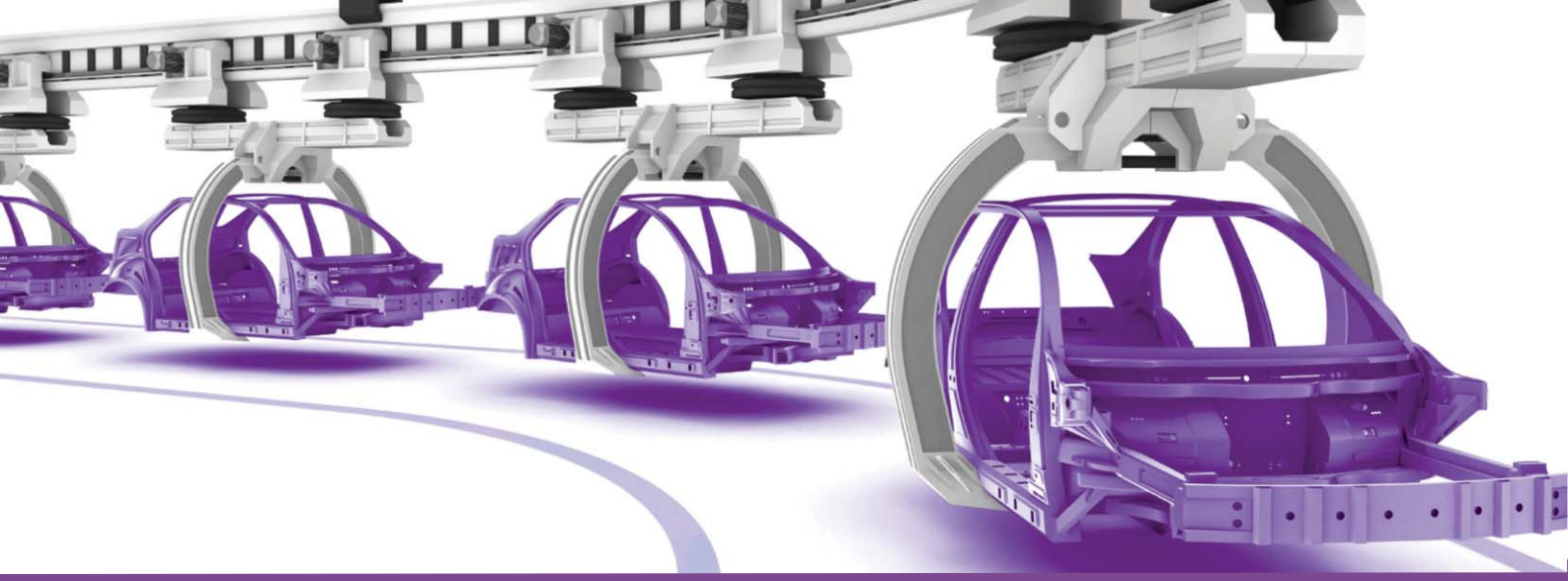

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The International Comparative Legal Guide to:

Product Liability 2012

10th Edition

A practical cross-border insight into product liability work

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The International Comparative Legal Guide to: Product Liability 2012

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EDITORIAL

Welcome to the tenth edition of *The International Comparative Legal Guide to: Product Liability*.

This guide provides corporate counsel and international practitioners with a comprehensive worldwide legal analysis of the laws and regulations of product liability.

It is divided into two main sections:

Ten general chapters. These are designed to provide readers with a comprehensive overview of key product liability issues, particularly from the perspective of a multi-jurisdictional transaction.

Country question and answer chapters. These provide a broad overview of common issues in product liability laws and regulations in 26 jurisdictions.

All chapters are written by leading product liability lawyers and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editors Ian Dodds-Smith of Arnold & Porter (UK) LLP and Michael Spencer QC of Crown Office Chambers for their invaluable assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The International Comparative Legal Guide series is also available online at www.iclg.co.uk

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PREFACE

I'm delighted to have been asked to introduce the tenth edition of *The International Comparative Legal Guide to: Product Liability*.

The guide continues to be an invaluable source of information and comes this year with ten very interesting and varied general chapters as well as the extremely informative country question and answer section, covering 26 jurisdictions.

I make constant reference to the guide for matters concerning product liability globally; I'm also aware that my colleagues in Europe and across the world continue to rely on the guide as a first port of call for information on product liability and helps inform their advice.

The area of product liability continues to provoke interest from all areas, which I hope will necessitate future editions of this excellent guide.

Tom Spencer
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Litigation, Product Safety, UK
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Recent Developments in European Product Liability

Ian Dodds-Smith

Alison Brown

Arnold & Porter (UK) LLP

Introduction

The Product Liability Directive, 85/374/EEC ("the Directive") lays down common rules governing liability for defective products in the European Union ("EU"). It imposes strict liability on the producer of a defective product for damage caused by the defect. A product is defective if it does not provide the safety that consumers generally are entitled to expect taking account of all of the circumstances, including the product's get up and presentation and its expected use.

This article discusses recent developments in European product liability law, including recent European case-law, the Consumer Rights Directive and proposals regarding collective consumer redress that could significantly change the legal environment for bringing product liability claims in the EU.

The European Commission's Fourth Report on the Application of the Directive

On 8 September 2011, the European Commission published its Fourth Report on the practical application of the Directive ("the Report"). The Report concludes that a review of the Directive is not presently merited, although the Commission will continue to monitor developments.

The Commission notes that over the period since its last report (published in September 2006) there appears to have been an increase in the number of claims being brought under national laws transposing the Directive; several Member States, including Austria, France, Germany, Italy, Poland and Spain, have recorded an increase in the number of product liability cases being brought, while other countries have reported an increased number of out of court settlements. This increase is attributed to external factors, such as greater consumer awareness and better organisation of consumer groups pursuing these type of claims.

Contributors to the Report predictably expressed different views about the Directive, with consumer groups pressing for enhanced consumer protection, while producers and insurers argued for stronger defences. However, overall the Commission concludes that the Directive strikes an appropriate balance between consumer protection and the interests of producers. It comments that the Directive provides consumers seeking compensation for damage caused by a defective product with an effective potential remedy.

While the Report notes some minor differences in application of the Directive in different Member States, it takes the view that these differences do not create significant trade barriers or distort competition in the European Union. In particular, it considers that different national procedural rules do not prevent injured parties from establishing causation where claims are brought under national laws implementing the Directive.

The Report considers the application of the Directive in a number of areas:

- The burden of proof (Article 4) - the Report highlights some differences in terms of the evidence needed to prove defect. In some courts, for example, in Belgium, France, Germany, Italy and Spain, it is sufficient for the claimant to prove that the product did not fulfil the function for which it was intended, whereas in other countries, such as Germany and the UK, the claimant must prove the precise nature of the product's defect in more detail. While some national authorities considered that consumers faced difficulties in proving that damage was caused by the product defect, the Report notes that such difficulties were mainly due to the cost of obtaining an expert opinion, rather than the application of the legal test.
- Defence of regulatory compliance (Article 7(d)) - the Report notes that there is very little case law on the application of this defence. Highly regulated industries, such as the pharmaceutical industry, argued in favour of the introduction of a broader regulatory compliance defence.
- Development risk defence ("DRD") (Article 7(e)) - the Report notes that national courts have adopted differing interpretations of this provision. For example, the German Supreme Court has ruled that the defence does not apply to manufacturing defects, whereas the courts in the Netherlands and the UK have applied the defence to all types of defects. It remains the position, as was the case when the Directive was first implemented, that Member States are divided as to whether DRD should continue to be available as an optional defence. Some national authorities, including those in Bulgaria and Malta, suggested in their feedback that that the Directive should be reviewed in order to remove this defence to improve the functioning of the internal market. However, other authorities including those in Greece, Italy, Lithuania and the UK remain in favour of the defence and commented that it contributes to maintaining a balance between the encouragement of innovation and consumer protection.
- Minimum damages threshold for property claims (Article 9) - some Member States argued for reducing or removing this threshold in order to guarantee more effective consumer protection, whereas industry representatives argued for an increase in the threshold to take account of the effect of inflation.

The Commission concludes that the available information is not sufficiently fact based and that, because amendment to one or more provisions would have an effect on the overall balance of the Directive, it would be premature to propose its review at this stage. However, it will continue to monitor developments in the area.

Scope of the Directive - the Dutrueux case

The extent to which the Directive is a harmonising measure has been considered again by the EUCJ in *Case C-495/10, Centre Hospitalier Universitaire de Besançon v Thomas Dutrueux*. The case concerned a claim for personal injury brought by Thomas Dutrueux, who was then aged thirteen, and suffered burns during surgery performed at Besançon Hospital which were caused by a defect in the temperature control of the heated mattress he was lying on while the surgery took place. At first instance, the French Court found Besançon Hospital liable to pay compensation, applying case law which imposed no fault liability on public hospitals where patients sustained damage as a result of the failure of a product or equipment used in connection with their treatment. On appeal, the hospital argued that this decision was incompatible with the Directive and the Conseil d' Etat sought a preliminary reference to the EUCJ seeking guidance on this issue.

The question before the Court was whether liability could be imposed on the hospital in circumstances where it was not liable under the Directive. The EUCJ concluded that while the Directive sought to achieve complete harmonisation of the matters regulated by it, it did not determine all liability for defective products. The liability of service providers using defective equipment in the course of providing services fell outside the scope of the Directive and such liability could, therefore, be determined under national law.

In reaching its decision, the Court reviewed its previous case law relating to the scope of harmonisation under the Directive. In particular, the Court considered its previous decision in *Case C-402/03 Skov and Bilka [2006]* ECR I - 199, in which the Danish Government had extended the scheme of no-fault liability provided by the Directive so that it applied to a supplier of the product, as well the producer: under Danish law, an injured consumer could decide whether to sue the producer or supplier of the defective product. The EUCJ held that this was not permissible. The Directive laid down the circumstances in which a supplier of the product was liable. The Court concluded that because the Directive was a harmonising measure and it regulated suppliers' liability for defective products (making clear that they could only be liable in the place of the producer in limited circumstances, where they had failed to identify the producer of the product), the Danish law which extended the scope of supplier liability was incompatible with the Directive.

In contrast, in the *Dutrueux* case, the Court concluded that the liability of a service provider fell outside the scope of the Directive. A hospital was not a "supplier" of a product within the meaning of Article 3 of the Directive, which refers to an economic operator in the production and marketing chain of the product in question. The hospital did not supply Mr Dutrueux with a product intended for use by him, but merely used a defective product in the course of supplying services. As a result, the Court concluded that the liability regime in respect of service providers established under French law fell outside the scope of the Directive: the Directive neither required nor precluded such liability.

The Judgment seeks to draw a distinction with the Court's earlier decision in *Henning Veedfald v Ärhus Amtskommune, Case C-203/99* [2001] ECR I - 3569. That case concerned a claim brought by Mr Veedfald regarding a failed kidney transplantation operation. A kidney donated by Mr. Veedfald's brother was damaged by a defective perfusion liquid manufactured by a local hospital which was used to flush the kidney, making the kidney unsuitable for transplantation. The EUCJ concluded that the Directive was applicable. The fact that the Defendant regional administrative authority (which was responsible for the local hospital in question) was a government body was irrelevant and the defence under Article 7(c) of the Directive, which applies to products that are manufactured for non-economic reasons, did not apply. The Court concluded that a product manufactured and used in the course of a medical service, consisting of preparing a human organ for transplantation, was being "put into circulation" and compensation was therefore potentially recoverable under the Directive for damage caused by such a defective product. It therefore concluded that a product supplied in the course of the provision of a service fell within the scope of the Directive, if the other requirements of the Directive were met. The EUCJ considered this decision in *Dutrueux* and concluded that it could be distinguished, as *Veedfald* considered the liability of a regional administration which was both a *manufacturer* and a service provider. The question of whether the Directive applied to service providers *per se* was not considered.

The Court also considered in what circumstances Member States can introduce national product liability laws and concluded that laws which fell outside the scope of the Directive were permissible, provided they did not adversely affect the Directive's overall liability regime, so that it remained possible to pursue the producer/manufacturer of a product under the Directive in circumstances where it was applicable.

It is clear that in determining the scope of the Directive the EUCJ draws a distinction between producers and suppliers involved in the supply chain for a product who are covered by its provisions, and service providers supplying services who are not. However, fine distinctions may need to be made in applying these decisions in practice. To use a hypothetical example, while a hospital which has dispensed a defective medicine, where the producer cannot be identified, may be a "supplier" and potentially liable under the national laws implementing the Directive, that same hospital is seemingly not liable under the Directive where they are acting only as a service provider, for example, where a patient is injured as a result of the use of defective equipment during their treatment.

Other European Developments - the Consumer Rights Directive

A new Directive has been approved which will clarify and strengthen the laws relating to consumer rights and update the existing legal framework in line with advances in modern technology and the increasing use of the Internet. The Consumer Rights Directive, 2011/83/EU, seeks to harmonise existing laws which are contained in two Directives governing distance contracts and contracts negotiated away from business premises (Directive 97/7/EC and Directive 85/577/EEC), and makes changes to some of the general laws governing consumer sales. Key changes include the extension to all consumer sales contracts of the requirement that traders provide consumers with key pre-contractual information about the basic terms of the contract, and new requirements relating to the supply of digital content. The Directive prohibits surcharges for the use of credit cards, premium rate consumer telephone services and the addition of hidden costs and charges, for example, by the use of 'pre-ticked' default options where products are purchased over the Internet. In respect of distance and doorstep contracts, the Directive introduces a standard 14-day cooling off period during which consumers may cancel and imposes stricter rules on the payment of refunds.

The Directive sets maximum standards from which Member States cannot derogate, although there are a number of exceptions to this general principle, for example, in general sales contracts Member States can impose additional requirements regarding the provision of pre-contractual information to consumers. Member States must

adopt national implementing legislation by 13 December 2013, which must take effect within 6 months, by 13 June 2014.

Other European Developments - Collective Redress

Possible changes to the procedural rules affecting many product liability claims may have a greater impact on the overall legal environment for such claims than changes to the Directive itself. As the Commission acknowledged in its Fourth Report, many of the disparities in the application of the Directive reflect the varying legal traditions and procedural rules in different Member States.

Over recent years, various EU institutions have progressed a series of initiatives which have reviewed the effectiveness and efficiency of existing EU collective redress mechanisms and the availability of alternative means of consumer redress (other than court proceedings), and have looked specifically at the problems faced by consumers in obtaining collective redress for infringements of consumer protection legislation. These reports found that only 13 Member States (Austria, Bulgaria, Denmark, Finland, France, Germany, Greece, Italy, the Netherlands, Portugal, Spain, Sweden and the UK) have collective redress schemes, and that there was considerable divergence in the way those schemes operated and were regulated. Existing collective redress mechanisms had been applied in relatively few cases and the level of compensation provided to consumers was low.

The reports concluded that the efficiency and effectiveness of existing mechanisms could be improved, that they may not provide adequate redress where a group of consumers pursue very low value claims, and the absence of any collective redress mechanism in some countries may leave consumers with no adequate means of obtaining compensation. In the light of these studies the Commission published a Green Paper on Consumer Collective Redress (COM (2008) 794 final) in November 2008, which concluded that because of weaknesses in the current EU framework, "a significant proportion of consumers who have suffered damage do not obtain redress". It sought views on a range of possible options (which could be combined or pursued independently) to address this issue.

A series of further EU initiatives have subsequently been progressed, including the issue of proposals for collective redress in the context of damages actions for breach of anti-trust rules and of a Discussion Paper published in May 2009. Following on from these developments, in February 2011 the Commission published a further consultation paper "Towards a Coherent European Approach to Collective Redress" which seeks to identify common legal principles on collective redress which would guide any future EU initiatives in this area. Collective redress is defined broadly to include any mechanism that may result in the cessation or prevention of unlawful business practices which affect a multitude of claimants or the compensation for harm caused by such practices. It includes actions for compensation and for injunctive relief (to stop the continuation of illegal behaviour). The consultation appears to respond to criticisms that previous initiatives were inconsistent and were advanced on a piecemeal basis, with separate legislative proposals being progressed in the areas of consumer protection and competition law. The Commission is therefore consulting horizontally, across a broad range of industry sectors, with the aim of developing a coherent approach to legislation relating to collective redress.

While the main aim of the consultation is to ensure that adequate mechanisms are in place so that citizens and businesses are able to seek redress on a collective basis, the consultation document acknowledges that improved mechanisms for collective redress could also assist consumers and businesses in initiating private actions against unlawful practices, thereby supporting regulatory agencies by indirectly policing breaches of EU law. This aspect of the proposal has proved controversial, with some commentators suggesting that promoting law enforcement is a matter for the EU enforcement agencies.

The consultation seeks views on whether any changes should be made to existing laws; whether new mechanisms of collective redress would add value; how they would work and whether they should be introduced generally or in specific areas, such as competition law and consumer law. It also identifies certain general principles which could guide any future EU initiatives for collective redress, which are:

(1) the need for effectiveness and efficiency of redress;

(2) the importance of information and of the role of representative bodies;

(3) the need to take account of collective consensual resolution as a means of alternative dispute resolution;

(4) the need for strong safeguards to avoid abusive litigation;

(5) availability of appropriate financing mechanisms, notably for citizens and small and medium sized enterprises; and

(6) the importance of effective enforcement across the EU.

In relation to the proposed safeguards to avoid the risk of "abusive litigation", the European Commission has made clear that it does not support the combination of factors present in so-called "US style" class actions, including the availability of punitive damages, the absence of limitations regarding standing, the availability of contingency fees and the wide ranging discovery procedures for documentary evidence, which it considers potentially provide economic incentives to litigate unfounded claims. It seeks views on safeguards which could be introduced to prevent such "abusive litigation" while still preserving effective access to justice for EU citizens and businesses, including the introduction of the "loser pays" principle (which means that the losing party pays the court and lawyers fees of both parties) and restrictions on when proceedings can be commenced (for example, the need for court approval prior to the commencement of proceedings). The Commission is presently considering the responses to that consultation.

In February 2012 the European Parliament published a Resolution responding to the consultation, which urges the Commission - if it considers that a collective redress scheme is necessary - to introduce a horizontal framework including a common set of principles providing uniform access to justice through collective redress. In discussing the type of principles that should be applied, the Parliament rejects the "opt-out" approach to collective actions, stating that any action must be based on the "opt-in" principle where claimants are clearly identified and have indicated their wish to take part in the proceedings; suggests that a Judge or similar body should have the discretion to determine if a collective action should be permitted to be brought; proposes that Member States should approve the representative bodies permitted to bring collective actions; suggests that any damages awarded must be compensatory and not punitive; and proposes that Member States should remain free to determine their own rules on costs and funding, commenting with approval that there must be rules to prevent the proliferation of unmeritorious claims, such as the loser pays costs rule under which the unsuccessful party must bear the costs of the successful party.

Conclusion

Although the Product Liability Directive has now been in force for over 20 years there have been relatively few cases on the

interpretation of its provisions. The ECJ's decision in *Dutrueux* provides helpful clarification on the application of certain key provisions and concepts underpinning the Directive. However, a number of areas of uncertainty remain. For example:

- the scope of the development risks defence; and
- what information may be taken into account in assessing whether a product is defective – whether this includes information and warnings supplied to intermediaries such as health professionals in the medicines and medical devices field, as well as information supplied directly to consumers.

It is hoped that the court will, in future, be invited to provide guidance in these areas. Nevertheless, the European Commission's Fourth Report has concluded that the Directive is operating in a satisfactory way, balancing the interests of consumers and producers. A number of new legislative initiatives are being pursued in parallel by the European Commission, particularly in relation to mechanisms for collective redress, that may in future enhance consumer rights in respect of defective products and make it easier to pursue claims for compensation.

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Mr. Dodds-Smith is a Fellow of the Royal Society of Medicine and is a member of the Defence Research Institute and the Federation of Insurance and Corporate Counsel. He has written widely on product liability issues including as co-author of the chapter on product liability for medicinal products in the Butterworths textbook on Medical Negligence.

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Ms Brown also provides advice on product safety and health and safety laws. She advises on all aspects of regulatory compliance, including the notification of product recalls to UK and EU authorities and enforcement actions/investigations by regulatory agencies. She also acts in litigation relating to the recovery of recall costs. She is a member of the British Institute of Comparative Law's product liability forum.

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Arnold & Porter is an international law firm with over 800 attorneys in nine offices in the U.S. and London and Brussels. With more than 100 attorneys engaged in product liability matters, Arnold & Porter is one of the most experienced firms internationally, providing clients with an integrated product liability service on a transatlantic basis.

The European product liability group is a recognised leader in the UK and Europe, with comprehensive experience in handling the defence of claims. Its lawyers have been at the forefront of "group action" litigation, with experience derived from the successful defence of many major multi-claimant cases that have been brought in the UK and elsewhere in the EU over the last 30 years. In the US, the firm has acted both as national counsel for companies and as trial counsel in cases involving personal injury and property damage claims.

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