

# International Product Liability Review

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Issue 51

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## About our Product Liability Practice

Hogan Lovells has the leading product liability practice covering all aspects of product safety as well as civil and criminal liability. We have experience of acting for clients in respect of a wide range of products including food, pharmaceuticals, cars, tobacco, mobile phones, cosmetics, electrical and electronic products, toys and children's products, sporting goods, blood products, aircraft and machinery. Hogan Lovells' product liability lawyers are supported by a dedicated Science Unit and Project Management Unit.

If you would like more information about Hogan Lovells' product liability practice, please visit our website at [www.hoganlovells.com](http://www.hoganlovells.com) or contact the Product Liability Group Leader, Thomas Rouhette, at [thomas.rouhette@hoganlovells.com](mailto:thomas.rouhette@hoganlovells.com) or any of the lawyers listed on the back page of this publication.

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### ABOUT INTERNATIONAL PRODUCT LIABILITY REVIEW

In December 2000, Lovells (as it then was) launched its quarterly *European Product Liability Review*, the only regular publication dedicated to reporting on product liability and product safety developments in Europe for international product suppliers, and others interested in international product issues. Over the next ten years, this unique publication featured hundreds of articles, from authors across our network, covering issues in Europe and, increasingly, further afield. Reflecting the growing globalisation of product risks, and following the creation of Hogan Lovells through the combination of Lovells with Hogan & Hartson in May 2010, the publication was renamed *International Product Liability Review* in March 2011.

Hogan Lovells' *International Product Liability Review* continues to be the only regular publication dedicated to reporting on global developments in product liability and product safety regulation. It is distributed worldwide free of charge to our clients and others interested in international product issues. If you would like additional copies of this publication, please return the form enclosed with this edition, or contact a member of the editorial team by e-mail:

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## In this issue...

### 1 Overview

#### FEATURE

#### 2 Feature – Navigating the discovery process in China-related cross-border disputes

Eugene Chen and Jieni Ji (Shanghai) look at some of the most common difficulties that can arise with foreign disputes involving Chinese parties, including aspects of discovery, difficulties in preserving attorney-client and attorney work product privileges, and the impact of the PRC State Secrecy Law.

#### EUROPE – EU

#### 6 European General Court considers implications of failure to comply with “Good Manufacturing Practices” for medicinal products

A recent decision in the European General Court confirmed that a failure to comply with the requirements of “Good Manufacturing Practices” can trigger significant regulatory intervention based on a mere risk of harm to public health created by that non-compliance. Rod Freeman and Vera Wichers (London) assess the implications of this decision for pharmaceutical companies.

#### EUROPE – FRANCE

#### 7 Pesticide litigation: a move towards an asbestos-style compensatory regime?

Sylvie Gallage-Alwis and Estelle Isik (Paris) look at recent case law and legislation indicating that the French authorities and courts have decided to facilitate the process of compensation for alleged victims of pesticides. This increases the risk of the phytosanitary industry being exposed to claims from employees and farmers.

#### 11 Uncertainty for machinery manufacturers regarding compliance with safety rules

Christophe Garin (Paris) reports on a recent decision by the French Supreme Court which provides further proof of the constant uncertainty for users of machinery and, indirectly, machinery manufacturers, regarding conformity with safety rules.

#### 14 Class actions are likely soon to be introduced in France

Following submission of a consumer bill to the French Council of Ministers, it appears that the French government is targeting implementation of class actions in France before the end of 2013. As Thomas Rouhette and Christine Gateau (Paris) comment, the fear is that this new tool will open the floodgates to compensation claims.

#### EUROPE – GERMANY

#### 17 Justified product safety expectations – “hot water under table unit” (*Heißwasser-Untertischgerät*)

Markus Burckhardt and Victoria Parr (Munich) report on a recent decision in the German Federal Supreme Court commenting on the definition of defective products – specifically what a justified expectation of safety should be, and by whose standards this should be judged.

#### 20 Recent decisions regarding so-called “quasi-producers” under the German Product Liability Act

Dorina Bruns and Eva Herion (Munich) discuss recent decisions in the German courts which indicate that if a company creates the impression of being a producer of a certain product, and assumes responsibility for that product’s quality and safety, then it risks being held liable for a defect in that product.

## In this issue...

### EUROPE – ITALY

#### 23 Contaminated blood products: Italian case law on causation and the statute of limitations

Recent litigation reconfirms the significance of Supreme Court guidelines on causation and the statute of limitations. Filomena Di Marino and Jacopo Bartolomeo (Milan) report on how there is now clearly an established case-law trend affecting not just contaminated blood litigation, but also torts and product liability claims at large.

### EUROPE – NETHERLANDS

#### 25 Dutch District Court rules that omitting to mention the side-effect of a drug makes it a defective product

Karen Jelsma and Sanne Bouwers (Amsterdam) discuss a recent District Court decision which underlines how a failure to warn consumers adequately about the potential for serious side-effects and dangers can render a product “defective”, even where it is in fact perfectly sound.

### EUROPE – SPAIN

#### 28 Class actions in Spain concerning product liability claims

Rafael Fernández and Cristina Redondo Belda (Madrid) explain why an amendment to the Spanish Procedural Law (which regulates the system for “collective actions”) should be expected soon, and discuss the impact this could have on class actions concerning product liability claims.

### EUROPE – UK

#### 29 Another case on foreseeability of injury for asbestos exposure after 1965

Alex Woods (London) summarises a recent case which continues a series of decisions examining the issue, previously viewed as settled, of foreseeability in cases involving asbestos exposure after 1965.

#### 30 Law Commission and Scottish Law Commission report on UK unfair terms legislation

The prominence requirements of the recently published Law Commission and Scottish Law Commission report on UK unfair terms legislation may pose challenges for businesses. Oliver Wilson (London) comments on how businesses weigh the risk of a term being challenged for unfairness against the practical constraints of what terms they can reasonably include on main order pages.

#### 32 Penalties for parties and lawyers for using unsatisfactory witnesses

Zen Cho (London) reports on two recent High Court decisions which, while they did not concern product liability, nevertheless underlined the importance of complying with the rules on the content of fact and expert evidence.

### NORTH AMERICA – US

#### 34 Liability of brand-name prescription drugs manufacturers for injuries caused by generic products

Lauren Colton and Lindsay Goldberg (Baltimore) comment on the potential implications for brand name and generic manufacturers of a recent decision in the Supreme Court of Alabama. This ignored the fundamental legal tenet (upheld in dozens of courts) against imposing liability on product manufacturers for injuries caused by a competitor’s identical product.

## Overview

As experience of product liability continues to grow in Europe, we are seeing the courts grappling with a number of fundamental principles that have implications for the liability risks for producers and suppliers of products. As the cases reported in this issue of *International Product Liability Review* highlight, the legal outcome very often points to important practical issues that companies need to consider in order to manage effectively their liability risks in Europe.

In Germany, the courts have considered the liability of non-manufacturers who permit their brand name or other trademark to appear on a product manufactured by a third party (page 20). The result is important because it has a direct impact on the practical decisions companies need to make when addressing their marketing practices, as well as in situations where one company might wish to licence another to use its trademark in association with a product. Also in Germany, the courts have considered issues related to what might be considered "justified" safety expectations for the purposes of the laws implementing the Product Liability Directive (page 17). The result in such a case raises practical issues about the extent to which a manufacturer needs to provide warnings and instructions having regard to the intended audience, as well as interesting issues relating to the effect where a product bears a quality mark from a third party certification body.

The question of the adequacy of warnings has also been considered by the courts in the Netherlands, specifically in the context of a pharmaceutical product and the risk of side effects (page 25). A key consideration in that case was whether the manufacturer could rely on the fact that the product warnings had been approved by the relevant regulatory authority, an issue which remains important – and controversial – in Europe. In the event the court ruled that the manufacturer did not have a defence on that basis, but rather had an independent obligation to warn of significant risks. This will certainly not be the last word in Europe on this fundamental issue.

We report on a number of developments in France on the regulatory and procedural fronts. Notably, we see France continuing to move towards introducing broad class actions provisions (page 14). We also report on the continuing controversy surrounding alleged risks associated with pesticides, in an article that provides

an interesting insight into how occupational health risks are uniquely dealt with in France, and how that can have very important implications for product manufacturers which could well extend beyond the borders of France (page 7). This article also highlights the important implications for the pesticides industry itself.

We highlight some recent cases in the UK that demonstrate the importance of a rigorous approach to evidence before English courts, and the possible consequences of dealing with those issues unsatisfactorily (page 32).

Our feature article in this issue of *International Product Liability Review* is an interesting and valuable guide to managing discovery processes when dealing with cross-border disputes involving China (page 2). As this article highlights, the regime in China presents a number of challenges, including in relation to the protection of what common law lawyers might consider to be "privileged" documents. The article is well worth a careful read by anyone involved in international litigation that may have a Chinese element.

As this issue goes to print, the debate in Europe surrounding the proposed reforms of the consumer product safety regulations is starting to warm up. Look out for our coverage of these important developments in the next issue of *International Product Liability Review*.



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