



Product Recall

in 24 jurisdictions worldwide

2014

Contributing editors: Alison M Newstead and Harley V Ratliff



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United Kingdom

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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 – 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 not due to come into force until 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 (giving 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 EU 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 General Food Regulations 2004. 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 Food Standards Agency Guidance Notes for Business Operators on Food Safety, Traceability, Product Withdrawal and Recall (July 2007).

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.

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

Pharmaceuticals

The MHRA uses an international clarification 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.

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- 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).

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- 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 EC directives on medical devices; they are legally not binding).

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- 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.

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- 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.

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- 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 loss, and that any prior recall or warnings would have been acted upon him so as to avoid the loss. (See *Coal Pension Properties Ltd v Nu-Way Ltd* [2009] ECWA 824 (TCC).)

Update and trends

The European Commission's Product Safety and Market Surveillance Package, adopted in February 2013, will see a number of substantial changes in the area of product recall, with the aim of improving product safety and market surveillance. The changes will take the form of two new Regulations: the Consumer Product Safety Regulation and the Regulation for the Market Surveillance of Products. These are not due to come into force until 2015. However, due to the increased obligations on manufacturers, importers and distributors, businesses should take steps now to determine how these are to be addressed.

In terms of recall trends, increased attention is being given to response rates for consumer products, with many commentators concerned that they remain too low in the UK. There are calls for the perceived insufficiencies of the current recall system to be addressed by implementing larger fines for companies who delay or fail to recall, with fines being linked to a percentage of profits. The new Regulations may go some way to addressing the low recall rates, but further more stringent regulation in this area is likely.

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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