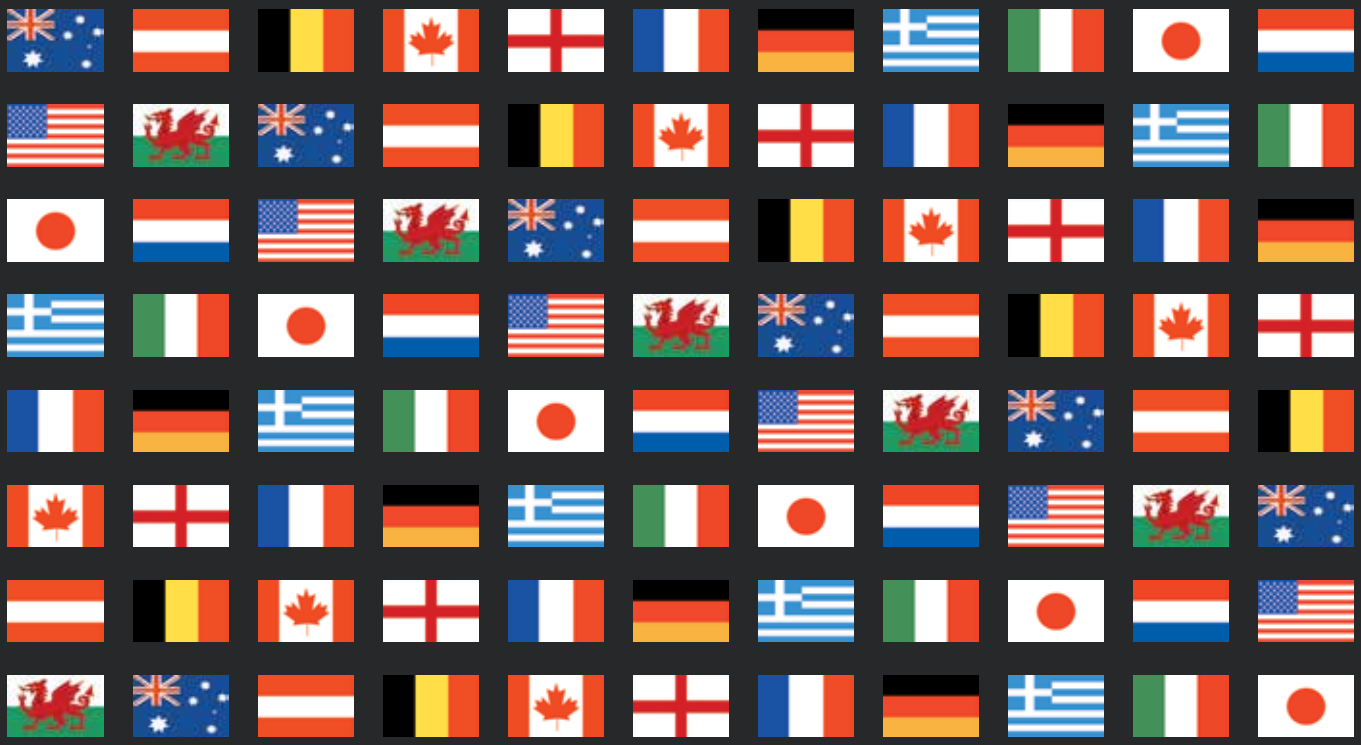
Product Recall

Contributing editors
Alison Newstead and Harley V Ratliff



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GETTING THE DEAL THROUGH

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Product Recall 2016

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Global overview

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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 but which are now likely to be implemented in 2016) are discussed in detail in the European overview chapter.

The European Commission produces an annual report outlining trends in European recall activity. The most recent report highlights the continued trend that more unsafe products are being identified in the EU and corrective action taken. The continued rise of unsafe product notifications is most likely as a result of more rigorous quality assurance and post marketing surveillance by manufacturers and distributors and increased market surveillance activity by regulators and customs authorities. China remains the country of origin of most unsafe products in Europe. The number of unsafe products of Chinese origin is steadily increasing (64 per cent in 2014, up from 38 per cent in 2004). Further work certainly needs to be undertaken with the Chinese product safety regulator, AQSIQ, to prevent unsafe products being designed, manufactured and exported for sale in the EU. By contrast, the number of unsafe products on the EU market that are of EU/EFTA origin has continued to decrease over the past decade. This suggests that good manufacturing processes, including quality control and post market vigilance, are being increasingly adhered to across the EU.

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. These will be further strengthened once the Regulation on Market Surveillance of Products comes into force.

It would appear that the growth in European recalls will continue. 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).

China remains the country of origin for the majority of recalled products. As a result, 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 yet to be adopted but in any event will be implemented gradually over a five-year period. 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 at EU level. 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.

England & Wales

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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 by the proposed EU Product Safety and Market Surveillance Package. The new proposed Regulation on Market Surveillance of Products (COM (2013) 75) will apply to consumer and commercial products and provides increased and new powers to market surveillance authorities. The Regulation was due to come into force in 2015, albeit this is now unlikely.

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 other 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 strengthens market surveillance activities. These proposals (in the form of a new Regulation on Consumer Product Safety and a Regulation on Market Surveillance of Products) were expected to come into force in 2015. However, the implementation of the Regulations has been delayed, particularly as a result of concern of stakeholders regarding the proposal that products be labelled with country of origin. 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 (Human Medicines Regulation 2012 (SI 2012/1916)) and medical devices (Medical Device Regulations 2002 (SI 2002/618)) as part of required vigilance systems. In terms of vehicles, in accordance with the Driver and Vehicle Standards Agency (DVSA) 'Vehicle safety defects and recalls: code of practice', 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, which were due to come into force in 2015. The new proposed Consumer Product Regulation sets out a specific requirement for traceability of certain products (including electronic traceability) which, due to their specific characteristics or specific conditions of distribution or usage, are susceptible to bear a serious risk to the health and safety of consumers. There are also proposed obligations to label the country of origin on the product, its packaging or the documentation accompanying the product. The new proposed Market Surveillance Regulation (which applies to commercial and consumer products) requires economic operators to make available any documentation that the Market Surveillance authorities require, including information which enables the precise identification and tracing of products.

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 penalty for offences committed after 12 March 2015 is an unlimited criminal fine.

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.

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

Penalties for offences in relation to food and drink products have no upper limit set by the relevant 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.

Products for commercial use
Penalties for contravention of safety requirements relating to commercial products under the HSWA are unlimited criminal fines (for offences committed after 12 March 2015). There are also provisions whereby individuals can be convicted of offences (eg, directors and officers of a corporation responsible for a product) for up to two years.Other enforcement powers are also 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?

Consumer products
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 new proposed Regulation on Consumer Product Safety also makes an exemption from notification 'if the manufacturers, importers or distributors can demonstrate that the risk can be fully controlled and cannot anymore endanger the health and safety of persons'.

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. (See the FSA's Guidance Notes for Food Business Operators on Food Safety, Traceability, Product Withdrawal and Recall, 2007).

Pharmaceuticals
Notification obligations are incorporated into manufacturers and wholesale dealers' licences and marketing authorisations. Generally the duty is to notify the Defective Medicines Report Centre (DMRC) division of the Medicines and Healthcare Products Regulatory Agency (MHRA) 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, 2014) 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. The European Commission also provides up-to-date guidance in document MEDDEV 2.12-1 Rev 8 (2013). Notification should be immediate upon the defect being known. The guidance contains guidelines on time limits ranging from two days to 30 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 were proposed affecting 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 at EU level and it is not yet clear when these reforms will come into effect.

Motor vehicles
Supplemental to the general consumer product laws above, the DVSA's 'Vehicle safety defects and recalls: code of practice' (2013) applies to all vehicles (private and commercial). It requires notification to the DVSA by manufacturers of vehicle or component parts, importers, distributors or concessionaires of 'safety defects' (defined as a failure due to design or construction which is likely to affect the safe operation of the product without prior warning to the user and may pose a significant risk to the driver, occupants and others). The DVSA's Code of Practice and Manufacturers' Guide to Recalls in the UK Automotive Sector (April 2014) 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 FSA (www.food.gov.uk), the DVSA (www.dft.gov.uk/dvsa) and the 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 DVSA.

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. Market Surveillance authorities will have new and expanded powers under the proposed EU Regulation on Market Surveillance of Products. The Regulation requires economic operators to make available on request any documentation or information that the surveillance authorities require.

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

The penalty for failing to properly notify the appropriate authority of a defective consumer product is an unlimited criminal fine 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 are contained in article 19 of Regulation EC/178/2002 on General Food Law. Article 19 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's Guide to Defective Medicinal Products (2014) refers to Article 117 of Directive 2001/95/EC, which specifies under what circumstances a recall may be required. A medicinal product should be withdrawn if (a) it is harmful under normal conditions of use; or (b) it lacks therapeutic efficacy; or (c) qualitative and quantative composition of the product is not as declared; or (d) the controls on the product or the ingredients have not been carried out or some other obligation relating to the granting of the market authorisation is not fulfilled.

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 where there is no threat to patients or no serious defect likely to impair product use or efficacy. These usually cover minor defects, for example, in packaging or printed materials 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' ('FSCA') 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. The European Commission's MEDDEV 2.12/1 Rev 8, sets out guidance on the medical device vigilance system, including field safety corrective action.

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 is appropriate in the particular circumstances (eg, warnings or recall). The authorities in the UK largely rely upon manufacturers 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 MEDDEV 2.12/1 Rev 8 (Annex 5).

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 that 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 (DVLA) can address and send letters direct to registered vehicle owners. The FSA, (for food) and the MHRA (for medicinal products and medical devices) 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

In accordance with the Consumer Rights Act 2015, a consumer will have a 'short term' right to reject the goods, after which the consumer will have a right to repair or replacement. The right to a price reduction or final right to reject is also available.

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 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.

In terms of medical devices, the MHRA may also issue a compliance notice for technical breaches of the Medical Devices Regulations 2002, when a device does not conform to the essential requirements, but does not compromise health and safety. The MHRA may also issue a restriction notice to restrict the availability of a particular medical device or of devices of a particular class or description to protect health and safety.

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 on 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 Regulation provides 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 Associatio*n (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. In accordance with the proposed EU Regulation on Market Surveillance, when a product (consumer or commercial) is considered as a serious risk by a market surveillance authority, it is obliged to take all necessary measures and may do so without requiring the economic operator to take corrective action first or providing the opportunity to be heard beforehand, This includes, ultimately, recall. As per the current position, if a product poses a risk and the economic operator cannot be ascertained or does not take appropriate corrective action, the market surveillance authority can take 'all necessary measures', including recall.

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.

The EU Regulation on the Market Surveillance of Products proposes that market surveillance authorities may charge fees to economic operators which wholly or partly cover costs of the activities of the market surveillance authorities, including testing or risk assessment.

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

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the loss. (See *Coal Pension Properties Ltd v Nu-Way Ltd* [2009] ECWA 824 (TCC)). See also the ECJ decision in *Boston Scientific Medizintechnik GmbH and Others (2014)* which held, inter alia, that where a product belongs to the same group or production series of products which had a potential defect, such a product may be classified as defective. There was no need to show that the product in question had such a defect. Furthermore, in relation to the question of whether a risk of failure could constitute a defect, the court held that for products that carry a high risk (such as pacemakers) the potential lack of safety would constitute a defect.

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.

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