

Product Recall

Contributing editors

Jason Harmon, Alison Newstead and Devin Ross



2019

GETTING THE
DEAL THROUGH

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Shook, Hardy & Bacon LLP

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For further information please contact editorial@gettingthedealthrough.com

Publisher
Tom Barnes
tom.barnes@lbresearch.com

Subscriptions
James Spearing
subscriptions@gettingthedealthrough.com

Senior business development managers
Adam Sargent
adam.sargent@gettingthedealthrough.com

Dan White
dan.white@gettingthedealthrough.com



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CONTENTS

Global overview	5	Germany	55
Alison Newstead and Harley Ratliff Shook, Hardy & Bacon LLP		Martin Alexander, Carsten Hösker and Joachim Krane BLD Bach Langheid Dallmayr PartGmbH	
European overview	7	Greece	60
Alison Newstead Shook, Hardy & Bacon LLP		Dimitris Emvalomenos Bahas, Gramatidis & Partners	
Argentina	11	Hong Kong	66
Gastón Dell’Oca and Luis Eduardo Sprovieri Forino Sprovieri Dell’Oca Aiolo Abogados		David Goh and Bindu Janardhanan Squire Patton Boggs	
Australia	14	Italy	69
Colin Loveday and Ross McInnes Clayton Utz		Daniele Vecchi and Michela Turra Gianni, Origoni, Grippo, Cappelli & Partners	
Austria	20	Japan	74
Lukas Weber and Arthur Nikolay Brauneis Klauser Prändl Rechtsanwälte GmbH		Kei Akagawa and Shigenobu Namiki Anderson Mōri & Tomotsune	
Brazil	24	Korea	78
Sérgio Pinheiro Marçal and Laura Beatriz de Souza Morganti Pinheiro Neto Advogados		Tony Dongwook Kang Bae, Kim & Lee LLC	
China	28	Mexico	82
Ellen Wang and Yu Du MMLC Group		Alfonso Sepúlveda, Habib Díaz and Luis Fuentes SEPLAW	
Colombia	36	South Africa	85
Daniel Arango and Mauricio Moreno Londono y Arango		Evert van Eeden and Elzaan Rabie Van Eeden Rabie Inc Louis van Wyk Spoor & Fisher	
Denmark	39	Spain	90
Søren Stæhr and Søren Elmstrøm Sørensen Gorrissen Federspiel		Consuelo Álvarez and Christian Krause Monereo Meyer Abogados	
England & Wales	43	Sweden	96
Alison Newstead Shook, Hardy & Bacon LLP		Ida Lindberg and Vencel Hodák Synch Advokat AB	
France	50	United States	100
Florian Endrös and Muriel Mazaud EBA Endrös-Baum Associés		Devin Ross and Jason Harmon Shook, Hardy & Bacon LLP	

Preface

Product Recall 2019

Tenth edition

Getting the Deal Through is delighted to publish the tenth edition of *Product Recall*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

Getting the Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Colombia and Mexico.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Jason Harmon, Alison Newstead and Devin Ross of Shook Hardy & Bacon LLP, for their continued assistance with this volume.

GETTING THE
DEAL THROUGH 

London
October 2018

Global overview

Alison Newstead and Harley Ratliff

Shook, Hardy & Bacon LLP

Product recalls continue to occur at an ever increasing rate. Barring rare cases of malicious tampering, each recall represents a breakdown of risk management, whether in design, manufacture or packaging, in communicating necessary information about the product's characteristics, or in foreseeing ways in which a product might be innocently misused.

High-profile recalls shine a powerful light on how damaging these failures can be – not just potential injuries for consumers and others at risk – but to the reputations of the companies responsible for the products and the value of their brands. The legal consequences are becoming increasingly damaging too. In 2015, the US Department of Transportation's National Highway Traffic Safety Administration imposed US\$200 million in civil penalties – the largest in history – against a Japanese automobile parts manufacturer related to potentially defective airbags. A Japanese court sentenced four former senior executives at Mitsubishi Motors to three years' imprisonment (suspended for five years) for the death of a truck driver after covering up vehicle defects in one of the country's biggest safety scandals. In the United Kingdom in 2007, confectionery producer Cadbury was handed criminal fines totalling £1 million for breaches of food safety legislation that led to the recall of seven products in its chocolate range. In China, severe penalties were handed down in January 2009 after the contaminated baby milk scandal involving misuse of the industrial chemical melamine, including death sentences and life imprisonment for some of those responsible.

The difficulty of the challenge facing managers suddenly tasked with a product safety crisis has been compared by one leading commentator to driving a car backwards at speed with little warning. In most developed countries, the days are gone when companies could internalise the information about the known dangers in their organisations and quietly manage the problem with what has been called a 'silent recall' – the removal of existing stocks of defective products. Globalised markets, higher consumer safety expectations and tighter legislation have made the processes of crisis management considerably more transparent. As well as having to deal with notifying government officials, putting the supply chain into reverse, publishing warnings and managing the logistics of restocking and resupplying large numbers of customers, there is the public admission of failure to be faced, and the threat of mass tort actions as well as regulatory penalties. Managers can be forgiven for thinking when contemplating recalls that they are damned if they do, and damned if they don't.

Many large companies operating in major economies nevertheless still undertake only the most rudimentary recall planning. Where preparations are made, the emphasis is often limited to damage limitation for the brand and public relations strategies. Communications and government relations consultants have developed specialist units that can assist with these functions. There is no doubt that these are critical considerations, sometimes affecting the very survival of a business. The legal and insurance aspects of recalls are often less well anticipated and understood. The need to obtain experienced legal advice early on in product crises, however, has never been greater. As the following chapters amply demonstrate, there has been a rapid growth in regulatory oversight of product recalls. But at the same time, this has increased the diversity internationally in the laws governing questions such as when a product defect is deemed to require notification to national authorities, how that information is dealt with, and how prescriptive

the procedures are for deciding on and managing the various steps to be taken after the need to address a defect has been identified.

United States

The most highly developed laws in this area are probably those found in the United States, whose Consumer Products Safety Commission (CPSC), which oversees more than 15,000 types of consumer goods, has steadily expanded its enforcement authority since its creation in 1972. In addition to the CPSC, the US enlists a host of other agencies, including the Food and Drug Administration (FDA), National Highway Traffic Safety Administration (NHTSA) and Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), to help enforce a myriad of sector-specific product safety laws.

The US overhauled its consumer protection laws when it passed the Consumer Product Safety Improvement Act of 2008 (CPSIA). Among other things, the CPSIA provided for uniform information in recall notices, enhanced powers for the CPSC to dictate how recalls or other corrective actions will be carried out and increased penalties for violations. These penalties include significant fines, possible imprisonment and forfeiture of assets, depending on the nature of the violation. The act also now permits the CPSC to share confidential product safety information with foreign governments and agencies.

The CPSIA also mandated the establishment of a public online hazards reporting database (www.saferproducts.gov). The database allows consumers to submit reports of safety risks or actual harm, as well as search for information on a variety of products and recalls. The CPSC transmits qualifying reports to manufacturers, which may then respond and provide comments to be posted alongside the reports. While the manufacturing industry has voiced concerns about false or inaccurate reporting, the CPSC insists that the database has safeguards in place to minimise these problems. In its first year, the database received reports from more than 6,600 consumers about products ranging from kitchen appliances to footwear to baby cribs. In 2012, in the first lawsuit of its kind, a federal district court in Maryland sided with a consumer product manufacturer and enjoined the CPSC from publishing a report it deemed to be inaccurate and misleading.

Europe

In Europe, the obligations of manufacturers and others in the supply chain were made clearer and more consistent across the EU member states by important revisions to the General Product Safety Directive taking effect from 2004. To promote traceability, Decision 768/2008/EC positively requires the name and address of manufacturers and importers of products placed on the market in the EU to be indicated on the products themselves, or where that is not possible on packaging or other documentation. Further, additional product safety and market surveillance requirements have been proposed in the European Commission's Product Safety and Market Surveillance Package (February 2013). These proposed revisions (due to come into force in 2015 but which have stalled) are discussed in detail in the European overview chapter.

The European Commission produces an annual report outlining trends in European consumer product recall activity. The most recent report indicates that, in 2017, there were 2,201 unsafe product notifications in the EU. China remains the country of origin of most unsafe products in Europe, with 53 per cent of unsafe products being notified

as originating in China. Continued work needs to be undertaken with the Chinese product safety regulator – the Administration for Quality, Supervision, Inspection and Quarantine (AQSIQ) – to prevent unsafe products being designed, manufactured and exported for sale in the EU. Good manufacturing processes, including quality control and post market vigilance, are being increasingly adhered to across the EU, which may account for the increased number of notifications.

Since 2008, the European authorities have been required to go even further to improve capabilities to meet more consistent minimum standards of market surveillance and enforcement by Regulation (EC) 765/2008 (which is part of a package of measures contained in what is known as the New Legislative Framework). The measures include stronger border controls to detect non-compliant products. These will be further strengthened once the Regulation on Market Surveillance of Products comes into force.

It would appear that the growth in European recalls will continue across the board, for consumer products, pharmaceuticals and medical devices and – more and more commonly – food.

Other regions

While the general trend is towards increased regulatory intervention in developed nations, the pace of change is different in other regions, especially Asia. Japan, for example, has had recall laws for a number of years, but it was only at the end of 2006 that it introduced binding rules for notification of ‘serious product accidents’ with defective consumer products to its authorities, and authorised the publication of this information by them. This threshold for notification – actual accidents – is much higher than in the US or Europe, which require there only to be a risk of injury, and only manufacturers and importers are subject to the duty. Japan has, however, increased its authorities’ powers to dictate recall measures.

A number of international bodies exist with the objective of increasing the effectiveness of information sharing and joint enforcement, including the OECD’s Committee on Consumer Policy (CCP), the International Consumer Product Safety Caucus, the International Consumer Product Safety and Health Organisation, the Product Safety Enforcement Forum of Europe and the Committee on Consumer Policy of the International Standards Organisation.

China remains the country of origin for the majority of recalled products in the EU. As a result, the EU, US and Japan have memoranda of understanding with AQSIQ for information sharing and cooperation in addressing problem products. The key issue of traceability of manufacturers of unsafe products in China continues to be a challenge for AQSIQ and the EU authorities. However, cooperation with Chinese authorities and businesses continues to be developed on an EU level. The ‘Rapex-China’ system, which allows for regular and rapid exchange of information between the EU and AQSIQ, has prevented various unsafe products from being exported to the EU. There are also other bilateral agreements, and protocols such as the US/EU guidelines for information exchange and on administration cooperation, and AUZSHARE, a computerised database on enforcement matters for Australian and New Zealand authorities.

Global trends

The direction of travel for international policy in this area can be discerned from the conclusions reached at a round-table meeting of regulators, business representatives and other stakeholders from around the world hosted by the OECD in October 2008. This concluded that there is a need for greater inter-governmental coordination and cooperation, harmonisation of product safety standards, a more proactive approach to product safety failures, an increase in resources available to regulators and a rapid international information exchange system to enable countries to notify each other about the presence of unsafe goods in markets. This was developed further by the OECD Working Party on Consumer Product Safety in 2011 when a web portal with a global inventory of product safety issues and events was established. The OECD’s Global Recalls portal was launched in October 2012 and pools information on recalls and emergency alerts on a single website. Searches can be carried out for recalls of specific products and specific jurisdictions. Consumers also have the option of reporting a health and safety concern to the relevant regulatory authority, such as the European Commission or the US CPSC.

Currently, a significant international trend vital in the recall context is that of product traceability. In Europe, the PIP breast implant scandal added impetus to the EU’s new regulatory framework for medical devices and in vitro diagnostic medical devices, which imposes more stringent standards regarding recall. Two new regulations strengthen the regulatory framework relating to medical devices including pre-market assessment of devices, post market surveillance and the transparency of data. The new rules will only apply after transitional periods of three years after entry into force for the Regulation on medical devices (May 2020) and five years after entry into force for the Regulation on in-vitro diagnostic medical devices (May 2022). Similarly, traceability features strongly in the proposals set out in the European Commission’s Product Safety and Market Surveillance Package, adopted in February 2013 (but still awaiting approval). The legislation, if implemented, will see the replacement of the General Product Safety Directive with a new Consumer Product Safety Regulation, including increased requirements on manufacturers and importers relating to labelling products with their country of origin and enhanced obligations regarding contact information for the manufacturer and importer in order to be better able to identify parties throughout the supply chain.

Finally, readers interested in global trends in product safety and recalls and comparisons between national legal and enforcement regimes will find useful information in a study produced for the OECD’s CCP entitled Analytical Report on Consumer Product Safety (DSTI/CP(2008)18/FINAL), and another report entitled Enhancing Information Sharing on Consumer Product Safety (DSTI/CP(2010)3/FINAL), both available at www.oecd.org.

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