





## Product Recall 2013

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# Global Overview

**Alison M Newstead and Harley V Ratliff**

Shook, Hardy & Bacon International LLP

Product recalls are happening all the time, as can readily be seen from newspapers, store advertisements, government agency announcements and a variety of other media. Relatively few grab the headlines in the way seen with the publicity over Toyota's worldwide recall of millions of Priuses and other vehicles in 2010. 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.

The recalls that do have a high profile 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 June 2009, the toymaker Mattel agreed to pay US\$2.3 million in civil penalties in the United States for violating a federal lead paint ban that led to the recall of millions of its Barbie, Dora the Explorer and other popular toys in 2007. 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 on 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) was established in the 1970s and where there have long been duties on manufacturers and others responsible for supplying products to notify the authorities when their products do not meet safety standards or might have defects posing substantial risks to consumers. As with many other countries the precise requirements vary from product to product. A number of other different sector-orientated regulators for products (eg, food, tobacco, drugs, pesticides, firearms and motor vehicles) sit outside the remit of the CPSC.

The Consumer Product Safety Improvement Act of 2008 (CPSIA) has overhauled consumer protection law generally in the US and, among other things, provides 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 contains various provisions dealing specifically with children's products, including limitations on hazardous substances and small parts, third-party safety testing requirements to ensure compliance and tracking label requirements to help determine a product's origin. The act was amended in August 2011 to allow the CPSC to grant exclusions to the tracking requirements where compliance would be impracticable, and at the time of this publication the CPSC is considering ways to reduce the burdens of third-party testing.

The CPSIA also provides for the establishment of an online hazards database ([www.saferproducts.gov](http://www.saferproducts.gov)), which the CPSC launched publicly in March 2011. 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, who 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 over 6,600 consumers about products ranging from kitchen appliances to footwear to cribs.

### 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 now 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.

The EU's 2011 Annual Report shows how awareness of these obligations, which require the notification of unsafe products, has increased considerably during this period. 2011 saw 1,803 unsafe product notifications, of which 1,556 were serious risk notifications reported through RAPEX. These notifications are ones that have been transmitted by the EU to authorities across the 27 member states and details of the products posing a serious risk are published on the RAPEX website.

The European authorities are now being required to go even further to improve capabilities to meet more consistent minimum standards of market surveillance and enforcement by Regulation (EC) No. 765/2008 (which is part of a package of measures contained in what is known as the New Legislative Framework). The measures also include stronger border controls to detect non-compliant products. Aside from consumer protection, one justification given for these measures is levelling the playing field for compliant businesses. It would appear that the growth in European recalls will continue. As a consequence of this growth, new guidelines for the management of RAPEX and member state information-sharing measures was published in Decision 2010/15/EU, including a new risk-assessment methodology for determining the seriousness of product defects and the need for urgent action.

### 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 United States 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 (ICPSC), the International Consumer Product Safety and Health Organisation (ICPSHO), the Product Safety Enforcement Forum of Europe (PROSAFE) and the Committee on Consumer Policy of the International Standards Organisation (ISO-COPOLCO).

The significant number of recalls involving products of Chinese origin (eg, 54 per cent of European RAPEX notifications in 2011) has led to recognition of the need for international liaison with the authorities in China. The EU, US and Japan have memoranda of understanding with the Administration for Quality, Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ) for information sharing and cooperation in addressing problem products. 2011 saw a round-table meeting in Beijing between the EU, US and Chinese authorities in which the parties considered the most effective ways of increasing awareness of EU and US product safety standards among those involved in the design, manufacture and export of products from China. The key issue of traceability of manufacturers of unsafe products in China continues to be a challenge for AQSIQ and the EU authorities. 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 and work commenced on a global data pool of product recalls, to be operational in 2012.

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](http://www.oecd.org).

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