

PANORAMIC

# PRODUCT LIABILITY

Italy



LEXOLOGY

# Product Liability

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# Contents

## Product Liability

### CIVIL LITIGATION SYSTEM

- The court system
- Judges and juries
- Pleadings and timing
- Pre-filing requirements
- Summary dispositions
- Trials
- Group actions
- Timing

### EVIDENTIARY ISSUES AND DAMAGES

- Pretrial discovery and disclosure
- Evidence
- Expert evidence
- Compensatory damages
- Non-compensatory damages
- Other forms of relief

### LITIGATION FUNDING, FEES AND COSTS

- Legal aid
- Third-party litigation funding
- Contingency fees
- 'Loser pays' rule

### SOURCES OF LAW

- Product liability statutes
- Traditional theories of liability
- Consumer legislation
- Criminal law
- Novel theories
- Product defect
- Defect standard and burden of proof
- Possible respondents
- Causation
- Post-sale duties

### LIMITATIONS AND DEFENCES

- Limitation periods
- State-of-the-art and development risk defence
- Compliance with standards or requirements

Other defences  
Appeals

## **SETTLEMENT AND ALTERNATIVE DISPUTE RESOLUTION**

Settlement  
Alternative dispute resolution

## **JURISDICTION ANALYSIS**

Status of product liability law and development  
Product liability litigation milestones and trends  
Climate for litigation  
Efforts to expand product liability or ease claimants' burdens

## **UPDATE AND TRENDS**

Emerging trends

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## CIVIL LITIGATION SYSTEM

### The court system

#### What is the structure of the civil court system?

The rules governing the civil process in Italy have been substantially modified by Legislative Decree No. 149 of 10 October 2022, which is generally referred to as the 'Cartabia Reform' (from the name of the Ministry of Justice who promoted the same).

The changes introduced by the Cartabia Reform came into effect on 28 February 2023 and apply to all civil proceedings that began after that date, thus as of 1 March 2023 (except for certain amendments for which the same Cartabia Reform provided otherwise). Civil proceedings already pending at the time continued being governed by the rules previously in force.

This guide will focus on the current framework of civil proceedings as structured following the enactment of the Cartabia Reform.

In Italy, there are three levels of courts: first-instance courts (justices of the peace and tribunals); second-instance courts (courts of appeal for judgments rendered by tribunals and tribunals for judgments rendered by justices of the peace); and the Court of Cassation (Supreme Court).

The justice of the peace has jurisdiction over legal actions up to the value of €10,000 and over proceedings related to damages caused by trafficking vessels or vehicles up to the value of €25,000. In accordance with another recent reform, starting from 31 October 2025, both of these thresholds will be raised respectively to €30,000 and €50,000. In addition to this, the justice of the peace also has jurisdiction over some specific subject matters. Cases filed with the justice of the peace in which the amount claimed is less than €1,100 may be decided 'according to principles of equity'. In these cases, the justice of the peace may depart from the rules of law provided that the principles of the legal system are respected. Starting from 31 October 2025, the relevant threshold will also be raised to €2,500.

Tribunals have first-instance jurisdiction over all cases not expressly allocated to other courts, including class actions and second-instance jurisdiction over decisions issued by the justices of the peace.

Courts of appeal have first-instance jurisdiction over some specific matters and second-instance jurisdiction over the challenge of decisions issued by tribunals.

Decisions issued by courts of appeal can in turn be challenged before the Court of Cassation, which is at the top of the Italian judicial hierarchy. It is the court of last resort and its task is to ensure the consistent interpretation and application of the law. The Court's review is limited to issues regarding the interpretation and correct application of the law, as the Court does not review any assessment of facts made in first and second instance proceedings.

In class action proceedings, orders of second instance ruling over the admissibility of the class cannot be further challenged before the Court of Cassation.

**Law stated - 30 luglio 2024**

## Judges and juries

### What is the role of the judge in civil proceedings and what is the role of the jury?

Italy relies upon an adversarial judicial system.

Juries are not contemplated in civil proceedings in Italy. Ordinary civil proceedings of first instance are held by single judges, whereas class action proceedings of first instance are held before tribunals, ruling in a panel of judges. Appeal proceedings are held before courts of appeal, ruling in panels. The proceedings before the Court of Cassation are also held by a panel of judges.

The judge is tasked with ruling on the parties' requests based on the evidence they have submitted. The judge governs the proceedings, setting out the dates for the hearings and the terms for the parties to perform judicial activities (eg, filing briefs, submitting evidence). They are not bound to apply the law identified by the parties.

**Law stated - 30 luglio 2024**

## Pleadings and timing

### What are the basic pleadings filed with the court to institute, prosecute and defend the product liability action and what is the sequence and timing for filing them?

In Italy product liability actions are governed by the same rules set forth by the Italian Code of Civil Procedure for ordinary proceedings.

A case begins with the plaintiff's writ of summons, which includes all the claims against the defendant. In the writ of summons, the plaintiff must clearly state, inter alia, the kind of relief sought (namely, claim for compensation for damage) and the facts and points of law supporting the claim. The plaintiff shall serve its counterparty with the writ of summons.

The defendant's first pleading (statement of defence), whereby appearance is entered in the proceedings, must include any defence arguments and must clearly and specifically challenge any fact or point of law indicated by the plaintiff to support the claims. By such brief, the defendant also has to submit the counterclaim, join third parties in the proceedings or raise any 'strict' objection (ie, any objection, procedural or on the merits, that cannot be raised by the judge ex officio) if they intend to do so (this is in fact the only opportunity for the defendant to do so). This brief must be filed within the mandatory term of 70 days before the first hearing indicated in the writ of summons.

After the 70-day time limit for the defendant's appearance has elapsed, the judge has a term of 15 days to issue a decree by which, inter alia, they verify the regularity of the adversarial procedure and establishes the date of the first hearing of appearance, confirming or postponing the date indicated by the plaintiff in the writ of summons.

Prior to this hearing, the parties have terms to file additional defensive briefs, namely:

- 40 days before the first hearing to lodge a first brief to propose the claims and exceptions that are a consequence of the counterclaim or the exceptions proposed by the defendant or the third party in their statements of defence, as well as to specify

or modify the claims, exceptions and conclusions already proposed, or even to join a third party in the proceedings;

- 20 days before the first hearing to file a second brief in reply to counterparty's first brief and submit means or requests for evidence; and
- 10 days to file a third brief in reply to counterparty's second brief and to indicate contrary evidence.

The parties must appear in person at the first hearing. At the hearing, the judge shall question the parties to obtain the necessary clarifications regarding the case and attempt conciliation. If the plaintiff, by reason of the content of the counterparty's statement of defence, has timely requested that a third party be called in the proceedings and the judge authorises the call, a new first hearing shall be set from which the time limits for the additional defensive briefs as indicated above shall be recalculated. If the judge does not order the postponement of the first hearing, after unsuccessfully attempting conciliation, there are two possibilities: either the judge rules on the evidentiary requests or they deem the case ready for the decision.

If ruling on the evidentiary requests, the judge shall set the schedule of hearings to carry out and complete evidence-gathering activities. When the evidentiary activities are completed and the judge finally deems the case ready for decision, the judge shall set a further hearing and shall assign the parties terms for specifying their conclusions, namely: (1) a term not exceeding 60 days before that hearing for the filing of notes aimed at specifying the conclusions; (2) a further term not exceeding 30 days before the hearing for the filing of closing statements; and (3) a term not exceeding 15 days before the hearing for the filing of reply briefs. At this hearing, the case enters the very final phase, where a decision has to be made.

**Law stated - 30 luglio 2024**

### **Pre-filing requirements**

#### **Are there any pre-filing requirements that must be satisfied before a formal lawsuit may be commenced by the product liability claimant?**

There are no general pre-filing requirements to begin a formal, ordinary lawsuit for product liability; though some specific rules exist.

In the case of claims relating to the payment of any amount between €1,100 and €50,000, before litigating in court, parties to a dispute must attempt to carry out negotiations in the presence of their attorneys at law to try to amicably settle their dispute (assisted negotiation). This is a condition for the admissibility of the legal claim and the plaintiff must necessarily indicate in their writ of summons that they have fulfilled the burdens required to comply with it. Such a procedure is not mandatory if the dispute concerns agreements entered into by professionals and consumers.

**Law stated - 30 luglio 2024**

### **Summary dispositions**

## Are mechanisms available to the parties to seek resolution of a case before a full hearing on the merits?

Under Italian law, several alternative dispute resolution mechanisms are available to the parties before starting litigation in court. Reference is made in particular to assisted negotiation and mediation.

In the case of claims relating to the payment of any amount between €1,100 and €50,000, before litigating in court, parties to a dispute must attempt to carry out negotiations in the presence of their attorneys at law to try to settle their dispute amicably (assisted negotiation). Such a procedure is not mandatory if the dispute concerns agreements entered into by professionals and consumers.

Mediation is a procedure by which the parties charge a third and impartial subject (usually a professional mediator appointed by conciliatory bodies) with the task of trying to find an amicable solution to the dispute. In the specific field of product liability, it is not compulsory by law to make an attempt to reach an out-of-court settlement as a pre-filing requirement. However, the plaintiff can, in any event, try to use this procedure as a way to attempt to reach an amicable agreement with the adverse party before starting litigation.

There are no mechanisms of summary dispositions available once proceedings are initiated.

**Law stated - 30 luglio 2024**

## Trials

### What is the basic trial structure?

Italian civil proceedings can be broadly divided into three phases:

- introductory phase: this is to assess the formal and procedural regularity of the proceedings, with regard to the parties (relevant legal standing and powers), the jurisdiction of the court seized (and all the other procedural issues that may prevent the case from reaching the subsequent phase) and to set the content of the case. The court examines the requests for evidence and grants the requests it deems appropriate;
- evidentiary phase: the evidence admitted by the court is gathered, witnesses are examined and experts appointed by the judge render their opinions; and
- decision phase: this includes the evaluation of the collected evidence and of the arguments submitted by the parties. This leads to the final decision.

There is no distinction between pretrial and trial phases, which is typical of the common law system. The same judge presides over all three phases of the proceedings, which are not formally divided. The judge sets the dates for the hearings, checks that there are no procedural flaws, rules on the requests of the parties, appoints experts and conducts and oversees the evidence-gathering activities up to the final decision. Only the judge can question witnesses; however, they pose questions that have been previously submitted by the parties and that they have already approved.

Proceedings are not public; access to court files is not permitted to third entities that are not a party to the proceedings. Nonetheless, hearings held for discussion of the case are open to the public. Further, the decision is publicly available.

**Law stated - 30 luglio 2024**

### **Group actions**

**Are there class, group or other collective action mechanisms available to product liability claimants? Can such actions be brought by representative bodies?**

Class actions as a mechanism to seek damage compensation for product liability have been effective in the Italian legal system since 1 January 2010 in relation to wrongful events that have occurred since 15 August 2009. On 3 April 2019, the Italian Parliament approved a bill of law for a reform of this procedural tool. The bill was converted into Law No. 31 of 12 April 2019 and the new rules governing class actions came into force on 19 May 2021. These new rules only apply to damaging conduct put in place on the date of or after the entry into force of the reform. For all other cases, the previous rules continue to apply.

Under the previous set of rules, class actions can be started by any single consumer as a class representative, as well as by associations or committees appointed by one or more consumers, to request compensation for damage or reimbursement in favour of consumers in the event of unlawful behaviour damaging a plurality of persons, including cases of product liability.

Class actions consist of two phases: a first stage in which the admissibility of the class action is assessed and a second stage dedicated to determining liability and damage. An essential condition for admissibility is homogeneity of the rights claimed by the members of the group. Once the court, ruling in panel, declares the action admissible, the order attesting the admissibility of the class action is made publicly known, being the action based on an opt-in system.

In the case of a positive outcome of the class action, the decision of the court can either be a direct condemnation of the respondent, ordering it to compensate the damages in the amount liquidated by the same decision, or set the criteria to be used to calculate the amount to be paid to the class members, possibly establishing the minimum amount to be paid to each consumer. In this second case, the assessment of individual damages can be referred to a subsequent settlement or litigation.

The reform significantly modified the nature and functioning of class actions. First, class actions can now also be started by associations or committees independently (ie, also if they have not been appointed by a consumer to do so). Further, class actions became a general remedy that is available not only to consumers but to everyone claiming compensation for the violation of 'homogeneous individual rights'. Thus, business-to-business disputes can also be litigated by a class action.

The new class action now consists of three phases: the first is for the assessment of the admissibility of the class; the second is dedicated to the decision on the merits of the case; and the third – newly established by the reform – is for evaluation of the requests for opting

in and the quantification of the sums due to the members of the class. This last phase is managed by a Delegated Judge.

Further to this, some major novelties were introduced by the reform:

- opt-in is also permitted after the publication of the decision ruling on the case and the establishment of the liability of the defendant;
- courts' powers in the field of evidence are enhanced;
- following the decision that ruled on the merits of the case, the court appoints a common representative of the class members who is in charge of preparing a distribution project for the class members, taking a position on each individual request; and
- the unsuccessful respondent must pay the common representative and the plaintiff's attorney a 'reward fee', set as a percentage of the total amount due to the members as compensation.

This last point is one of the most highly debated aspects of the reform; in fact, the business community is concerned that the reward fee may result in punitive damages and that the high amounts involved may render class action – as in the United States – a relevant money-making business. Another important novelty brought by the reform is the introduction of an IT platform dedicated to class actions within the Telematic Services Portal of the Ministry of Justice. Through this platform, whose aim is to facilitate and encourage the recourse to class action by class members, it is now possible to access the court files of class actions and analyse the relative documentation, including court orders. Moreover, the requests to opt in the class action can now be filed by class members within the court file of the class action registered on this platform. This novelty simplifies the process for opting in the class action as pursuant to the rules applicable to the previous class action scheme, the request to opt in had to be filed within the clerk's office of the competent court.

Further, Italian law also provides for the possibility of a representative action being brought by consumers' associations, but for the protection of the collective interests of consumers. By this kind of action, consumers' associations may seek injunctive or declaratory relief, by requesting the court to order the concerned business to refrain from conduct harming the interests of consumers and to adopt measures to remove the prejudicial effects of previous conduct. These procedures have also been extended to other matters in addition to consumer matters and have been made available to all individuals.

Lastly, it should be noted that Legislative Decree No. 28 of 10 March 2023, implementing EU Directive 2020/1828, introduced the so-called 'representative action'. The new legislative provisions apply as of 25 June 2023.

This action differs from the class action governed by the Code of Civil Procedure in that its scope of application is limited to the protection of the collective interests of consumers for violations only of specific provisions contained in European Union regulations and acts transposing the relevant directives.

More specifically, 'collective interests of consumers' are those arising from violations of the regulations and directives listed expressly in Annex I of the Legislative Decree No. 28 of 10 March 2023 (among the many subjects listed are product liability for defective products, unfair terms in consumer contracts, air carrier liability in the carriage of passengers and their luggage, indication of prices of products offered to consumers sale and guarantees of

consumer goods, electronic commerce, code relating to medicinal products for human use, general product safety, electronic communications code, food safety and unfair commercial practices).

Representative actions may have a domestic or cross-border nature, depending on whether the state of standing of the plaintiff coincides with the state in which the action is initiated. Only entities specifically authorised to do so can initiate the representative action, even in the absence of a consumer mandate. Legitimate entities are those included in a special list to be kept by the Ministry of Enterprise and Made in Italy, which is responsible for verifying the requirements for legitimacy and communicating this list to the European Commission by 26 December 2023.

The action can be brought against any natural or juridical person, regardless of whether it is a public or private entity, and its aim is to obtain injunctive relief or compensatory relief for the violation of consumer rights.

With regard to the injunctive protection, the plaintiff may apply to the court to obtain the cessation or prohibition of the omissive or commissive conduct that breaches the rights of consumers and in the publication of the order in newspapers. The court may also issue indirect coercive measures, setting a deadline for the fulfilment of the established obligations with provision for payment of a sum of money for each day of delay.

As for compensatory protection, it is aimed at remedying the injury suffered by payment of a sum of money, by repair, replacement, termination of the contract or by reduction or refund of the price. Before the case is settled, the parties may file a settlement or conciliatory proposal and the court may invite the parties to reach a settlement.

**Law stated - 30 luglio 2024**

### **Timing**

**How long does it typically take a product liability action to get to the trial stage and what is the duration of a trial?**

The average length of ordinary first instance proceedings, which rules also govern product liability actions, ranges from one and a half to three years or more, depending mainly on the complexity of the evidence-gathering activity needed and on the workload of each individual court.

**Law stated - 30 luglio 2024**

## **EVIDENTIARY ISSUES AND DAMAGES**

### **Pretrial discovery and disclosure**

**What is the nature and extent of pretrial preservation and disclosure of documents and other evidence? Are there any avenues for pretrial discovery?**

The law sets forth a duty to preserve documents for companies and professionals in the event of litigation. The extent of such duty may vary depending on the nature of the documents concerned.

Formal US-style discovery, by which each party can access its counterparty's entire internal documentation, does not exist in Italy. Once the proceedings have started, any party can ask the judge to order the counterparty or any third party to file specific documents within the court.

In addition, the judge may order the parties to the proceedings or any third party to subject themselves to inspections on their own persons or on goods that are in their possession, if this is deemed necessary to assess the facts under dispute and if such inspections can be put in place without serious detriment to the parties or third parties concerned.

Should one of the parties fail to comply with the judge's order of exhibition without a valid reason to do so, or refuse to allow the judge's inspections order, the judge may infer arguments from such conduct to rule on the case and sentence the same party to a fine from €500 to €3,000. In the case the third party fails to comply with the relevant order, the judge may also issue a fine against it in the range between €250 to €1,500.

Very limited pretrial activities are allowed for procuring evidence (witnesses, ascertainment over the status of goods, technical experts) prior to the beginning of proceedings. In general terms, this possibility is limited to cases where there is a particular matter of urgency or a risk of not being able to procure the same evidence later on.

**Law stated - 30 luglio 2024**

## **Evidence**

### **How is evidence presented in the courtroom and how is the evidence cross-examined by the opposing party?**

In the Italian civil law system, considerable weight is given to written evidence. The basic principle is that oral testimony is allowed in cases where documents are either unavailable or unreliable.

With regard to oral testimony, when submitting their requests for evidence the parties must also include a list of people to be called to testify, along with the list of questions that could be submitted to them. The judge rules on the admissibility of both witnesses and questions. Witnesses can only testify as to factual circumstances and cannot express personal evaluations.

Witness statements are given verbally at the hearings, under oath. The parties are not entitled to question the witnesses directly and no formal cross-examination exists; it is only the judge who questions the witnesses while the parties can suggest questions to the judge. Written witness statements in the form of depositions are admissible, albeit within strict limits depending on the nature of the matter, the agreement of the parties and the discretionary evaluation of the judge.

The parties to the proceedings cannot be heard as witnesses. Upon request of the counterparty, however, each party, or its legal representative in the case of a legal person, can be summoned for a 'formal examination'. Formal examination is a kind of evidence,

aimed only at achieving a confession. Also, in this case, the party can be questioned only by the judge and on the questions previously approved. The party cannot be forced to appear, but if they fail to appear or refuse to answer, the judge can consider the facts to which the questions relate as admitted.

Moreover, the court can order the parties to appear to question them informally (free examination). During a free examination the party is not bound to answer and the statements rendered are not considered as technical evidence.

Formal and free examinations are not used often, because the examination is not under oath and a possible lie would not be punished as perjury as the party is not – technically – a witness (principle of 'privilege against self-incrimination').

A party's 'oath' is a sworn statement affirming that one or more of the alleged facts are true. It is taken only upon the request of the opposite party and the party requested to take the oath may also ask the other party to do the same. The oath, when taken, provides 'legal' evidence and conclusive proof of the facts. On the contrary, when the party requested to take the oath refuses to do so or fails to appear, the relevant facts are regarded as established. In practice, oaths are rarely used.

The court can rely only upon evidence provided by the parties and must refrain from personally investigating facts deemed relevant to the case. Nonetheless, the judge enjoys several ex officio powers with regard to evidence-gathering activities: they are entitled to appoint one or more experts to ground their decision on facts or circumstances of general knowledge and to call as witnesses persons referred to by other witnesses during their testimony. The judge may ground their findings on certain particular items of evidence and disregard other items, provided that a logical and detailed explanation for this is given in the decision.

**Law stated - 30 luglio 2024**

### **Expert evidence**

#### **May the court appoint experts? May the parties influence the appointment and may they present the evidence of experts they selected?**

When the case requires specific technical knowledge, the judge may appoint, also upon a party's request, one or more technical experts (CTUs) to act as the judge's assistants and provide their technical opinions.

The CTU is selected from among experts included in lists filed in court. Otherwise, should the expert to be appointed not be included in these lists, the authorisation of the court president is necessary. The parties can oppose the appointment of the CTU on proper grounds, such as risk of partiality and bias.

The CTU cannot make legal assessments, establish the existence of legal provisions, assess documentary evidence or provide evidence of the facts at issue in lieu of the parties. Their role is strictly limited to answering the technical questions posed by the court. Each party can appoint its own retained expert (CTP) to work together with the CTU.

The results of the CTU's expertise are put in writing. The CTU submits a preliminary draft report to the CTPs, who can reply within a given period with their observations and remarks.

The process ends with the filing of a final report by the CTU, including comments on or remarks to the CTPs' notes. The CTU can be summoned to the hearing to explain the outcome of their activity or to reply to the questions raised by the lawyers and by the parties' experts.

It is the judge's duty to evaluate the findings of all experts. The judge may disagree with the conclusions reached by the CTU, as long as they provide adequate grounds for this disagreement in their decision.

Even if the court does not appoint a CTU, the parties may appoint retained experts who can draft technical reports to be submitted to the court as exhibits in the case. In addition, the parties can ask the court to hear their retained experts as witnesses.

**Law stated - 30 luglio 2024**

## **Compensatory damages**

### **What types of compensatory damages are available to product liability claimants and what limitations apply?**

Any damage, including pecuniary and non-pecuniary damage, suffered by the injured party is recoverable. As a general remark, product liability claims can be raised to seek compensation for personal damage, as well as for damage to objects normally used for private purposes and damaged by defective products.

For decades, case law and scholars have made reference to four categories of compensable damage:

- economic damage, consisting of monetary damages (pecuniary loss incurred or loss of profits); and
- non-economic damage, namely:
  - biological damage: damage to the physical or psychological integrity of a person, directly related to their health;
  - moral damage: non-pecuniary damages (pain and suffering), which can be awarded only in the cases provided for by law (mainly in cases involving criminal offences); and
  - existential damage: this is a category of non-pecuniary damage 'created' by case law to compensate damage not covered by the moral damage category. The category can cover any event that negatively affects 'quality of life'.

By a standout ruling of 2008, the Joint Sections of the Court of Cassation stated that non-pecuniary damage is compensable only in the cases provided for by law, namely in two sets of cases: cases in which compensability is expressly acknowledged (eg, in cases in which the tort is characterised by elements that make it amount to a criminal offence); and cases in which, although compensability of such kind of damage is not expressly provided for by any legal provision, the tort seriously prejudiced a personal right that is directly protected by the Constitution (Judgment No. 26972 of 2018). Based on this decision, damage defined as 'existential' is practically no longer compensable as an autonomous

category of damage, but as a subcategory of the wider category of non-economic damage, so as to avoid duplications of compensable damages.

In Italy, decisions, even from the Supreme Court, do not constitute binding precedents and have only a persuasive effect on judges having to rule on similar cases. In recent years, however, the trend of both high and lower courts has been to follow the above interpretation. After almost a decade, the same principles have been reaffirmed by the Court of Cassation (Judgment No. 30997 of 2018, subsequently confirmed by Judgments Nos. 16153 of 2021, 8622 of 2021, 4099 of 2020 and 13786 of 2024), which clarified once again that non-pecuniary damage is a sole category of damages, including all prejudices to personal constitutional rights.

The damage may also be proved on the basis of mere presumptions, but the damaged person still has to allege the factual elements from which the existence and the extent of prejudice may be gathered.

It is up to the judge to quantify the compensable damages to be awarded to the damaged party, based on the evidence submitted to the court. As to the quantification of non-economic damage, the most recent court practice has been to base the assessment in this regard on tables setting forth criteria for such quantification depending on several objective elements, as provided for by tables drafted by some Italian courts (mainly the Milan and Rome Court) (Judgment No. 10335 of 2023).

**Law stated - 30 luglio 2024**

### **Non-compensatory damages**

#### **Are punitive, exemplary, moral or other non-compensatory damages available to product liability claimants?**

Italian law does not allow for punitive damage to be awarded in the fields of product liability and tort liability. Compensation is allowed only as restoration of damage actually suffered; in accordance with Italian traditional legal theories, any damage not aimed at fully compensating the injured party for distress actually suffered (ie, punitive or exemplary damages) is not permitted. Some scholars and some legal provisions, in specific areas, are anyway to some extent in support of allowing damages that are not strictly compensatory.

In 2017, the Court of Cassation, without any intention of introducing such a feature into the Italian legal system, conceded a slight opening in favour of 'punitive damages' (Judgment No. 16601 of 2017). This opening was, however, limited to a very specific case, that is to say, recognition in Italy of a foreign judgment ordering the losing party to pay 'punitive damages'. By its decision, the Court of Cassation clarified that punitive damages are not, per se, incompatible with the Italian legal order and with the nature and function of tort liability under Italian law. The Court found that when the award of punitive damages is included in a foreign judgment issued in accordance with the foreign national law, and the Italian judge is called to enforce such judgment, punitive damages are not incompatible with national public policy. The principles of law affirmed in this judgment were most recently confirmed by the Court of Cassation (Judgment No. 6723 of 2023), which upheld the recognition in Italy of a Danish judgment ordering the losing party to pay 'punitive damages'.

For completeness, when the judge orders the losing party to the proceedings to do something, upon request of the adverse party they can also provide for a penalty for any subsequent violation of such an order and for any delay in complying with the order. The judge evaluates at their discretion whether this penalty is appropriate given the specifics of the case. The judge determines the amount of the penalty on the basis of the value of the dispute, the nature of the obligation that is the subject matter of the order, the damage that may be suffered by the winning party if the aforesaid obligation is not performed and any other relevant facts. This is in fact an additional penalty that may be inflicted on the party that fails to voluntarily perform their obligations under the court order.

Law stated - 30 luglio 2024

### Other forms of relief

#### May a court issue interim and permanent injunctions in product liability cases? What other forms of non-monetary relief are available?

The Italian Code of Civil Procedure provides for different kinds of interim measures, which can also apply to product liability cases. In general, the parties may apply for an interim measure both *ante causam* (ie, before ordinary proceedings) and during the proceedings to ensure that their rights are not affected by the duration of the proceedings. For example, the parties may apply to a court asking for a seizure over movable or immovable assets; for a measure of preventive investigation, which can be issued to ensure evidence-gathering when there is the risk that this evidence becomes unavailable in the future; or for any urgent measure that may be needed from time to time, based on a case-by-case analysis. The court releases the interim measure if the applicant proves that their claims will likely be admitted at the end of the proceedings and that there is an actual risk that the right they want to safeguard might be irreparably undermined by the duration of the proceedings.

With regard to other forms of non-monetary relief, Italian law provides for specific actions aimed at safeguarding the interests of consumers (eg, inhibitory action). Accordingly, consumers and consumers' associations in accordance with the rules governing class actions introduced in Italy by Law No. 31 of 12 April 2019, as well as entities specifically authorised to initiate representative actions in accordance with Legislative Decree No. 28 of 10 March 2023, are entitled to take action to protect the collective interests of consumers and users by applying to the court and asking it to:

- prohibit acts and conduct that are detrimental for the interests of consumers and users;
- take appropriate measures to correct or eliminate the harmful effects of the infringements established; and
- order the publication of the measure in one or more national or local newspapers where publicity for the measure may help to correct or eliminate the effects of the infringements established.

Moreover, with reference to agreements concluded between consumers and professionals, consumers' associations may apply to a court asking to prohibit the use of the general terms and conditions included therein if these terms and conditions are considered to

be detrimental to the interests of consumers. Before applying to a court, consumers' associations may initiate a conciliation procedure to settle the dispute.

Law stated - 30 luglio 2024

## LITIGATION FUNDING, FEES AND COSTS

### Legal aid

**Is public funding such as legal aid available? If so, may potential defendants make submissions or otherwise contest the grant of such aid?**

An indigent party can access legal aid, provided that the claim is not clearly groundless. To obtain legal aid, the party must file an application to the local bar association. Thereafter, the court before which the proceedings are pending may revoke the legal aid if the income of the party is found to be above the threshold set forth by the law, or if it finds that the requirements provided by the law are lacking or that the party has acted or defended itself with malice or gross negligence. Legal aid includes lawyers' fees and any other costs linked to the case. When legal aid is granted, some of the costs are anticipated by the state and others are waived. Legal aid is, however, not widely resorted to, because of its limitation in admissibility and because – in general – litigation in Italy is not particularly expensive.

Law stated - 30 luglio 2024

### Third-party litigation funding

**Is third-party litigation funding permissible?**

Generally, third-party litigation funding is permissible but not very common. Nonetheless, relevant developments are expected in this regard because some important international funders are becoming active in Italy.

Law stated - 30 luglio 2024

### Contingency fees

**Are contingency or conditional fee arrangements permissible?**

Contingency or conditional fees have become admissible some years ago. Accordingly, legal fees can be agreed as a percentage of the value of the claim filed to court. Such agreements must be made in writing. In any case, if the agreement sets out that the lawyer is paid with a portion or percentage of the award, this agreement is still prohibited.

Law stated - 30 luglio 2024

### 'Loser pays' rule

**Can the successful party recover its legal fees and expenses from the unsuccessful party?**

The court's final decision also awards costs. As a general rule, the losing party has to pay both the expenses and the fees incurred by the winning party; however, this does not mean that the winner will certainly recover all the relevant amounts. As a matter of fact, the court does not liquidate the effective costs incurred by the winning party, but determines them on the basis of certain – quite restrictive – criteria as established by law. In accordance with these criteria, fees are calculated with regard to the value of the claims and the activities carried out by the lawyers in each and every phase of the proceedings (ie, study of the case, introductory, evidence-gathering and ruling phases; and the enforcement procedure).

The court may also (wholly or partly) set off the expenses between the parties under certain conditions; that is, when:

- it assesses that the costs to be reimbursed to the winning party are excessive or superfluous;
- all the parties are losing under some aspects of the final decision;
- there are serious and exceptional reasons to do so; and
- the case regards a new matter that has never been decided before by case law or the final decision departs from case law, establishing a principle that revises or overrules what had been established until then by the case law.

In any event, irrespective of the outcome of the proceedings, the court may order one of the parties that, by its conduct, breached its duty of loyalty and probity in the same proceedings to reimburse to the other party the costs borne as a consequence of the same proceedings. According to Cartabia Reform, the judge may also issue a fine against said party due to its conduct, ranging between €500 and €5,000.

Courts frequently deem it not appropriate for a company to recover costs against losing individuals.

**Law stated - 30 luglio 2024**

## SOURCES OF LAW

### Product liability statutes

#### Is there a statute that governs product liability litigation?

EU Directive 85/374/EEC on product liability was implemented in Italy in 1988 by the Product Liability Act, as amended by Legislative Decree No. 25 of 2001 (PLA). The PLA was, to a certain extent, supplemented by Legislative Decree No. 115 of 1995, which implemented the European Directive 92/59/EEC (as amended by Legislative Decree No. 172 of 2004, which in turn implemented European Directive 2001/95/EC, which introduced general obligations on product safety), imposing an obligation on manufacturers and producers to withdraw unsafe products from the market. All the above acts were subsequently incorporated into the Consumer Code, enacted in 2005 (Legislative Decree No. 206 of 2005).

In general terms, the provisions of these acts were conceived as a response to the difficulties that consumers had been facing in seeking damages caused by a defective product by relying on the 'traditional theories of liability', namely in contract or in tort; the former, in fact, implies that the action must be laid against the party that the consumer had signed a

contract with (usually the seller), while the latter implies the fault of the manufacturer, which has to be proven by the consumer.

On the contrary, the EU Directive and the Consumer Code have set forth a new kind of liability, which is strict, not fault-based, and can be claimed directly against the manufacturer, regardless of the existence of a contract between the latter and the consumer or user.

The provisions of the Consumer Code only apply to those products that are not covered by other sector-specific legislation (eg, toys, food, machinery and pharmaceuticals). The Consumer Code also complements the provisions of sector-specific legislation, where the latter does not cover certain matters.

**Law stated - 30 luglio 2024**

## **Traditional theories of liability**

### **What other theories of liability are available to product liability claimants?**

Further to the provisions of the Consumer Code, claimants may consider claiming compensation on the basis of tort or contract liability, or both. In particular, it is very common for the consumer to submit both a claim for product liability and, alternatively or subordinately, a claim for general tort liability in relation to the same events.

Tort liability is based on the 'duty of care' concept. The main rule in this regard establishes that: 'Any person who wilfully or negligently commits an act causing another party to suffer unjust damage shall be required to pay compensation for such damage'. Additionally, the Italian legal system provides for a strict liability regime, based on a presumption of liability, on subjects who perform a 'dangerous activity', so that 'whoever has caused injuries to others while performing dangerous activities (defined as dangerous by their nature or because of the type of instruments used to perform them), is required to pay compensation, if he or she is unable to prove that all measures that would have been suitable to avoid any injury have been adopted'. The presumption of liability exempts the injured party from the burden of proving the fault of the allegedly liable party. Therefore, if the claim in question concerns a product that is dangerous in itself, owing to its inner nature (eg, gas cylinders, fireworks), the consumer may consider filing an action on rules concerning liability for dangerous activities. Nonetheless, based on the case law of the Court of Justice of the European Union and of the Italian courts, the applicability of the rules on product liability derived from EU law to cases of damage caused by the use of a product would exclude the possibility to apply another kind of strict liability regime to the same case, such as the above-mentioned rules on liability for dangerous activities.

Contractual liability, based on the breach of an obligation undertaken by one of the parties, relies on the general rule according to which, in the event of non-performance or imperfect performance of the contract (which includes the supply of a defective product), the seller and the lessor are liable to the buyer, leaseholder or user, unless they can prove that non-performance was due to facts beyond their control. For contractual liability, compensation is limited to reasonably foreseeable damages at the time of entering into the contract.

**Law stated - 30 luglio 2024**

## Consumer legislation

### Is there a consumer protection statute that provides remedies, imposes duties or otherwise affects product liability litigants?

The Consumer Code entered into force in 2005 to consolidate all the different provisions concerning consumers already in force in Italy.

Part IV of the Consumer Code sets forth provisions on liability for defective products. Part V deals with consumers' associations and access to justice, including class actions. In this regard, Law No. 31 of 2019, which came into force on 19 May 2021, reformed the previous rules governing class actions and collective actions, which are now regulated by articles 840-bis – 840-sexiedecies of the Code of Civil Procedure. However, the new sets of rules only apply to claims regarding damaging conducts that occurred on the date of or after the entry into force of the reform. In this part, new provisions regarding representative actions have been included as a result of Legislative Decree No. 28 of 10 March 2023, which implemented Directive EU 2020/1828.

**Law stated - 30 luglio 2024**

## Criminal law

### Can criminal sanctions be imposed for the sale or distribution of defective products?

Pursuant to the Consumer Code, it is the manufacturer's duty to ensure that products placed on the market are safe. Further, the Consumer Code grants the power to the relevant authorities to monitor the safety of products and to order or impose certain measures aimed at preventing any possible damage.

From a criminal law perspective, should an unsafe product cause harm to someone, the manufacturer of the product might face criminal charges, depending on the facts of the case and the seriousness of the damage caused by the product (eg, personal injury, manslaughter). In this case, criminal proceedings may begin and the damaged person may also bring a civil action in the criminal proceedings to seek compensation.

Further, Italian law provides for other more-specific penalties if the manufacturer or the distributor places dangerous products on the market, violates a ban from the competent authorities not to market a certain product or fails to adopt measures aimed at remedying the risks deriving from an unsafe product. More specifically:

- unless the conduct constitutes a more severe criminal offence, the manufacturer or distributor that markets dangerous products, or violates a ban issued by a government authority to market a product, may be punishable with imprisonment for up to one year and pecuniary sanctions from €10,000 to €50,000;
- unless the conduct constitutes a more-severe criminal offence, the manufacturer or distributor that does not comply with an order issued by the competent authorities to make sure that a certain product is safe or that consumers are warned about possible dangers may be punishable with pecuniary sanctions from €10,000 to €25,000;
-

the manufacturer or distributor that does not cooperate with the competent authorities in the performance of their monitoring and surveillance activities may be punishable with pecuniary sanctions ranging from €1,500 to €40,000; and

- if a more serious crime is also involved (eg, injury or manslaughter), the relevant criminal provisions will also apply.

**Law stated - 30 luglio 2024**

### **Novel theories**

#### **Are any novel theories available or emerging for product liability claimants?**

There are no significant novel theories available. In general terms, theories on product liability litigation are still developing.

**Law stated - 30 luglio 2024**

### **Product defect**

#### **What breaches of duties or other theories can be used to establish product defect?**

In accordance with the Consumer Code, a product is defective when it does not provide the safety a person can reasonably expect, taking into account all circumstances or, in the case of manufacturing defects, when it does not provide the safety normally provided by other category specimens. In assessing this standard, various factors are considered, including: the manner in which the product was distributed and marketed; its clear features; the instructions and warnings provided; the reasonably foreseeable use of the product; and the time the product was put on the market.

Consumers' safety expectations are evaluated on the basis of a series of objective parameters, including price, technical rules (mandatory standards that the manufacturer or producer must comply with), any trial, test and present state of technical and scientific knowledge available at the date of distribution of the product. Finally, the reasonable use of the product is evaluated not in abstract terms but rather in relation to the users to whom the product is destined (such as the foreseeable use of a toy for children). To assess the safety of a product for this purpose, reference must now also be made to the General Product Safety Regulation (GPSR) (Regulation (EU) 2023/988), which entered into force on 12 June 2023.

Three types of defects are set forth under the Consumer Code: manufacturing defects (when the defect is the result of an error in production of an otherwise well-conceived product); design defects (when the defect is inherent to the project of the product); and defects based on inadequate information (when the product is well conceived and manufactured, but it is dangerous as it has been placed on the market without adequate information to users or consumers).

**Law stated - 30 luglio 2024**

## **Defect standard and burden of proof**

**By what standards may a product be deemed defective and who bears the burden of proof? May that burden be shifted to the opposing party? What is the standard of proof?**

The injured party bears the burden of proof with regard to the defect of the product, the damage suffered and the existence of a causal link between the defect and damage.

A traditional trend of merit courts was to assume the existence of the defect by the damage caused; in other words, in accordance with this stance, the mere fact that the use of a product caused damage would be enough to infer the existence of a defect. However, this trend has been overturned by some decisions of the Supreme Court, which can be now regarded as a benchmark in the matter (Court of Cassation, Judgment No. 6007 of 2007). Indeed, assuming a more severe approach, the Supreme Court established that the general rules on burden of proof set out in the Civil Code must be applied also in product liability cases. Italian decisions, even if from the Supreme Court, do not consist of binding precedents and only have a persuasive effect. Nonetheless, so far, the trend of both high and lower courts is to follow the interpretation at issue. In addition, more recent case law of the Supreme Court confirms the requirement for the damaged party to prove that the damage suffered was caused by the 'defect' of the product (which has therefore to be identified) and not merely by the product itself (see Court of Cassation, Judgments Nos. 11317 and 3695 of 2022, 12225 of 2021, 13148 of 2020, 29828 of 2018, 23477 of 2018).

However, if the proof of the defect is not easily attainable, presumptions may be resorted to so as to demonstrate their existence. In this regard, the Court of Cassation confirmed that the demonstration of a 'secondary fact', if based on clear and demonstrated facts, may be considered sufficient by judges to indirectly infer the existence of the 'main fact', such as the defect of the product (Court of Cassation, Judgment Nos. 12225 of 2021, 29828 of 2018).

A decision of a trial court (Court of Appeals of Brescia, Judgment of 2 February 2014) in which the relevant case was sent back by the Supreme Court to be decided again on the merits (Court of Cassation, Judgment No. 20985 of 2007) established that the injured party can meet its burden to prove the defect of the product by merely submitting evidence that the same product cannot be used safely, as it could be legitimately expected. Thus, according to this decision, it is not necessary that the injured party indicate and detect the inherent vice owing to the project or the manufacturing of the product at issue (in this case, the defect regarded a breast implant, which emptied out just two years after it was inserted).

In line with the relevant decision of the Court of Justice of the European Union in a case concerning medical devices, the detection of a potential defect of products belonging to the same group or series may legitimately lead one to assume that a single item from this group or series is defective without the need to conduct a specific assessment of the single item (Judgment of 5 March 2015, Cases Nos. C-503/13 and C-504/13).

**Law stated - 30 luglio 2024**

## **Possible respondents**

## Who may be found liable for injuries and damages caused by defective products? Is it possible for respondents to limit or exclude their liability?

The principle is that manufacturers shall be liable for damage caused by their products. To this purpose, the definition of 'manufacturer', as described by the Consumer Code, includes anyone manufacturing the product (either the finished product or a component of the same or its raw materials), as well as the importer in the EU.

Distributors may also be held liable, but only if manufacturers are not identified or identifiable. Distributors can be released from liability if they allow the identification of the manufacturers.

**Law stated - 30 luglio 2024**

### Causation

## What is the standard by which causation between defect and injury or damages must be established? Who bears the burden and may it be shifted to the opposing party?

With reference to the standard for establishing causation, the stance of the Supreme Court is to consider the threshold of probability in civil cases lower than that required in criminal cases; consequently, in civil cases, a causal chain can be determined on the logic of 'more probable than not'. It follows that the relevant causal chain, for which wrongdoers shall be liable, relates to consequences that are 'usually' produced by their actions, unless a new fact occurs in relation to which they have no duty or possibility to act (in compliance with the 'theory of causal regularity'). The law does not set forth any reversal of the burden of the proof, which lies on the plaintiff.

**Law stated - 30 luglio 2024**

### Post-sale duties

## What post-sale duties may be imposed on potentially responsible parties and how might liability be imposed upon their breach?

Pursuant to the Consumer Code and to the GPSR, the manufacturer and the distributor must place only safe products on the market. They also have a general duty to carry out 'post-market controls' (testing the product, monitoring consumers' claims, etc) and a number of post-sales duties aimed at preventing damage that a defective product might cause. These may include the withdrawal of the product from the market, the recall from consumers or users and provision of supplementary information aimed at making consumers aware of risks and instructing them on how to avoid damages. Manufacturers are also required to inform the competent authorities of any of their products' defects or risks and cooperate with them in all activities aimed at preventing damage.

In turn, the authorities have the power to instruct manufacturers to withdraw or recall any product they deem to be faulty and to provide supplementary information to prevent damage.

**Law stated - 30 luglio 2024**

## LIMITATIONS AND DEFENCES

### Limitation periods

#### What are the applicable limitation periods?

For product liability claims, the statute of limitations period is three years from the day on which the injured party becomes or should have become aware of the damage, the defect and the identity of the liable party. In any event, the right to be compensated for the damage caused by a defective product expires after 10 years from the day on which the manufacturer or the importer within the EU of the product places it on the market.

If the action is based on the general tort rules, the statute of limitations period is five years from the day of the harmful event or, as clarified by case law, the day the harmful event becomes discernible. In contract liability actions, the relevant limitation period is 10 years from the consumer's awareness of the breach of contract.

**Law stated - 30 luglio 2024**

### State-of-the-art and development risk defence

#### Is it a defence to a product liability action that the product defect was not discoverable within the limitations of science and technology at the time of distribution? If so, who bears the burden and what is the standard of proof?

Pursuant to the Consumer Code, liability is excluded if 'the scientific and technical knowledge available at the time the product was put on the market was not yet of such a kind as to allow the product to be considered faulty'. According to some authors, this exemption from liability would be tacitly revoked, or in any event tempered, by the rules governing product safety that impose post-selling obligations. The burden of proof in this regard is borne by the defendant.

**Law stated - 30 luglio 2024**

### Compliance with standards or requirements

#### Is it a defence that the product complied with mandatory (or voluntary) standards or requirements with respect to the alleged defect?

The fact that the product is in compliance with mandatory standards or requirements is a valid defence. As pursuant to the Consumer Code, liability is excluded if the defect is owing to the compliance of the product with a mandatory law or a binding order.

According to commentators, this defence may be applied if the mandatory law or a binding order imposes specific conditions, formalities or features of the product on the manufacturer, but not if the mandatory law or a binding order sets forth minimum safety standards. In this case, compliance with these minimum safety standards does not amount to a valid defence.

**Law stated - 30 luglio 2024**

## Other defences

### What other defences may be available to a product liability defendant?

Liability is excluded if:

- the manufacturer did not place the product on the market;
- the defect that caused the damage did not exist at the time the manufacturer placed the product on the market; or
- the manufacturer did not manufacture the product for sale or distribution against payment of consideration, or did not manufacture or distribute it in the exercise of its business.

Moreover, another defence for the exclusion of liability that has, in our experience, proved to be fairly effective is that based on the contribution given by the injured party to the causation of the claimed damage. The Consumer Code allows for exclusion from compensation if the damaged party, although aware of the defect and the related risks, voluntarily exposes themselves to the risk of damage, thereby accepting this risk. Further, if the consumer contributed to the causation of the damage, compensation is proportionally reduced based on the seriousness of the negligence attributable to the consumer and the extent of the relevant consequences.

**Law stated - 30 luglio 2024**

## Appeals

### What appeals are available to the unsuccessful party in the trial court?

Decisions issued in first-instance proceedings for product liability can be appealed by ordinary means before courts of second instance.

Tribunals have first-instance jurisdiction over all cases not expressly allocated to other courts, including class actions, and second-instance jurisdiction over decisions issued by the justices of the peace. Courts of appeal have first-instance jurisdiction over some specific matters and second-instance jurisdiction over the challenge of decisions issued by tribunals. Decisions issued by courts of appeal can always in turn be challenged before the Court of Cassation, which is at the top of the Italian judicial hierarchy. It is the court of last resort and its task is to ensure the consistent interpretation and application of the law. The Court's review is limited to issues regarding the interpretation and correct application of the law, as the Court does not review any assessment of facts made in first and second instance proceedings.

Second-instance courts can rule again on the merits of the case. Generally, new claims and new challenges are not admissible. New evidentiary means or requests cannot be admitted unless the party proves that they could not have been submitted during first-instance proceedings for reasons not attributable to the same.

Appeal decisions can in turn be challenged before the Supreme Court for limited reasons of law, but are not subject to further review on the merits and facts of the case. In class action

proceedings, orders of second-instance ruling over the admissibility of the class cannot be further challenged before the Court of Cassation.

Law stated - 30 luglio 2024

## SETTLEMENT AND ALTERNATIVE DISPUTE RESOLUTION

### Settlement

#### What rules and procedures govern the settlement of product liability cases?

Under Italian law, no specific regulation is provided in relation to the settlement of product liability cases. Depending on the availability of the parties, disputes can be settled either before or during the proceedings. If proceedings are pending, settlements can be reached by the parties out of court or under the court's guidance.

A dispute that is the subject matter of class action proceedings can also be settled out of court by the parties without the need to ask for the court's prior approval. However, the settlement agreement does not affect the rights of the consumers who did not expressly approve it. Further, Law No. 31/2019, which recently reformed the previous rules governing class actions and collective actions, introduced provisions to encourage the consensual settlement of disputes, such as the possibility for the court to formulate a proposal for a settlement agreement and the possibility for the common representative of the class members to agree with the defendant on a project for a settlement agreement, which must be approved by the judge. Legislative Decree No. 28 of 10 March 2023, which implemented Directive EU No. 2020/1828 and introduced the new provisions on representative actions, also contains provisions that encourage the parties to reach settlement and conciliatory agreements.

Law stated - 30 luglio 2024

### Alternative dispute resolution

#### Is alternative dispute resolution required or advisable before or instead of proceeding with litigation? How commonly is ADR and arbitration used to resolve claims?

Several alternative dispute resolution (ADR) mechanisms are available and, in some instances, they are compulsory for the parties before starting individual litigation in court. For instance, in the case of claims related to the payment of any amount between €1,100 and €50,000, before litigating in court, the parties to a dispute must attempt to carry out negotiations in the presence of their attorneys at law and try to amicably settle their dispute (assisted negotiation (ie, negotiation with the assistance and support of lawyers)). Further, pursuant to Legislative Decree No. 28 of 2010, anyone who intends to bring an action in court relating to a dispute concerning, inter alia, property rights, insurance, banking and financial contracts and medical and healthcare liability, must initiate a mediation procedure in an attempt to solve the dispute out of court before starting any judicial proceedings. Nothing prevents the parties to any dispute from making such an attempt on a voluntary basis. Since 30 June 2020, recourse to mediation before bringing a legal action is compulsory for

disputes concerning breach of contractual obligations attributable to covid-19 containment measures.

ADR is still not broadly used to solve domestic claims. Recourse to arbitration is often preferred to solve disputes that concern parties from different jurisdictions for business-to-business claims and for claims of a high value, considering the costs involved.

Law stated - 30 luglio 2024

## JURISDICTION ANALYSIS

### Status of product liability law and development

Can you characterise the maturity of product liability law in terms of its legal development and utilisation to redress perceived wrongs?

Although theories and case law on product liability are still developing, there does appear to be a good balance between the provisions governing product liability in terms of compensation of damages suffered by consumers and those aimed at preventing these damages and, in particular, those enforcing post-sales duties and post-market controls.

However, statistically, the plaintiffs' lawyers still tend to rely largely on the rules concerning tort liability rather than on specific product liability rules. Consequently, the number of cases concerning product liability decided every year, albeit seemingly increasing, remains limited. The familiarity of the judiciary with this area of the law still has room for improvement. Moreover, differences can be seen between lower and higher courts, and also in different territorial areas across the country.

Law stated - 30 luglio 2024

### Product liability litigation milestones and trends

Have there been any recent noteworthy events or cases that have particularly shaped product liability law? Has there been any change in the frequency or nature of product liability cases launched in the past 12 months?

Until the end of the 1960s, judges based manufacturers' liability on general tort rules. This solution was extremely detrimental to injured parties in that, in accordance with the applicable rules, the burden of proving the manufacturer's fault lay with the injured party. Case law underwent a crucial transformation in the *Saiwa* case, decided in 1964 by the Court of Cassation (Judgment No. 1270 of 1964). In that case, the judges rendered their decision on the basis of the criteria of strict liability and the fault of the manufacturer was assumed as *culpa in re ipsa*; in other words, the manufacturer's fault was presumed simply based on the damaging nature of the product.

Further to the *Saiwa* case, judges began – although case law was far from uniform – to decide cases of product liability by presuming liability on the part of the manufacturer. In particular, from the 1980s onwards, case law began to refer to other rules to simplify the injured party's position, including article 2050 of the Italian Civil Code on dangerous activities, affirming that an activity could also be defined as 'dangerous' based on the nature and

characteristics of the product that is the final result of the relevant activity. In this regard, case law on infected blood products and drugs should be mentioned.

In 1988, the Product Liability Act, as amended by Legislative Decree No. 25 of 2001 (PLA), was introduced and then amended by Legislative Decree No. 25 of 2001. However, the PLA had limited application in Italy, as shown by the few rulings rendered specifically based on this regime. In fact, the first action based on the rules set forth by the PLA, known as the *Mountain Bike* case, was brought in 1991, concerning personal injuries owing to the sudden breakage of the column supporting the front gear shift of a mountain bike and the consequent detachment of the bicycle wheel. Another well-known decision was issued by the Court of Cassation, which excluded the liability of the manufacturer in relation to a swing. In ruling on the case, the Court held that: 'The manufacturer of a product that has caused damage shall be exempt from liability [...] when it is shown that the safety defect of the product was only manifested in relation to a method of use thereof that did not fall within the use that can be reasonably foreseen by the manufacturer.'

Two other significant decisions were issued in 2008 by the Joint Sections of the Supreme Court, ruling on causation and on statute of limitation. The Joint Sections have held that in civil litigation the existence of causation does not require a certainty beyond any reasonable doubt; rather, the criterion of 'more probable than not' applies. The Supreme Court also maintained that, when evaluating causation, judges must take into account whether the event could have been foreseen, in the sense that, to grant compensation for the damage, the harm resulting from an act or omission must be reasonably predictable on the basis of statistical or scientific criteria.

In this regard, it is also worth mentioning that the awareness of the risks or the relevant warnings turned out to be a winning defence argument in product liability litigation (several cases in connection with tobacco litigation). With respect to warnings, some merit courts ruled on the relevant standard and clarified that the warning must be sufficiently explicit to enable the consumer to appreciate the particular hazard involved, especially where the hazard is likely to arise from normal use of the product. This interpretation was confirmed by the Court of Cassation. In a case for compensation of damage caused by the use of sun tanning lotion with no sunscreen protection, the Supreme Court stated that the product could not be considered as 'defective' only because of its potential riskiness, as the liability of the manufacturer of a defective product could only be ascertained if the damage had been caused by this product when used 'in accordance with its normal use', namely, in accordance with the instructions and warnings provided for by the manufacturer (Judgment No. 25116 of 2010). This principle was subsequently followed by both higher and lower courts.

In recent years, Italian case law on product liability has developed in line with its consolidated trends: the Court of Cassation confirmed its previous rulings in relation to the applicable burden of proof and the notion of defective product. Regarding the burden of proof, the Court of Cassation reiterated that the damaged party is relieved from the proof of negligence or wilful misconduct by the damaging party but not from the proof of the 'defect' (Judgment Nos. 11317 and 3695 of 2022, 12225 of 2021, 29828 of 2018, 23477 of 2018, 3258 of 2016, 15851 of 2015) and of the existence of a causal link between the defect and the alleged damage. With regard to the notion of a defective product, the Court of Cassation rejected a claim for compensation for damages allegedly caused by the explosion of a toxic house detergent, stating that the product itself could not be considered 'defective', as it was manufactured and distributed in line with the safety standards required for this kind of product (Judgment No. 3258 of 2016). Thus, in this case, the Court of Cassation found

again that a product is defective only if it lacks safety in comparison with consumers' safety expectations.

**Law stated - 30 luglio 2024**

### **Climate for litigation**

**Describe the level of 'consumerism' in your country and consumers' knowledge of, and propensity to use, product liability litigation to redress perceived wrongs.**

As for the instrument of representative actions introduced by Legislative Decree No. 28 of 10 March 2023, it is still impossible to assess their development since the relevant provisions only came into force on 25 June 2023.

That said, on 3 April 2019, the Italian Parliament approved a bill of law for a reform of class actions, converted into Law No. 31 of 12 April 2019. The new rules governing class actions came into force on 19 May 2021 and only apply to damaging conduct put in place on the date of or after the entry into force of the reform. Law No. 31 of 2019 introduced significant changes to the discipline of class actions in the attempt to reform the above scenario and encourage the recourse to this procedural tool. According to the IT platform dedicated to class actions within the Telematic Services Portal of the Ministry of Justice, there are currently 51 actions pending.

As for the instrument of representative actions introduced by Legislative Decree No. 28 of 10 March 2023, it is still impossible to assess their development since the relevant provisions only came into force on 25 June 2023. The entities qualified to promote the action have been identified by the Ministry of Enterprise and Made in Italy with the Ministerial Decree dated 26 July 2023.

**Law stated - 30 luglio 2024**

### **Efforts to expand product liability or ease claimants' burdens**

**Describe any developments regarding 'access to justice' that would make product liability more claimant-friendly.**

Litigation based on product liability claims is still developing in Italy. A series of laws introduced in the past few years may have a role in speeding up this development. These laws introduced a class action procedure in Italy – which has been recently reformed – and the possibility for clients to enter into some kind of contingency fee agreements with their lawyers, which used to be inadmissible. Third-party funding (which is not prohibited but which at the same time is not regulated) may also contribute.

Nonetheless, to date, statistics show that the above mechanisms are still timidly approached by plaintiffs and that general awareness of their availability and potential effects is not yet mature.

On 3 April 2019, the Italian Parliament approved a reform of class actions through Law No. 31 of 12 April 2019. These new rules only apply to claims for damaging conduct put in place after 9 May 2022, whereas claims regarding damaging conduct put in place before that date

remain subject to the rules previously applicable. The reform aims at favouring and enlarging the recourse to class action and deeply modified the nature and the scope of the class action.

As for the effectiveness of different instruments of representative actions introduced by Legislative Decree No. 28 of 10 March 2023, it is even more difficult to make an assessment. Indeed, the relevant provisions only came into force on 25 June 2023. The entities qualified to promote the action have been identified by the Ministry of Enterprise and Made in Italy with the Ministerial Decree dated 26 July 2023.

**Law stated - 30 luglio 2024**

## UPDATE AND TRENDS

### Emerging trends

#### Are there any emerging trends or hot topics in product liability litigation in your jurisdiction?

As to legislative developments in the field of consumer law (while waiting for the implementation of the new EU Product Liability Regulation, which is expected to be a breakthrough), the most relevant one concerns the reform of the rules on class actions and collective actions for injunctive relief, which became effective on 19 May 2021.

With regard to Italian case law, the majority of the decisions recently rendered by Italian courts focus on the causal link between the defect of the product and the damage suffered by the consumer, as well as on the allocation of the relevant burden of proof between the parties.

Further, work has been done on the adoption of the New Deal for Consumers, launched in April 2018 by the European Commission (ie, a package of new provisions with the purpose of improving the level of consumer protection in the EU). The main purpose of the initiative was to empower qualified entities to start actions on behalf of consumers, as well as to provide the competent authorities of the member states with stronger sanctioning powers in the field of consumer law and to attain a higher level of protection for consumers in online marketplaces. More specifically, the Representative Action Directive, aimed at modernising and replacing Directive 2009/22/EC, was adopted on 25 November 2020. The Representative Action Directive introduced a harmonised model for representative action in all member states, to ensure that consumers are protected against mass harm and, at the same time, to ensure appropriate defences from abusive lawsuits. Besides general consumer law, the scope of the Representative Action Directive includes violations in matters including, but not limited to, data protection, telecommunications, the environment and health. The Representative Action Directive has been implemented in Italy by Legislative Decree No. 28 of 10 March 2023, the provisions of which apply as of 25 June 2023. In the near future, it will be possible to assess the impact of this new law on Italian litigation.

**Law stated - 30 luglio 2024**