Product Recall

In 22 jurisdictions worldwide

Contributing editors
Alison M Newstead and Harley V Ratliff

2015

GETTING THE DEAL THROUGH

GETTING THE DEAL THROUGH

Product Recall 2015

Contributing editors

Alison M Newstead and Harley V Ratliff

Shook, Hardy & Bacon International LLP

Publisher
Gideon Roberton
gideon.roberton@lbresearch.com

Subscriptions
Sophie Pallier
subscriptions@gettingthedealthrough.com

Business development managers
George Ingledew
george.ingledew@lbresearch.com

Alan Lee
alan.lee@lbresearch.com

Dan White
dan.white@lbresearch.com

Law Business Research

THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 7908 1188
Fax: +44 20 7229 6910

First published 2009
Sixth edition
ISSN 2042-2040

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

CONTENTS

Global Overview

Alison M Newstead and Harley V Ratliff
Shook, Hardy & Bacon International LLP

Product recalls continue to occur at an ever increasing rate. In the US, the Federal Food and Drug Association's Centre for Devices and Radiological Health recently reported that the number of medical device recalls increased by 97 per cent between 2003 and 2012. Similar increases have been seen across other consumer product industries. Although by no means alone in terms of high volume recalls, General Motors Co recalled more than 29 million vehicles in 2014. 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), 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 United States 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 (TSA), to help enforce a myriad of sector-specific product safety laws.

The United States 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), 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. 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.

The CPSC continues to aggressively push the limits of its enforcement authority. One recent trend, for example, has been the CPSC's pursuit of legal actions against defunct companies and their former employees. The CPSC has also recently begun mandating that companies seeking to settle CPSC legal actions implement sweeping internal compliance systems to improve regulatory compliance and product hazard reporting.

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) are discussed in detail in the European Overview chapter.

The EU's 2013 Annual Report shows how awareness of product safety and market surveillance obligations, which require the notification of unsafe products, has increased considerably since 2004. 2013 witnessed a 4 per cent increase in notifications of unsafe products throughout Europe. There were 2,364 unsafe product notifications in total, of which 1,981 were serious risk notifications. These notifications are those that have been transmitted by the EU to authorities across the 28 member states and details of the products posing a serious risk are published on the RAPEX website. The reason for this recent upward trend in notifications is unclear: it may be that increased numbers of dangerous products are entering the European marketplace; conversely the vigilance efforts by member states may be leading to an increased number of products being detected. It is of note that 64 per cent of total notifications were products of Chinese origin (a 6 per cent increase on 2011). This demonstrates the need for international cooperation and coordination by regulatory authorities.

As from 2008, the European authorities were 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 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, detailed guidelines for the management of RAPEX and member state information-sharing measures were 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).

Recalls involving products of Chinese origin continued to increase in 2012 and have 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. 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, with encouraging results. The 'RAPEX-China' system, which allows for regular and rapid exchange of information between the EU and the Chinese Product Safety Administration has certainly proved beneficial, often preventing 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 scandal added impetus to the EU's proposals for a new regulatory framework for medical devices and in vitro diagnostic medical devices. The proposals will impose more stringent standards, including improved traceability of products. The proposals are expected to be adopted in 2014 and to be implemented gradually between 2015 and 2019. Similarly, traceability features strongly in the proposals set out in the European Commission's Product Safety and Market Surveillance Package, adopted in February 2013. These proposals are currently being considered by the European Parliament and are expected to come into force in 2015. 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.

European Overview

Alison M Newstead
Shook, Hardy & Bacon International LLP

The success of the European market has led to increasing numbers of products moving freely across European borders. The result of this free movement is that the same products (and their inherent safety risks) are commonly found in many jurisdictions. A pan-European structure therefore needs to be in place to effectively manage any product safety issues that may arise.

The aim of European product safety legislation is to ensure that a consistent approach to the regulation of product safety issues is adopted across the EU. A uniform approach facilitates the smooth running of cross-border commercial activities and gives assurance to community citizens that effective measures are in place to ensure that the products they use in their daily lives are safe.

Laws governing product recall in Europe

In Europe, the laws governing the safety requirements that consumer (non-food) products must meet and the corrective action that needs to be taken by producers (and others) when a product poses a safety risk are set out in the General Product Safety Directive (2001/95/EC) (GPSD). These requirements are implemented in each member state by way of national laws.

The main obligations prescribed by the GPSD are monitored and enforced by competent national authorities; however, there is an important overarching supervisory function played by the European Commission, which ensures that information obtained regarding unsafe products is disseminated quickly and efficiently throughout the EU.

The obligations set out in the GPSD apply to products intended for, or likely to be used by, consumers. Other similar regulatory regimes are in place for food products, pharmaceuticals and medical devices. In addition, Regulation (EC) No. 765/2008 on Accreditation and Market Surveillance (RAMS) contains extra provisions that apply to 'professional' products covered by EU harmonisation legislation (eg, machinery, electrical goods): this means that member states – through their market surveillance authorities – should have powers not only to restrict the sale of non-compliant products but to order their recall as well. Thus recall powers are not limited to consumer products and may extend to products used for business purposes if they are subject to EU harmonised requirements. This chapter deals primarily with the current regime as it applies to non-food consumer products.

It should be noted that the current EU legislative framework is likely to be revised in 2015 in response to the proposals set out in the European Commission's Product Safety and Market Surveillance Package, adopted in February 2013. These proposals are currently being considered by the European Parliament and are expected to come into force in 2015. The Package, if implemented, will see the replacement of the General Product Safety Directive with a new Consumer Product Safety Regulation and the introduction of a Regulation on the Market Surveillance of Products. If implemented in their current draft form, these Regulations will have significant practical implications for those who manufacture, distribute or sell products within the EU. In particular, there will be additional obligations with regard to labelling, preparation of risk assessments, extended obligations to manufacturers, importers and retailers regarding notification of risks, penalties which are linked to the size of the business, increased scope of market surveillance provisions and additional obligations on national authorities with regard to investigations, in addition to explicit powers regarding recall.

Who are 'producers' and what are their obligations?

Under the GPSD, 'producer' is a term that encompasses manufacturers, first importers into the EU, 'own branders', and 'other professionals in the supply chain insofar as their activities may affect the safety of a product'. To this end, the reach of the GPSD's obligations is widely cast.

The GPSD sets out an obligation on producers to only place safe products on the market. In accordance with article 2(b) of the GPSD, a safe product is:

> *any product which, under normal or reasonably foreseeable conditions of use [...] does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:*
> - *the characteristics of the product [...];*
> - *the effect on other products [...];*
> - *the presentation of the product, the labelling, any warnings and instructions for its use [...];*
> - *the categories of consumers at risk when using the product, in particular children and the elderly.*

This definition may be expanded in 2015 if the provisions of the proposed Consumer Product Safety Regulation remain as drafted. The definition will additionally cover the appearance of a product and, in particular, where a product, although not foodstuff, resembles foodstuff and is likely to be confused with foodstuff due to its form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics.

In addition to the obligation to only place safe products on the market, producers are also obliged to provide information and warnings to consumers as to any inherent risks that a product may pose. Such measures commonly comprise instruction booklets containing safety advice and warnings or labels on the products themselves.

On an administrative level, producers also have to ensure that they have adequate systems in place to enable them to monitor and address any safety risks, and to take any appropriate action such as issuing warnings, or withdrawing or recalling the product from the market should a safety risk arise.

Specific requirements are set out as to 'traceability', requiring products or their packaging to bear details of the producer and the product reference or batch number. Consumers should therefore be able to easily identify and contact producers directly in the event that they experience a problem with a product. Product references (eg, model and serial number) or batch number information allows the producer to identify quickly and concisely which products may be affected and where they have been distributed. Such information is vital when addressing a potential safety risk: primarily in order to carry out risk-assessment investigations on the correct products, and subsequently in order to embark on appropriate and effective corrective action, whether this is by way of new or additional warnings, withdrawal, recall or otherwise.

The new proposed Consumer Product Safety Regulation sets out increased requirements on both manufacturers and importers (the new proposed Regulation does not use the term 'producer' as defined in the GPSD) as to labelling products with their country of origin. There are also enhanced obligations regarding contact information for the manufacturer and importer and the ability to identify parties throughout the supply chain.

In order that producers are kept adequately informed of the risks that their products may pose, producers are also currently required to carry out sample testing on their products (where appropriate) and, if necessary, to keep a register of complaints. Sample testing has the obvious benefit of identifying potential safety issues before the products reach the market and a register of complaints is an ideal tool to monitor trends and carry out risk-assessment investigations at an early stage. However, any internal register or list of complaints will only be useful if it is regularly reviewed and acted upon by producers. National authorities may also request access to any such register when considering whether appropriate and timely steps have been taken by a producer to address a safety problem. Authorities will not look kindly on those producers who have a record of an emerging potential safety risk, but have failed to act upon it.

The new proposed Consumer Product Safety Regulation, if implemented, sets out new obligations on manufacturers to prepare and retain technical documentation, including a documented risk assessment. Technical documentation which is used to put together the risk assessment must also be retained for 10 years and presented to the market surveillance authorities on request.

What are the obligations of distributors?

It is not just producers who are obliged to take positive action under the GPSD; distributors also play a key role in the supply chain and they therefore also have obligations to assist producers in ensuring that products are safe. Of course, the nature of a distributor's role and its contact with consumers is likely to vary from product to product, but the provisions of the GPSD make it clear that distributors should play an active role in monitoring product safety, by passing on information to producers and national authorities about product risks, maintaining appropriate documentation so that unsafe products may be traced and cooperating with producers and competent authorities should any redress action need to be taken.

In addition to the current obligations, the proposed Consumer Product Safety Regulation sets out additional obligations for importers to ensure that manufacturers have complied with their documentation and labelling obligations and to deal with non-compliance with obligations by other parties in the supply chain.

How is a notification of an unsafe product made to a national authority?

When a producer or distributor knows, or ought to know, that a product is unsafe, notification should be made immediately to the relevant authorities in each of the territories where the product has been marketed.

Notifications are usually made by way of a standard format and are commonly sent to national authorities by e-mail, fax or post. There is also an option for EU businesses to use an online notification system called the 'GPSD Business Application' (see below).

In making a notification, details should be provided as to the product, the risk that it poses and the action that is to be taken to protect the consumer from that risk. While the obligation is to notify the authority in each member state where the product has been marketed, this is not necessary if the product poses a serious risk. All other member states will be notified through the RAPEX information system in any event.

The Commission's outline notification form can be found on the European Commission's website. Each national authority will specify the exact information that they require and will commonly revert to the party making a notification for further information, if necessary.

If a product poses a serious risk to health and safety, information given to the national authority must include details as to the authorities and companies receiving the notification, the party making the notification, the identity of the product or batch of products in question (and their country of origin), a full description of the risk that the products present, all available information relating to the tracing of the product, a description of the corrective action undertaken to prevent risks to consumers and details of companies in the distribution chain.

Part IV of the Commission's guidelines on the notification procedure and RAPEX sets out the standard notification form which is used by member states to make notifications to the European Commission. Producers should be aware of the content of this standard form and be ready to supply such information to their national authority if requested.

To make notification quicker and easier, the European Commission has set up an online notification procedure called the 'GPSD Business Application'. This allows producers or distributors to complete the notification form online and send it to all of the member states of the EU.

Any businesses that are established in the EU, or that have a representative in the EU, can use this online notification system. However, the traditional forms of notification (fax, e-mail and post) are still accepted.

The portal through which online notifications can be made can be found on the European Commission's website. This portal includes a manual on how to complete the online notification process and sets out the form that needs to be completed by the party making the online notification.

Access to the information submitted to this online system is limited exclusively to the competent authorities in each member state and cannot be accessed generally by the public.

Who should make the notification?

The GPSD suggests that it is for the distributor, as well as the producer, to make the necessary notification to the national competent authority should a safety risk arise. In practice, however, it is accepted that it is commonly only the producer who makes the notification. This is generally for practical reasons; the distributor may well have passed all information to the producer as to possible safety issues (eg, via customer complaints), but it is unlikely to be equipped with the necessary technical information about the product to carry out the risk-assessment process and decide whether a notification is necessary. As a result, notification is something that is commonly handled by the producer who has the relevant information, resources and expertise to hand. The duplication of notifications is not necessary. If a distributor or producer knows that all relevant information has been conveyed to the competent authority by the other party, then it is not obliged to repeat the notification.

When should a notification be made?

The GPSD states that notifications should be made 'immediately'. Guidance from the European Commission suggests that notifications should be made 'as soon as the information on the dangerous product has become available and in the case of serious risk within three days and any other cases within 10 days in any event'. The member states have different interpretations as to what is considered to be 'immediate', although the drafting of the GPSD clearly suggests that investigations and notifications to competent authorities should not be unduly delayed.

In some cases, a producer may initially have scant information to enable it to commence a risk assessment and determine whether a notification is necessary. Practices differ in each member state, but in some circumstances a producer may inform national competent authorities that a potential safety risk is being investigated and a decision as to formal notification will be made once risk assessments are complete. The Commission's view is that parties should not delay in submitting a notification because all information as to the potentially dangerous product has not been collected and reviewed. This is sometimes difficult to square with the need to carry out a thorough risk assessment and decide whether notification is required at all.

Under article 5(4) of the GPSD, producers and distributors are obliged to cooperate with their national competent authority in respect of any corrective action that is undertaken (whether voluntarily or as deemed appropriate by the national authority). The GPSD leaves it to the national authorities to establish procedures for cooperation and exchange of information, but commonly there is a continuing dialogue between the parties once notification has been made. The Commission expects national authorities to monitor the effectiveness of any corrective action and to ensure that additional measures including enforcement action are taken, if necessary.

Who are the national competent authorities?

The GPSD sets out the framework for each member state to establish or nominate national bodies to ensure that obligations under the GPSD are complied with and that information about safety risks is circulated to the European Commission for onward transmission to other member states.

The GPSD specifically advocates that national authorities should have wide-ranging powers to ensure that adequate measures are taken to address product safety risks. These measures include a requirement to affix warnings to products, temporary bans on supply in order to carry out investigations, total bans on marketing of a product, withdrawal, recall and destruction. Nevertheless, any such measures that are taken must be proportionate and take into account the precautionary principle.

While the GPSD conveys wide-ranging powers to national authorities to ensure that adequate steps are taken to address the problems of unsafe products on the market, the idea of voluntary rather than formal action is

advocated. In practice, responsible producers commonly embark on voluntary corrective action and fully cooperate with national authorities to ensure that they take measures which are both proportionate and acceptable to the national authorities. It is usually only where producers fail to take any action, or their action is not deemed to go far enough, or indeed where the producers cannot be identified, that national authorities call on these powers to deal themselves with products posing a risk.

Should the new proposed Regulation on Market Surveillance be implemented, national authorities will have enhanced obligations with regard to investigating the safety of products and sharing information with other authorities, including those outside the EU.

What about penalties for non-compliance?

The GPSD is not prescriptive as to the level of penalties that should be applied for failure to comply with obligations under the GPSD; it is left for national law in each member state to set out the penalties for infringement. Nevertheless, the GPSD is clear that such penalties should be 'effective, proportionate and dissuasive'. It should be noted, however, that the proposals in the Product Safety and Market Surveillance Package include an obligation on national authorities to take into consideration the size of the undertaking and whether previous infringements have been committed.

How is information in notifications conveyed between member states?

Although day-to-day monitoring and compliance with product safety obligations is carried out at a national level, the European Commission remains very much at the heart of the product safety network. The Commission takes an active role in the operation of a European network of national competent authorities and is the central point for transmission of information in notifications to all member states.

If steps are taken to restrict the placing of consumer products on a market, or there is a withdrawal or recall of a product from a national market, to the extent that the European Commission is not required to be notified through the RAPEX system (see below), the national competent authorities are required to notify the European Commission of the steps that are being taken in that territory, and the reasoning behind the particular action being adopted (the national authorities must also inform the Commission if the particular measures are modified or lifted).

It is then for the European Commission to forward the information contained in the notifications to the other national authorities for their information. A list of the 'National Contact Points' to whom information is disseminated by the Commission can be found on the Commission's website.

It is possible that, in some instances, a safety issue may only be concerned with one particular member state. In such circumstances, although notification to the relevant national authority is required, measures taken only need to be notified to the European Commission if there is information that the Commission may consider as of interest from a safety point of view, or if the action is taken in response to a new type of risk that the Commission may not have previously come across in other notifications.

What is the RAPEX system, when is it employed and how does it work?

Information as to unsafe consumer products that do not pose a serious threat is exchanged between national enforcement authorities and the European Commission by way of the 'notification procedure'. However, it is the RAPEX system that plays a key role in ensuring that information as to products that pose a serious threat, and the measures that are being taken to address this, can be disseminated and acted upon quickly throughout the European market.

There are currently 31 countries that participate in the European RAPEX system – all of the EU member states and the EEA/EFTA countries of Liechtenstein, Norway and Iceland.

RAPEX does not apply to products that are covered by specific and equivalent notification mechanisms established under other EU legislation such as food and feed (Regulation (EC) No. 178/2002), for which a separate EU information system exists – the Rapid Alert System for Food and Feed (RASFF). Separate alert systems are also in place for medicines and medical devices.

When a producer has identified that a product poses a serious safety risk to consumers and steps are taken in conjunction with the national competent authority to address this risk (whether measures preventing, restricting or imposing conditions on the marketing or use of consumer products), notification is made immediately to the European Commission, via the national authorities and the National RAPEX Contact Point. Such notifications are made regardless of whether the measures are taken on a voluntary or compulsory basis. Any modifications to the action taken or decisions not to proceed or cease the corrective action are also notified to the Commission.

If a product poses a serious risk to the health and safety of consumers but, in addition, emergency action is required by the member states as the product in question poses a life-threatening risk, or there have been fatalities associated with the product, then the national authority will make the notification to the European Commission additionally stating that it requires 'emergency action'.

On receipt of RAPEX information, the Commission is at liberty to carry out its own investigations and the member states are required to supply the Commission with information 'to the best of their ability' in order that such investigations may be completed. In practice, such requests for further information are likely to be passed on directly to producers, who will need to be ready to provide the information requested.

If a product that poses a serious risk is limited to a single EU country, then the RAPEX system is not employed, but the general notification procedure is followed instead.

When notifications are received by the Commission through the RAPEX system, they are forwarded to all other member states, which in turn are obliged to inform the Commission immediately of any steps that are taken to address the risks within their territories.

Products that pose a serious risk and have been notified to the Commission are published each week on the Commission's website.

The weekly notifications set out the year and week of the notification, the notifying country, a description of the product (and a photograph, if available), the product's country of origin, the danger posed by the product, measures adopted by the notifying country, and details of other countries in which the products were found and measures taken.

There is also a search facility on the Commission's RAPEX website allowing users to search for previous notifications using keywords relating to the product, the risk it poses, or the country in which the notification was made.

How are 'serious risks' identified?

In January 2010, new guidelines were published by the European Commission (Decision 2010/15/EU), which provide detailed assistance to national market surveillance authorities as to how to carry out risk assessments in respect of products and determine whether they pose a serious risk to health and safety.

The guidelines set out a risk-assessment method whose aim is to assist market surveillance authorities (and thus producers) in each member state to take a uniform approach in determining whether a product poses a serious risk to 'the public interest', including health and safety. Previous risk-assessment methods used (eg, the nomograph method, the matrix method and the method previously recommended by the Commission for the RAPEX system), were found to produce differing results. The 2010 guidelines were therefore intended to improve the risk-assessment process, providing a standard approach to addressing the questions of hazard, probability and risk, without ruling out the use of other methodologies.

The guidelines are detailed and provide a step-by-step guide as to what steps should be taken, and what questions should be asked in order to build up a risk assessment. The guidelines look at the product, the hazard it poses, the category of consumers likely to be affected, injury scenarios, the severity of injuries, the probability of injury and a final determination of risk. Guidance is also given as to how to decide what corrective action is appropriate to address the risks identified.

The guidelines specifically state that the risk assessments should be documented 'describing the product and all the parameters you chose while developing it, the type(s) of consumer you chose for your injury scenario(s) and the probabilities with the underlying data and assumptions'. In documenting how the risk assessment is carried out, producers should be able to give a reasoned explanation to national authorities as to the level of risk the product poses and to justify the corrective action proposed. By having a clear document of the risk-assessment methodology, a producer will also then be able to easily update the risk assessment should new information come to light. Failure to keep an accurate record of the approach adopted could lead to criticism by the national authority and make it difficult to challenge any different conclusions as to risks that the national authorities may reach, should they carry out their own risk-assessment investigations.

The results of any risk assessment carried out by a producer or distributor are not binding on the national authorities and national authorities may come to a different conclusion from producers as to the risks that a product may pose and the action that should be taken. The national authorities work through the risk-assessment procedure on receipt of any notification to assess whether the product poses a serious risk and a RAPEX notification is necessary, and what corrective action they consider producers and distributors should take. This assessment is checked by the National Contact Point before being submitted to the RAPEX system.

What are the current European recall trends?

Each year, the European Commission publishes an annual report on the operation of the RAPEX system, providing an overview of recall trends in the EU.

The 2013 Annual Report highlights a number of key trends:

- Between 2004 and 2010 the total number of notifications saw a continual upward trend, rising from 139 notifications in 2003 to 2,244 notifications in 2010. 2011 saw a decrease of 20 per cent in notifications to 1,803. However, the upward trend began again in 2012, with 2,278 notifications, and continued in 2013 with 2,364 notifications.
- The most notified product categories in 2013 were clothing, textiles and fashion (25 per cent) and toys (25 per cent), followed by electrical appliances and equipment (9 per cent), motor vehicles (7 per cent) and cosmetics (4 per cent). Other categories constitute 30 per cent of the notifications.
- The most frequently notifying countries were Hungary, (12 per cent), Spain (11 per cent), Germany (11 per cent) Bulgaria (8 per cent) and the UK (6 per cent).
- 64 per cent of all notifications through the RAPEX system in 2013 related to products originating from China.
- Only 15 per cent of notifications related to products of EU or EEA/EFTA origin.
- 74 per cent of notifications made in 2013 concerned products which could be traced by brand and type or model number. In 21 per cent of cases either the brand or type or model number were known. In only 5 per cent of cases were there no details of brand or type or model available, thus hindering traceability.

Worldwide cooperation

As products move globally and not just across EU borders, the European Commission has embarked on a number of initiatives with other countries to improve product safety for the benefit of citizens worldwide.

The most important of these initiatives is the links that the European Commission has with China. China is currently the greatest source of unsafe consumer products on the EU market. A memorandum of understanding signed between the European Commission and the Chinese product safety regulator, AQSIQ, in 2006 (and revised in 2008), establishes a framework for cooperation and collaboration between the two authorities to ensure the safety of consumer products exported into the EU. A 'RAPEX China' application has also been set up to forward RAPEX information to AQSIQ when notifications are made in respect of products of Chinese origin. Details are provided to AQSIQ as to products which have been identified as dangerous and withdrawn or banned from the EU market. AQSIQ then investigates in China and takes steps, where necessary, to prevent the further export of dangerous products. AQSIQ reports to the Commission on a quarterly basis as to follow-up action which is taken as a result of these notifications.

Bilateral cooperation also exists between the European regulators and the regulators in the US and Japan. Trilateral discussions and initiatives between Europe, US and China also exist with a view to ensuring the protection of consumers on a global basis.

United Kingdom

Alison M Newstead

Shook, Hardy & Bacon International LLP

General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

Consumer products

The General Product Safety Regulations 2005 (GPSR) require that producers shall not place products on the market unless they are safe and provided with appropriate warnings and instructions for use. Producers must also monitor the safety of their products after they have been placed on the market. The duties are essentially the same as those provided for in the EU General Product Safety Directive 2001/95/EC (GPSD).

Distributors (ie, others in the supply chain) are required to help ensure compliance with safety requirements, including participating in monitoring of the safety of products on the market by passing on information about risks.

Commercial products

The UK currently has separate legislation (not derived from the EU) covering the safety of products intended for commercial use, principally section 6 of the Health and Safety at Work Act 1974 (HSWA) which is enforced by the Health and Safety Executive (HSE). Manufacturers, importers and other suppliers are required to ensure, so far as is reasonably practicable, that the products are safe and without risks to health at all times when they are being used or maintained. They must also arrange for the carrying out of appropriate testing and examination to ensure products are safe. The market surveillance powers of the HSE are in the process of being extended – see 'Update and trends'.

Sector-specific safety legislation

Numerous regulations govern particular types of products, for example, food, pharmaceuticals, medical devices, machinery, electrical items, vehicles and toys. Often these regulations implement European directives and legislation will be similar to that of European member states.

The European Commission's Product Safety and Market Surveillance Package, adopted in February 2013, sets out increased obligations for manufacturers, importers, distributors and national authorities to improve the safety of products on the EU market and market surveillance activities. These proposals (in the form of a new Consumer Product Safety Regulation and Regulation for Market Surveillance of Products) are currently being considered by the European Parliament and are expected to come into force in 2015. Further details are set out in the European Overview chapter.

2 What requirements exist for the traceability of products to facilitate recalls?

Requirements for traceability of consumer products are that products should be supplied with details of the producer's name and address and the relevant product reference or batch marking. There are no generic requirements for commercial products' traceability.

Some sector-specific legislation contains more detailed requirements. For example, the General Food Regulations 2004 and the Food Safety and Hygiene Regulations 2013 (which give effect to European Regulation EC 178/2002) contain requirements for extensive traceability systems throughout the supply chain. Traceability of products also features in legislation for pharmaceuticals and medical devices as part of required vigilance systems. Under the Vehicle and Operator Services Agency's (VOSA) Code of Practice on vehicle safety defects, the UK Driver and Vehicle Licensing Authority will assist in tracing vehicle owners.

Additional obligations as to traceability requirements are set out in the proposed Consumer Product Safety Regulations, due to come into force in 2015.

3 What penalties may be imposed for non-compliance with these laws?

Consumer products

The UK does not have a system of administrative fines. Penalties are dealt with in the criminal courts. Offences are mostly based on strict liability, but may be subject to a defence of due diligence. The principal penalties are criminal fines imposed on companies after conviction of up to £20,000 per offence. Provision also exists for suppliers or others who are natural persons (as opposed to corporations) to be imprisoned for up to 12 months, though this is rarely used. Criminal proceedings are brought in most cases against the corporate entity that is responsible for manufacture or supply of the product in the UK. Directors, senior executives and other individuals can also be prosecuted personally where they are responsible for a contravention by a corporation, although cases are uncommon.

Penalties for offences in relation to food and drink products may be higher, with the potential for fines with no upper limit set by the legislation. In 2007 chocolate-maker Cadbury was fined a total of £1 million for breaching food safety laws in a salmonella outbreak that affected over 40 people.

The authorities may also apply to the courts for an order for the forfeiture (ie, seizure) of consumer products that are dangerous, and these goods will be destroyed unless the courts direct otherwise.

Various other enforcement powers are available to the authorities that do not require them to first obtain court orders, including suspension notices (which require the temporary suspension of supply or marketing of products that are suspected of contravening product safety requirements, while tests and other investigations are carried out); and requirements to mark (notices requiring clear and comprehensive warnings to be marked on products of their risks, or to make products' marketing subject to prior conditions). See also withdrawal notices, requirements to warn and recall notices below. Recipients of such notices are entitled to appeal against them.

The proposed Consumer Product Safety Regulation goes further and requests member states to take account of the size of businesses when considering penalties and any previous infringements.

Products for commercial use

Penalties for contravention of safety requirements relating to commercial products under the HSWA are criminal fines of up to £20,000 if cases are dealt with in the lower courts. Cases of greater seriousness are dealt with in the higher courts where there is no statutory limit on the amount of the fine that may be imposed. There are provisions whereby individuals can be convicted of offences (eg, directors and officers of a corporation responsible for a product) for up to two years. Sector-specific legislation may also create separate offences, with lower penalty limits. The HSE may, where offences under the HSWA and sector specific legislation overlap, in effect choose which offence it deems appropriate to proceed with (*Re Bristol Magistrates Court and Others, ex parte Junttan Oy* (2003) UKHL 55). Other enforcement powers are available to the HSE (see question 19).

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

Consumer products

The GPSR require producers or distributors to notify the enforcement authorities if they know that products they have placed on the market or supplied do not comply with the general safety requirement. Although the obligation to notify applies to producers and distributors, in the UK the authorities' approach is that notification by one of them is sufficient.

In general the requirements concern notification of information concerning defects or newly discovered risks, irrespective of whether any incident, injury or damage has yet occurred.

Commercial products

There are currently no UK statutory requirements yet requiring notification to the authorities of defective products for commercial use. (See, however, the rules referred to in question 5 for specific sectors.)

Where products have been tested or certified by a third party it is possible there may be a contractual obligation incorporated into the agreement requiring the manufacturer or its representative to inform the body concerned. This body might in turn inform the authorities.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

The criterion for notification is simply that a consumer product is known to have risks that are incompatible with the general safety requirement – namely, that it is not safe. It is not necessary for there to have been an incident involving personal injury or property damage. 'Isolated circumstances or products' do not need to be notified.

The UK government has published guidance on when notification is appropriate (Notification Guidance for Producers and Distributors (DTI, September 2005)). This refers to the European Commission's methodological framework for assessing risk contained in its published Guidelines for the Notification of Dangerous Consumer Products (2004) for the purposes of the GPSD. However, these risk-assessment guidelines have been superseded by Decision 2010/15/EU, which sets out revised risk-assessment guidelines. The aim of the new guidelines is to provide a practical and transparent risk-assessment method for use by member states' competent authorities when they assess risk in non-food products. The risk-assessment methodology looks at the product itself, the product hazard, the abilities and behaviour of the consumer (in particular vulnerable consumers), injury scenarios, the severity and probability of injury and the determination of risk. The number of products supplied or users potentially affected is not a relevant consideration for notification, although it may be taken into account in determining what action to take to address the risk.

The obligation under the GPSR is to notify the authorities 'forthwith' (or immediately) upon knowing a product is unsafe. The UK government guidelines advise that in practice this means making a notification as soon as possible, and no later than 10 calendar days of a risk assessment or obtaining other information showing the product is unsafe. Further, where there is a serious risk, the notification should be made no later than three days after the information has been obtained.

Food and drink

Obligations to notify the Food Standards Agency (FSA) and relevant local authority of unsafe food and drink products are governed by Regulation EC/178/2002 on General Food (article 19) and the Food Safety and Hygiene Regulations 2013. A food business operator must notify the authorities if it considers or has reason to believe that food it has placed on the market may be injurious to health.

Pharmaceuticals

Notification obligations are incorporated into manufacturers and wholesale dealers' licences and marketing authorisations. Generally the duty is to notify immediately once investigations have identified a defect that could result in recall or other restrictions on supply. See: A Guide to Defective Medicinal Products (MHRA, 2004) and guidance on the website of the European Medicines Agency, www.emea.europa.eu.

Medical devices

The medical devices directives require vigilance systems which include reporting to the Medicines and Healthcare Products Regulatory Agency (MHRA) by the manufacturer or its authorised representative of malfunctions or deteriorations in a device, inadequacies in labelling or instructions for use that might lead or have led to a patient's or user's death or serious health effects and any technical or medical reasons for a systematic recall of the devices.

The MHRA's Directives Bulletin 3 – Guidance on the operation of the EU vigilance system in the UK (September 2008) – provides interpretation and guidance on notification of different types of incidents, based on the European Commission guidance document MEDDEV 2.12-1 Rev 5. Notification should be immediate upon the defect being known. The guidance contains guidelines on time limits ranging from two days to 10 days depending on the seriousness of the issue. It should be noted that in September 2012 the European Commission adopted a package of proposals relating to medical devices including a new regulatory framework. Important changes are proposed which will affect the scope of the current legislation, the pre-market assessment of devices, their control once on the market, the transparency of data concerning devices and the management of the regulatory system by the authorities. These proposals are currently being considered by the Council of the European Union and it is not yet clear when these reforms will come into effect.

Motor vehicles

Supplemental to the general consumer product laws above, the VOSA's Code of Practice on vehicle safety defects applies to all vehicles (private and commercial). It requires notification to the VOSA by manufacturers of vehicle or component parts, importers, distributors or concessionaires of 'safety defects' (defined as features of design or construction liable to cause significant risk of injury or death). VOSA's Code of Practice and Manufacturers' Guide to Recalls in the UK Automotive Sector (March 2013) advocate early notification of alleged safety defects, even when all the information usually supplied on the official notification form is not available.

6 To which authority should notification be sent? Does this vary according to the product in question?

For most consumer products the appropriate authority for notifications is the Trading Standards Department of the local government authority for the area in which the manufacturer's or supplier's business is based. For contact details see www.tradingstandards.gov.uk.

Other authorities responsible for sector-specific notifications are the Food Standards Agency (FSA) (www.food.gov.uk), the Vehicle and Operator Services Agency – (VOSA) (www.dft.gov.uk/vosa) and the Medicines and Healthcare Products Regulatory Agency (MHRA) (www.mhra.gov.uk).

These authorities may forward the information notified to them to the EU authorities for the purposes of RAPEX (the rapid alert system for dangerous non-food consumer products), RASFF (rapid alert system for food and feed) or other rapid alert systems in Europe for pharmaceuticals and medical devices, or for the purposes of information sharing systems pursuant to other EU legislation.

7 What product information and other data should be provided in the notification to the competent authority?

The information to be notified for consumer products generally is the nature of the defect, the action being taken to prevent risks to consumers and the details of other EU member states in which the product is known to have been supplied or marketed. The reporting form for general consumer products is available at www.bis.gov.uk. Different forms are available for specific products from the FSA, MHRA and VOSA.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Where it has only been possible to provide incomplete notification data within the time limits, updated information should be provided as soon as possible thereafter. There is a duty on producers and distributors to cooperate with the authorities in taking action to avoid risks to consumers. The

authorities also have formal enforcement powers to require the provision of additional information and records if they require in order to investigate a breach of product safety legislation or to decide whether to use their enforcement powers to, for example, serve safety notices. Failure to provide information requested may be an offence.

9 What are the penalties for failure to comply with reporting obligations?

The offence of failing to properly notify the appropriate authority of a defective consumer product is a criminal fine on the company of up to £5,000 or up to three months' imprisonment (for an individual producer or distributor or, for example, a director of a corporation) or both.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

There is limited protection for commercially sensitive information. The authorities are obliged to make available to the public information on the identity and risks associated with a defective product, and the measures taken to avoid the risk. There is no obligation on the authorities to disclose information that is covered by professional secrecy, unless its disclosure is necessary to protect the public.

Under the Freedom of Information Act 2000 (FOIA) any person may request information from the authorities on a product safety matter. The original provider of the information has no right to prevent its disclosure. The authorities have a discretion whether to release information which is provided in confidence or which could prejudice a person's commercial interests.

The FOIA recognises that in many circumstances it may be inappropriate for a public body to disclose the information that it holds. The FOIA therefore contains a number of exemptions that protect information from potential disclosure. Of particular relevance to product safety notifications and recalls are those exemptions relating to 'investigations', 'law enforcement' and 'information provided in confidence'.

Information provided compulsorily under consumer protection legislation obligations may be protected from disclosure by provisions of the Enterprise Act 2002. (This extra protection does not extend to information originally provided voluntarily.) Disclosure of the information to a claimant for the purposes of civil proceedings may nevertheless be permitted.

11 May information notified to the authorities be used in a criminal prosecution?

It is likely that the information obtained by the authorities will be relied upon if there were criminal proceedings or other enforcement action. There is no bar to the information being used as evidence. In some cases it might amount to an admission of an offence.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

The General Product Safety Regulations (GPSR) provide that a producer of consumer goods must be prepared to take 'appropriate action' to deal with unsafe products including, where necessary to avoid risks, withdrawal from the supply chain, warnings to consumers or ('as a last resort') recall from consumers. No legal criteria are laid down in these regulations for determining what action is appropriate in any given circumstances. Published codes of practice for recall will be relevant, including the Consumer Safety in Europe Corrective Action Guide (2012). The GPSR incorporate the 'precautionary principle' (see EU COM (2001) 1), which may justify the action even where the risk cannot be determined with sufficient certainty.

Commercial products

For commercial products, the duty in section 6 of the HSWA may comprise taking reasonably practicable steps to recall or modify products if this is necessary to prevent risks of injury. Again, there are no specific legal criteria to determine thresholds of risk requiring such precautions.

The common law of negligence is also relevant as it may comprise a duty to take reasonable steps to warn users or to prevent use of consumer or commercial products until they can be modified or replaced. This duty may apply even where the risk arises only where the product is incorrectly maintained or used.

Food and drink

The criteria for recall or other action contained in article 19 of Regulation EC/178/2002 on General Food Law apply in the UK. This requires the withdrawal of foodstuffs from the supply chain if there is any non-compliance with the 'food safety requirements', to inform consumers of the reason for the withdrawal, and recall from consumers 'if necessary [...] when other measures are not sufficient to achieve a high level of health protection'.

Pharmaceuticals

The MHRA uses an international classification system for medicine recalls:

- class 1: the defect presents a life threatening or serious risk to health;
- class 2: the defect may cause mistreatment or harm to the patient, but it is not life-threatening or serious; and
- class 3: the defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the marketing authorisation or specification.

'Class 4 drug alerts' also exist for minor defects, for example, in packaging and where there is no threat to patients. The extent and urgency of the recall will generally be discussed and agreed with the MHRA using these criteria.

Medical devices

The MHRA adopts the EU term 'field safety corrective action' to embrace recall and related warnings. Guidance on determining the need for a recall is contained in the MHRA's Directives Bulletin No. 3 – Guidance on the Operation of the EU Vigilance System in the UK (2008), which refers to risk assessments being carried out in accordance with the international standard BS EN ISO 14971. This guidance is currently being reviewed in light of revision 7 of the European Commission MEDDEV 2.12/1 on the medical devices vigilance system.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Under the GPSR it is primarily for the manufacturer of a consumer product to determine whether a product is unsafe (and thus requires notification to the enforcement authorities) and what corrective action in the form of, for example, warnings or a recall from users is appropriate in the particular circumstances. The authorities in the UK largely rely upon manufacturers deciding, and then voluntarily taking, the appropriate corrective action. Should an enforcing authority not be satisfied with the approach taken by a manufacturer or other responsible party, it is likely to voice its concerns and informally request that additional corrective action be taken. The GPSR require the authorities to act in a manner proportionate to the seriousness of the risk and to encourage and promote voluntary action by manufacturers and distributors. The authorities nevertheless have powers to impose requirements (see question 19).

14 Are there requirements or guidelines for the content of recall notices?

UK legislation does not generally set out specific requirements or guidelines for the content of recall notices. Some bodies (such as the British Retail Consortium) have drawn up product recall guidelines, which outline the key elements that should be included in notices to suppliers, notices for the trade press or the general public. Examples of notices can be found in the European Guide to Corrective Actions Including Recalls (PROSAFE etc). Generally notices should contain the following:

- the fact that the notice is a 'product recall' or other important safety announcement;
- the product name and photograph or description (including model and serial number);
- any relevant coding, sell-by date or batch number and where to locate it on the product;
- information as to whether only a certain period of purchase is affected;
- outline of the detail of the problem;
- outline what the consumer should do (eg, stop using the product immediately and telephone the helpline number or return to the retailer for a replacement or refund); and

- details of the company name and a (free phone) contact telephone number or website address where more information can be obtained.

For medical devices there is a template for 'field safety notices' – see Vigilance MEDDEV 2.12/1 rev 5 (part of a set of guidelines relating to questions of the application of EU directives on medical devices; they are legally not binding).

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

There is no prescriptive list of the media which must be used to publish or communicate warnings or recalls to suppliers or users. Producers can convey messages for example by local or national newspapers or advertisement in specialist magazines, letters to suppliers and end-users (eg, using warranty records), web-postings, e-mail or text messages, posters at the point of sale, communications to installers or maintainers, or a mixture of each of these or other approaches.

A plan of the proposed action has to be submitted to the relevant regulatory authority as part of the notification process. If the enforcing authority does not consider the approach to communication of information to users and others to be adequate, additional or alternative forms of corrective action can be requested.

In some sectors there will be involvement by the regulator in the chain of communication. For vehicle recalls the Driver and Vehicle Licensing Agency can address and send letters direct to registered vehicle owners. The FSA and the MHRA can also publish their own alerts.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There are no set targets or time periods at which a recall is deemed to have been successfully completed. Enforcing authorities are likely to request update reports as to the success rate of any corrective action that is taken. The enforcing authority may require additional measures to be adopted, including repeat recall notices if they consider the response to corrective action to have been unsatisfactory.

The government has previously published success rates of recalls for different types of product based on the percentage retrieved of the overall numbers sold. See Product Recall Research (DTI, 2000). However, it is questionable whether some of the data accurately represents typical outcomes of recalls in practice. Due to the ability to trace vehicle owners directly through the DVLA, vehicle recalls often have much higher success rates in recall than other product sectors.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

There is no positive obligation on a producer conducting a recall to offer to repair, replace or pay compensation as part of its corrective action programme. Practices vary but, unless the items in question are of low value or perishable, manufacturers generally tend to offer repair or replacement products.

Rights of recovery for any loss or damage relating to the product simply ceasing to be usable will largely be against the seller from whom the consumer directly purchased the products, (unless he or she has suffered injury or property damage when a claim in that regard against the manufacturer or importer into the EU may be made). Whether or not the seller can obtain recourse for the costs of repair or replacement, etc, from the manufacturer or others in the supply chain is an issue that will be determined by reference to the terms of the relevant supply contracts.

Consumer products

A consumer (someone not acting in the course of business) has the right to request from his or her immediate seller either repair or replacement of a defective product (section 48(a) to 48(f), Sale of Goods Act 1979, as amended by the Sale and Supply of Goods to Consumers Regulations 2002). (The right arises where the product was defective at the time of sale; any non-conformity of the product arising during the period of six months after its delivery to the buyer will usually deem the product defective at the time of sale unless the contrary is proved or unless applying the six-month durability period would be incompatible with the nature of the product or the defect.) Sellers must comply within a reasonable time, at their own cost, and without significantly inconveniencing the consumer, as long as the remedy requested is not impossible or disproportionate in comparison to another remedy. (If a repair of goods is not performed to the consumer's satisfaction, the consumer might still reject the goods (*J&H Ritchie v Lloyd* [2007] UKHL 9).)

As an alternative where repair or replacement are not available options, a consumer may request a refund for recalled products from the immediate seller or to rescind the contract of sale altogether. The amount of money refunded may be reduced if the consumer made significant use of the product before it was recalled.

The Unfair Contract Terms Act 1977 renders invalid exclusion clauses affecting private consumers' rights. (The Unfair Terms in Consumer Contracts Regulations also restrict such exclusions.)

Commercial products

Subject to the express or implied terms governing quality in the contract of sale, the owner of a commercial product that has been recalled may be able to reject the product, if not already accepted, and reclaim the purchase price as well as additional losses incurred. More usually though the owner will be deemed to have accepted a product already in use, and the owner's rights will consist of a claim for damages for breach of warranty against the immediate seller. The damages would comprise the loss to the owner flowing directly and naturally resulting in the ordinary course of events from the breach of warranty.

In the event of the immediate seller being liable to the owner, the seller may, depending on the relevant contractual terms, be able to recover the losses from others in the supply chain.

18 What are the penalties for failure to undertake a recall or other corrective actions?

See the penalties referred to in question 3.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

Consumer products

The enforcing authority may serve 'withdrawal notices' to prohibit a person from supplying a product without the authority's consent. The notice may also require the person on whom it is served to take action to alert consumers to the risks that the product presents. If a product is already on the market, such a notice may only be served in circumstances where the action of the producer or distributor concerned is considered to be unsatisfactory or insufficient. The authorities also have power to serve a 'requirement to warn'. This can dictate the form and manner of publication warnings to consumers.

'Recall notices' may be used in situations where the enforcement authority has reasonable grounds for believing that a product is dangerous and that it has already been supplied or made available to consumers. Such notices require the person on whom they are served to use reasonable endeavours to organise the return of the product from consumers. Such notices can only be used by enforcing authorities in situations where other voluntary action would not suffice to prevent the risks posed by the product and the action taken by the person on whom the notice is to be served is deemed to be inadequate or insufficient, unless the risk is serious and deemed to require urgent action.

Commercial products

The HSE is empowered to issue enforcement notices in respect of unsafe products. An 'improvement notice' may be used to require a manufacturer or other supplier to provide warnings or safety information. A 'prohibition notice' may be used to stop the supply of a product. It is doubtful that such notices can require the recall or modification of a product. In cases of serious danger the HSE may seize products.

The European Commission's proposed Regulation for Market Surveillance, which is due to come into force in 2015, extends beyond consumer products, allowing enforcing authorities to deal with potential product risks, irrespective of the intended end-user. The draft regulations provide for Market Surveillance authorities to carry out risk assessments and to inform 'economic operators' (manufacturers, distributors, importers) of the corrective action which must be taken and the period in which it must be taken.

20 Can the government authorities publish warnings or other information to users or suppliers?

It is common for the authorities to publish alerts about unsafe products (see question 15). Generally this will be done in association with manufacturers or others responsible for recalls, and will reiterate warnings and other advice issued voluntarily by them. However, the authorities are not permitted to issue press releases or call for a recall or other action unless they do so in cooperation with manufacturers or other responsible persons, or they act within the limits and procedural frameworks of the GPSD, RAPEX or other European notification frameworks and the enforcement powers above (*R v Liverpool City Council, Ex parte Baby Products Association* (1999), *The Times*, 1 December).

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Where an enforcement authority has been unable to identify any person on whom to serve a consumer product recall notice, or the person on whom such a notice has been served has failed to comply with it, then the authority may itself take such action as could have been required by a recall notice.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Enforcing authorities may recover any costs or expenses they reasonably incur in carrying out the actions stipulated in a consumer product recall notice and which have not been complied with by the person on whom the recall notice was served. Apart from this, administrative and other costs are not recoverable. In any proceedings for forfeiture of products, or for criminal prosecutions for the original supply of unsafe products, the court will generally order the parties to pay the authorities' legal and other costs.

23 How may decisions of the authorities be challenged?

A special process exists whereby, before a consumer product recall notice is issued, the recipient is first permitted seven days in which to request the authority to obtain independent advice on whether a recall is necessary. A scheme for these purposes exists under the auspices of the Chartered Institute of Arbitrators. Use of this scheme is however extremely rare.

Public law remedies may also be used to challenge the actions of enforcement authorities through court proceedings known as judicial review. This may be appropriate where, for example, an authority has acted outside the scope of its statutory powers, has failed to observe the correct procedural requirements or where its decision can be shown to be wholly irrational.

A person on whom an enforcement notice has been served and a person having an interest in a product in respect of which a safety notice (other than a consumer recall notice) has been served may apply to a court within 21 days for an order to vary or set aside the terms of the notice. A person on whom a recall notice has been served may, before the end of the period of seven days beginning with the day on which the notice was served, apply for an order suspending the effect of the notice.

The current procedural requirements differ for commercial products, in that appeals against HSE improvement notices and prohibition notices are dealt with by the employment tribunals.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

It is very likely that a plaintiff claiming for injury or property damage will plead that a recall notification and associated warnings amount to admissions of there having been a defect in relation to the product. It will be a question of fact in each case whether the defect existed in the plaintiff's particular product. It is, however, a matter for the court to determine whether any defect was actually present if the defendant argues that the recall action was purely precautionary. Even where this is established, the plaintiff will still need to prove the defect caused his or her loss, and that any prior recall or warnings would have been acted upon so as to avoid the loss. (See *Coal Pension Properties Ltd v Nu-Way Ltd* [2009] ECWA 824 (TCC).)

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Disclosure of documents is generally required by procedural rules in UK courts, and parties may be required to reveal documents that assist their opponents' cases. The usual rules as to document discovery apply to any documents (including electronic documents) that are created in the course of investigations, notifications to the authorities and recall communications. However, communications with lawyers and documents created for actual or contemplated litigation purposes may be protected from disclosure by legal privilege.

Alison M Newstead **anewstead@shb.com**

25 Cannon Street
London EC4M 5SE
United Kingdom

Tel: +44 20 7332 4500
Fax: +44 20 7332 4600
www.shb.com

Getting the Deal Through

Acquisition Finance
Advertising & Marketing
Air Transport
Anti-Corruption Regulation
Anti-Money Laundering
Arbitration
Asset Recovery
Aviation Finance & Leasing
Banking Regulation
Cartel Regulation
Climate Regulation
Construction
Copyright
Corporate Governance
Corporate Immigration
Data Protection & Privacy
Debt Capital Markets
Dispute Resolution
Domains and Domain Names
Dominance
e-Commerce
Electricity Regulation
Enforcement of Foreign Judgments
Environment
Foreign Investment Review
Franchise
Gas Regulation
Government Investigations
Insurance & Reinsurance
Insurance Litigation
Intellectual Property & Antitrust
Investment Treaty Arbitration
Islamic Finance & Markets
Labour & Employment
Licensing
Life Sciences
Mediation
Merger Control
Mergers & Acquisitions
Mining
Oil Regulation
Outsourcing
Patents
Pensions & Retirement Plans
Pharmaceutical Antitrust
Private Antitrust Litigation
Private Client
Private Equity
Product Liability
Product Recall
Project Finance
Public-Private Partnerships
Public Procurement
Real Estate
Restructuring & Insolvency
Right of Publicity
Securities Finance
Ship Finance
Shipbuilding
Shipping
State Aid
Tax Controversy
Tax on Inbound Investment
Telecoms and Media
Trade & Customs
Trademarks
Transfer Pricing
Vertical Agreements

Also available digitally

Online

www.gettingthedealthrough.com

iPad app

Available on iTunes

Law Business Research

Product Recall
ISSN 2042-2040

THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

LACCA
LATIN AMERICAN CORPORATE COUNSEL ASSOCIATION

Official Partner of the Latin American Corporate Counsel Association

ABA Section of International Law
Your Gateway to International Practice

Strategic Research Sponsor of the ABA Section of International Law