THE PRODUCT REGULATION AND LIABILITY REVIEW

Tenth Edition

Editors
Chilton Davis Varner, Madison Kitchens and Franklin Sacha

THE LAWREVIEWS

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This article was first published in March 2023
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Published in the United Kingdom
by Law Business Research Ltd
Holborn Gate, 330 High Holborn, London, WC1V 7QT, UK

www.thelawreviews.co.uk

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ISBN 978-1-80449-157-7

ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following for their assistance throughout the preparation of this book:

BAKER MCKENZIE WONG & LEOW

CLAYTON UTZ

KING & SPALDING LLP

NISHIMURA & ASAHI

SEPULVADO, MALDONADO & COURET

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PREFACE

In today's global economy, product manufacturers and distributors face a dizzying array of overlapping and sometimes contradictory laws and regulations around the world. A basic familiarity with international product liability is essential to doing business in this environment. An understanding of the international framework will provide thoughtful manufacturers and distributors with a strategic advantage in this increasingly competitive area. This treatise sets out a general overview of product liability in key jurisdictions around the world, giving manufacturers a place to start in assessing their potential liability and exposure.

Readers of this publication will see that each country's product liability laws reflect a delicate balance between protecting consumers and encouraging risk-taking and innovation. This balance is constantly shifting through new legislation, regulations, treaties, administrative oversight and court decisions. However, the overall trajectory seems clear: as global wealth, technological innovation and consumer knowledge continue to increase, so will the cost of product liability actions.

This edition demonstrates how countries sought to maintain that delicate balance between consumer protection and innovation in 2022, particularly with respect to cutting-edge technological, supply chain and environmental issues. In the autumn of 2022, the European Commission took a significant step by publishing a draft revision of its 37-year-old Product Liability Directive. The revised Directive would extend product liability law not only to typical manufactured products, but also to digital products such as software and artificial intelligence systems. In addition to expanding the substantive reach of the Directive, the proposed draft would also ensure that business entities based in the European Union can be held liable for a defective product, even if the product is purchased from a manufacturer outside the European Union. That change reflects the modern global supply chain system, where products are often manufactured in one nation and sold in another through third-party distributors or fulfilment companies. Under the EU proposal, any natural or legal person who modifies a product (for instance, through a software update) or a fulfilment service provider can be liable for damage from a defective product. This change could dramatically expand companies' exposure to product liability actions. In addition, the draft Directive also includes consumer-friendly procedural changes, including requirements that manufacturers disclose evidence, flexibility for filing deadlines and a reduction in the burden of proof in complex cases (such as pharmaceutical actions). Spain has already taken steps to implement the new rules set out in the Directive.

Another theme of this edition reflects growing concerns about environmental sustainability and consumer health. For instance, France enacted new rules with the goal of promoting the 'circular economy', in which manufacturers produce goods with the intention that those goods will be recycled and reused, therefore reducing waste and promoting

sustainability. To achieve that goal, France enacted a rule that requires certain household products to include a label that informs consumers about the environmental impact of the product. The US government took significant steps in 2022 to regulate per- and polyfluoroalkyl substances (PFAS), commonly known as 'forever chemicals', with the goal of reducing the presence of PFAS in the environment and requiring companies to pay for clean-up costs. Those regulatory shifts likely augur more litigation on this front in the United States.

Although product manufacturers face a heightened regulatory environment across the globe, particularly for hot-button technological and environmental issues, they also notched important wins in the courtroom in 2022. Manufacturers of the heartburn drug Zantac scored a massive victory in the United States in a mass tort litigation arising from allegations that the drug's active ingredient causes cancer. A federal court granted the manufacturers' motions to exclude the plaintiffs' experts who sought to prove a link between Zantac and cancer, finding that no scientist outside the litigation had found that connection. The court's decision effectively ended tens of thousands of lawsuits, put the plaintiffs on the defensive in other Zantac-related lawsuits throughout the United States, and underscored the critical (and sometimes dispositive) role that experts play in product liability cases. And in a case involving asbestos liability in the construction context, Japan's Supreme Court held that asbestos manufacturers were not required to issue warnings about asbestos in building materials. Despite those victories, litigation challenges remain for product manufacturers. For example, Australia saw the removal of certain requirements for the operators of class action litigation funders, which will make it easier for plaintiffs to bring lawsuits. This litigation funding continues to grow in various jurisdictions, especially in the mass tort context. Those types of developments throughout the world underscore the need for product manufacturers to remain abreast of legal and regulatory changes in all jurisdictions where they operate or sell products.

This edition covers 10 countries and territories and includes a high-level overview of each jurisdiction's product liability framework, recent changes and developments, and a look forward to expected trends. Each chapter contains an introduction to the country's product liability framework, followed by four main sections: regulatory oversight (describing the country's regulatory authorities or administrative bodies that oversee some aspect of product liability); causes of action (identifying the specific causes of action under which manufacturers, distributors or sellers of a product may be held liable for injury caused by that product); litigation (providing a broad overview of all aspects of litigation in a given country, including the forum, burden of proof, potential defences to liability, personal jurisdiction, expert witnesses, discovery, apportionment, whether mass tort actions or class actions are available and what damages might be expected); and the year in review (describing recent, current and pending developments affecting various aspects of product liability, such as regulatory or policy changes, significant cases or settlements, and any notable trends).

Whether the reader is a company executive or a private practitioner, we hope that this edition will prove useful in navigating the complex world of product liability and alerting you to important developments that might affect your business.

We wish to thank all the contributors who have been so generous with their time and expertise. They have made this publication possible.

Chilton Davis Varner, Madison Kitchens and Franklin Sacha
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March 2023

Chapter 8

SPAIN

Cristina Ayo Ferrándiz[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

In the Spanish legal system, product liability regulations were to be found, until 2007, in Article 1902 of the Civil Code (CC), which used to set out the rules concerning liability in tort; in the General Law for the Protection of Consumers and Users; and in the Defective Products Liability Act, which transposed the EU Product Liability Directive.[2]

The moment at which the product had been put into circulation determined which particular set of rules applied. For these purposes, 'putting into circulation' meant the voluntary delivery of the product by the manufacturer, which, for practical purposes, meant distributing the product or making it available to the relevant persons.

Under the Defective Products Liability Act's final provision, this Act applied to those instances of product liability in which the relevant product had been put into circulation after 8 July 1994 (i.e., on the day following the entry into force of the Defective Products Liability Act). The General Law for the Protection of Consumers and Users applied to any products put into circulation between 13 August 1984 and 8 July 1994. And Article 1902 of the CC applied to any products put into circulation before the General Law for the Protection of Consumers and Users entered into force (i.e., before 13 August 1984).

Where one particular set of rules applied, the rest did not, and the moment at which a product was put into circulation determined which set of rules applied.

The rules differed in matters such as the identification of the person responsible, the circle of possible injured persons and the damages covered. However, the underlying purpose of all sets of rules and the definition of a defective product were the same. The latter was explicitly addressed in the EU Product Liability Directive and the Defective Products Liability Act, which transposed the Directive.

The diversity of product liability regimes came to an end by virtue of the enforcement of Royal Legislative Decree 1/2007, which enacted the Consumers and Users Protection (Consolidation) Act and other complementary regulations.

Both the General Law for the Protection of Consumers and Users and the Defective Products Liability Act (among other consumer protection regulations) were repealed following their consolidation into Royal Legislative Decree 1/2007. This means that Royal Legislative Decree 1/2007, which does not substantially differ from the Defective Products Liability Act (and therefore follows the guidelines laid down by the Product Liability Directive), is currently the only set of rules applicable to liability for defective products.

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2 Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

The third transitory provision of Royal Legislative Decree 1/2007 provides specific rules applicable to any product put into circulation before 8 July 1994 (i.e., before the entry into force of the Defective Products Liability Act). However, a scenario calling for the application of these transitory rules is highly unlikely to arise. This is because under Section 144 of Royal Legislative Decree 1/2007, the liability of manufacturers expires after 10 years from the date the product was put into circulation, as was the case under Section 14 of the Defective Products Liability Act.

II REGULATORY OVERSIGHT

Although Royal Legislative Decree 1/2007 contains some provisions regarding general safety of products, it is Royal Decree 1801/2003 concerning general product safety that transposed into Spanish law the EU General Product Safety Directive,[3] the main and general regulation for safety issues.

As with the Directive, Royal Decree 1801/2003 is a general and horizontal non-contractual regulation on general product safety, applicable to all product types put into circulation in Spain. Pursuant to this regulation, only safe products can be put into circulation on the Spanish market.

The regulation applies to all product types that do not have specific existing regulation. There are some product categories (i.e., food, cosmetics and medicines) that have specific safety regulations and sometimes need prior administrative approval to be put on the market.

The Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN)[4] is the regulator with nationwide competence, and the regional authorities are competent[5] within their own territories.

AECOSAN is competent if there is no specific body in charge of the safety of specific products (such as the Spanish Agency of Medicines and Medical Devices).

III CAUSES OF ACTION

Taking into consideration the regulations noted in Sections I and II, the following are the causes of action when putting a product into circulation.

3 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

4 The National Consumer Institute was the competent regulator. Following a recent restructuring, the National Consumer Institute was merged with the Spanish Agency for Food Safety and Nutrition to create the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN).

5 The Directorate-General for Consumer Affairs in Andalucia, Aragón, the Balearic Islands and Madrid; AECOSAN in Asturias; the Directorate-General for Trade and Consumer Affairs in the Canary Islands, Cantabria and Valencia; the Civil Protection and Consumer Agency in Castilla and León; the Consumer Affairs Institute of Castilla-La Mancha in Castilla La Mancha; the Catalan Consumer Affairs Agency in Catalonia; the Ministry of Health and Consumer Affairs in Ceuta; the Consumer Affairs Institute of Extremadura in Extremadura; the Galician Consumer Affairs Institute in Galicia; the Directorate-General for Public Health and Consumer Affairs in La Rioja; the Directorate-General for Health and Consumer Affairs in Melilla; the Directorate-General for Citizens, Drug Addiction and Consumer Affairs in Murcia; the Directorate-General for Families, Children and Consumer Affairs in Navarra; and the Consumer Affairs Department in the Basque Country.

i Civil law

Royal Legislative Decree 1/2007

A product is deemed to be defective when it does not sufficiently guarantee the safety that is expected of it. To establish whether a given product is defective, it must satisfy the non-safety test. Other tests, including that of substandard quality or unfitness for purpose, do not apply.

Royal Legislative Decree 1/2007 does not draw a distinction among the three types of defects traditionally identified by legal scholars:

a manufacturing defects that arise from flaws in the manufacturing process and often affect individual products within the same series;

b project or design defects that arise from flawed technical designs prior to manufacture (i.e., at the technical ideation stage of the product) and often affect all the units manufactured; and

c information defects that arise from flawed, incomplete or insufficient information that misleads consumers as to the manner in which a given product should be used or its degree of safety.

As to information defects, it could be argued that by using the degree of safety test to establish whether a product is defective, the law actually calls for an assessment of the extent to which the potential risks associated with a particular product are known. In this way, a product will be regarded as defective when it falls short of providing the safety expected of it or, to put it differently, when it does not provide the safety that consumers expect.

Conversely, no liability will arise where the risks associated with a given product are known by the injured person as, in these circumstances, the fact that a product is not safe is part and parcel of what is to be expected from the relevant product (theory of assumed risks). This may occur because:

a the risks are obvious (e.g., a knife or a pair of scissors are cutting instruments);

b the risks are socially and culturally known by the public (e.g., risks associated with tobacco or alcohol consumption); or

c the manufacturer, in compliance with its duty to provide the necessary information about its product, had provided to the injured persons adequate instructions for the product's use and information about the risks associated with its use.

Clearly, safety expectations are to be assessed from an objective standpoint and by having regard to the average individual's knowledge and to the manufacturer's lawful expectations about use. The subjective perspective of the particular injured person must be disregarded for these purposes.

Both the Product Liability Directive and Royal Legislative Decree 1/2007 provide that the product presentation, the reasonable use of the product and the moment at which it was put into circulation are criteria that must be taken into account to establish the expectations that injured persons could properly have of the relevant product.

The scope is limited to the liability of producers and suppliers exclusively for bodily harm sustained as a result of the use or consumption of a defective product and for damage caused to things other than the product itself, provided that the defective product itself was meant for private consumption (i.e., not intended for professional use).

Any other type of damage (moral or by the product itself) must be sought under general civil regulation.

Royal Decree 1801/2003

Under Royal Decree 1801/2003, only safe products can be put into circulation on the Spanish market. This means that each party in the distribution chain must take appropriate measures to ensure that all products are safe, and where any party knows that a product already put into circulation is not safe, it must take appropriate corrective measures.

A product will be considered safe provided that, under normal and reasonable conditions of use, it does not present any risk or presents only risks that are acceptable and compatible with the intended use of the product, taking into consideration circumstances such as the characteristics of the product, any information provided with it or the consumer it is directed towards.

Royal Decree 1801/2003 also sets out a presumption that a product is safe when it has been produced in accordance with Spanish or European compulsory regulations on health and safety or, where no specific regulation exists, in accordance with Spanish standards (UNE standards), European Commission recommendations or the current state of the art – for instance, that the state of scientific and technical knowledge at the time of putting the product into circulation would not enable the existence of the defect to be discovered.

Conversely, Royal Decree 1801/2003 presumes that a product is not safe when it has been produced without a CE or an EC mark,[6] or whenever a product has been produced without passing any compulsory authorisations or controls.

This regulation applies to producers and distributors, although it is also applicable to any party in the production and distribution chain.

ii Criminal law

Criminal law provides for certain crimes in the field of product liability. Causing risk to persons (without it being necessary for the risk to have materialised in harm to specific persons) by placing medicines and products intended for human consumption on the market, whether by violating safety or health regulations or by unauthorised adulteration or handling, is defined as a crime against public health. In cases other than those involving the manufacture and marketing of medicines and products intended for human consumption, the damage caused by a defective product can be characterised as a crime of homicide or of injury, in both cases owing either to gross or to ordinary negligence, provided that the violation may be qualified as criminal depending on the importance of the safety rules that have been violated.

IV LITIGATION

i Forum

Civil procedure is regulated by the Spanish Civil Procedural Act, enacted on 7 January 2000.

The Spanish legal system is unitary and uniform throughout the territory. This means that its courts are organised in territorial terms into provincial districts, each of which groups together several geographical areas, which, in turn, comprise several municipalities.

6 The CE or EC mark is a symbol indicating that the product that is being marketed or is about to be marketed has passed an evaluation process and meets the essential manufacturing, design and health and safety requirements set out in the European safety regulations.

The lowest level of the civil jurisdiction is made up of the courts of first instance, which are each formed by one single judge. In general, these courts hear, in the first instance, all proceedings in which the parties are private individuals and companies, and they are almost exclusively in charge of hearing and examining evidence and pleadings submitted by the parties and, subsequently, rendering the judgments in these proceedings.

The provincial court of appeal hears appeals against decisions rendered by the courts of first instance. There is a provincial court of appeal in each of the 50 provinces that make up the Spanish territory, and in populous provinces the court of appeal is divided into several sections, each sitting with three magistrates.

Apart from the Superior Courts of Justice (the highest court in each of the Spanish territory's autonomous communities), which are in charge of hearing motions for dismissal in connection with specific matters of law in their respective autonomous communities, the Supreme Court is the highest court in product liability cases, although some issues may be brought before the Constitutional Tribunal.

In product liability cases, the jurisdictional function, in terms of both fact-finding and the legal declaration of liability, corresponds exclusively to the judges and the courts. Jury courts before which some crimes are tried do not have jurisdiction over product liability cases.

Furthermore, in Spain, there are two basic declarative procedures for seeking payment of compensation: verbal proceedings or ordinary proceedings. The stream a case falls under will depend on the amount claimed: cases in which payment of compensation of up to €6,000 is sought are dealt with in verbal proceedings, and cases in which the amount claimed is more than €6,000 are dealt with in ordinary proceedings.

In both cases, the civil procedure starts with the filing of the claim. The claim must include all factual allegations on which it is based, in as much detail as possible, as well as the legal grounds on which it is based. However, under the principle of *jura novit curia*, the plaintiff is not required to set out the legal grounds in thorough detail, and the legal grounds claimed are not binding on the judge, who may uphold the action based on alternative legal grounds.

If verbal proceedings are initiated, once the claim has been filed and given leave to proceed, the defendant is notified so that they may present a defence (or a counterclaim brief) within a term of 10 working days (which includes all days of the year except Saturdays, Sundays, national holidays, non-working days in the autonomous region or city where the proceedings take place, and the month of August).[7]

Subsequently, the court will call the parties to a hearing in which they propose the evidence they are going to submit; the evidence is produced and, if the court deems it necessary, final conclusions are presented.

If ordinary proceedings are initiated, once notified of the lawsuit, the defendant will have a 20-working-day period to file the brief of response. Subsequently, the court will call the parties to a preliminary hearing in which they propose the evidence they are going to submit and, finally, the court calls the parties to the trial where the evidence and final conclusions are presented. In this case, therefore, there are two different hearings.

7 Until very recently, the main difference between verbal and ordinary proceedings was that in verbal proceedings the plaintiff historically filed a written lawsuit, but the defendant did not file a written response to the lawsuit. In this type of proceeding, the court summons the parties to a hearing where the defendant presents their response orally and the evidence is submitted. However, this has been recently modified in the Spanish Procedural Act, and in verbal proceedings the brief of response is also submitted in writing.

ii Burden of proof

The general principle that the burden of proof of a factual allegation lies on the person who makes the allegation is one that presides over the Spanish legal system.

In accordance with the general civil liability regime under Royal Legislative Decree 1/2007, the party claiming product liability must provide evidence of the existence of a defect in the product, of the damage or injury and of the causal relationship between the two.

In Spain, the standard of proof of that causal link is, in theory, high. The Supreme Court formally requires that evidence of the existence of a causal link must be clear and precise and not based on mere deduction, conjecture or probability. Therefore, in principle, it requires absolute evidential certainty.

Consequently, in Spain, tests applied elsewhere, such as the 'more probable than not' rule, are, in theory, not applicable. And statistics or epidemiology do not appear to be sufficient by themselves to prove a causal link.

In practice, however, judges and courts often reach decisions in a manner that comes close to applying the more probable than not rule – in particular, through recourse to the judicial presumption, whereby the judge or court applies human logic rules to deduce a fact and deems it proven (deduced fact) on the basis of the evidence of one or more basic facts.

On other occasions, the courts have determined the causal relationship by reference to statistics and epidemiology – which are deemed to be insufficient by themselves to establish the causal link – in combination with other basic facts.

The ruling on a rapeseed oil case is an illustrative example of the use of epidemiological studies by the Spanish Supreme Court. Although the events took place in 1981, the Supreme Court did not issue a final judgment on this case until 26 September 1997.

In the case, the Supreme Court found that:

a a link between the consumption of rapeseed oil and the disease suffered by more than 20,000 injured parties had been epidemiologically determined;

b the pathology found in the injured parties was new (it had never before been diagnosed), and consequently no risk factors inherent to the disease had been identified by the scientific community;

c none of the parties to the proceedings proposed any alternative causal hypothesis other than the consumption of rapeseed oil; and

d once the denatured rapeseed oil was removed from the market and its consumption had been suspended, no new cases of intoxication were diagnosed.

Importantly, epidemiology was not considered in itself to be sufficient proof of a causal relationship. Epidemiology was just one more link in the Supreme Court's logical reasoning chain that led to the evidential conclusion of the existence of a causal relationship.

iii Defences

Royal Legislative Decree 1/2007 specifically provides for the statutory limitation of actions brought by virtue of this law within three years of the time the victim sustained the injury or damage.

It also provides that the rights of the victim will elapse 10 years after the date the product was put into circulation (provided that no legal action has been instigated in that period).

In relation to the start of the computation of the limitation period, Article 1969 of the CC provides that 'the time limit for all sorts of legal actions, when not otherwise provided for

under a special provision, will start on the day that the actions may be brought'. As for the time when the case is deemed to be actionable, it has been chiefly understood to be identified as the time when the injured party learnt of the damage or injury sustained ('from the time the aggrieved party learned of it', as noted under Article 1968.2 of the CC).

This criterion regarding the start of the time limit is also applied within the product liability context: 'from the date the injured party sustained the injury or damage'.

In any consideration of limitation periods, the Spanish courts tend to lean generously in favour of the interests of the plaintiffs.

Apart from the statute of limitations defence, Royal Legislative Decree 1/2007 provides that manufacturers or importers are not liable, as long as evidence of any of the following circumstances is provided:

a the product was not put into circulation by the relevant manufacturer or importer;

b having regard to the circumstances, it was to be expected that no defect existed at the time at which the product was put into circulation;

c the product was not manufactured for sale or for any other method of distribution for an economic purpose, or was neither manufactured nor imported, supplied or distributed in the course of a professional or business activity;

d the defect was the result of manufacturing the product in accordance with mandatory rules in force; or

e the state of scientific and technical knowledge at the time the product was put into circulation was not such as would enable the existence of the defect to be discovered (i.e., the state of the art defence).

Under this exemption of liability clause, damage caused by a defective product is not compensable where the state of scientific or technical knowledge at the time the damage was caused was not such as would have enabled the damage to be avoided.

Therefore, manufacturers whose production activity adheres to the scientific and technical knowledge available at the time their products were put into circulation will be relieved of liability, provided that the state of scientific and technical knowledge at that time was not such as would have enabled the discovery of the defect.

Some scholars suggest that reliance on generally known empirical knowledge is not enough for manufacturers to successfully prove this exemption of liability cause. Manufacturers also need to ensure that they rely on state-of-the-art scientific knowledge and research. This is tantamount to an implicit duty on the part of manufacturers to conduct research into the safety of their products whatever the manufacturer's turnover, market position or financial resources.

There are two product types for which manufacturers will be liable despite having conducted their activity in accordance with the state of scientific and technical knowledge available at the time their products were put into circulation: drugs and foodstuffs meant for human consumption. This means that the law imposes a more stringent and direct duty to conduct research into the safety of these products.

In addition to the grounds for exoneration listed above, Royal Legislative Decree 1/2007 contemplates the possibility that a manufacturer's liability may be reduced owing to the intervention of third parties or of the injured party, and in the latter case the manufacturer's liability may not arise at all.

If a third party has intervened in the manufacturing of a product, a manufacturer that would have paid any applicable indemnity sum would be entitled, by means of a 'recovery or repetition action', to recover from the third party that party's share of the cost of the damage.

With regard to intervention by the injured party (fault of the victim), the manufacturer must prove that the damage would not have occurred without the injured party's intervention, or that the injury or damage caused would, at least, not have been so serious.

iv Personal jurisdiction

As a member of the EU, Spain is subject to the provisions set out in Article 7.2 of Council Regulation (EU) No. 1215/2012[8] on jurisdiction, recognition and enforcement of judgments in civil and commercial matters. Under that Article, any person who has suffered damage as a consequence of a defective product can sue any EU manufacturer before the courts of the country where the harmful event has occurred or may occur. That will normally coincide with the courts of the claimant's own domicile.

The same rule is set out in Spanish law in connection with cases involving non-EU manufacturers. Therefore, foreign manufacturers are subject to Spanish jurisdiction provided that the damages caused by the defective product have been caused within the Spanish territory.

However, where the product has not been manufactured in Spain and has not been sold or advertised in Spain, but the injury occurs within the Spanish territory, it may be argued that the harmful event has not properly occurred in Spain (i.e., although damage as such will have occurred in Spain, the harmful effect – the putting into circulation of a defective product – may not be understood to have occurred therein).

v Expert witnesses

The Spanish Civil Procedural Act provides for an expert witness who is a person with the technical, scientific, artistic or practical knowledge of the relevant issue, as well as the direct knowledge or news of the facts or events as a witness.

As a general rule, experts' reports should be filed together with the initial writs of claim and of defence; however, a number of exceptions are set for cases where special circumstances exist.

Thus, if a plaintiff shows that the proper defence of their rights prevented them from delaying the filing of their claim, they may submit an expert report subsequently, provided that they announce it in the writ of claim and the report is filed prior to the pretrial hearing. Logically, this possibility is absolutely limited, in principle, to cases of statutory limitations taking into consideration that the defendant has only 20 working days to file the brief of response. They can file it five days prior to the preliminary hearing, provided that they justify that it could not be obtained before the expiry of the term provided by law to file the defence brief and they announce its filing in the brief of response.

If the need for expert witness evidence becomes manifest in view of the pleadings contained in the defendant's writ of defence, or in view of the complementary pleadings made by any of the parties prior to or at the preliminary hearing, the parties may provide any expert witness report until five days before the start of the trial.

8 Regulation (EU) No. 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, which entered into force on 10 January 2015 (formerly regulated by Article 5.3 of Council Regulation No. 44/2001).

Moreover, any of the parties may prefer to request from the court the appointment of an expert, but they should do so expressly in their initial writ.

In principle, expert reports, as with any other means of evidence, must be proposed by the parties; however, the law provides that the appointment of an expert by the court can also be requested when the need for expert testimony becomes evident either in view of the pleadings contained in the writ of defence (in which case, only the plaintiff may request it) or in view of any complementary pleadings by any of the parties before or at the preliminary hearing.

vi Discovery

The Spanish legal system does not provide for a general disclosure procedure.

However, the law does provide for coercive measures in relation to document disclosure in two specific situations.

If preliminary proceedings[9] have commenced, the law provides for the option for the court to enter and search premises to obtain certain documents requested by the plaintiff in cases where the person or entity to which they refer, or who is in possession of the documents, refuses to disclose them.

During ordinary proceedings, the law provides for the option to request from the other parties disclosure of documents referring to the object of the proceedings.[10] Should the party or parties unjustifiably refuse to disclose the requested private documents, the court may either attribute to the document the evidential value alleged by the requesting party or issue an express injunction for the documents to be furnished when it is deemed advisable, given the nature of the documents, the other evidence brought to the proceedings, and the contents of the allegations and claims made.

However, unlike in preliminary proceedings, here the law does not provide for the entry and search of premises in the event of a refusal to disclose documents. However, a party that refuses to disclose documents required by the court may be in contempt of court, which is characterised as a criminal offence.

vii Apportionment

Spanish courts may apportion liability if several agents have contributed to the damaging event, where it is possible to determine the specific level of contribution of each agent; however, market share liability has not yet been applied by the Spanish courts.

However, if it is not possible to determine the specific level of contribution of each agent to the damaging event (while it is certain that they all contributed to it to some – unknown – extent), courts may find all the agents liable jointly and severally.

In the case of merger or acquisition of the manufacturing company, the beneficiary of the merger or acquirer undertakes any potential product liability incurred by the acquired company as a result of its manufacturing and putting into circulation of unsafe products. The aforementioned succession of liability does not occur, however, where a company purchases a brand or a producer's product line but the producer continues to exist as such.

9 This is an exceptional procedure, simply aimed at preparing the proceedings (and therefore conducted prior to filing the lawsuit). Its purpose is for the potential plaintiff to verify the suitability of the defendant and the object of the claim.

10 In cases such as these, the requesting party must provide a simple copy of the requested document or, in the absence thereof, indicate the contents of the requested document in the most accurate terms possible.

viii Mass tort actions

The Spanish Civil Procedure Act instituted a system of collective actions whereby certain consumer associations can exercise a legal action on behalf of either a determined (or easily determinable) or undetermined number of consumers who have sustained injuries or suffered a loss as a consequence of consuming a product or using a service.

The Civil Procedure Act states that if the number, identity and specific circumstances of the aggrieved consumers are determined or are easily determinable at the declaratory stage of the proceedings, both the consumer associations and the groups of aggrieved consumers by themselves (i.e., they do not need to be represented by a consumer association) hold capacity to sue on behalf of all the aggrieved consumers. In this regard, the group is considered to be legally constituted as the representative plaintiff (i.e., as the plaintiff in the proceedings) when at least 50 per cent of its members have joined it.

In turn, only the consumer associations that are members of the Spanish National Consumer Committee have legal standing to file legal actions on behalf of an undetermined number of consumers.

Although the specific requirements that a collective claim must fulfil to be accepted (as happens with class actions) are not regulated, the Civil Procedure Act requires that the damaging event be the same.

In the case of joinder of actions, which also exists in the Spanish regulations, a plaintiff can aggregate different legal actions against different defendants provided that the issues of fact that underlie each of the actions are sufficiently common. Pursuant to this regulation, the damaging event does not need to be the same, but there must be a connection between actions. Taking into consideration that each case can be somehow different, although must be connected, the limit of this type of action is the procedural economy principle.

However, this regulation will undergo some changes in the near future due to the implementation in Spain of the Representative Actions Directive.[11] A draft law that transposes the Directive has just been approved; the text has been published and is subject to comments. This text implies major modifications of the current Spanish procedural rules that will have a significant impact on the way mass tort actions will be handled in the future.

ix Damages

The Spanish civil liability system is based on compensatory grounds. Consequently, indemnifiable damages should match the impairment or loss suffered by a person as a result of a given event or fact, whether the impairment or loss affects the person's natural vital attributes or their property or assets.

Indemnifiable damages include both strictly economic damages and also 'non-material damages' (including, for instance, for suffering or pain).[12]

Punitive damages are not contemplated in the Spanish legal system.

11 Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers, repealing Directive 2009/22/EC.

12 Non-material damages are not economically assessable, although compensation for non-material damage is imposed by law. In practice, each court determines the economic value of the non-material damage according to each specific case, and this is generally proportional to the strictly economic damages that are granted.

Royal Legislative Decree 1/2007 establishes an accrued liability limit of €63,106,270.96 (this is a global civil liability for producers for death and personal damages caused by identical products affected by the same defect).

Damages in respect of the cost of medical monitoring can be recovered.

In addition, according to Spanish tort law, nothing prevents a claimant from seeking compensation in kind (*in natura*, as opposed to monetary compensation). In this regard, to the extent that it could be understood as a means of compensation in kind in connection with mental damage (suffering or anxiety), medical monitoring may be accepted as a form of compensation.

V YEAR IN REVIEW

In November 2021 and March 2022, two different courts of first instance of Madrid issued decisions on a product liability regime related to the damages allegedly caused by a drug. After determining that the case was a product liability action to which the specific Product Liability Directive regime applied, the courts considered that the action had expired as the lawsuit was filed after the 10-year liability period set forth in the Spanish product liability regime had elapsed.

More recently, in April 2022, the Court of Appeal of Albacete rendered a decision regarding an alleged defective washing machine that caused personal damage to a woman. Allegedly, the washing machine could have been opened while the drum was spinning, causing personal damage to the plaintiff. Although the defendant argued lack of diligence by the plaintiff because she opened the door and put her arm in the drum while it was still rotating, the Court of Appeal considered that the absence of a device that detects that the drum was still rotating is a design defect. However, the Court also stated that the injured party herself lacked the diligence that she should have observed before opening the door of the washing machine, consisting of verifying that the drum had stopped and that the acoustic signal that indicates the end of the cycle had also stopped. Given that the damage caused was jointly due to a defect in the product and the negligent conduct of the plaintiff, the Court reduced the liability requested by the plaintiff by 50 per cent, consequently reducing the amount of the compensation granted.

On 4 December 2020, the EU Representative Actions Directive was finally approved, incorporating important changes at a European level by requiring EU Member States to rule on a collective action mechanism through which specific entities are entitled to seek a compensation remedy on behalf of affected consumers, either by joining it to an injunction action or separately.

The Directive would introduce a new representative action regime in Spain. The draft law implementing the Directive has recently been made public; this includes important modifications to the current regime that will change the way in which representative actions are litigated, and it features the following:

a the extension of representative actions to any infringement of legislation referring to consumer interests (which goes beyond the Directive regime);

b a preference for the opt-out system;

c a certification phase, which will involve a hearing after the claim has been submitted, discussing whether the conditions for the action are met (i.e., the necessary homogeneity (which exists, in essence, when there is no need to consider factual or legal aspects that are particular to each of the consumers concerned) and that the action is not manifestly

unfounded). In this phase, the existence of a conflict of interest (as defined in the draft law) in relation to third parties funding the proceedings will also be analysed. The certification order must determine the conduct (objective scope) and the specific consumers affected by the process (subjective scope) or, when this is impossible, the characteristics and requirements that must be met to qualify as a beneficiary. This must be communicated separately, if possible, or publicised in the media, and consumers will be given a time period (of between two and four months) to express their wish to be excluded (or included, if an opt-in system applies) from the representative action through an electronic platform. The certification order can be appealed, regardless of whether it has been approved. If it is denied by final decision, no further representative actions for redress can be brought in relation to the same subject matter. A final certification order has the following effects on individual actions:

- a consumer filing an individual action during the period in which consumers may exclude themselves from the action is equivalent to expressing a wish to be excluded from the action; once the period expires, individual actions for damages will no longer be admissible; and
- in pending individual actions, the claimant consumer must state whether they wish to be bound by the representative action;

d limiting the legal standing to consumer associations and certain public entities;

e settlement agreements, which must be approved by the court to be binding. Once a settlement agreement has been approved, no representative action over the same subject matter can be filed. To promote settlement agreements, the draft law sets forth that a redress settlement does not mean that the defendant has acknowledged liability or guilt; and

f enforcement: if all the beneficiaries are identified, the defendant must pay them the corresponding damages as set forth by the court. If they are not identified, the defendant must deposit a lump sum in the court's deposit account, and the claimant entity will be appointed as a liquidator to distribute this sum among the beneficiaries. Any dispute regarding the amounts to be distributed will be heard by the court of first instance that heard the original case.

At the time of writing, the draft law is still to be discussed in depth in the Spanish Parliament; therefore, the above provisions are subject to change.

The Product Liability Directive is included in the list of regulations set out in the Appendix to the EU Representative Actions Directive; therefore, the product liability regime in Spain is likely to be impacted by the introduction of the EU Directive. The draft law implementing the EU Directive rules on important changes to the current regime, such as the inclusion of artificial intelligence within the scope of the Product Liability Directive and the introduction of the presumption of causation.

Appendix 1

ABOUT THE AUTHORS

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Cristina Ayo Ferrándiz is a member of the litigation practice of Uría Menéndez in the Barcelona office. She joined the firm in September 2000 and became counsel in January 2012.

Cristina focuses her practice on contentious and pre-contentious civil and commercial issues. She specialises in judicial proceedings before the Spanish courts and tribunals relating to contractual liability, non-contractual liability and product liability, as well as contractual, corporate, lease agreements, banking, financial and private party disputes. She has also successfully defended the interests of car manufacturers, pharmaceutical companies, tobacco companies and the chemical industry in some of the most important product liability cases in Spain, including several collective claims.

Cristina is considered a leading litigation lawyer by international legal directories such as *Best Lawyers*.

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ISBN 978-1-80449-157-7