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Global Legal Group

# The International Comparative Legal Guide to: Product Liability 2011

A practical cross-border insight  
into product liability work

Published by Global Legal Group, in association with CDR,  
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## Cover Design

F&F Studio Design

## Cover Image Source

stock.xchng

## Printed by

Ashford Colour Press Ltd.  
May 2011

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ISBN 978-1-908070-00-5

ISSN 1740-1887



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## EDITORIAL

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Welcome to the ninth edition of *The International Comparative Legal Guide to: Product Liability*.

This guide provides the international practitioner and in-house counsel with a comprehensive worldwide legal analysis of the laws and regulations of product liability.

It is divided into two main sections:

15 general chapters. These are designed to provide readers with a comprehensive overview of key product liability issues, particularly from the perspective of a multi-jurisdictional transaction.

Country question and answer chapters. These provide a broad overview of common issues in product liability laws and regulations in 31 jurisdictions.

All chapters are written by leading product liability lawyers and industry specialists and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editors, Ian Dodds-Smith of Arnold & Porter (UK) LLP and Michael Spencer QC of Crown Office Chambers, for all their assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The International Comparative Legal Guide series is also available online at [www.iclg.co.uk](http://www.iclg.co.uk)

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# The Practicalities of Managing a Global Recall

Richard Matthews



Fabian Volz



Eversheds

### Introduction

Increasingly, consumer products are sold on a global basis and a strategy for dealing with any safety or quality issue which emerges after a product is launched must cover all the jurisdictions where the product is sold. In recent years, the regulatory environment governing product safety has tightened. Consumer expectations from products continue to increase and legislators have responded to high profile incidents such as the Mattel toy recalls with tougher controls and increased sanctions. Regulators are becoming more proactive, with greater co-operation between national regulators contributing to increased enforcement activity. The reputational risk facing international businesses who fail to adapt to this new environment grows as information about their products can spread worldwide, literally overnight via blogs, consumer websites and 24-hour news channels. Adopting a co-ordinated and consistent approach to a product issue across all the affected regions of the world before a crisis gathers its own momentum is critical in order to protect international brands and reputations from the damage that can be caused by adverse media coverage. In this chapter, we examine some of the practical issues to be considered when formulating and implementing a multi-jurisdictional product recall.

### Investigation and Risk Assessment

When a company receives reports of problems with a product, it should:

- Assemble a team to investigate the facts - including details of any reported incidents or complaints - as thoroughly, yet rapidly, as possible. The team will need to be small so that it can act quickly and decisively and should typically include representatives from the technical, purchasing, sales, marketing, finance and legal functions within the company. The team should be led by a senior officer who has authority on behalf of the company, ideally has had crisis management training and will take responsibility for making difficult business decisions often based on incomplete and uncertain information.
- Commission a detailed technical analysis into the possible safety or quality issues using internal resources or an independent expert (the choice may depend upon the nature of the potential defect, the complexity of the investigation, the extent of relevant internal expertise and the time available).
- Seek to understand the scope of the problem for example whether it is limited to particular models or batches of products the output of specific manufacturing sites and the affected date range, to establish how many units are affected, how many have already been sold and what proportion

remains in the company's control or in the distribution network.

- Undertake an assessment of the risk that the product may present a danger to users and the likely consequences if it does. There are a number of different risk assessment methodologies - but essentially most involve identifying the hazard and its cause, estimating how many products are affected, which users of the product are at risk and whether this includes particularly vulnerable sections of the population such as children or the elderly. The overall risk can then be estimated based upon the severity and likelihood of injury. Finally, how obvious is the potential hazard and is there any warning to alert users of the product. The European Commission have prepared new more detailed guidelines for undertaking a risk assessment and determining whether notification of regulators is required in EU Member States where the product is sold (see Commission Decision 2010/15/EU (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:022:0001:0064:EN:PDF>)). The amended guidelines consider the likely behaviour of consumers in the event of an accident and may make it less likely that product risks are notifiable in some circumstances.
- Consider options for responding to the incident and formulate an appropriate strategy for minimising the risk presented by the defective products. There are many actions short of a full consumer recall which might be appropriate in different circumstances depending on the risk assessment, the traceability of the affected products and the sales channels, including:
  - ceasing future sales until the product is re-designed or the stock in the supply chain is rectified;
  - issuing safety warnings or more detailed instructions to users which, if followed, minimise the risk;
  - withdrawing the product from sale by retailers (often referred to as a trade withdrawal);
  - a modification or retro-fit of products in consumers' premises or elsewhere in the field.

The appropriate response should reflect the legal obligations in respect of product safety the relevant jurisdictions and the commercial imperative of acting, and being seen to act, in the best interests of consumers. Often a company will take a combination of corrective measures in parallel as part of a co-ordinated response. The proposed strategy should be limited as far as practicable to the affected products with a view to completing the exercise as quickly and cost effectively as possible.

One of the major issues to consider in any product recall strategy is how to notify the risk associated with the product to the end users who bought the product before the problem was identified. The investigation team will need to understand the extent of traceability

through to end users. Direct communication with end users is far more effective than indirect measures such as “point of sale” notices in stores, warnings posted on company websites, newspaper advertisements or announcements in the media. Manufacturers may need to liaise with distributors and retailers for documentation which will contain end user names and details.

The company has a clear interest in contacting as many end users as possible and alerting them to the risk. Claims by customers or end users will directly impact the company financially, but often the greatest impact will be on a company’s brand or reputation. A company should not be seen as balancing the risk of injury to end users, and associated claims against the costs of taking steps to minimise the risks. This approach significantly increases the likelihood of criminal proceedings or other enforcement action against the company and adverse media comment.

It is rare that national legislation will dictate the detail of the corrective measures which are required. A product recall or other corrective action will need to be tailored to the individual facts. In many cases, the company will need to satisfy regulators that the proposed measures are sufficient. A company needs to be clear that the solution which it is proposing is effective. For example, a solution which involves the insertion of an additional fuse in an electrical appliance to avoid the risk of fire where there is an electrical surge is not a practical solution if the fuse blows every few days and the appliance cannot be used. This may well create an even greater PR crisis for the company. Sufficient testing should be undertaken to ensure that the modifications made to a product design address the prior safety issue.

Different standards and regulations will often apply as regards product safety in different countries and the regulators in some jurisdictions are more interventionist than in others. However, a company should be cautious before adopting inconsistent approaches in different countries or regions as this can attract negative publicity, unless these differences can be clearly justified. Maclaren attracted some negative publicity in November 2009 when it failed to offer a free safety kit to European owners of a baby stroller in the same way as it had in the United States.

One of the first steps which a manufacturer or distributor should take when it receives information that one of its products may be unsafe is to investigate whether it has insurance which may respond. Product liability insurance cover will typically protect a company against its liability for personal injury or damage to property other than to the defective product supplied. A business may also have specific product recall cover (either as a stand alone policy or an extension to a product liability/public liability policy), although this is less common. A product recall policy may indemnify a company in respect of the costs of undertaking a product recall or other remedial action as well as the company’s liability for financial losses suffered by customers or end users. If there is any potential for a policy to respond to meet future liabilities or costs associated with a potentially defective product, notification should be made to insurers as early as is practicable. A company needs to comply with all conditions under the relevant policy. In practice, it should keep insurers informed of the steps which it proposes to take to minimise the risk of injury from use of the defective product, the details of any threatened or actual claims which are received and any other material developments.

Where the product in question has been manufactured by a third party or if the defect in the product arises from the supply of a defective component or raw material, then it may be sensible to notify the supplier that it is held responsible for all associated costs. The extent to which the supplier is liable will depend on a company showing that there has been a breach of the express or implied terms of the contract between them. In many cases, however, a company

may want to work with the supplier to make necessary changes to rectify the defect or change the design of the product going forwards. In practice, this can be more difficult when there is a dispute with the supplier as to who should bear ultimate liability for the recall costs.

### Dealing with Multiple Regulators

Where a manufacturer of a consumer product has reason to believe that the product is unsafe, it is typically obliged to notify the national regulators in countries where the product is sold. In the United States, there is a strict duty to notify the Consumer Product Safety Commission (CPSC) where there is:

- non-compliance with a safety rule or voluntary standard;
- a defect creating a substantial product hazard; or
- an unreasonable risk of serious injury or death.

A company must report to the CPSC within 24 hours of receiving information which reasonably supports the conclusion that the issue is notifiable. If the issue is not “clearly notifiable”, the company must conduct a “reasonably expeditious” investigation to evaluate the information, which should not take more than 10 days.

In the European Union, producers and distributors must notify the authorities in any Member State as soon as they know, or should know, that a consumer product poses an unacceptable risk. There is no centralised EU reporting authority. The notification should include details of the product involved, a full description of the risk which the product presents, information enabling the product to be traced and details of the corrective action taken or proposed to be taken. There is considerable subjectivity in the application of any risk assessment (notwithstanding the new European Commission guidelines) and in reality regulators in different European countries take different views as to what level of risk they regard as acceptable. There is an obligation to notify risks identified as serious or moderate under the risk assessment guidelines, with low risks exempt from notification. The European Commission’s guidance on notification provides that the relevant national authority should be informed without delay when it has information indicating a product is dangerous and in any case within 10 days of obtaining such information. In the case of serious risks, there is a three-day time limit for notification and in emergency situations where immediate action is required, immediate notification should be made “by the fastest means”.

In practice, a company will not want to notify any regulator until it not only understands the nature and scope of the problem, but has decided what corrective measures need to be undertaken. In many cases there is a tension between the obligation to notify regulators within a short timescale and the desire to complete an investigation and decide on an appropriate corrective action before bringing the existence of a potential safety defect to the attention of anyone outside the company. In Europe, there is little evidence of authorities contemplating action against companies for late notification under the General Product Safety Directive. However, in the United States, the risks and sanctions for not reporting or delaying reporting are significantly greater and if in doubt companies should report in a timely fashion. In practice, the company (supported by technical teams and lawyers) will want to be working as quickly as possible to have a clear strategy in place for dealing with the product risk before they go to the regulator.

Where there are a number of countries involved, a company should choose where it wants to lead and co-ordinate the process of notifying regulators. This may be the country where the company maintains its corporate headquarters or the country where most sales of affected products have taken place. The company should

take specialist advice as to whether particular authorities are likely to be satisfied with the corrective action which the company proposes. It should consider where it has the best relationships with regulators and enforcement authorities as if a company or its lawyers have a good working relationship with the relevant authorities this can help in resolving the product issue in a professional and efficient manner. Due to the importance and size of the market, and the stringent regulatory regime, backed by substantial sanctions, many international businesses let the CPSC take the lead in the United States in a global recall. The CPSC can be more demanding than other regulators, for example in relation to required response rates from a recall programme.

Across Europe, although there is essentially a harmonised regime by virtue of the General Product Safety Directive, there is considerable variation of approach between the regulations of Member States. Some authorities require more information than others; some will require meetings whereas others are satisfied with a written notification; some authorities are more likely to question the adequacy of the investigation or the proposed corrective action; and some are more proactive than others and require information to monitor a recall programme. Although the European Commission has powers in relation to product safety, for example to initiate product recalls and to ban product recalls, in practice it does not exercise these powers and rarely intervenes in the decisions of Member States, even where there is a dispute as to the extent of a risk which has pan-European implications.

A company will want to make a simultaneous notification of relevant regulators. This is due to the desire to control the PR message in a co-ordinated manner and a necessary consequence of communication between regulators. As a result of the General Product Safety Directive, there is a common timeframe for notification across Europe. In practice, we would recommend that one law firm take the lead in working with the company and seeking to ensure that the legal strategy is aligned with the objectives of the business. This will typically involve working closely with the company in investigating the cause of the problem, seeking to minimise product risk and thus the exposure to claims arising out of the incident, interviewing factual witnesses, engaging any relevant technical experts and developing defence theories. The lead law firm should co-ordinate the global notification of regulators.

Although formal notification should take place on the same day in all regions, the company and its lawyers may want (and are invited by the European Commission's guidance to seek) informal, earlier dialogue with certain authorities. This gives comfort that the proposed solution will be regarded as satisfactory by regulators. One country in Europe can be used to create the blue-print of the master notification pack, containing the completed notification form and additional documentation such as the risk assessment and proposed safety notice. The notification form sets out prescribed information such as details of the defect, the affected batches, the number of units affected, the countries in which the product has been marketed and the proposed remedial action. A company will want to decide, in conjunction with its lead lawyers, how much additional information is provided to regulators and how best to present the information such that national regulators do not need to ask questions or request further detail which causes unnecessary delay. To reduce the prospect of individual regulators intervening or questioning the adequacy of the proposed corrective action, a company will want to ensure that the regulator understands the international nature of the recall exercise and that their country is just one piece in a much larger jigsaw.

Following any informal meetings, the master notification pack can then be translated as necessary for submission to other regulators.

In relation to serious risks which may have a significant impact on the company's business, local product liability lawyers should be retained in each of the affected countries to make any necessary amendments to the documentation to reflect the nuances of local regulations or practice. The company, or more often its lead lawyers, should carefully manage the costs of the notification exercise, agreeing a fixed fee in advance with the local lawyers for checking the documentation and attending to the notification procedure.

Practice varies across Europe concerning the approach to formal notification. Generally speaking, there are benefits in fixing a meeting with the regulator. It demonstrates the seriousness attached to the problem by the company and a willingness to discuss the issue. Ideally the company will already have a relationship with its regulators, but if not it will need to gain the trust of the regulator. In most situations, the company will not want to implement its proposed solution until it is satisfied that fundamental concerns will not be raised by the regulator. This is more likely to be achieved at an early stage through a meeting. Who attends a meeting will depend upon the circumstances and the normal practice in the country in question. In most cases, no more than two or three representatives should attend. It is more common for lawyers (whether external or in-house) to attend in continental Europe than in the UK. A person with a technical background should attend to be able to explain the cause of the problem and the proposed solution.

It is important to be honest and straight-forward with the regulator. If the information provided to the regulator appears inaccurate or inconsistent, it is more likely that the regulator will take a more aggressive and interventionist approach. Where the risk assessment and proposed solution have been worked through systematically and professionally, the regulator may have greater confidence that the company will take the right approach without extensive questioning or monitoring.

It is possible for companies to make a single notification across the affected countries within the European Economic Area, through use of the General Product Safety Directive Business Application on-line procedure. This procedure has been available since 1 May 2009. The notification form is transmitted electronically to the relevant authorities in the Member States which a company wants to notify. Relevant translations need to be attached to the form reflecting the countries to be notified. Many companies still prefer to co-ordinate the individual notification of European Union regulators, using meetings and a completed notification pack. The advantage of direct contact with the regulator is that it should be easier for the company to gauge the reaction of the regulator and to satisfy him or her as to how seriously the matter is being treated by the company and the adequacy of the proposed corrective action. Other companies prefer to use the single notification procedure to save on legal costs and management time.

A regulator in any European Union Member State is obliged to share information concerning "serious risks requiring intervention," with the European Commission using the Community Rapid Alert System for non-food consumer products (RAPEX). In appropriate cases, the Commission shares that information with other Member States and with regulators outside the European Union, in particular the United States and China (in respect of consumer products made in China). Each Friday, the Commission publishes a summary of the information notified to it by Member States on the DG SANCO website. The Commission does not disclose the whole notification to the public, especially not detailed risk descriptions, test reports or details of distribution channels which may be confidential. The approach of different countries as to whether to make a RAPEX notification varies considerably. Some countries apparently make a

notification as a matter of course, whereas other countries use the system rarely - Belgium have only made 72 RAPEX notifications in the last six years, compared to 1057 by Germany. Although it is principally a matter for the Member State in question as to whether it makes a notification, in the Commission's notification guidelines provided for the option that a company notifies in one Member State and that that country's regulator makes a RAPEX notification to the other Member States, e.g. upon a company's request, even if there is no serious risk. Companies may be permitted to have sight of the proposed RAPEX notification form.

Proactive use of RAPEX may be one strategy in circumstances where the company would prefer not to incur the costs in making separate notifications in all Member States where the product was sold. Companies should however recognise that they may well face questions from regulators in other Member States besides the one in which the original notification was made and there is an increased risk of authorities taking an interest in these circumstances. Regulators may well visit stores to see if the product is still being sold and may undertake random testing on such products or simply make contact with the local subsidiary and raise questions concerning the product. In serious cases, we advise companies to notify directly at least in the key countries affected as regulators are more likely to raise queries and objections if they first receive indication of a product problem from a regulator in another country, or even worse, through the media.

Frequently companies are concerned that commercially sensitive information that they provide to regulators may enter the public domain or become accessible to their competitors. In the European Union, there is a presumption of public disclosure in respect of information regarding the risks to consumers, in particular information concerning the identification of the affected products, the nature of the risk and the corrective measures taken. Information which "by its nature, is covered by professional secrecy in duly justified cases" is protected where its disclosure is not necessary to alert the public to the risk which the product presents. Guidance indicates that regulators in Member States and the European Commission should not make disclosure of information which undermines the protection of court proceedings or monitoring and investigation activities. In these circumstances, it may be possible to get assurance from the Commission that information will not be made available. It is significantly easier to get protection for confidential information from the CPSC in the United States if the information is marked as confidential and its status is not challenged by the CPSC.

### Public and Media Relations

In recent years, the Mattel and Toyota recalls have shown the massive publicity which global product recalls can attract and the scrutiny placed on international businesses in their response to product safety concerns. It is crucial for any business facing a product safety issue to have a clear strategy for dealing with the media. Companies want to be seen as being as proactive and in control in dealing with a product crisis and not constantly one step behind developments or unable to give information expected by the media in a timely fashion.

This can be easier said than done when a story suddenly breaks and the company does not have all the information it needs to make informed decisions on its response. Speed is critical and it is often necessary to make decisions without all the information which a company would want to consider in a normal business context. We live in a 24-hour, multi-media age and the speed of decision-making needs to reflect this, in order to minimise damage to a company's reputation.

On occasions, a company may need to broaden the scope of a recall or take additional corrective measures. This might be where new information comes to light which indicates that additional product models or batches also present a safety risk or for example where new information (e.g. a serious injury) leads to a re-assessment of the potential risk. This is an inevitable consequence of the need to take decisive action without being able to wait for all the relevant information to become available. This can be extremely damaging from a PR perspective as a further announcement tends to create a further wave of publicity and the company risks losing public credibility. An example of this was the series of toy recalls by Mattel between August and November 2007.

The company should engage Public Relations professionals to work with its management and legal team. Where possible, there are benefits in having a single senior spokesperson to talk on behalf of the company and to explain the action it is taking and why it is taking this action across different regions. The spokesperson will benefit from media training as he or she becomes the face of the company which is in the spotlight. It is easier for a spokesperson with no direct personal background or prior involvement in event leading to an incident to remain calm, to stick to the officially approved messages and to avoid being drawn into detail on the investigation. In different regions, the company may want to appoint additional points of contact for communications purposes. All enquiries should be channelled through the designated points of contact. These contacts need to be fully briefed on developments and the company needs to ensure that a clear and consistent message is delivered in all countries. It is necessary to take control of the situation at an early stage and explain the company's commitment to conduct a thorough investigation. The company should be available and co-operative with the media, ensuring that journalists are made aware of the contact points and the proposed timing of any press statements.

A company's reputation can be enhanced by effective management of a crisis. It wants to portray itself as forward-thinking and committed to safety, quality and customer service. How a company handles a crisis is often remembered long after the product issue is resolved. Thorough preparation ensures that key information concerning the nature and extent of the product issue is communicated effectively and the responses to questions demonstrate that the company is acting promptly and responsibly in light of the available information. The company needs to be seen as accountable for its product, to be sincere and genuine in its communications and show concern and sympathy for any injured persons. Public statements should be in plain language, avoiding technical jargon, and avoid speculation if the cause of the problem is unknown. A press statement and accompanying pack can be useful for the initial briefing of the media and lists of questions and answers should be worked up for responding to consumer and press enquiries, including how to deal with difficult areas where the company may face criticism for its actions.

Companies need to take into account the legal consequences of any statements they make. In many circumstances, the company will not want to accept that its product is unsafe or that it is legally required to undertake a consumer recall. There may well be a potential dispute between a supplier and the company as to the cause of the problem. Where insurers are involved, it may be necessary to agree in advance the content of proposed communications. No admissions of liability or incriminating statements should be made without insurers' consent and a proper understanding of the implications in terms of claims by or against the company. In most circumstances, it is unhelpful in the media to seek to pass blame onto third parties, such as a supplier, testing house or sub-contractor. This can suggest a lack of accountability

and may fuel a public debate between the relevant businesses in the media, such as that between Ford and Firestone/Bridgestone over the cause of road accidents involving Ford Explorers with Firestone tyres, which further damaged the reputations of both companies.

Companies should, either themselves or through their PR advisers, monitor the publicity surrounding the product crisis. Often the press want to overstate the safety risks to increase a story's profile and the attention which it receives. Companies should be quick to correct any inaccuracies in reporting and ensure that the risk is fairly portrayed. Analogies can often be useful in putting a product risk in its appropriate context. A record should be maintained of the press releases and public statements made on behalf of the company as well as any interviews which are conducted.

### Implementing a Recall

The appropriate response will depend upon:

- the technical investigation into the cause of the problem;
- whether it concerns all products or just certain batches;
- the outcome of the risk assessment as to the likelihood of further incidents involving consumers;
- the severity of injuries that may occur; or
- any warnings which are included on the product or packaging.

A full consumer recall is generally a last resort if no other steps will effectively minimise the risk to consumers. There is no simple formula as to the number of incidents or what proportion of products need to be potentially unsafe before action is required. This needs to be considered as part of the risk assessment. The company may want to involve both lawyers and PR advisers in its deliberations. Many companies will have an incident management plan to use as a tool in formulating and implementing its proposed strategy. The solution will want to be acceptable to the public and to regulators in light of the nature and extent of the risk which the products present. The company will want to ensure that the proposed solution is effective, addresses the potential hazard and does not give rise to other safety or quality issues. The solution should be as convenient and easy as possible for consumers, to minimise the potential for further brand damage in its implementation.

The proposed corrective measures should reflect the nature of the product, where it is installed and how consumers use the product. The costs and practicalities need to be properly thought through. The proposed solution will want to ensure that only owners of affected products can take advantage of the recall and that the dangerous products are returned or destroyed (e.g. in exchange for a replacement or refund). In broad terms, it is easier to return smaller consumer goods for refund or replacement than large items or products which are in constant use, where measures to repair the product *in situ* may be the best solution. Real difficulties can arise when there is a risk that a product may not be safe to use, but consumers will not regard any significant period whilst it cannot be used as acceptable (e.g. a car or refrigerator).

There may be a need to find a creative solution. For example, where there is a very large volume of product which needs to be modified in end users' homes, where the risk is relatively low, it might be possible to implement the corrective action in tranches (with the highest risk end users first) to avoid customer care issues caused by significant delays between notification letters to end users and the issue being resolved. With certain products, technology can provide a cheap and effective solution to identification and communication with end users (via text message or interactive websites). The proposed solution should also reflect

consumers' rights. Legal advice may need to be taken in various countries as to whether consumers can insist on a refund or whether a company is entitled to repair a defective product.

In most circumstances, where regulators are satisfied with the company's proposed response to an incident, they will leave the company to deal with the matter on a voluntary basis, often requesting that they be kept informed of developments. However, most authorities (including those in Europe and the United States) have broad powers to order a recall to be undertaken or take other steps if they are not satisfied with the company's response. There is an obligation on EU Member States to notify the European Commission where the Member State in question takes any measure to restrict, withdraw or recall products from the market. This includes measures in response to non-serious product risks.

In many cases, where manufacturers, wholesalers or importers are implementing a product recall, they will choose to deal direct with end users, for example arranging a direct product exchange rather than expecting consumers to go to return the defective product to a retail store for replacement. Retailers prefer not to be involved and their involvement will have a cost implication for the manufacturer. Dealing directly with consumers gives the manufacturer greater control over its brand and arguably will be perceived by consumers as showing greater accountability for its products. Some companies affected by a recall will outsource part (e.g. the call centre facility) or all of the exercise to a specialist service provider, which has experience and the resources to implement the solution.

Delivery addresses, completed guarantees, warranties or registration cards and details of bank debit and credit card purchases can all provide information to enable direct contact to be made with end users. Distributors and retailers are expected to cooperate with manufacturers in identifying end users where a product presents a safety risk. This is a typical exception to data protection restrictions on the release of personal end user information. Where information is available, direct contact should be made with end users - typically by letter or by e-mail.

In many situations, a company will not have names and addresses of purchasers of a significant proportion of the products. It is therefore faced with how best to bring the risk to unidentified purchasers' attention. Common steps include:

- Establishing a designated free telephone number (or series of freephone numbers in different countries) for consumers to call for more information and to register for a retro-fit or the supply of a replacement product. Sufficient additional personnel need to be briefed to answer telephone calls.
- Publishing a safety notice in national newspapers, specialist magazines or the trade press. Practice varies between countries concerning the size of the notice and the number of newspapers in which such notices are placed, but these details are typically at the discretion of the company. Occasionally, regulators stipulate certain requirements. As part of the planning process, space in the newspaper needs to be booked a few days in advance.
- Issuing a press release concerning the incident. Although this does not need to be in identical terms as a safety notice or the factual information on the company's website, care should be taken not to under-state the risks. This may provoke regulators to pay closer scrutiny to a company's response and may also potentially open the company up to a greater risk of regulatory claims, in particular if there are future incidents involving the product. Where a matter is newsworthy, a press release provides an opportunity for the company to get its message across and will also generate press coverage which will in turn alert further consumers to a recall programme.
- Details of the defect, potential hazard and the

proposed corrective action can be put on the company's website as well as those of regulators and consumer associations. The company webpage might allow consumers to provide details of their model and product number to check whether it is included within the batches caught by the recall programme. The company can then make arrangements for supply of a replacement product or alternative corrective action. Companies frequently prefer to direct consumers to the website or encourage them to send e-mails as this makes it easier and cheaper to manage significant volumes of enquiries.

- Copies of the safety notice can be made available to retailers to affix in stores where affected products were sold in the past.
- In serious cases where there is a risk of immediate harm, manufacturers may choose to alert end users through television and radio advertisements. This is rarely adopted by manufacturers due to the high costs and a concern that it may have a broader negative impact on their brand.

It is important for companies to maintain a record of the steps which they have taken to identify affected consumers and details of all communications with such consumers. If there was a subsequent incident arising from use of the product and enforcement action was being contemplated against the company, this information can be provided to a regulator to evidence the action taken by the company to minimise the risk. The company may be able to show that it contacted the end user. The company should monitor a product recall or rectification programme by tracking the rate of response (e.g. the proportion of affected products which have been exchanged or rectified). The response rate will inform the company and regulator's decision as to whether additional steps are needed, such as placing repeat or additional safety notices in newspapers if the initial response rate is disappointing or in extreme cases using television or radio announcements.

The public are becoming increasingly de-sensitised to product recalls and response rates are accordingly much lower than might be expected. In addition to traceability through to end users, the response rate will be affected by factors such as:

- the purchase price (the more expensive the product, the greater the likelihood of consumers going to the trouble of returning the product);
- the sales period the recall covers and the normal life of the product (the more disposable the product and the further in the past it was bought, the less likely it will be returned);
- the remedy which is available to consumers (more end users will respond if there is the option of a full refund rather than a repair or replacement); and
- the extent of the risk (the greater the risk of injury, the less likely that consumers will ignore the safety notice).

Where there is good traceability through to end users and a serious safety risk, a response rate of over 50% might be expected. Where there is poor traceability and a less serious risk of harm, the response rate might be below 25%.

In deciding on whether to take action, companies will want to comply with legislation and to minimise the risk to consumers. However, they will also be seeking to be seen to "do the right thing" for the purposes of brand protection and to minimise the prospect of future criminal or regulatory action against the company or its senior management by authorities. It can be argued that increasingly companies are taking action that is not strictly necessary from a legal perspective because of a more risk-averse approach to business.

As part of any recall or other corrective programme, a company should consider the lessons it learns. It should look to turn the

negative situation into a positive opportunity. This might involve matters such as improved design standards or quality systems, increased vigilance in post-sale monitoring or keeping contingency plans up-to-date. However, the company should also consider whether the product should be re-launched and if so how to maximise the impact on the market.

### Managing Costs and Claims

Global recalls can be extremely expensive. In addition to lost sales and a diversion of senior staff from core duties, companies face significant costs in implementing a recall (e.g. in manufacturing and supplying a replacement product free of charge, setting up call centres, recruiting additional staff, logistics costs, advertisement costs, testing costs and professional fees). A detailed record of these costs should be kept with supporting evidence - particularly if there is any prospect of the costs being met by insurers or by a supplier. The greatest risk is the potential impact on future sales of the manufacturer's products or on its brand.

Claims by end users who have suffered injuries or financial claims by customers can be very significant. Where a company receives notification of claims, it should bring these to the attention of its insurers. A manufacturer, importer or brand owner may face liability to consumers in negligence or under statute (e.g. strict liability principles), or contractual claims from its customers.

Companies who place unsafe products on the market can face parallel proceedings in different jurisdictions and the risk of multi-party or class actions. Companies will want to minimise their damages exposure. They may want to influence where claims are brought - for example, preferring claims not to be heard in the United States where punitive damages and conditional fees are available to injured parties. American companies will typically want to have claims by European individuals seeking to join a United States class action dismissed on the basis of *forum non conveniens*, i.e. arguing such claims should be heard in the country where the products were bought, regulated and where the damage occurred. Within Europe, injured parties often have a choice as to where they bring proceedings and in most cases it will be impossible to have claims dismissed on the basis that another forum is more appropriate.

In recent years, more European countries have introduced legislation whereby individuals who have claims involving common issues of fact or law can join together in taking action. The procedures vary and may involve a representative or consumer association bringing an action on behalf of the individuals or some other form of collective action. The effect of these changes is to make it easier and cheaper for individuals to pursue compensation claims where they are affected by the same defective product from the same manufacturer or supplier. These developments significantly increase companies' potential exposure to product liability claims. Looking forward, the risks for businesses operating in Europe are likely to increase as consumers become more aware of their rights, there is greater use of the internet to bring proposed compensation claims to the attention of injured parties and lawyers became more proactive in using the new procedures. Additional options for collective redress procedures on a pan-European level are currently being considered by the European Commission.

In an international context, companies will benefit from experienced lead lawyers to advise on a defence and settlement strategy and co-ordinate with local law firms in relevant jurisdictions to ensure that the company's case is consistently presented in any national courts, with regulators and in the media.

## Document Management

The management of documents is a crucial aspect of risk management in a product crisis. A company will want to be able to produce contemporaneous records to show that it acted responsibly having regard to the relevant legislation and the best interests of consumers and was justified in taking the decisions which it took. A record should be maintained throughout a crisis, documenting the information which was available at particular times, the investigation which was undertaken and the rationale underlying the decisions which were taken by the crisis committee based on such information and investigation. It is important to adopt and adhere to a document retention policy whereby documentation is available to assist in the defence of product liability claims in the future. Documents relating to product safety should not be destroyed.

Care should be taken in documenting the minutes of the crisis committee meetings on the basis that such record may be considered by regulators in the future in deciding whether to take enforcement action against the company or by a customer or group of injured parties who are pursuing a damages claim against the company.

At the outset of a product crisis, employees should be reminded about the potential harm that might be caused to the business by creating documents which are prejudicial to the company's interests. Particularly in e-mails, due to their conversational and informal nature, employees can frequently exaggerate or speculate about the cause of a problem. E-mails are far more likely to be inaccurate as they are rarely checked. A company can improve its prospects of successfully defending civil claims or regulatory actions if it is sensible about the content and circulation of documents.

Lawyers can play an important role in relation to document management. In certain jurisdictions, it may be possible to gain the

protection of legal privilege in respect of communications with lawyers and documents created for the purpose of taking legal advice or as part of the litigation process. Companies should not seek to use the doctrine of privilege inappropriately or to hide the true position from regulators or potential claimants. However, on occasions the doctrine of privilege may enable frank exchanges of information between a company and its lawyers or allow technical experts to explore lines of enquiry or undertake additional testing (at the instruction of the lawyers advising the company on threatened or actual proceedings), without such underlying material having to be disclosed.

Since the rules of disclosure and privilege vary significantly, the creation and circulation of documents should be considered carefully with lawyers across the relevant jurisdictions. Care should be taken regarding the distribution of documents as this may cause privilege to be lost. In an international context, where documents are shared with another group company, they may become disclosable in proceedings against the recipient company in that jurisdiction.

## Conclusion

Companies with international activities face an increasingly difficult set of challenges in their handling of product risk and compliance issues. No company is immune from a product crisis. Managing a global recall needs experienced product liability lawyers to advise companies not only on their legal obligations but also on practical considerations, which can make the difference between failure and success. Whilst there is no substitute for specialist legal advice tailored to the particular circumstances of a specific product incident, we hope that this chapter provides a useful reference point for companies preparing for, and managing, a serious incident with cross-border implications.

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Richard heads Eversheds' International Product Liability Group. Richard has advised many leading manufacturers, suppliers and retailers on product safety and product liability issues and acted on major commercial disputes following product failures. He has considerable experience in managing product recalls, crisis management and product liability claims.

High profile cases in which Richard has been involved include a series of multi-million pound Court actions involving drinks manufacturers who recalled product following the discovery of trace levels of benzene in carbonated drinks, various significant claims on behalf of food manufacturers arising out of the contamination of spices with Sudan 1 and Para Red and substantial claims arising out of the discoloration of u-PvC window profiles. He has co-ordinated the recall of a number of business and consumer products, including global and pan-European recall and regulatory notification programmes.

Richard has experience in the consumer products, automotive, food, pharmaceutical and medical devices and chemical sectors. Richard specialises in defending companies who face multi-party and cross-border proceedings and devising and implementing strategies to minimise their exposure. Richard is recognised as a leading expert on the development of "class action" procedures in Europe, having presented widely on this subject. He was a member of a Task Force of the International Bar Association which considered guidelines for the international harmonisation of class action procedures.

Richard is a named product liability expert in the UK legal directories and identified as one of the "World's Leading Product Liability Lawyers".

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Fabian studied law at Eberhard-Karls-Universität in Tübingen and was admitted to the bar in 1997. He worked as a lawyer in an international law firm and specialised in product liability, product safety and insurance/reinsurance. In 2001 Fabian was seconded to the legal department of a major US electronics corporation. He joined Heisse Kursawe Eversheds as a partner in 2007. Fabian regularly publishes articles and speaks at national and international conferences.

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