/en/Consumer-Protection

Consumer Protection Department, Sharjah

W sedd.ae/web/cp/home

Consumer Protection Department, Dubai

W www.consumerrights.ae/en/Consumers/Pages/default.aspx

11. Is pre-trial disclosure/discovery required and which rules apply? If not, are there other ways to obtain evidence from a party or a third party?

There is no disclosure and inspection process for documents or pre-trial exchange of evidence. Parties are not obliged to file documents that go against their case. However, a party to the litigation can request the court to compel his or her opponent to submit useful documents that are useful to the party's case (*Article 18, Federal Law No. 10 of 1992*). The documents a party wishes to rely on are submitted to the courts in writing.

12. Is there liability for spoliation of evidence/a remedy for destruction of or failure to preserve evidence (in particular, the product)?

Courts must appraise the consequences of scratching off, erasure, insertion and other material defects in the document which forfeit or depreciate its value as evidence (*Article 22, Federal Law No. 10 of 1992 concerning evidence*). This applies to product liability. The courts will evaluate the consequences of the failure to preserve or preserve properly evidence of a defective product (including documents and the products itself) in a complaint. The law does not specify any penalties or remedies in relation to this.

13. What types of interim relief are available before a full trial and in what circumstances?

The Consumer Protection Department will immediately apply the remedies and penalties listed in the Consumer Protection Laws when these laws have been breached by a supplier.

14. Can the successful party recover its costs associated with the litigation, such as legal fees and experts costs and to what extent?

The successful party can recover its costs associated with the litigation such as attorney's fees. The appointment of an expert must be funded by the consumer bringing the complaint although they are generally minimal. However, this depends on the judgment and is at the judge's discretion. The appointment of an expert must be funded by the consumer bringing the complaint, although they are generally minimal and do not exceed AED1,000.

15. What types of appeal are available?

The parties have a right to appeal the Consumer Protection Department's decision to the Ministry of Economy. The second decision can also be appealed to the courts in the UAE.

Class actions/representative proceedings

16. Are class actions, representative proceedings or co-ordinated proceedings available? If so, what are the basic requirements? Are they commonly used?

Class actions are not recognised in the UAE. Individual claimants in product liability cases usually bring their claim in the local Consumer Protection Department, which charges no fees, or in a court. Court fees are minimal and do not generally exceed AED1,000.

Litigation funding

17. Is litigation funding by third parties allowed? Is it common? Are contingency fee or no win no fee arrangements allowed?

The only regulation governing third-party funding in the UAE is the Dubai International Financial Center's (DIFC's) Practice Direction 2 of 2017. In the DIFC courts (which have their own jurisdiction), litigation funding by third parties is allowed if the other parties are informed of this. In the rest of the UAE, there is no regulation prohibiting litigation funding by third parties, however, the practice is not common.

Remedies

18. What remedies are available to a successful party in a product liability claim?

The remedies available in a product liability claim are damages such as medical costs, compensatory damages and economic damages. Punitive damages can be awarded at the court's discretion, although there is no legislative provision for this.

19. How are damages calculated and are there limitations on them? Are punitive or exemplary damages available and in what circumstances?

Damages in tort are calculated based on the actual damage suffered by the consumer and any consequential losses flowing from the tortious act.

Contractual damages are based on what has been agreed to in the consumer's contract.

There is no legislative provision covering punitive damages.

20. Is liability joint and several/how is liability apportioned, including where a partially responsible entity is not a party to the proceedings?

A manufacturer and a supplier can be jointly liable for a defective product, especially if the manufacturer is located in the UAE. The Consumer Protection Laws (*see Question 1*) state that providers are liable for faulty products, and the definition of providers includes anyone who is involved in the circulation of the product. Partially responsible entities that are not a party to the proceedings can be held liable.

PRODUCT SAFETY

21. What are the main laws and regulations for product safety?

There is no specific legislation addressing product safety but this area is covered by the Consumer Protection Laws (*see Question 1*).

22. Are there general regulators of product safety issues? Are there specific regulators for particular goods or services? Briefly outline their role and powers.

The Consumer Protection Department of each emirate (*see Question 1*) is responsible for consumer safety. These departments have the power to ban goods that are deemed dangerous to the public.

Part four of the Consumer Protection Law lists requirements for suppliers and safety and quality standards for products

There are no specific regulations for particular goods or services in relation to product safety.

The Ministry of Economy has set up a consumer protection hotline and launched a recall website for defective products at:

www.economy.gov.ae/english/Recall/Pages/HealthandSafety.aspx

Product recall

23. Do rules or regulations specify when a product recall is required or how companies should make decisions regarding product recalls and other corrective actions? Are any criteria specified?

Recall procedures must be followed when a justified warranty claim is made by a consumer. Factors to be considered include the likelihood that the defect is inherent in the product and will affect a large batch of the product, and the impact of the threat posed by the defect to the consumer's safety (Article 17 allows the Ministry of Economy to request recalls in this case).

In the event of a recall, the consumer has a right to select a remedy such as replacement, repair or a refund.

24. Are there mandatory advertising requirements for product recalls? Are there other rules governing how a product recall should be conducted?

Regulations require the Ministry of Economy to be given notice of a recall by a supplier within 14 days of the recall. The supplier must also provide the Ministry with the information to include in advertisements in local newspapers to effect the recall. A report must be provided to the Consumer Protection Department on the goods repaired or replaced within 30 days of the recall (*Article 14, Federal Law No. 24 of 2006*).

25. Is there a mandatory obligation to report dangerous products or safety issues to the regulatory authorities?

There is no obligation to report dangerous products to the regulatory authorities on behalf of consumers. However, the Consumer Protection Law requires suppliers to report defective products to the relevant Consumer Protection Department.

26. Is there a specific requirement to provide progress reports and/or keep the authorities updated about the progress of corrective actions? In practice, do authorities expect periodic update reports?

A provider must provide the relevant Consumer Protection Department with a report of the goods repaired or replaced, and the defective parts repaired, within 30 days from the start of the recall process (*Article 14, Federal Law No. 24 of 2006*). The report must include:

- Quantity sold.
- Quantity recalled.
- Quantity of goods repaired, replaced or whose prices have been refunded.
- Procedure to be adopted to avoid such defects.

RECENT TRENDS AND REFORM

27. Are there any recent trends in product liability and safety law? Have there been any recent significant changes or important cases? Are there any legal or procedural issues that are attracting particular interest in your jurisdiction?

Recently, nearly 40,000 Toyota vehicles were recalled in the UAE due to a defect with airbag inflators. This is the largest recall in the UAE automotive industry. The faulty airbags were made by the supplier Takata, and have led to a total of 16 deaths globally so far. Although UAE already uses strict practices to ensure that the products sold on the market are safe to use, this large recall could lead to stricter regulations.

28. Are there any proposals for reform and when are they likely to come into force?

There are no proposals for reform in relation to product liability although the UAE has seen a rise in the regulation of consumer rights due to the establishment of Consumer Protection Departments in all of the Emirates.

Contributor Profiles

Zisha Rizvi, Partner
STA Law Firm
T +971 4 368 9727
F +971 4 369 5126
E corporate@stalawfirm.com
W www.stalawfirm.com

Professional qualifications. LLB (Honours)

Fatima Al Sakkaf, Associate
STA Law Firm
T +971 4 368 9727
F +971 4 369 5126
E corporate@stalawfirm.com
W www.stalawfirm.com

Professional qualifications. LLB

Languages. English, Hindi, Malayalam, Tamil, French, Arabic, Portuguese, and Spanish.

Publications.

- STA's publications are available at *https://www.stalawfirm.com/en/downloads/lists/publications.html*
- STA publishes a monthly blog entitled Court Uncourt, available at *www.stalawfirm.com/en/blogs/lists.html*

Product liability and safety in the UK (England and Wales): overview

Rod Freeman, Sarah-Jane Dobson and Carol Roberts
Cooley LLP

global.practicallaw.com/w-013-0564

SOURCES OF LAW

1. What are the main areas of law and regulation relating to product liability?

The main source of law relating to product liability in England and Wales is Part 1 of the Consumer Protection Act 1987 (Consumer Protection Act). This implements the strict liability regime introduced by EU Directive 85/374/EEC on liability for defective products (Product Liability Directive).

The rights set out for consumers under the Consumer Protection Act are not exclusive of other rights, and persons who suffer damage as a result of defective products may also have rights under common law principles of tort and contract.

Further consumers' rights in relation to defective products are set out by the Consumer Rights Act 2015 (Consumer Rights Act). The introduction of the Consumer Rights Act consolidated many existing laws, and also expanded the authorities' powers and manufacturers' duties.

2. What is required to establish liability under the most common causes of action? When is a product defective? Does strict liability apply in certain circumstances?

The most common causes of action when bringing a claim relating to product liability are:

- Common law action for negligence.
- Breach of contract.
- A claim under the Consumer Protection Act.

Negligence

A claimant who has suffered loss, either personal injury or property damage, as a result of a defective product can bring a claim for negligence against the manufacturer. To establish the manufacturer's liability, the claimant must prove the following four elements, on the balance of probabilities:

- The manufacturer owed them a duty of care.
- The manufacturer breached that duty.
- The breach caused the damage in question.
- The damage was not too remote from the breach.

Contract

A claimant may also be able to bring a claim for breach of contract. This can either be breach of an express contractual term relating to the safety of the defective product or, alternatively, the Consumer Rights Act sets out a list of implied contractual terms when a business sells a product to a consumer including that:

- Goods must be of satisfactory quality.
- Goods must be fit for a particular purpose if that purpose is known to the contracting party.

Consumer Protection Act

Consistent with the Product Liability Directive, the Consumer Protection Act imposes no-fault liability on a producer for damage caused by a defective product. The claimant does not need to prove fault on the part of the producer and all the claimant needs to prove to succeed in a claim under the Consumer Protection Act is that:

- The product was defective;
- The claimant suffered damage; and
- There was a causal link between the defective product and the damage suffered.

When determining if a product is defective for these purposes, section 3 of the Consumer Protection Act states that a product is defective if the safety of the product is not what persons are generally entitled to expect, taking into account the following factors:

- The manner in which, and the purpose for which, the product has been marketed.
- Any instructions for use or warnings.
- What might reasonably be expected to be done with or in relation to the product.
- The time when the product was supplied (that is, a product is not unsafe just because a safer product was subsequently developed, or because industry safety standards were raised after the product was supplied).

There is an increasing body of case law in the UK on the principles for determining a defect in a product for these purposes. For example, the court in Wilkes *v Depuy [2016] EWHC 3096 (QB)* considered the determination of a defect in a product and provided guidance for understanding section 3 of the Consumer Protection Act as it applies to product liability. The key points which came out of this judgment were that:

- The defect in the product must be identified first (rather than identifying the harmful characteristic that caused injury, as was the case in *A v National Blood Authority [2001] EWHC QB 446*).
- The reasonable expectation of safety was an objective test in relation to a consumer's legal entitlement, as opposed to subjective expectation of the consumer or consumers generally.
- The balance of risk and benefit in a product feature was important to take into consideration when deciding whether that feature constituted a defect for the purposes of the Consumer Protection Act.

There is also important case law in relation to liability in negligence for certain diseases (such as mesothelioma) where the exact cause of the arising injury is indeterminable. For example, in *Heneghan v Manchester Dry Docks Limited [2016] EWCA Civ 86* it was held that the appropriate apportionment of liability was to be judged based on the contribution of each defendant to the risk of the disease developing, rather than their actual contribution to the development of the disease. This is a much lower threshold for a claimant to satisfy and makes it difficult for defendants to avoid liability in its entirety.

3. Who is potentially liable for a defective product? What obligations or duties do they owe and to whom?

Under the Consumer Protection Act, liability is imposed on the producer of the product. As specified in the Product Liability Directive, the producer is defined as either:

- The person who either manufactured the product, won or abstracted it, or carried out the process for attributing the essential characteristics of the product.
- An own-brander (a person who holds itself out as the producer by placing its name or trade mark on the product).
- An importer into the EU.

Where there are entities in more than one of the above categories, liability is joint and several, and the claimant can choose to sue one or all of them.

Defences

4. What are the defences to a product liability claim? Is there a time limit in which proceedings can be brought?

There are various defences to a product liability claim including:

- The defendant did not supply the product to another.
- The defect did not exist in the product at the time it was supplied.
- The product was not supplied in the course of business.
- The damage is purely economic.
- The producer could have not reasonably have been expected to discover the defect given the state of scientific and technical knowledge at the time (known as the development risks defence).
- The user had knowledge of the defect.
- The action is time-barred.

An important case in this area is *Howmet Ltd v Economy Drives Ltd & Ors [2016] EWCA Civ 847*, which held that a user's knowledge of the defect in the product before any damage occurred could be used by the producer to exclude liability if the user voluntarily continued to use that product.

The time limit in which proceedings can be brought is set out in the Limitation Act 1980, which stipulates that there is a limitation period of six years for actions in respect of simple contracts and actions in tort occasioning claims for damages other than personal injury. Where damages claimed include damages in respect of a personal injury to the claimant, there is a shorter limitation period of three years from the date on which the cause of action came into existence or the date on which the injured person gained knowledge of the injury.

For Consumer Protection Act claims, the Limitation Act states that the general rule is that a claimant must bring an action against a defendant within three years of either:

- The date on which the cause of action came into existence.
- The date of knowledge of the claimant or of any person in whom the cause of action was previously vested, if earlier.

There are a few exceptions to this general rule (for example, any period in which the person seeking to bring an action was under a legal disability for unsoundness of mind is not counted). However, an absolute long-stop exists of ten years from when the defective product was first put into circulation. Generally, "put into circulation" is accepted to mean when the product is taken out of the manufacturing process and enters a marketing process in which it is offered to the public to be consumed.

Excluding/limiting liability

5. Can a supplier limit its liability for defective products and are there statutory restrictions on a supplier doing this? Do consumer protection laws apply? Are guarantees or warranties as to quality implied by law? Is there a mandatory or minimum warranty period for consumer products?

The general common law position is that a party can limit its liability arising from defective products by including contractual terms that limit or exclude that liability. However, there are several statutory restrictions on the ability of manufacturers to exclude or restrict liability in this manner.

Under section 7 of the Consumer Protection Act, a party is prohibited from limiting or excluding liability for damages arising from a defective product, whether through contractual means, a notice or any other provision.

Similarly, the Consumer Rights Act enforces other statutory restrictions in business-to-consumer contracts, making certain contractual terms statutorily unenforceable. For example, a business cannot exclude liability for their product not being of satisfactory quality or fit for purpose.

More generally, the Unfair Contract Terms Act 1977 (UCTA) precludes businesses from incorporating contractual terms limiting liability that are disproportionately prejudicial to a consumer. This might include making liability dependent on onerous requirements (such as requiring a consumer to report damage within 24 hours). UCTA also prohibits manufacturers from excluding liability for negligence that causes personal injury or death. Exclusion of liability for negligence occasioning property damage is permitted, as long as the exclusion or restriction passes the reasonableness test.

Practical considerations for limiting liability include:

- Implementing an internal quality assurance body.
- Ensuring sufficient warnings are provided with the product, proportionate to the risk the product could present to a consumer.
- Implementing an effective system for any consumer complaints and/or enquiries relating to the product.
- Implementing an effective post-market surveillance procedure so that any risks or potential liabilities with a product are identified early and can be rectified before liability occurs.

The Consumer Rights Act implies certain warranties into any contract between a business and a consumer, including:

- An implied term that the goods supplied under the contract are of satisfactory quality.
- An implied term that the goods supplied are fit for a particular purpose, if that purpose has been made known to the supplier expressly or by implication.

The Consumer Rights Act affords consumers certain minimum statutory warranties, which cannot be contracted out of. For example, consumers are afforded the right to reject the product for a full refund in the first 30 days from taking delivery and ownership of the goods, where the product is unsatisfactory, unfit for purpose or not as described.

Consumers also have the right to require the relevant retailer to repair or replace a defective product within the first six months of the goods being delivered to the consumer. During this time, the onus is on the retailer to prove that the product is not defective. After this period, the onus flips onto the consumer to prove that the product was defective at the time of purchase. If the required attempt at repairing or replacing the product is ineffective, the consumer is entitled to a refund or, if they wish to retain the product, a price reduction.

These rights are subject to them not being unfairly disproportionate on the retailer, or simply impossible to implement. For example, a retailer can replace a defective product rather than attempt to repair it if that is more cost-effective.

Certain sectors also have exceptions to these general statutory requirements. For example, in the automotive industry, manufacturers are entitled to offset any refund against fair use after the first 30 days from purchase have passed.

PRODUCT LIABILITY LITIGATION

6. In which courts are product liability cases brought? Are product liability disputes generally decided by a judge or a panel of judges? Are juries used in certain circumstances?

Product liability cases are heard in the first instance in either the High Court or the County Court depending on the track to which the particular case is assigned. Judges allocate defended claims to one of three procedural tracks at an early stage. These are the:

- Multi-track.
- Fast track.
- Small claims track.

Multi-track claims can be heard in either the High Court or the County Court. However, claims worth less than GB£50,000 that have been commenced in the High Court are generally transferred to a County Court unless there is a specific reason for them to be tried in the High Court (such as a particularly difficult question of law or an unusually great public interest in the outcome).

Fast track and small claims are typically heard in the County Court because the value and complexity of the claims assigned to these tracks are low.

Civil claims are heard by a judge alone in the first instance, but there are multiple judges in any appeal proceedings. Jury trials are not available in product liability cases.

7. How are proceedings started?

Under the English Civil Procedure Rules (CPR), before proceedings are commenced, litigants are strongly encouraged to participate in pre-action exchanges of correspondence and, in some cases, evidence, according to prescribed procedures (pre-action protocols). Failure to comply with these pre-action protocols can have ramifications for the defaulting party and the court can:

- Take the failure to comply into consideration when awarding costs.
- Apply sanctions against the offending party.
- Stay proceedings entirely until there is pre-action compliance.

Following this pre-action phase (assuming no settlement is agreed) proceedings are started by the claimant issuing and serving their claim form (in the prescribed format) on the defendant(s).

8. Who has the burden of proof and to what standard?

The burden of proof is generally on the claimant to prove the elements of the claim. In civil matters, the standard is to prove the case against the defendant on the balance of probabilities. This standard is lower than the criminal standard, which is that the case must be made out beyond all reasonable doubt.

The judgment in *Hufford v Samsung Electronics (UK) Limited [2014] EWHC 2956 (TCC)* showed the threshold that claimants must reach to show that a product was defective under section 3 of the Consumer Protection Act. The claimant could show that a destructive fire began around the product in question but could not prove that the product itself was the catalyst for that fire. The court found in favour of the defendant, as this was deemed to be insufficient evidence to discharge the claimant's burden to show the product was defective.

9. How is evidence given in proceedings and are witnesses cross-examined?

Evidence is given in proceedings in accordance with the CPR, which states that any fact that needs to be proved by the evidence of a witness is to be proved at trial by their oral evidence given in public. Any witness evidence that a party wishes to rely on at trial must have been served in the form of a written witness statement before trial. It is rare for a court to allow new evidence to be orally submitted at trial which was not included in the witness' written statement.

ONLINE RESOURCES

legislation.gov.uk

W www.legislation.gov.uk

Description. Official website containing the Consumer Rights Act 2015, Consumer Protection Act 1987 and General Product Safety Regulations 2005.

PROSAFE

W www.prosafe.org

Description.PROSAFE is a non-profit professional organisation for market surveillance authorities and officers from throughout the European Economic Area. Its primary objective is to ensure consumer safety and promote best practice for manufacturers.

Generally, witnesses are subject to cross-examination.

Any documentary evidence that is intended to be relied on is typically served as an exhibit alongside the relevant witness statement in which it is referred to.

10. Are parties able to rely on expert opinion evidence and are there special rules or procedures for it?

Parties can rely on expert opinion evidence, but only that which is reasonably required to resolve the proceedings. There has been a recent trend for courts to control costs more tightly in relation to expert evidence, as part of a general reform across the civil litigation system.

The CPR sets out the procedure for expert opinion evidence. The expert evidence must be in the form of a written report unless the court directs otherwise. The other side can put written questions to the expert.

In some cases, the court may exercise its power to appoint a single joint expert for both parties.

Experts are expected to be impartial in their analysis and must acknowledge their duty to act independently when preparing their report.

11. Is pre-trial disclosure/discovery required and which rules apply? If not, are there other ways to obtain evidence from a party or a third party?

The CPR provides for pre-trial disclosure in civil proceedings. Standard disclosure requires parties to disclose all documents that:

- They intend to rely on at trial.
- Adversely affect their own case.
- Adversely affect another party's case.
- Support another party's case.

When searching for documentation for disclosure, all parties are under an ongoing duty to perform a reasonable search for any such documentation. The court may also make an order for specific disclosure, either relating to a specific identified document or a category of documents believed to be in the party's control.

12. Is there liability for spoliation of evidence/a remedy for destruction of or failure to preserve evidence (in particular, the product)?

There can be liability for spoliation of evidence. Failure to preserve all potentially disclosable documents when litigation is contemplated can give rise to very serious sanctions, including:

- Costs sanctions.
- The striking out of a party's particulars of claim or defence (or part thereof).
- The drawing of adverse inferences as to the contents of those documents.

13. What types of interim relief are available before a full trial and in what circumstances?

There are a number of interim applications that can be awarded by the court before the full trial, including:

- Applications for interim injunctions to preserve a position.
- Orders for security for costs.

A non-exhaustive list of potential interim remedies can be found in CPR Part 25. There are different thresholds of proof and evidence for each type of interim application, as the severity of the orders fluctuate. A party should always consult the CPR for guidance as to their specific application.

14. Can the successful party recover its costs associated with the litigation, such as legal fees and experts costs and to what extent?

The general principle is that the losing party pays the costs of the successful party. This general principle can be modified in a number of ways in practice. Ultimately, the court has wide discretion as to whether costs are payable by one party to another, the amount of those costs and when they are to be paid.

The civil litigation system has recently been reformed, with the effect that courts are taking an increasingly stringent look at whether costs were reasonably incurred. Those costs the court deems unreasonable will be unlikely to be recoverable.

Generally, the court takes a holistic view of the merits of the case, the conduct of the parties and procedural compliance when making a costs order.

15. What types of appeal are available?

Appellants require permission to appeal a County Court or High Court judgment. The application for permission is generally heard without

an oral hearing (meaning the application is considered solely on the basis of the parties' written submissions) unless the judge deems that the application cannot be fairly heard without an oral hearing.

The appellant must show that the judgment of the court is wrong or unjust because of a serious procedural or other irregularity. A judgment is considered "wrong" for the purposes of an appeal, if it can be shown that there is an error of law, an error of fact or an error in the exercise of the court's discretion. Appeals made on the basis of an error of fact are less common than the other available grounds. Permission to appeal on this ground is rarely granted, as the appellate courts do not interfere with a finding of fact that was open to the first instance court.

Class actions/representative proceedings

16. Are class actions, representative proceedings or co-ordinated proceedings available? If so, what are the basic requirements? Are they commonly used?

While true "class action" proceedings are not available for product liability claims, there are procedural mechanisms available that enable claims to be considered in a grouped fashion. The court can use its broad case management powers to do so, or claims can be consolidated through the issue of a Group Litigation Order (GLO).

Any number of claimants or defendants can be joined as parties to a claim, and these can then be consolidated by the court using its discretion under the CPR. For a party to take part in a consolidated claim, they must show that they have the same interest at all stages of the proceedings and not just at the final date of judgment (*Emerald Supplies Ltd v British Airways plc [2010] EWCA Civ 1284*).

A GLO can also be made where there are several claims that give rise to common or related issues of fact or law. The GLO must:

- Contain directions about the "group register" into which all relevant claims should be placed.
- Specify the GLO issue that identifies any claims that should be managed in the group.
- Specify the court that will manage the claims on the group register.

This means that a judgment on the group register in relation to one or more GLO issues is binding on the parties to all other claims that are in that group.

Litigation funding

17. Is litigation funding by third parties allowed? Is it common? Are contingency fee or no win no fee arrangements allowed?

Third party litigation funding is allowed and is becoming increasingly common in civil litigation in England and Wales following the recent Jackson Reforms. These reforms were the result of a high-level review of civil litigation costs conducted by Lord Justice Jackson, an eminent judge of appeal, in 2009 in response to a perceived spiralling of litigation costs which were increasingly disproportionate to the issues in dispute. Similarly, damage-based agreements and conditional fee arrangements are both permitted under the CPR and are fairly common for impecunious claimants. Full contingency fees are not allowed.

Remedies

18. What remedies are available to a successful party in a product liability claim?

The remedy available to a successful party is limited to compensatory damages only, with very few exceptions. The courts do not generally award punitive damages.

Damages are separated into monetary loss (damage or destruction of property and lost profits) and non-monetary loss (death or personal injury). There are well-established principles for calculating damages (*see Question 19*).

The courts can award exemplary damages where a defendant's conduct has been particularly outrageous.

19. How are damages calculated and are there limitations on them? Are punitive or exemplary damages available and in what circumstances?

The fundamental principle for the calculation of damages in tort is that the claimant should be compensated for the damage caused by the tortfeasor. In other words, the claimant should be restored, as far as is possible, to the position they would have been in had the tort never occurred. These principles are also generally applied in claims under the Consumer Protection Act.

The general principle is similar for a claim grounded in breach of contract, where the claimant should be placed in the same position as if the contract had been performed.

Punitive damages are exceedingly rare, as the general motive behind damages is to compensate the claimant rather than punish the defendant. Punitive damages are reserved for cases involving deliberate torts where the defendant has calculated that the money to be made from the wrongdoing exceeds the damages payable. Punitive damages are not an available remedy for breaches of contract.

20. Is liability joint and several/how is liability apportioned, including where a partially responsible entity is not a party to the proceedings?

In a tortious claim, liability can be joint, several, or joint and several. Parties are considered joint tortfeasors where the cause of action against each is the same (that is, the evidence and facts support the same action against each party) and concurrent tortfeasors where each party is responsible for separate torts but those torts combine to produce the injurious result.

In both of those cases, the tortfeasors are jointly and severally liable, meaning that the defendant can claim the full value of their damages from one of the parties, who may then recover a proportion from all the other tortfeasors. The contribution from each party is determined under the Civil Liability (Contribution) Act 1978 which states that their contribution will be according to what is just and equitable having regard to the extent of their responsibility for the damage in question. Therefore, a party who is only partially responsible for the damage would make less of a contribution to the total damages paid than a party who committed a fundamentally negligent action.

PRODUCT SAFETY

21. What are the main laws and regulations for product safety?

There is a wide range of laws and regulations in the UK governing product safety, most of which derive from EU legislation. Product safety in the UK is mainly governed by the General Product Safety Regulations 2005, which implement Directive 2001/95/EC on general product safety (General Product Safety Directive). The fundamental principle is that a party must only introduce "safe" products to the market, defined as a product that under reasonably foreseeable conditions of use does not present any risk to the consumer, or only minimal risk that is compatible with the nature of the product.

Part II of the Consumer Protection Act also governs product safety and gives the regulatory authorities broad powers to issue sector-specific safety regulations, as well as dealing with aspects of enforcement.

22. Are there general regulators of product safety issues? Are there specific regulators for particular goods or services? Briefly outline their role and powers.

The Department for Business, Energy and Industrial Strategy (BEIS) is responsible for high-level policy and strategy in relation to regulating product safety issues. Day-to-day responsibility for enforcement is delegated to local authorities (although various sectors have their own specific enforcement agencies). Local authorities have a duty to enforce product safety laws in their jurisdiction, which they do through their trading standards departments. Under the General Product Safety Regulations, Part 3, local authorities have broad enforcement powers, which include issuing requirements to warn, and recall notices. They can also enter and search premises, and seize documents or products. The local authorities also liaise with BEIS in making RAPEX (rapid alert system for dangerous non-food products) notifications to the European Commission concerning product defects.

The Consumer Rights Act gives broad powers to local authorities to act using generic consumer law enforcement powers, that allow them to:

- Require information.
- Test equipment.
- Observe the carrying on of business.
- Inspect products.
- Seize and detain goods.
- Issue a withdrawal notice against products deemed dangerous to the consumer, which restricts their import and sale.
- Issue a product recall enforcement notice, on ten days' notice to the relevant manufacturer.

Product recall

23. Do rules or regulations specify when a product recall is required or how companies should make decisions regarding product recalls and other corrective actions? Are any criteria specified?

Manufacturers of consumer products have obligations to conduct corrective actions to deal with unsafe products sold in the UK under the General Product Safety Regulations.

Product recall is considered a last resort. Other corrective measures may suffice, such as a withdrawal from the supply chain, or warnings to consumers.

There is little guidance on how a risk assessment is to be conducted or how a decision to recall is to be taken. BEIS is currently working on a code of practice to provide guidance in this area. There is guidance provided at EU-level to assist manufacturers undertaking corrective actions, including recalls, in accordance with EU directives, UK regulations and European standards. The most relevant guidance is:

- European Commission Guidance on EU general risk assessment methodology.
- PROSAFE Consumer Product Safety in Europe Corrective Action Guide (November 2011).

See *Question 24*.

24. Are there mandatory advertising requirements for product recalls? Are there other rules governing how a product recall should be conducted?

There are no mandatory advertising requirements, or other specific regulatory requirements as to the way in which product recalls should be conducted. However, there is European-level guidance available for businesses seeking to initiate a product recall. PROSAFE is a non-profit professional organisation for market surveillance authorities and officers from throughout the European Economic Area. Its primary objective is to ensure consumer safety and promote best practice for manufacturers. The PROSAFE guidance provides the following suggestions as to what a corrective action announcement should contain:

- A clear heading that draws attention to the announcement containing words such as "Important Safety Warning".
- Product identification details (brand, model, batch number, serial number, bar code, colour, size and a picture or a drawing of the unsafe product).
- A clear description of what is wrong with the product.
- Details of the safety risk or the potential safety risk.
- Information on the type of corrective action proposed and any proposed refund or replacement.
- Clear instructions on how to deal with the product (such as whether and where to bring or send back the product or how to arrange for a repair).
- A website address or hotline for further information.

25. Is there a mandatory obligation to report dangerous products or safety issues to the regulatory authorities?

There is a mandatory obligation to report dangerous consumer products under Article 9 of the General Product Safety Regulations, and under some sector-specific regulations.

If a producer fails to make this notification, they commit an offence under s20(3) of the General Product Safety Regulations. On summary conviction they are liable to imprisonment for a term not exceeding three months or to a fine not exceeding level 5 on the standard scale or to both. Thestandard scale of fines for summary convictions is found in section 37 of the Criminal Justice Act 1982 and goes up to a maximum of level 5, which levies a £5,000 fine against the guilty party.

26. Is there a specific requirement to provide progress reports and/or keep the authorities updated about the progress of corrective actions? In practice, do authorities expect periodic update reports?

The supervision of product recalls is generally left to the discretion of local authorities. In practice, the expectations of the authorities can vary widely. This is a rapidly changing area of the law.

RECENT TRENDS AND REFORM

27. Are there any recent trends in product liability and safety law? Have there been any recent significant changes or important cases? Are there any legal or procedural issues that are attracting particular interest in your jurisdiction?

The question of consumer product safety is very much in the public spotlight in the UK. The focus is mainly on domestic fire risks associated with electrical products, but the implications affect all product sectors. See *Question 28*.

More broadly, the potential impact of Brexit is attracting much comment across all areas of law. Many currently applicable EU regulations concerning product liability and safety will cease to have effect, and will be incorporated into UK law. At the time of writing, the House of Commons was considering the European Union (Withdrawal) Bill and proposed amendments and additions, and so it is unclear at this stage exactly what form that will take. Whether there will be changes to this area of law as a result of Brexit (for example if product safety laws will be amended to be more relaxed or stringent) is yet to be seen. The government is using various steering and working groups comprised of legal experts and industry professionals to guide this transitional period.

28. Are there any proposals for reform and when are they likely to come into force?

In November 2014, the UK government announced that it was launching a review of the UK product recall system. A report was published in February 2016, which eventually led to the establishment of a Recall Review Steering Group. The report of that Steering Group is likely to be published imminently. In addition, a new code of practice for product recalls is currently being produced and will shortly be published.

In the House of Lords, the upper chamber of the UK Parliament, there was discussion regarding proposals for reform on 18 October 2017. The previous year, a prominent consumer campaigner Ms Lynn Faulds Wood was tasked by the Consumer Affairs Minister with chairing an independent review into the UK's product recall system and general product safety framework. Ms Wood's report was published in February 2016, and the House of Lords suggested that the recommendations of Ms Wood should be seriously considered and implemented in the near future. Her report echoed general pressures for a more centralised authority governing the initiation and monitoring of product recalls in the UK, specifically the creation of a national product safety agency or a "centre for excellence" to co-ordinate the entire system. As of yet, the government has not fully implemented her recommendations.

Contributor Profiles

Rod Freeman, Partner
Cooley (UK) LLP
T +44 20 7556 4429
E rfreeman@cooley.com
W www.cooley.com

Professional qualifications. England and Wales, Solicitor

Areas of practice. Product liability, product safety, product compliance, investigations, commercial litigation, consumer products, life sciences, cosmetics, new technologies including IoT and Artificial Intelligence, automotive, sporting goods, machinery, electrical and electronics, chemicals, and asbestos

Recent litigation and transactions

- Representing a Core Participant in a Public Inquiry arising from the Grenfell Tower Fire tragedy in the UK.
- Co-ordinated one of the largest ever global consumer product recalls, involving more than 150 million products across some 60 countries.
- Co-ordinated international defence of product liability claims arising out of the supply of contaminated products used in the pharmaceutical industry.
- Retained as advisor to OECD Consumer Policy Committee on liability issues arising from new technologies.

Professional associations/memberships:

- International Consumer Products Health and Safety Organization (Director).
- Product Liability Advisory Council (US).
- International Association of Defense Counsel.
- Defense Research Institute.
- Product Liability Forum – British Institute of International and Comparative Law.

Sarah-Jane Dobson, Associate
Cooley (UK) LLP
T +44 20 7556 4432
E sdobson@cooley.com
W www.cooley.com

Professional qualifications. Queensland, Australia, Solicitor

Areas of practice. Product liability, product compliance, investigations, commercial litigation, life sciences, cosmetics, medical devices, new technologies (IoT, artificial intelligence), automotive, sporting goods, machinery, electrical and electronics, chemicals.

Recent litigation and transactions

- Representing a Core Participant in a Public Inquiry arising from the Grenfell Tower Fire tragedy in the UK.
- Manages international portfolios of consumer claims against pre-eminent global manufacturers.
- Representing a pre-eminent manufacturer in respect of criminal investigations into alleged product safety issues under UK product safety legislation.
- Co-ordinates some of the largest international product recalls in the world, including those involving consumer electronics, cosmetics and toys.

Languages. French, German

Professional associations/memberships:

- International Association of Defense Counsel.
- International Bar Association.
- Defense Research Institute.
- Product Liability Forum – British Institute of International and Comparative Law.
- International Consumer Products Health and Safety Organisation.

Publications. Monthly product safety article in the *Product Safety Letter* publication since May 2016.

Contributor Profiles

Carol Roberts, Associate
Cooley (UK) LLP
T +44 20 7556 4226
E croberts@cooley.com
W www.cooley.com

Professional qualifications. England and Wales, Solicitor

Areas of practice. Product compliance, product liability, commercial litigation, retail and consumer products

Recent litigation and transactions

- Advising a number of leading companies with the launch of innovative consumer-electronic products.
- Advising a global company on international product compliance requirements in respect of a new product roll-out.
- Advising a number of global companies on multi-jurisdictional product recalls.
- Advising a global company on the impact of new European proposals for market surveillance and enforcement.

Languages. French

Professional associations/memberships. British Institute of International and Comparative Law.

Product liability and safety in the United States: overview

Kenneth Ross and Ted Dorenkamp
Bowman and Brooke LLP

global.practicallaw.com/w-012-8129

SOURCES OF LAW

1. What are the main areas of law and regulation relating to product liability?

Product liability law in the US is an amalgam of state and federal laws and the common law, which makes it difficult to clearly describe the law and legal requirements for importers, manufacturers and product sellers.

For product liability, most of the US law is common law that has developed in each state. It is court-made law and is based on prior case law from the trial courts and appellate courts. Some product liability law was first established in the common law and then adopted or modified by state legislatures in state laws. Some state legislatures first adopted product liability laws in their state despite the lack of case precedents on which to base their statutory law.

Through this process, the law has developed differently in the various states. Therefore, the key to determining an entity's potential responsibility for an injury or damage is first knowing which state law applies.

There is generally no federal product liability common law. It is viewed as a matter for each state to establish as it is local law that affects state residents and companies that sell into each state.

There are federal laws that affect product safety and three main government agencies that deal with it: the Consumer Product Safety Commission, the National Highway Traffic Safety Administration, and the Food and Drug Administration. The Congress passes laws that create pre-sale and post-sale product safety responsibilities for various entities and then the agencies pass regulations to implement these laws. Violation of these laws and regulations can result in fines and lawsuits by the agencies against manufacturers and product sellers. The fines and lawsuits can adversely affect pending or future product liability cases.

2. What is required to establish liability under the most common causes of action? When is a product defective? Does strict liability apply in certain circumstances?

The original theory of liability in product liability cases is negligence. In negligence cases the injured party must prove:

- There was a defect in the product that caused the plaintiff harm.
- The product was defective when it left the hands of the manufacturer or product seller.
- The defect was brought about through the defendant's negligence.

The original basis for proving a defect was the consumer expectations test. This test allowed a consumer to say that the product was more dangerous than they expected and that this caused their injury. The result was that many cases were brought against manufacturers and attorneys believed that proving their case would be fairly easy.

However, this test was criticised as being too vague and not providing much guidance to manufacturers or juries. The risk-utility test was therefore developed in the 1970s, which was adopted by many courts and, in 1998, was incorporated into the new Restatement of Torts 3d: Product Liability (Restatement), a leading source for the description of product liability law as it existed in 1998 and for the development of product liability law in the future.

Under the risk-utility test, there are various relatively clear factors that the jury can use to decide if the product is defective or not. These factors allow the jury to weigh the risks in the product against the ability of the manufacturer to reduce the risks. This test is viewed as making it harder for plaintiffs to recover because the manufacturer can defend itself by saying that it made the product as safe as necessary or as possible. Therefore, even if the product was more dangerous than the plaintiff realised, the manufacturer may prevail.

The risk-utility test, which originally applied to strict liability, is very close to negligence as it allows a manufacturer's conduct or fault to be considered. As a result, in the states that have adopted risk-utility, there has arguably been a merging of the concepts of strict liability and negligence.

Today, the majority of states use the risk-utility test. The Restatement adopted risk-utility and rejected consumer expectations. However, there are some states that still use the consumer expectations test. In those states, they still talk about negligence and strict liability as separate theories of liability.

In most lawsuits, the plaintiff sues for both negligence and strict liability. As the case progresses through discovery, they may drop one of these theories as they can affect the type of evidence that may be admissible into court during a trial.

3. Who is potentially liable for a defective product? What obligations or duties do they owe and to whom?

Any entity in the supply chain can be liable for a defective product. This includes the raw material supplier, component part supplier, finished product manufacturer, distributor, retailer and maybe a company that does the installation or delivery of the product.

The obligations and duties are complex as they are dependent on where the entity is in the supply chain. The raw material supplier may have obligations and duties under a contract with the component part supplier. Therefore, they have no direct obligations and duties with the finished product manufacturer or the product seller or consumer.

The finished product manufacturer has contracts with its immediate suppliers of components and its immediate purchasers. However, there can be multiple tiers of suppliers and sellers where each relationship has different contractual requirements. Therefore, identifying the exact obligations and duties in any given situation is very fact specific.

Product liability law in the US abolished the necessity of privity of contract and therefore the injured party can sue any entity in the supply chain directly. Despite that, various procedural rules and contractual rules will help to determine which entity in the supply chain is ultimately responsible. However, a jury can hold everyone who has been sued jointly liable and then the defendants can determine which entity pays what amount (*see Question 20*).

Defences

4. What are the defences to a product liability claim? Is there a time limit in which proceedings can be brought?

The primary defence to product liability claims (strict liability, negligence and breach of warranty) is lack of causation. These claims usually centre around design or manufacturing defect, failure to adequately warn or instruct, and breach of implied and express warranties related to product safety. The thrust of a lack of causation defence is that the product is not defective, but even if defective, the defect was not the proximate cause of the injury. Similarly, even if product warnings are defective in failing to sufficiently warn, causation does not exist where a plaintiff failed to read them.

The theory of liability dictates the available defences, often as a matter of state law. Negligence claims evaluate the conduct or fault of a defendant. As a defence, a defendant can raise a plaintiff's conduct, for example product misuse, as having caused or contributed to the injury by asserting contributory or comparative negligence. Intervening negligence of third parties can also be a defence. As strict liability typically does not evaluate the conduct of a defendant, but rather simply whether the product is defective, defences in some states are narrower than with negligence claims.

Defences to breach of implied and express warranty claims include lack of notice to the defendant of the claim prior to filing the lawsuit, and some states permit the defence of lack of privity of contract between the injured plaintiff and the defendant. Additionally, statutes of limitation and statutes of repose impose restrictions on the time within which a claim must be brought. Statutes of limitations and repose vary by state, and vary by claim. For example, in some states a plaintiff must bring a strict liability case within four years of the injury but has six years within which to bring a negligence claim. Some states have enacted statutes of repose that impose absolute limits on the time frame for asserting any product liability claim.

Excluding/limiting liability

5. Can a supplier limit its liability for defective products and are there statutory restrictions on a supplier doing this? Do consumer protection laws apply? Are guarantees or warranties as to quality implied by law? Is there a mandatory or minimum warranty period for consumer products?

There are many ways a manufacturer can reduce or limit its liability for injury, damage and loss resulting from selling defective products. A finished product manufacturer buys components to incorporate into its products. Through the contract, it can achieve some protection against liability when the component supplier is negligent or sells a defective component or the wrong component for the finished product; the buyer or manufacturer wants to use warranties and indemnification clauses given by the component part supplier to protect itself.

The manufacturer is also a seller of a finished product. In this role, they also want to use the contract with their purchaser to protect themselves or limit their liability. They want to provide a reasonable warranty and then include warranty disclaimers and limitation of liability clauses to put some cap on their potential liability.

For the product itself, there are a multitude of techniques that are meant to reduce the chance that the product has a manufacturing defect, design defect or defect in warnings and instructions. Quality assurance programmes help with manufacturing defects. Risk assessment and other safety evaluations help reduce the risk of design defects and defects in warnings and instructions.

The goal is to anticipate risks from intended use and reasonably foreseeable misuse, and then design and manufacture a product that results in reasonable risks. Warnings and instructions can be given for residual risks that cannot be designed out.

PRODUCT LIABILITY LITIGATION

6. In which courts are product liability cases brought? Are product liability disputes generally decided by a judge or a panel of judges? Are juries used in certain circumstances?

Product liability lawsuits can be brought in either state or federal court depending on the (state) citizenship of the parties and the amount and nature of damages at issue. Product liability and its related negligence causes of action are constructs of state law. If the case is commenced in state court, a state court judge will preside over the case and will rule on evidentiary issues in accordance with state substantive and procedural law. The parties may request a trial by jury or by the presiding judge. A federal district court may have jurisdiction where the lawsuit involves a plaintiff and defendant that are citizens of different states. In that case, the federal court will follow the state substantive law and federal procedural law. As in state court, the parties may request a trial by jury or a bench trial by the presiding judge. Typically, federal district judges preside over the conduct of the trial and hearings involving evidentiary issues. An appointed magistrate judge will preside over hearings involving discovery and other pre-trial matters, and may preside over trials by consent of the parties.

7. How are proceedings started?

A case is typically commenced by filing a complaint in state or federal court (*see, for example, Federal Rules of Civil Procedure 3*). In some states, a case officially commences with the formal service of the complaint on a defendant or by publication. In those states, procedural rules ordinarily require the plaintiff to file the complaint with the court within a certain period of time, for example within one year after service on the defendant.

8. Who has the burden of proof and to what standard?

The plaintiff has the burden of proof, which means that he must produce evidence of the product's liability. When the plaintiff presents evidence, the burden of production shifts to the defendant to present evidence that contradicts or answers the plaintiff's evidence.

The plaintiff has the burden of persuasion to prove the defendant's guilt in a civil case by a preponderance of the evidence, meaning that for the jury or judge to find in favour of the plaintiff, they must conclude based on the evidence presented that it is more likely than not that the defendant's product is defective and caused the plaintiff's injuries. In some states that allow punitive damages in product liability cases, the plaintiff has a heightened burden of persuasion and must demonstrate entitlement to punitive damages by clear and convincing evidence.

9. How is evidence given in proceedings and are witnesses cross-examined?

Evidence can be testimonial, opinion, real or demonstrative. Evidence can be presented through live testimony of witnesses or qualified expert witnesses, can be read into the record or can be judicially noticed by the court (*see Federal Rules of Evidence 201; 601*). A party's witnesses can be cross-examined by the opposing party. However, the scope of cross-examination is generally limited to the subject matter of the direct examination and to issues bearing on the credibility of the witness (*see Federal Rules of Evidence 611*).

10. Are parties able to rely on expert opinion evidence and are there special rules or procedures for it?

Expert opinion is often required in product liability cases where the subject matter is beyond the layperson's common knowledge and experience. In federal court, an expert must be qualified as an expert in the subject matter, the opinion must be helpful to the determination of the issues, and must be based on sufficient facts or data. The opinion must also be the product of reliable principles and methods, and it must be applicable to the facts of the case (*see Federal Rules of Evidence 702*). Additionally, the facts and data on which the expert opinion relies must be of the kind that would be reasonably relied on by experts in the subject matter (*see Federal Rules of Evidence 703*). The court acts as a gatekeeper to the admissibility and scope of expert opinion testimony. Consequently, before presenting the opinion to the trier of fact, the court will evaluate:

- Whether the theory or technique can be (and has been) tested.
- Whether the theory or technique has been subjected to peer review and publication.
- The known or potential rate of error.
- Whether there are applicable standards.
- Whether the theory has been generally accepted.
- Any other factor that can bear on the reliability of the expert opinion.

(See *Daubert v Merrell Dow Pharmaceuticals, Inc, 509 US 579 (1993); Kumho Tire Co v Carmichael, 119 SCt 1167 (1999); General Elec Co v Joiner, 522 US 136 (1997)*). Some states apply slightly different expert admissibility criteria, most notably as it relates to novel scientific evidence or non-scientific evidence, with a focus on general acceptance and foundational reliability.

Federal court rules generally require that an expert retained to provide expert opinions prepare a report that must be disclosed 90 days before trial or as set out in the court's pre-trial scheduling order (*see Federal Rules of Civil Procedure 26(a)(2)(D)*). The expert's report must contain a complete statement of opinions and bases for them, facts or data relied on, describe exhibits that will be used to summarise or support the opinions, a description of the witness' qualifications with a list of publications, a list of prior testimony and a billing summary (*Federal Rules of Civil Procedure 26(a)(2)(B)*). Witnesses that a party intends to provide expert testimony at trial but who are not specially retained, such as employees of a party (for example, engineers, accountants, and so on) or treating physicians, need not provide a report, however, the party must disclose the subject matter on which the witness will testify and a summary of facts or opinions (*Federal Rules of Civil Procedure 26(a)(2)(C)*). Generally, expert opinions must be disclosed in the expert's report, rebuttal report (if permitted) or during the expert's deposition. The expert will be prohibited from testifying as to any undisclosed opinion at trial. State court rules may differ insofar as some do not require preparation of any expert report, and some do not permit the expert to be deposed prior to trial absent special circumstances.

11. Is pre-trial disclosure/discovery required and which rules apply? If not, are there other ways to obtain evidence from a party or a third party?

Federal Rules require parties to exchange initial disclosures shortly after the commencement of a lawsuit (*see Federal Rules of Civil Procedure 26(a)*). Under this rule, each party must identify witnesses, disclose documents, electronically stored information (ESI) and tangible things the party will use to support its claims or defences, a description of damages, and whether there is any applicable insurance coverage. In usual cases, parties can subsequently serve requests for production or inspection (of documents, ESI and tangible things), written interrogatories, requests for admission and requests for mental or physical examination on other parties (*see Federal Rules of Civil Procedure 33 to 36*). Additionally, parties can perpetuate or obtain testimony through depositions (*see Federal Rules of Civil Procedure 30 to 31*). Parties must also make expert disclosures in accordance with applicable court orders and in any event under Federal Rules of Civil Procedure 26(a)(2). Parties must also disclose trial witnesses and evidence in accordance with applicable court orders and in any event under Federal Rules of Civil Procedure 26(a)(3). For evidence in the possession, custody or control of third parties, any party can

obtain testimony and production by subpoena under Federal Rules of Civil Procedure 45. Most state courts operate under similar rules. The exception ordinarily is for expert witness disclosures, which are often not required before trial. Additionally, state courts have limited jurisdiction to issue subpoenas.

12. Is there liability for spoliation of evidence/a remedy for destruction of or failure to preserve evidence (in particular, the product)?

Spoliation is the intentional destruction, mutilation, alteration or concealment of evidence. The duty to preserve evidence begins when litigation is pending or reasonably foreseeable. Destroying or failing to preserve information that is relevant to the lawsuit is spoliation. Sanctions for spoliation vary depending on state law. In some states an adverse inference jury instruction is warranted in cases of intentional or even negligent spoliation of evidence. The instruction may be that they (jurors) are to presume that the lost or spoliated evidence, if produced, would have been detrimental or unfavourable to the party who destroyed or lost the evidence. In federal cases, spoliation is generally defined by state law, however, federal law will control what inference can be drawn from that spoliation. Sanctions can range from dismissal of a plaintiff's claims or striking of a defendant's defences, to an adverse inference or some lesser sanction depending on the gravity of the harm.

13. What types of interim relief are available before a full trial and in what circumstances?

Apart from procedures to perpetuate testimony and secure evidence, a product liability plaintiff must litigate through to the conclusion of the matter, whether by settlement or trial, to obtain relief or an enforceable judgment. Procedural mechanisms can allow the defence to obtain relief (dismissal) through a motion to dismiss or motion for summary judgment.

14. Can the successful party recover its costs associated with the litigation, such as legal fees and experts costs and to what extent?

Generally, each side pays its own attorney's fees and costs in the absence of a statutory or contractual provision providing otherwise (*Key Tronic Corp v United States, 511 US 809 (1994)*). However, the prevailing party in a trial can recover certain costs, such as court filing fees, copies, transcripts, expert, witness and interpreter fees (*see Federal Rules of Civil Procedure 54(d); 28 USC § 1920*). The prevailing party is loosely defined as the party who prevails on the significant issues of the case. Costs must be reasonably necessary to the case or related to the trial proceeding, rather than simply investigative. Recoverable costs include those associated with witness travel and lodging for trial, provided they are at the most economical rate. In some states, attorney's fees and costs may be recoverable to the prevailing party in limited circumstances, such as in actions under certain consumer protection statutes, or in actions determined to be frivolous.

15. What types of appeal are available?

Appeal from a civil trial judgment and interlocutory appeals are available from state and federal court proceedings. Court decisions prior to judgment, for example on motions to dismiss or for summary judgment that do not dispose of the case entirely, or certain orders given during discovery, may be subject to an interlocutory appeal (*see 28 USC § 1292(b)*). A party can also seek a writ of mandamus for interlocutory rulings. A party may seek interlocutory appeal where the decision involves a controlling question of law that is critical to the outcome of the case, and that cannot be reasonably addressed on a standard appeal after judgment. Federal rules permit appeal of decisions granting or deny class certifications (*Federal Rules of Civil Procedure 23(f)*). An appeal is typically a claim that the lower court erred in an evidentiary or legal ruling. An appellate court reviews a trial court's evidentiary rulings on an abuse of discretion standard, while reviews of rulings regarding a point of law will be reviewed de novo. Appellate courts typically empanel three judges for an appeal. A party may petition the appellate court for an en banc hearing of the entire appellate court.

Class actions/representative proceedings

16. Are class actions, representative proceedings or co-ordinated proceedings available? If so, what are the basic requirements? Are they commonly used?

Class actions are available under either state or federal law in which one or more class representatives sue on behalf of a class of persons similarly situated. Federal Rules allow class actions only if the class is so numerous that joinder of all members is impracticable, where there are questions of law or fact common to the class, where the claims or defences of the representatives are typical of the class, and where the court finds the representative parties will fairly and adequately protect the interests of the class (*Federal Rules of Civil Procedure 23(a)*). The party seeking class certification must also demonstrate that "questions of law or fact common to the members of the class predominate over any questions affecting only individual members" and that the class action is "superior to other available methods for the fair and efficient adjudication of the controversy" (*Federal Rules of Civil Procedure 23(b)*). A party seeking class certification must affirmatively demonstrate compliance with each element in this rule (*Wal-Mart Stores, Inc v Dukes, 564 US 338 (2011)*). Individuals falling within the class must usually affirmatively opt out if they wish to preserve their individual cause of action. Settlements usually require court approval. Class action product liability litigation has become more common in recent years. However, because issues of causation and damages in personal injury claims are usually personal to the individual plaintiff, class certification is often denied. Class actions are a preferred method to recover economic damages.

Personal injury plaintiffs can opt for a mass tort action where pre-trial matters are consolidated and a few of the individual cases are selected to be bellwether trials, that is, cases usually selected by agreement of the lead counsel for both parties or the court as being exemplary of the parties' respective claims and defences. The intention is that the outcome of these bellwether trials will inform the parties on likely outcomes of future trials on these claims and issues and facilitate resolution of the other cases short of trials. Mass tort actions brought in state court can be removed to federal court and consolidated under the Class Action Fairness Act (*see 28 USC § 1332(d)(11)*). Federal statutes also provide a mechanism to co-ordinate or consolidate several cases pending in different federal districts in one judicial district where all pre-trial matters are conducted (multi-district litigation) (*28 USC § 1407*).

ONLINE RESOURCES

Consumer Product Safety Commission (CPSC)

W www.cpsc.gov

Description. This is the website of the CPSC, which has extensive information on reporting requirements and corrective action programmes.

Food and Drug Administration (FDA)

W www.fda.gov

Description. This is the website of the FDA, which has extensive information on reporting requirements and corrective action programmes.

National Highway Traffic Safety Administration (NHTSA)

W www.nhtsa.gov

Description. This is the website of the NHTSA, which has extensive information on reporting requirements and corrective action programmes.

Product Liability Prevention

W www.productliabilityprevention.com

Description. This website contains over 90 articles written by Kenneth Ross on most of the issues involved in product liability, product safety, regulatory compliance and product liability prevention. There is also a page on this website devoted to online resources in this area.

Litigation funding

17. Is litigation funding by third parties allowed? Is it common? Are contingency fee or no win no fee arrangements allowed?

Rules applicable to third-party financing of lawsuits have relaxed in recent years and it is now generally permissible in the US. However, litigation financing presents risks to the protections afforded by the attorney-client relationship and under the rules of professional conduct. The more common and preferred method of financing product liability lawsuits is through contingency fee agreements, where counsel will receive a percentage of the recovery as fees, in addition to costs. Contingency fee arrangements are generally governed by each state's rules of professional conduct.

Remedies

18. What remedies are available to a successful party in a product liability claim?

Remedies available in product liability lawsuits vary by state and are generally compensatory in nature, which typically include pecuniary loss (economic damages, including medical expenses, lost wages and earning capacity) and non-pecuniary (pain and suffering, loss of consortium, counsel, aid and comfort). Many states impose statutory caps on recovery of certain damages, like loss of consortium or pain and suffering. Plaintiffs can also recover punitive or exemplary damages, although the standard for showing entitlement to these damages is much greater than for product defect or negligence. In some states a plaintiff is prevented from asserting a claim for punitive damages in the initial complaint, but must file a motion showing prima facie evidence of the defendant's malice or deliberate disregard for safety. If the court approves the motion, a plaintiff can usually include a punitive damages instruction to the jury. In most cases, punitive damages can be obtained only where the plaintiff proves the defendant's malicious or deliberate disregard by clear and convincing evidence.

19. How are damages calculated and are there limitations on them? Are punitive or exemplary damages available and in what circumstances?

See *Question 18*.

20. Is liability joint and several/how is liability apportioned, including where a partially responsible entity is not a party to the proceedings?

Each state has its own product liability statutes, including statutes that govern joint and several liability, comparative fault or contributory negligence, and apportionment of liability. In pure comparative fault jurisdictions, a plaintiff's damages will be reduced by the percentage of fault that is apportioned to the plaintiff. In other jurisdictions, a plaintiff cannot recover anything if his percentage of responsibility for the injury is greater than the percentage of fault attributed to the alleged product defect.

Many states have abolished or limited joint and several liability as part of larger tort reform efforts. The doctrine allows a solvent defendant only minimally at fault to bear the full burden of judgment where the tortfeasor to whom the major portion of fault was attributable is either insolvent or unavailable. Even in jurisdictions retaining joint and several liability, its liability can only extend to economic damages. In other jurisdictions, a defendant is jointly and severally liable only where a jury has found its fault greater than 50% of the total, or, if its fault is less than 50%, where its fault is aggregated with a co-defendant's fault with a finding of common enterprise for a total combined fault of greater than 50%. In many jurisdictions, particularly those that have abolished joint and several liability, a jury can only allocate liability to an empty chair (for example, settled defendant, employer immune from suit under workers' compensation laws, or unavailable third party) non-party that a jury determines caused or contributed to the alleged injury or damages.

PRODUCT SAFETY

21. What are the main laws and regulations for product safety?

Product safety is governed by the common law of product liability unless there is a government agency or state law that provides additional requirements.

Industrial products (mostly products used in a workplace by employees or workers) have no government agency that dictates safety requirements directly imposed on manufacturers. The Occupational Health and Safety Administration (OSHA), however, has requirements for employers for the machinery used in a workplace.

For workplace machinery, most of the product safety requirements for manufacturers come from safety standards issued by industry groups made up of the manufacturers of such products. US manufacturers also pay attention to the requirements of Directive 2006/42/EC on machinery, and amending Directive 95/16/EC (recast). The machinery directive was subsequently amended by Directive 2009/127/EC with regard to machinery for pesticide application.

Most other products have a government agency that has some safety requirements that must be complied with before sale. Consumer products are governed by the Consumer Product Safety Commission (CPSC). Food is governed by the Food and Drug Administration (FDA) and the Department of Agriculture (USDA). Drugs and medical devices are governed by the FDA and motor vehicles of all types driven on public roads and accessories such as trailers are governed by the National Highway Traffic Safety Administration (NHTSA). Boats and other products used on the water are governed generally by the Coast Guard (USCG) and airplanes are governed by the Federal Aviation Administration (FAA).

The FDA has many safety requirements and, with some complex products, undertakes pre-sale analysis and testing of the medical devices before the manufacturer is authorised to start selling the product. The FDA also pays very close attention before sale to the quality and efficacy of drugs and the safety of food.

The NHTSA has a number of safety standards that must be complied with by vehicle manufacturers. However, these standards are not comprehensive and there are many more industry standards that provide safety requirements.

The CPSC has a number of safety regulations that must be complied with. However, unlike the FDA, the CPSC does not generally inspect or test or evaluate the safety of consumer products before they are sold. Their focus is much more on requiring consumer product manufacturers to report safety problems to them after sale and undertaking a corrective action programme to fix the problem.

The CPSC's laws and regulations do not define the term consumer; it is basically anyone who is not working at a business location. Therefore, a product can be deemed a consumer product if it subjects consumers to some risk, even though that person did not buy or is not using the product. A bystander who is subjected to a risk of harm by a consumer product is protected by the laws and regulations of the CPSC.

22. Are there general regulators of product safety issues? Are there specific regulators for particular goods or services? Briefly outline their role and powers.

See *Question 21* for a list of US regulators.

There are also state regulators in those states that have product safety related laws and regulations. Most of these agencies can force the manufacturer to stop selling its product and recall it. All of these agencies can issue safety regulations for products under their jurisdiction. The regulations and ability to enforce them differ from agency to agency. It is generally up to the people administering the agency as to how stringent they are on issuing and enforcing regulations. As people change in the agencies depending on which political party is in charge of Congress and the Presidency, the level of activity can change from year to year.

Product recall

23. Do rules or regulations specify when a product recall is required or how companies should make decisions regarding product recalls and other corrective actions? Are any criteria specified?

Each of the three main agencies have regulations concerning when a manufacturer or product seller has a duty to report a safety issue to them (*see Questions 21 and 22*). These regulations are significantly different between agencies. The Consumer Product Safety Commission mainly focuses on whether the product has a defect that can create a substantial product hazard. The National Highway Traffic Safety Administration focuses on whether the vehicle has a safety related defect. The Food and Drug Administration requirements differ significantly between drugs and medical devices and food.

The reporting requirements and the determination of an appropriate corrective action are based on an assessment of current and future risk, that is, whether there is a risk of a serious injury or death to someone using the product or being near the product. The definition of defect varies from agency to agency and the acceptable or unacceptable probabilities of harm are also different with different products in the same agency.

Each safety issue is complex and very fact specific. Therefore, whether to report and whether to recall the product or perform some other corrective action is very dependent on many factors and it is up to the manufacturer and the agency to negotiate a plan that makes sense given the risks.

24. Are there mandatory advertising requirements for product recalls? Are there other rules governing how a product recall should be conducted?

There are rules on what kinds of public notices are necessary, which depend on future risk to consumers and the ability of the company to identify who bought the recalled product.

For example, with consumer products, the usual method of announcing a recall is through a press release issued by the Consumer Product Safety Commission (CPSC) and then putting up posters in stores. In most situations, the consumer is not known. In some circumstances, where serious accidents have occurred and continue to occur, the CPSC may want the company to take out paid advertising and issue a second press release. In addition, the CPSC may issue a video news release and possibly have a news conference. Where the product was sold through a membership warehouse store, that store knows what products were purchased by their members and they can send them an individual letter informing them of the recall.

With medical devices, there are usually direct letters to doctors informing them of the safety recall. If consumers are using the device at home, there could be a press release or a letter to the consumer if they can be identified. With motor vehicles, the car manufacturers can obtain the list of registered owners of the cars to be recalled and can directly send them a letter.

There have been many serious food recalls and the injuries can be significant. If there is a food recall, the distribution patterns will be analysed by the Food and Drug Administration (FDA), and the food distributor and retailer will have to quickly implement an appropriate recall strategy that is acceptable to the FDA.

25. Is there a mandatory obligation to report dangerous products or safety issues to the regulatory authorities?

See *Questions 21* to *24*.

The triggers are different, and the time frames are different (*see Question 24*). There are no obligations on manufacturers of industrial or commercial products used in a workplace to report safety issues to a government agency. Other than those products, virtually every other product has a government agency that has jurisdiction over safety issues.

There are many examples of fines issued by these agencies against manufacturers and product sellers for failing to report or for reporting and providing incomplete or inaccurate information to the government agency.

The Consumer Product Safety Commission (CPSC) has a relatively low limit for fines, although the limit has recently been raised. In 2016, the CPSC levied a fine of more than US$15 million that concerned multiple violations. The Food and Drug Administration levied a fine in excess of US$10 million that also concerned multiple violations. The National Highway Traffic Safety Administration levied a fine of US$200 million against Takata, the airbag manufacturer, in 2015.

26. Is there a specific requirement to provide progress reports and/or keep the authorities updated about the progress of corrective actions? In practice, do authorities expect periodic update reports?

The Consumer Product Safety Commission (CPSC) requires monthly reports for an unspecified time. They can be submitted for around nine to 18 months depending on the number of returned products each month. If the returns are minimal, the CPSC will close the file and not require monthly reports with the understanding that the manufacturer must report any new serious incidents or injuries indicating an increase in the risk.

The National Highway Traffic Safety Administration requires quarterly reports for six quarters. The Food and Drug Administration requires monthly reports specific to the risk and recall results.

RECENT TRENDS AND REFORM

27. Are there any recent trends in product liability and safety law? Have there been any recent significant changes or important cases? Are there any legal or procedural issues that are attracting particular interest in your jurisdiction?

Product liability lawyers and scholars have considered new technology developments and made suggestions as to application of the law. The new technology includes autonomous vehicles, internet of things, 3-D printers and drones. There have been very few, if any, cases involving these products; however, it is still mostly an open question as to how safe these products must be and what duties a manufacturer of such products has.

The regulatory agencies have been adjusting to the change in political administrations. The likelihood is that the adoption of new safety regulations will significantly slow down and that enforcement of the existing regulations will somewhat lessen. Therefore, the threat of fines and other civil actions should be less in the foreseeable future.

On the litigation front, most of the significant litigation has involved a series of cases involving the same product and how the courts will efficiently resolve them. Cigarettes, asbestos, drugs, food and medical devices are the prominent series of cases that the courts are struggling with. The courts are also trying to deal with class actions that do not involve any injury. Questions abound on the certification of the class action and how to determine damages when no injury has occurred, and how to resolve the cases.

Many individual cases continue being litigated in state and some federal courts around the US, and there have been few significant opinions that would change the way in which some cases will proceed and be resolved. Unlike past years, the scope of product liability law and litigation is not really expanding.

28. Are there any proposals for reform and when are they likely to come into force?

See *Question 27*.

There have been some proposed laws and enacted laws in individual states that affect the product safety of products sold in these individual states. Most of them pertain to the types of chemicals allowed in certain products, especially toys, and what limits for those chemicals may be imposed on the manufacturers. As the federal government lightens the burden on manufacturers, or at a minimum does not impose significant new burdens, it can be expected that some states in the US will enact their own product safety regulations. Whether these are legal is still an open question as manufacturers cannot sell different products in each state and therefore these state-wide regulations impose a burden on manufacturers who sell products nationally.

Contributor Profiles

Kenneth Ross, Of Counsel
Bowman and Brooke LLP
T +1 952 210 2212
E kenrossesq@gmail.com
W www.productliabilityprevention.com

Professional qualifications. California, Missouri, Minnesota and Utah and many federal courts.

Areas of practice. Product liability, product safety, and regulatory compliance.

Non-professional qualifications. Juris Doctor degree, 1973

Professional associations/memberships. American Law Institute; Defense Research Institute; International Consumer Product Health and Safety Organization.

Publications. Authored dozens of articles on product liability, product safety and regulatory compliance. Many of these articles can be accessed at *www.productliabilityprevention.com*.

Ted Dorenkamp
Bowman and Brooke LLP
T +1 310 525 6633
T +1 310 719 1019
E ted.dorenkamp@bowmanandbrooke.com
W www.bowmanandbrooke.com

Professional qualifications. California, Minnesota, Wisconsin and several federal courts.

Areas of practice. Product liability, product safety, and regulatory compliance.

Non-professional qualifications. Juris Doctor degree, 2000

Languages. English, Japanese

Professional associations/memberships. Defense Research Institute; International Consumer Product Health and Safety Organization; Association of Southern California Defense Counsel.

Publications. *The Rise of Commercial Drones, Emerging sUAS Manufacturer Concerns*, For the Defense Research Institute, Inc (December 2016) (most recent article).

CONTACT US

THOMSON REUTERS
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EMAIL: **info.practicallaw@thomsonreuters.com**

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INTERNATIONAL CO-ORDINATORS

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ROD FREEMAN

CALL: **+44 20 7556 4429**

EMAIL: **rfreeman@cooley.com**

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