



International Product Liability Review

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About our Product Litigation and Compliance Practice

Hogan Lovells has the leading international product litigation and compliance practice covering all aspects of product liability, compliance and mass torts. We focus on acting for clients around the world covering all product sectors including food and beverages, pharmaceuticals and medical devices, cars, tobacco, mobile phones, cosmetics, electrical and electronic products, chemicals and hazardous substances, toys and children's products, sporting goods, aircraft and machinery. Hogan Lovells product litigation and product safety lawyers are supported by a dedicated Science Unit and Project Management Unit.

If you would like more information about Hogan Lovells product litigation and compliance practice, please visit our website at www.hoganlovells.com or contact the Product Litigation and Compliance Group Leader, Rod Freeman, at rod.freeman@hoganlovells.com or any of the lawyers listed on the back page of this publication.

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 litigation and product 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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Meet the team

We are pleased to introduce two of the authors who have contributed to this edition of *International Product Liability Review*: Phoebe Yan (Shanghai) and Gabor Fellner (London).



Phoebe Yan

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When clients are faced with product liability issues product recalls, FCPA investigations, trade secret and labour law disputes they turn to Phoebe for her assistance. She has a wealth of experience representing multinational companies in anti-bribery and product quality related government investigations and company audits in the automobile and consumer products industries. She also assists in many product quality and product safety related campaigns for multinationals in China, including voluntary recall actions before the China General Administration of Quality Supervision, Inspection, and Quarantine.

Prior to joining Hogan Lovells, Phoebe worked at a top-tier Chinese law firm. She gained strong researching and analysing skills as well as in-depth knowledge of Chinese civil law and court system from the training she received.

Phoebe holds a JD from the University of Iowa, College of Law. She earned her bachelor's degree from Peking University and she is qualified in both New York and China.

See page 2 for Phoebe's article "*Consumer products in China: new recall regulations*"



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Gabor is an Associate in the Product Litigation and Compliance team of the London office at Hogan Lovells. He has experience advising clients on a broad range of product-related advisory, commercial and compliance matters, as well as dispute resolution (including ADR). He has advised clients around the world on complex compliance issues relating to innovative consumer electronics, textiles and apparel, motor vehicles and chemicals.

Gabor has coordinated advice relating to new product launches in multiple jurisdictions for market leading brands. He has worked closely on behalf of clients with test houses, external technical consultants, certification organisations and industry experts to advise clients on practical compliance solutions which suit their commercial needs.

Gabor also works with clients on major international product withdrawals, recalls and other corrective actions, communicating with national authorities, coordinating advice from local counsel and managing the reporting process in affected jurisdictions.

See page 9 for Gabor's article "*REACH into the future: recent developments in the EU chemicals regulation*"

In this issue...

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FEATURE

2 Consumer products in China: new recall regulations

New measures have been introduced in China that provide uniform guidelines on recall procedures for defective consumer products. It's a development that provides some welcome clarity around the responsibilities of manufacturers and other value-chain participants. Eugene Chen and Phoebe Yan (Shanghai) sum up the principal impacts.

Europe – EU

6 All change: towards a complete overhaul of EU medical devices regulation

With political agreement reached on the introduction of two new Regulations covering medical devices and *in vitro* diagnostic medical devices, major changes to current EU regulation in this area look extremely likely. Elisabethann Wright and Fabien Roy (Brussels) sum up some of the principal impacts of the Regulations (if adopted in their current form) and advise manufacturers how best to prepare for them.

9 REACH into the future: recent developments in the EU chemicals regulation

The legal framework of EU chemicals regulations is under review by the European Commission. Gabor Fellner (London) sums up developments, including the Commission's review of REACH and proposals to fast-track the restriction of certain substances used in textiles. This article is intended as a "speed-read" of the current developments for manufacturers, importers, distributors and other economic operators that supply or use chemicals.

12 Reflections: what's been happening for IoT and product safety and regulation in the EU?

The Internet of Things (IoT) is often viewed as the next generation of computing, and it's important for all those involved in the manufacture and supply of IoT products to remain up to date, not just with the technology, but also with the relevant legal and regulatory landscape. For companies launching IoT products, it can be challenging to track developments in this area while maintaining effective compliance with existing regulation. Valerie Kenyon (London) sums up the state of play in the EU and the US, highlights priority areas for manufacturers and looks ahead to upcoming initiatives.

EUROPE – NETHERLANDS

15 Dutch product safety: turnover-related fining has arrived

Karen Jelsma and Laura-Jean van de Ven (Amsterdam) look at recent amendments to the Administrative Penalties (Commodities Act) Decree. Limited to cases involving either intention or gross negligence on the part of the perpetrator, the new "turnover-related" fine that's been introduced applies only to companies with an annual turnover equal to, or over, €10 million. It's likely to have a significant impact on those it is applied to.

EUROPE – UK

18 Beyond mesothelioma: extension of the exception to standard causation

Matthew Felwick (London) discusses a recent Court of Appeal decision that looked at the scope of the relaxed test for causation in mesothelioma cases. Key issues covered include the applicability of the causation test, use of epidemiological evidence to assign liability between defendants, and how liability for damages should be apportioned.

23 UK in pole position for autonomous vehicles

With no legislation to prevent the testing of autonomous cars on its roads, and a government determined to promote research and innovation, the UK is a very attractive place for investment in autonomous vehicles. Valerie Kenyon and Thomas Caldwell (London) summarise the current regulatory landscape for this technology, and look ahead to likely forthcoming developments.

NORTH AMERICA – US

26 Failure to warn claims: California adopts the "sophisticated intermediary doctrine" for raw materials suppliers

Brenna Nelinson (Baltimore) sums up a recent California case with significant impact on suppliers of raw materials. The decision provides suppliers of raw materials with another defence when facing failure to warn claims from end-users. But they will have to prove that they provided adequate and precise warnings about the dangers associated with a raw material to the intermediate purchaser, or that the purchaser was already knowledgeable about the dangers.

ASIA-PACIFIC – AUSTRALIA

29 New "Country of Origin" food labelling laws: clarity or more confusion?

Compliance with Australia's new Country of Origin Food Labelling Standard will be mandatory from 1 July 2018. Stuart Green (DibbsBarker, Sydney), Hayley Upton and Kelli Stannard (DibbsBarker, Brisbane) summarise the changes that are being introduced by the new Standard, and advise companies to take prompt steps to meet its demands. Rolling out new "Country of Origin" labels will come at a cost and businesses may need to consider significant redesigns – or even complete rebranding – of some packaging.

Overview

The regulation of medical devices has been under scrutiny at a policy level for some time in Europe. In this issue, we report on the latest development – the finalisation by the EU of the text of two new Regulations to overhaul the regime for the regulation of medical devices (page 6). The upcoming changes will have wide ranging effects on existing medical device manufacturers and distributors, as well as on those who manufacture and supply products that will be caught for the first time by regulation in this sector. More broadly, the changes being implemented for medical devices might, over time, serve as something of a blueprint for the regulation of other safety-critical products in the EU.

Regulatory change is also being implemented in China. In our feature article in this issue we report on some significant changes that affect the conduct of product recalls and other actions in the context of potentially dangerous products (page 2). These new rules mark a further step forward in bringing China well into line with the level of regulation and supervision of product recalls that exists in other parts of the world, such as the United States and the EU. We are yet to see the way in which these new regulations will be enforced by the Chinese authorities. At this stage international product manufacturers and suppliers need to understand these new obligations, and ensure that they comply with them when dealing with potentially unsafe products that have been placed on the Chinese market.

In the United States, we see an important development in the consideration of the obligations of suppliers of potentially hazardous raw materials (page 26). The Californian Supreme Court has extended the potential application of the so-called "sophisticated intermediary doctrine" to suppliers of raw materials. However, it has imposed some strict conditions on the application of that doctrine in that context, which suppliers of raw materials should pay attention to.

Back in the EU, we provide an update on the policy-level consideration of the regulation of the Internet of Things (page 12). This is an issue that ultimately will affect virtually every product sector. The approach taken to the regulation of related technology will have a significant impact on how the technology can be commercialised, as well as on the liabilities of those in the supply chain for "connected" products. This is a significant topic for international product manufacturers.

The regulation of new technologies will be a major focus of the European Commission at the upcoming International Product Safety Week, to be held from 14 to 18 November 2016. Part of this programme will be the Annual International Conference of ICPHSO (the International Consumer Products Health and Safety Organisation). For more information about this programme, which will include high level speakers from around the world, visit www.icphso.org.



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