

EXECUTIVE REPORT

Product Recall

Highlighting the main risks and identifying practical solutions for dealing with recall incidents

“We had to move this 700-tonne component more than 600 kilometres. Scores of risks, but Zurich made us feel confident we were well protected.”

Herbert Peters, Managing Director,
Sasol-Huntsman, Moers, Germany

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Foreword & contents

European manufacturers may consider product recalls to be rare events, but some retailers' websites tell a different story. Recalls appear to be considered so common that there's actually a button that you can click on to pull up news of the latest recalled products. The statistics produced by the European Commission's Rapid Alert System for non-food consumer products (RAPEX) and Rapid Alert System for Food and Feed (RASFF) also highlight the number of notifications that are received in respect of potentially dangerous products.

The risk is very real and companies that don't take it into account are in danger of not even living to regret it! Recalls don't just cost a lot of money, they can also have a serious impact on brand and reputation – far more than most companies estimate.

This special report looks at the causes, costs and implications of product recalls, and identifies some of the strategies that can be of most value in minimising likelihood and costs. Good risk management is an essential ingredient, and must include effective quality control. For example, most of the notifications received by RAPEX concern products – usually imported – that contravene EU regulations and standards.

This report also looks at issues relating to handling product recalls. Today, the media is very quick to judge the way companies deal with a crisis. Effectively dealing with a major recall reduces its impact on both costs and reputation. Of course, the reverse is true if a company fails to handle the situation well.

Product recall insurance has been something of a 'Cinderella' for insurance buyers. First, it wasn't widely available some years ago. Indeed, some risk managers who felt they needed this cover used their captive insurers to underwrite it, faced with a lack of capacity in the conventional market. Secondly, and this applies to some extent today, many companies found it difficult to quantify the maximum exposure and so assess the value of recall insurance in an informed way.

One of the commentators in this report likens the situation of product recall insurance today to that of directors' and officers' liability insurance (D&O) in Europe some years ago. No one then felt they needed D&O and now no major company will be without it. Certainly, in the current environment of increased scrutiny of product safety, recall insurance has to be climbing the agenda to take its place with other established covers and deserves serious consideration.

Patrick Amschwand

Chief underwriting officer,
Zurich Global Corporate in Europe and the Middle East



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Recalls & risk management

As reporting requirements become more stringent and pressure to reduce costs more pressing, the likelihood of product recalls increases. It is essential to have a robust crisis management system in place in advance and ensure that your business's suppliers do the same

The number of notifications of potentially dangerous products distributed in the EU for both general consumer products, notified through the Rapid Alert System for non-food consumer products (RAPEX) website, and for food and feed products (notified through the Rapid Alert System for Food and Feed (RASFF), rose yet again in 2009. Does this mean that there are more dangerous products on the market and that the number of product recalls is also increasing?

Patrick Amschwand, Zurich Global Corporate's chief underwriting officer for Europe and the Middle East, thinks not. "In the years following the enactment of the 2001 EU product safety directives in the different member states, we have seen tighter and more complex legislation surrounding product safety in the EU. Companies are making notifications in circumstances that they would not have previously reported. There is an underlying change in the legal framework that has driven more reporting and pushed the numbers up."

Globalisation adds risk

However, Amschwand accepts that some changes in the way goods are produced have created more risk challenges. "We've seen significant globalisation, with companies moving production from their home countries to cheaper labour markets in countries like China and India, and also looking to export to developing areas. The drive to increase margins and reduce costs is putting additional pressure on product safety risk management procedures at a time when manufacturing processes are becoming more complicated."

Another feature of globalisation is the prevalence of extended and complicated supply chains. Amschwand explains: "This makes the challenge of quality assurance and product safety more testing and the control of contractual terms and conditions through this extended supply chain more challenging. There's more room now for risk being introduced."

Not all recent trends, however, have increased the likelihood of product defects

creeping in. The growth in technology and ever-improving automation in production and testing processes is helping to remove risk, with less scope for human error.

Whether products have become riskier or the growth in statistics is the result of more stringent reporting requirements, it is clear that some companies are not as well prepared for a potential product recall as they might be. As Amschwand says, it isn't cost effective to prepare for absolutely every risk event. Companies have to take a view on what represents reasonable and appropriate contingency planning and preparation. However, companies tend to underestimate the impact of a recall on their business and brand.

It is a challenge for a company to quantify its estimated maximum financial loss from a recall for a number of reasons.

'Do not wait until a recall happens to start drafting messages to go to your trading partners. Legislation requires you to act immediately'
Patrick Amschwand,
Zurich Global Corporate

Amschwand explains: "It is difficult to quantify the damage that may be sustained by a brand and how long it will take before customers are willing to return following a breach in product safety controls. Often, too, there are very complicated contractual chains which make the allocation of financial risk [to the various parties in the supply chain] hard to assess.

"Furthermore, companies don't always identify the interdependencies between production lines. If one plant is shut down while an investigation into a product contamination is under way, how much of that production can be switched to an alternative

site? Assessing business interruption is probably the most difficult aspect.

"Significant underestimation of a potential loss from a recall – and of the likelihood of a recall happening – can give companies a false sense of security. As a result, they may not prioritise prevention, planning and preparation as they would if they realised the true scale of the possible loss. For this reason, a key feature of Zurich Global Corporate's product recall cover is access to consultants to help clients make the right decisions and provisions for pre-loss risk improvement."

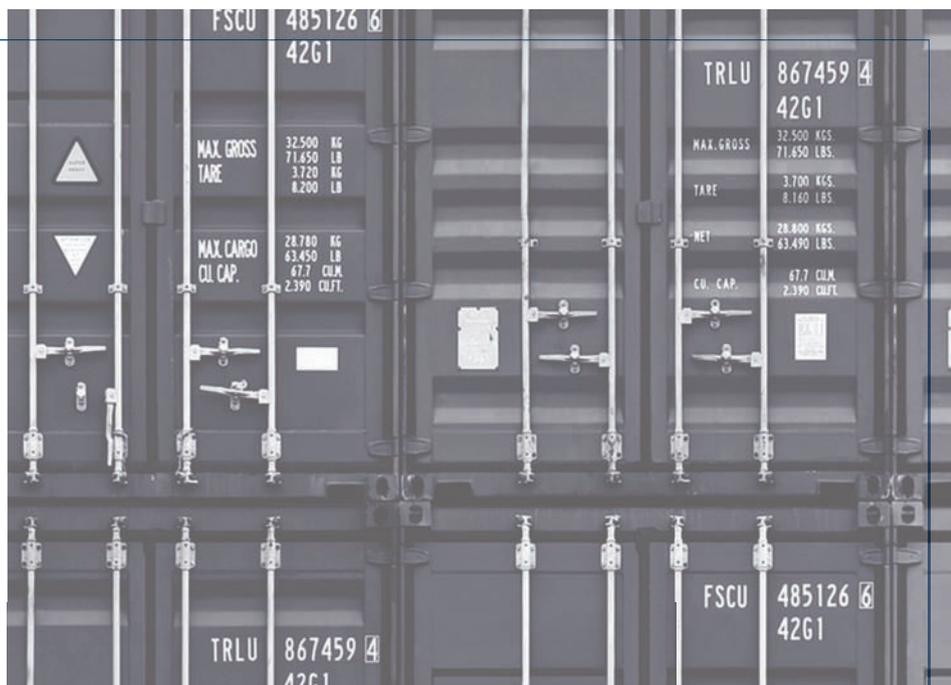
Minimising the dangers

Good quality management is key to reducing the likelihood of a recall. This includes effective product safety controls, personnel training, auditing suppliers, and rigorous testing processes at all stages of product development, design and production.

Minimising the potential consequential costs if a product recall does become necessary involves additional strategies. For example, Amschwand recognises the need for companies to establish rigorous contractual controls, such as contracts with suppliers that ensure they can pass the risk back if a supplier's ingredients or components have caused the problem. "We still see companies signing hold harmless agreements with suppliers that mean they may not have any legal recourse against them," he says.

Limiting batch sizes and swift identification of the defective products are also key. Lars Sempelkamp, risk engineer at Zurich Global Corporate Germany, points out that there's a big cost difference between withdrawing 1,000 or 100,000 products. "If companies reduce the quantities in each batch, they can identify affected products more easily and limit the impact. This can often be done quite cheaply, using electronic data processing (EDP) systems." Keeping back a sample from each batch also saves time if a product needs to be tested when a company is deciding whether a recall is necessary.

Where a product consists of a number of components, a company should ensure that



it can identify each component. If a complex mechanical product is involved, each part will usually have its own ID number, but dismantling the product to check identification is time-consuming and expensive. Simpelkamp says that attaching radio frequency identification tags to components helps here, allowing each part to be identified at a distance of around two metres. It's easy to see how useful this is when, say, checking a number of products stored in a warehouse or in locations where access is difficult.

Companies manufacturing huge quantities of fairly simple cheap items, such as plastic toys, need to employ different identification and limitation strategies, says Simpelkamp. "If a company is using raw materials such as plastics or metals, each time it changes the batch or source of the raw material, it could identify the change in the EDP system," he suggests.

Paul Howard, head of insurance and risk management at Sainsbury's, agrees that batch numbers, order tracking and product tracking are essential. Businesses selling direct to the public may also benefit from their use of loyalty cards, he says. "Loyalty card data – customers' names and addresses – can be valuable in identifying a high percentage of the people who have bought a particular product, rather than relying on advertisements and notifications."

Work with suppliers

Howard stresses the need to work in partnership with suppliers on any product and packaging changes. "You need to be aware of their contingency plans and processes as well as their operations. It's a partnership approach to ensure anything relevant is flagged up before a potential loss."

Last year's RAPEX notifications highlighted China as by far the largest source of defective and potentially dangerous products. However, Simpelkamp resists the implication that sourcing manufacturers in China is necessarily hazardous. "There are some market-leading companies in terms of quality producing in China and some not so good companies in

Europe. The important thing is for a company to ensure that all its production areas around the world have consistent standards of quality and controls, including testing and reporting procedures," he says.

He warns that companies who push their suppliers to agree to very low prices might need to do more in terms of ensuring quality control as those suppliers may try to cut corners, for example using cheaper materials than those specified. "This is, of course, dangerous for product quality. The company that is bringing the product into the market must carry out proper investigations of its suppliers and similarly test any outsourced components before integrating them into the product," he adds.

Make plans and stick to them

A properly pre-prepared robust crisis management plan and an established recall management team are essential. The team must have the training, the knowledge and the data to act immediately and in a well co-ordinated manner, says Simpelkamp.

Management must also be able to communicate effectively with the media and other stakeholders. Amschwand suggests getting communications prepared in advance. "Do not wait until a recall happens to start drafting messages to go to your trading partners. Legislation requires you to act immediately and it is not likely that you will have a clear picture of the full circumstances before you are obliged to make some kind of comment to the local government agencies, customers or maybe the media." Howard points to the need to be as transparent and open as possible – and to communicate widely.

Simpelkamp also stresses that acting quickly is crucial. "It's important not to lose two days thinking about what you need to do and how, which is why prior training and testing against recall scenarios are vital."

The crisis plan and communication procedures should reflect the company's potential exposure and the affected product's complexities, for instance taking into account geographical distribution and any specific handling and storage requirements. Simpelkamp gives the example of a product that is temperature sensitive and has to be kept in a chilled environment: "The company will need to be able to access special warehouses and transport facilities very quickly."

Ian Harrison, executive director of Lockton's global risks team, stresses the need for companies to stick to the crisis plans that they have established. "In practice, many times they do not follow the plans that they've laid out for themselves, probably because of media and time pressures. Events can often overtake them. But following the logical processes that they designed before the crisis will generally still serve them well."

Harrison also advocates using any crisis management hotlines that may be provided within the applicable product recall policy. "The advice these give can be very valuable."

Amschwand concludes: "All companies recognise that they cannot completely eradicate any chance of a product safety issue arising. However, they can ensure that they reduce the potential impact."

KEY POINTS

Tighter and more complex product safety legislation has driven up numbers of recalls

Many businesses underestimate the damage a recall can do to their brand

Put together a robust crisis plan and draft statements ready in advance

Recalls & the law

Europe has stringent rules and processes for product recalls, which vary between countries and make cross-border product safety decisions complex. Lawyers can help with compliance as well as assessing potential liabilities and recoveries

The problems arising from large, multi-jurisdictional product recalls involving well-known brands have been well covered by the media. Customers have instant access to more information – and potential misinformation – than ever before. So it’s essential to ensure regulatory compliance, reduce the risk of litigation and protect reputation.

“Unless companies have robust risk assessment and decision-making processes in place, cross-border product safety issues can be difficult to manage, with potentially catastrophic consequences. It is vital to demonstrate that you are taking considered and timely actions,” was the message to delegates at last June’s Airmic conference from John Leadley, head of product and operational risk at international law firm Baker & McKenzie.

The EU’s General Product Safety Directive 2001, now enacted in member states, lays down guidelines, including those related to notifications and recalls. Although in theory there is an EU-wide regulatory regime, there are differences in national legislation.

If European companies think they have a product safety problem that should be notified, calling in external advisers can help. Jim Sherwood, partner at Berrymans Lace Mawer, says independent advice can help risk managers and internal counsel put their concerns to the board before the worst happens.

He explains: “Risk managers, particularly in the retail sector, are concerned about the potential financial and reputational impact of a recall. It’s possible that, in the current recession, recall has dropped down the board agenda, and management may want to reduce money spent on checking that their

recall strategy is in place. Flagging up potential issues can be helpful and remind board members of their potential liabilities, criminal and otherwise.”

Know when to notify

If a problem does emerge, such as a number of customer complaints in respect of a particular product, companies need to identify whether or not this is a serious issue that needs to be addressed with the appropriate authority.

“In-house lawyers might not have experience of dealing with the regulatory regime relating to product safety and notifications. And the company’s recall strategy may not be the same in all parts of the world – the approach taken by the different national authorities can vary and there may be cultural issues – so local advice in the different jurisdictions helps here too,” Sherwood adds.

REPORTING REQUIREMENTS IN KEY EU COUNTRIES

Belgium

Notification of a dangerous product to the competent authority should provide at a minimum:

- information identifying in an exact manner the product, or lot of products at issue;
- a complete description of the risks connected to the relevant products;
- all information available on the basis of which the product can be traced; and
- the steps taken to prevent risk to users.

The General Product Safety Act states that producers and distributors must inform the authority immediately when they know or should know that a product poses risks to the consumer. The primary responsibility for determining whether a product is safe rests with producers and distributors.

When there is a serious risk the company should inform the authorities within three days of receiving the information that warrants the notification (10 days if the risk is not serious).

France

A producer or distributor that becomes aware that the consumer goods it has put on the market are not safe and may create a health

hazard must immediately inform the competent administrative authorities and indicate the measures it intends to take to eliminate any risk to consumers.

Compulsory notification of safety issues applies only in respect of end-user goods and must at a minimum contain the following:

- the date of the notification;
- the name or company name and address of the notifying enterprise;
- the name(s) and address(es) of its (suppliers);
- the name(s) and address(es) of its distributors;
- the description of the product, in particular denomination, trademark, batch references, the volume intended for the French market;
- the description of the danger and of the measures taken by the enterprise; and
- any other information that the company considers to be potentially useful.

Germany

The German Equipment and Product Safety Act (GPSG) requires the manufacturer, its authorised representative, the importer and the dealer to notify the competent authority

without delay if they know or have firm indications, on the basis of information in their possession or their experience, that a consumer product they have placed on the market represents a danger to the health and safety of consumers. In particular, the manufacturer must give notification of the measures it has taken to prevent this damage.

Mere ‘concerns’ without concrete indications would not trigger the notification duty, but notification of a hazardous product may not be delayed while additional testing is carried out.

Italy

The report to the surveillance authorities must contain at least all the information required by the notice form that is attached to the General Safety Product Directive.

The Italian Consumer Code does not specify what level of hazard of a defective product must be reported to the market surveillance authorities but states that the producer and/or distributor must inform the competent authorities about products that pose risks for consumers and thus do not comply with general safety requirements.

The company decides whether a product defect has reached a hazard level that must be reported. However, the competent authority

He points out that a product recall is often the last resort. There are other corrective actions that manufacturers and importers can take. Non-compliance with obligations in respect of unsafe products can result in stringent penalties: fines for the business and fines, even imprisonment, for company officers.

Jason McNerlin, associate at Sedgwick, Detert, Moran & Arnold, says that insured companies have a duty to notify their insurers of a potential safety risk from a product. The insurers will invariably instruct solicitors if the amount involved is significant enough.

KEY POINTS

A company’s recall strategy may have to vary around the world

Product recall lawyers can help assess the liability of several suppliers

Some EU countries require concerns to be notified even if a recall is not necessary

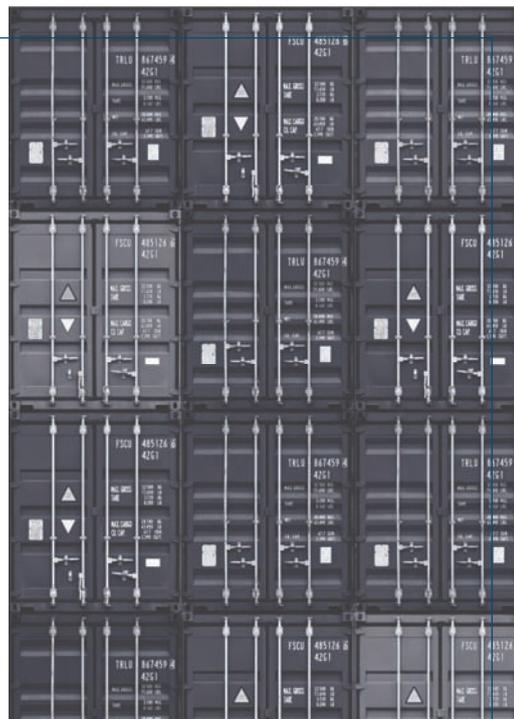
Which supplier is liable?

“If it’s not clear whether a product should be recalled or what the scope of the recall should be, the company or insurer will ask lawyers for their opinion – early decisions are critical in determining the size of any eventual loss,” says McNerlin.

Complex products and supply chains can make it difficult to determine which component is involved and who is responsible. McNerlin explains: “You may have a product that consists of three different components. You know there is a problem with the end product but cannot identify which component is faulty or if it’s the effect of one interacting with another. So you can’t go to the component producer and talk to them about ways of limiting the loss and the scope of the corrective action.

“In almost every case we see, several parties are involved in making the components and ingredients. While it may be necessary to carry out a recall in the first instance, after that you may need to establish the root cause of the problem and seek to apportion the liabilities between the various producers.”

Assessing potential liabilities and recoveries is an important part of product recall lawyers’ work. Sometimes a company will become



aware of an adverse test result relating to products already in the market. “They will need immediate advice on whether they should be notifying a potential problem, even if it does not culminate in a recall,” says McNerlin. “Usually time is of the essence.”

A potential health risk puts people under pressure and, as well as legal advice, companies will probably also want scientific advice and evidence. No one wants to be alarmist and incur unnecessary loss. There’s a delicate balance between not taking chances and not over-reacting.

may independently evaluate the hazard and accordingly adopt any alternative or additional measures it deems necessary.

Netherlands

Manufacturers or distributors must notify the competent authority without delay if they know, or should know, on the basis of information in their possession or their experience, that a product (consumer or other) they have placed on the market represents a danger to the health or safety of the public. In particular, they must give notification of the measures they have taken to warn of and prevent this danger.

The competent Dutch authorities are not entitled to recall products but they can issue public warnings. The threat of a public warning often leads manufacturers or distributors to initiate a ‘voluntary’ recall.

Spain

Manufacturers and distributors that are aware, or should be aware on the basis of the information they possess and experience, that a product which has already been made available or supplied to consumers poses risks conflicting with their general obligation to ensure product safety, must report it

immediately to the competent authorities. This notice must contain at least:

- details clearly identifying the product or batch of products;
- a full description of the risk;
- any information useful for tracking the product; and
- a description of the action taken to prevent risks for consumers. This action must include the withdrawal of the products from the market or those measures deemed appropriate for preventing risks.

Sweden

Product manufacturers and distributors and service providers in Sweden must notify the competent authority immediately upon learning that a product and/or service the company has provided is unsafe. This notification must be made even if the company decides that a recall is unnecessary: for example, if it issues a warning notice.

The notification to the competent supervisory authority must include:

- information enabling a precise identification of the product or batch of products affected;
- a full description of the risk;
- all available information relevant to the tracing of the product; and

- a description of the actions taken or planned to protect consumers.

UK

If a producer or distributor realises it has placed an unsafe consumer product on the market or has supplied such a product, it must notify the competent authorities in the country or countries affected about the safety concern and the action taken. The required information is very similar to that required in France.

Notification is not required where the risk relates to a limited number of specifically identified products or isolated circumstances. However, in this case, the producer must have solid evidence to prove the risk is controlled and that its cause has been dealt with.

EU generally

Although the notification should be sent to the relevant authorities of all EU member states where the producer or distributor believes the product has been marketed or supplied, it is possible to ask a single member state to accept the notification as a single, EU-wide notification in cases of serious risk or otherwise by agreement. However, the local laws of certain member states may still require a parallel notification to be made.

Source: *Global Product Recall Handbook* second edition, Baker & McKenzie

Recalls & product reputation

The costs of a recall can extend far into the future if the company concerned finds it hard to win back brand market share and customer trust. Managing the recall well is key

“Companies that mishandle recalls will ultimately find that their poor performance affects their bottom line; consumers are less likely to buy their brands in the future.”

So warns Tim Lockett, managing director of public relations and communications agency Hill & Knowlton.

Lockett says that the success of recalls is often judged on the amount of the products that are returned. “If after a period of recall of a month or so companies have failed to recover less than 50% of the affected product, that would be deemed a failure,” he explains. “If the recall is not handled correctly and communicated properly, companies can get into some awful difficulties.” Both regulators and consumers might put pressure on the company concerned and its reputation will inevitably suffer.

Lockett cites the Toyota recall in early 2010 over concern about faulty accelerator pedals as an example of mishandling. “Communication was very slow. It was a slow drip of bad news and the company seemed more concerned about putting out press releases on other topics than explaining clearly what the recall issues were,” he says. Also, Toyota only belatedly started using online and social media to get its messages across.

In such a situation, the result is usually utter customer confusion, which leads to erosion of trust in the brand.

Software can help head off a crisis

Pre-event planning can minimise the potential adverse reputational effects of a recall. It’s not just about maintaining quality standards – companies’ efforts in this direction are taken for granted in developed countries. It falls under the heading of crisis planning – something that most risk managers should be doing anyway.

Deborah Young, business unit director of governance risk and compliance management software company, SwordAchiever, stresses that prevention is better than cure. “Brand name ruination and profit loss can be irredeemable to a business, so the best solution is to safeguard as much as possible against it happening. Companies must proactively assess and manage their product recall risks.”

She advocates using appropriate software to quantify and pinpoint potential exposures,

analyse resources available to respond to such risks, and limit the financial and reputational impact of a product recall.

“A tailored information management system will log issues and put corrective actions in place to prevent it happening again. A post-audit [function can] give full traceability and sourcing to identify where a fault may lie so the cause of a problem can be investigated,” Young says.

Keep communication clear and simple

Lockett stresses the importance of planning a communications strategy should a recall occur. “It’s important to have a simple process for people to follow, and we frequently train people with simulations on how they should act in the event of a recall,” he explains.

‘Brand name ruination and profit loss can be irredeemable. Companies must proactively manage their product recall risks’
Deborah Young, SwordAchiever

If a product does turn out to present some problems, the first question has to be: “Is this product safe?” So the company concerned has to do a risk assessment of whether the product might be dangerous to human health. Often, time is of the essence, but looking at the number and content of any complaints received and product testing is an important first stage. Lockett says that testing should include third-party testing, perhaps using an appropriate laboratory.

“If there’s even a minute chance that the product could lead to a fatality, clearly you will want to recall. If it does not look like the product poses any immediate threat to life but it may pose a potential health threat, even though this is not serious, you may want to withdraw the product as a precautionary measure,” he explains. A precautionary recall gives the company the opportunity to decide whether it wants to cease manufacture or change the ingredients or components of the products concerned.

Lockett says that most of his company’s work in this area is about ensuring effective communication to get the product recalled and keep everyone involved informed. “Typically, that will involve statements and question-and-answer documents. We liaise closely with the appropriate authorities, such as the Food Standards Agency in the UK. We need to get the regulators on board and possibly also politicians who may get involved if the product poses a serious threat. We have to develop a position not just for customers but also for the retailers.”

A recall will only be successful if customers know that they need to return the product. It goes against the grain for some companies to have to advertise widely that they’ve sold an unsafe product. They need to remember that holding back could result in human casualties, which in the long term would have a far more devastating effect on their business.

In some countries there are legal requirements for advertising a product recall, but in the UK it is good practice, depending on the product, to advertise in a range of national print titles, Lockett says. “Companies may also take out some radio advertising, and would certainly think about displaying notices at the point of sale, such as in stores.”

Having prepared for the problem and conducted the recall, the third stage is rebuilding customers’ trust. Carefully targeted advertising campaigns can be useful here, says Lockett. He concludes: “There have been companies that have worked fast and handled recalls effectively, and this has all been around quick and early communication. The companies that end up with reputational issues tend to be those that have tried to avoid the recall up to the eleventh hour.”

KEY POINTS

Have a plan in place for a crisis, but also plan to avoid one

Quick and early communication makes recalls effective

Rebuilding customer trust will require a whole new strategy

Product Recall

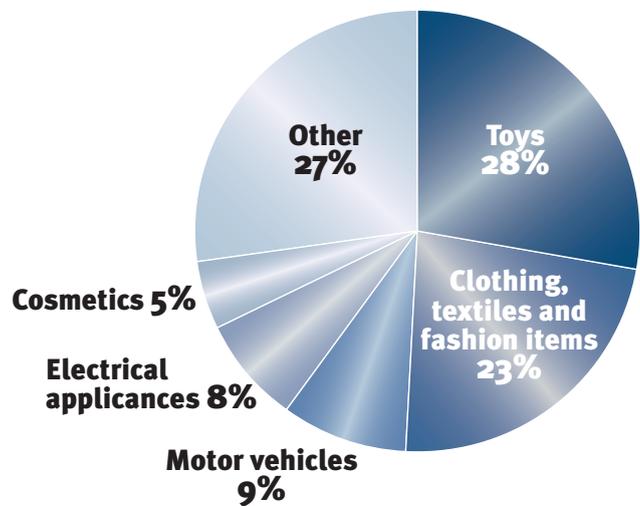
Executive summary

This pull-out summary presents a brief synopsis of the key points covered in this report. It is provided as a quick guide for risk managers and also as a tool to inform their board members of the considerations and risks relating to product recall.

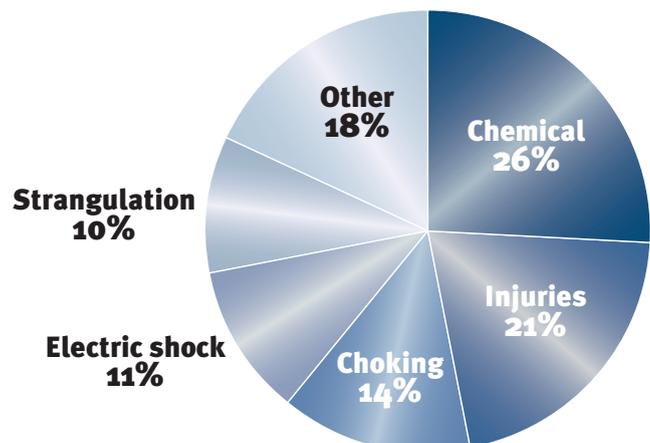
Brand and reputation issues

- A successful product recall often requires publicity. This usually has an adverse impact on brand and reputation.
- Market share often drops after a recall – how much and for how long depends on how well the recall is handled.
- Companies that mishandle recalls will ultimately find that their poor performance affects their bottom line, with consumers less likely to buy their brands in the future.
- The companies that get into difficulties tend to be those that try to carry on to the 11th hour to avoid the recall and end up with greater reputational damage.

THE FIVE MOST FREQUENTLY NOTIFIED PRODUCT CATEGORIES IN 2009



THE FIVE MOST FREQUENTLY NOTIFIED TYPES OF RISK IN 2009



Source: RAPEX
 Figures do not include food recalls.

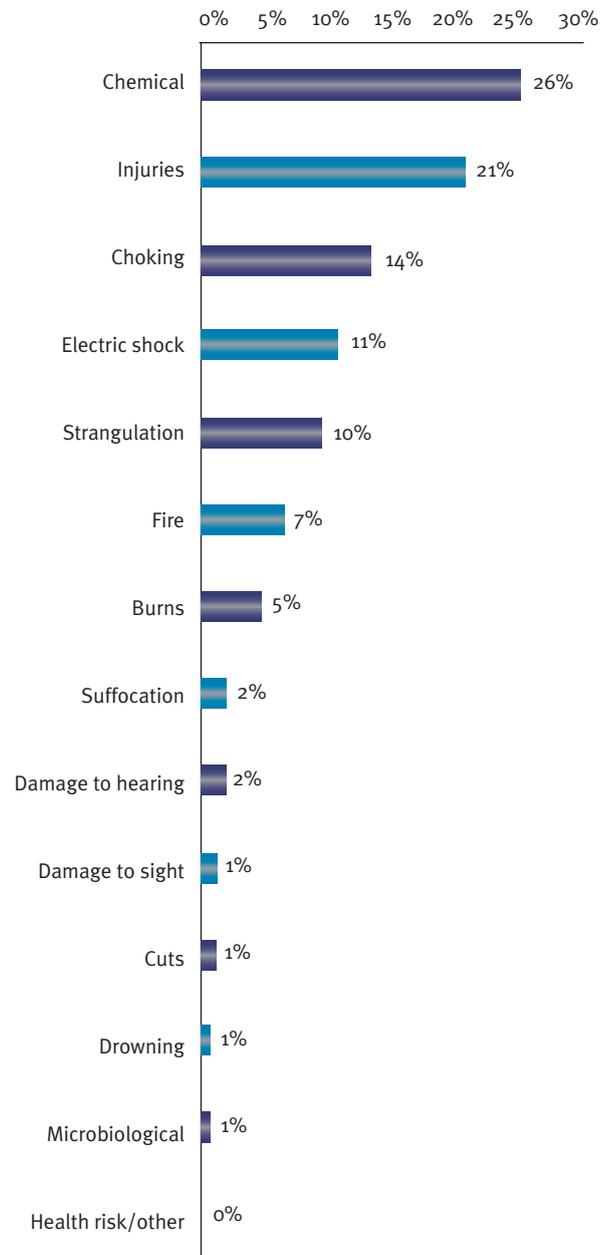
Market dynamics

- The number of European notifications of potentially dangerous products has increased. This may be due to a changed legal framework rather than more dangerous products coming onto the marketplace – but it is a worrying trend.
- The drive to increase margins and reduce costs is putting additional pressure on risk management procedures and quality assurance.
- Globalisation means that products are travelling further, both inwards from outsourced suppliers and outwards to more remote markets.
- Longer, more complex supply chains than before allow more room for risk to be introduced, while handling recalls in culturally different areas may require a different approach than in the home market.

Assessing the risk

- Many companies significantly underestimate the potential costs of a recall.
- Business interruption often accounts for 50% or more of product recall costs while plants and production sites are closed for investigation and sales are lost.
- Advertising costs can escalate very quickly, particularly if the products involved are sold in different countries and continents.
- There can be considerable fall-out from a product recall, with possible loss of contracts from trading partners such as retailers.

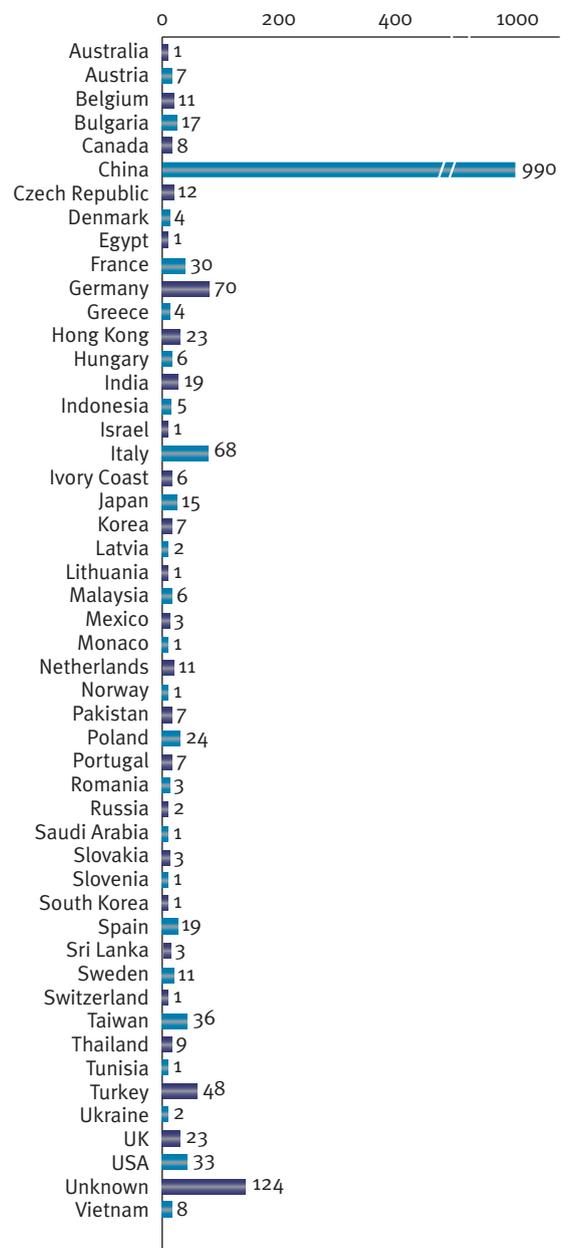
NOTIFICATION BY TYPE OF RISK



Reducing loss potential

- Companies need a robust system for monitoring customer complaints. They are often the first sign that something is wrong with a product.
- Small, relatively cheap measures, such as reducing batch quantities and keeping back samples from each batch, can have a big impact on reducing later recall costs.
- Rigorous contractual arrangements allow companies to pass the risk back if a supplier's ingredients or components have caused the problem.
- Accessing consultants can help companies make provisions for pre-loss risk improvement and deal with post-loss issues like communications. Some product recall insurers provide access to experts as part of the cover package.
- Working in partnership with suppliers on any product and packaging changes can flag up potential problems.
- A robust crisis management plan and an established recall management team are essential in minimising the impact of a recall.
- China remains the largest source of notified potentially dangerous products, but standards within the country vary and there are some very high-quality producers.
- No company can completely eradicate any chance of a product safety issue arising. But companies can ensure that they reduce the potential impact.
- Companies should consider insuring this risk, just as they cover other liabilities, because product recalls are not rare events and can represent huge costs.

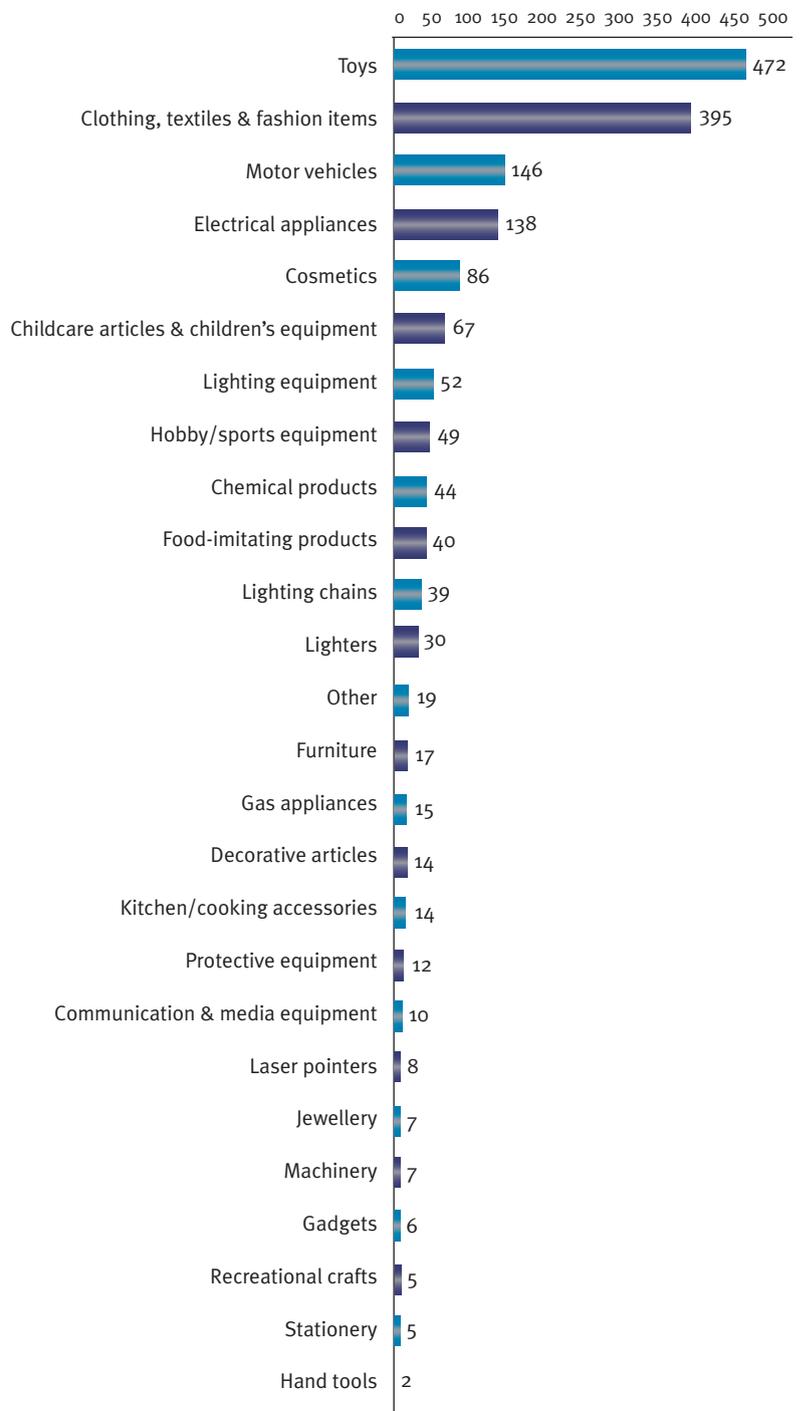
NUMBER OF NOTIFICATIONS BY COUNTRY OF ORIGIN OF THE NOTIFIED PRODUCT



Handling problems

- Time is of the essence – the quicker a company acts, the lower its potential liabilities.
- Stringent reporting requirements mean that companies often have to report the product safety issue to government authorities before they have a clear view of the nature and extent of the problem.
- Non-compliance with obligations in respect of unsafe products can result in stringent penalties – fines for the business and fines, or even imprisonment, for company officers.
- Product recall is often the last resort; there are other corrective actions that manufacturers and importers can take if they have identified a potential issue.

NUMBER OF NOTIFICATIONS BY PRODUCT CATEGORY (ABSOLUTE VALUES)



Counting the costs

The expenses of a product recall can include data gathering, tracking, logistics, communications, interrupted business and more. Understanding of the big picture can be limited among risk managers and even insurers, which explains why take-up of recall insurance is relatively low

In February this year, Toyota estimated the cost of its global safety recall of cars with acceleration faults at \$2bn, including an estimate for lost sales. However, some analysts are putting the costs at more than double that. The fact is that it's extremely difficult to put a price on the cost of recalls.

Simon Plumridge, head of product safety and recall at Zurich Global Corporate, explains: "Chief executives, chief finance officers and risk managers have a very real challenge in quantifying their recall exposure. One client who estimated recall exposures of \$10m-\$20m had to revise this figure by a multiple of 20 following advice from their broker."

Difficulties in quantifying costs reflect the uncertainties surrounding a recall, particularly if it involves a well-known brand. It's hard to estimate how badly a brand may be damaged and how long it will take to recover. The problems are compounded if any injuries or illnesses result from the faulty product. A significant product recall has to involve publicity, and the inference that a brand is 'dangerous' can have a devastating effect on sales.

How the costs add up

You only have to look at the processes associated with product recall to see how the expenses can mount up.

The first signs that there is a problem may be a spike in customer complaints. Alternatively, a company's own routine testing can throw up a potential problem before customers are aware of it.

The next step is for the relevant parties in the supply chain to identify the seriousness of the breach in product safety and the whereabouts of the affected products. It is crucial to establish which batches may represent a risk. This frequently involves identifying samples from the suspect batch and carrying out laboratory tests to establish the cause and nature of the problem. Clearly, the most significant concerns arise where the affected products cause illness, injury or damage.

The whereabouts of the affected product is also an important factor in the risk assessment. The key issues are how much of the faulty product has been distributed into the supply chain – and where exactly it is likely to be located. Is it in warehouses, with distributors or retailers, or already with the end customer?

Plumridge says: "This stage involves a lot of data sifting. Companies are very reliant on their batch coding and the efficiency of their tracing capabilities. They also need good data in order to contact the businesses involved in the various stages of their supply chain."

'One client who estimated recall exposures of \$10m-\$20m had to revise this figure by a multiple of 20' Simon Plumridge, Zurich Global Corporate

If a problem is confirmed, companies in the EU are then obliged to inform the appropriate local authority immediately. If the product is sold in other European countries, the national authority may well pass the details on to its European counterparts. Because of this stringent reporting requirement, companies are frequently obliged to report the product safety issue before they have a clear view of the nature and extent of the problem.

If a company needs to conduct a recall that extends as far as consumers, it has to make some further difficult decisions. For example, which media channels should it use to release the recall message? And how does it manage the relationships with distributors and other key stakeholders in its business to retain their trust?

Deciding what to say and where and how to say it is a crucial consideration. Plumridge stresses that ideally companies need to communicate a single message that identifies very specifically the affected product. "The aim is to leave consumers with peace of mind that you are acting in a responsible and caring way,

that you are going to protect them, and that the rest of your product line is not affected," he says. Advertising costs can escalate very quickly, however, particularly if the products involved are sold in different countries and continents. Also, Plumridge suggests that the message might be different depending on the geography and culture of the consumer audience.

Next come the logistics expenses. The manufacturer might need to physically remove the affected product. Or it might have third-party expenses, for example if retailers have to remove the affected product from their shelves and require reimbursement for their cost and consequential losses.

Repair, disposal and replacement costs can be another key expense, according to Jacqueline Barth, Zurich Global Corporate's chief underwriting officer for casualty in Europe and the Middle East.

The ripple effect

There can be considerable fallout from a product recall. If the problem has been serious, distributors – such as supermarkets in the case of food products – can be disgruntled and contracts can be lost. This is an area where there are significant potential costs.

In addition, product manufacturers can incur extra expenses because of the need to divert expertise to manage the crisis, potentially losing sales.

There will probably be business interruption costs. For example, if

KEY POINTS

Costs can include long-term fallout and loss of business

Underwriters can find it difficult to put a price on brand value

However, insurance solutions are becoming more sophisticated

contamination in the production line or a particular plant has caused the problem, that production line or plant may have to be closed down while the problem is being investigated and remedied. This can take days, weeks or months. It's not surprising that Plumridge and Barth say that the largest single element of the average recall insurance claim is for business interruption.

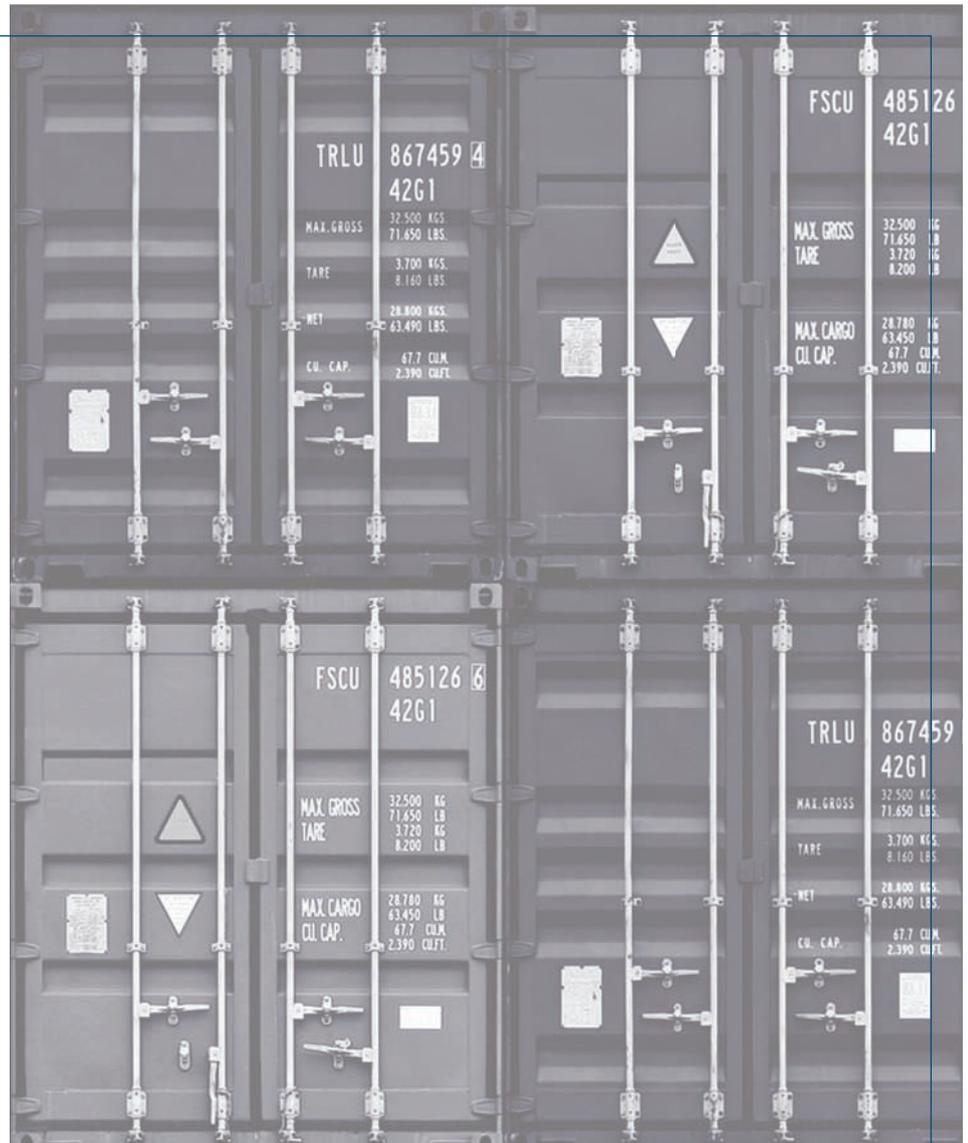
Extra expenses during the recall might include hiring consultants and lawyers, and perhaps additional temporary staff to help the business manage its way through the crisis.

Once the business has emerged from the product recall incident, the costs aren't over. The company needs to look at restoring its brand back to the position it was in before the recall occurred, so there will be 'rehabilitation' costs. For example, Plumridge says that a food company may decide to hold a 'two for one' offer to encourage customers back to the affected brand.

A vulnerable exposure?

Product recall insurance is available, but it's not widely bought. Plumridge believes this is because the exposure is still not generally well understood. He says: "We recognise the challenge of accurately assessing the financial impact of a product recall and we want to support our customers and brokers in this regard. This is not, of course, an altruistic ambition. We know that the companies and risk managers who understand their own exposure best are the ones who are most likely to purchase product safety and recall insurance. Organisations who have not fully assessed their product recall risks do tend to underestimate their exposure and therefore undervalue the insurance industry's solutions."

Barth agrees. "While organisations are quite well aware of what could happen in terms of risk, there is a widespread range in the level of awareness and understanding in respect of product recall. There's a limited understanding within organisations and also much of the broking community as to what could actually



happen and the magnitude of costs that companies could face."

Ian Harrison, executive director of Lockton's global risks team, adds a broker's perspective. "Generally the market is much more developed than it was 10 years ago and the numbers of buyers and sellers are a great deal higher in the marketplace. Companies want to protect some of the areas of their true balance sheet, like brand value. When they define this very broadly, there are elements that underwriters find very difficult to price. The market is much more sophisticated now, but it probably has not answered everyone's dream of protection of their brand yet."

Cover can be broader than you think

However, Harrison's message to businesses with potential product recall losses is "investigate the market". He says that risk managers often have preconceived perceptions as to what product recall insurance will provide. "It is often far broader than people think. Zurich Global Corporate has broadened the cover for companies – and the more insurers that come into this market, the more innovation we will get."

Although compared to the property and casualty market, the product recall market is small, it is growing, according to Harrison. He comments: "It's very much like D&O cover was in Europe 20 years ago, when it was a very specialised class. We think product recall insurance will be very much a mainstream purchase in five to 10 years' time."

Barth points out that, for an organisation that hasn't got specialist experience in evaluating and handling product recall claims, "it is extremely difficult to work out the individual costs that you could be faced with. You basically need to work with a third party such as an insurance company or professional broker to help you evaluate these costs. For example, having certain back-up systems in place could help businesses avoid or minimise the costs of those otherwise very expensive business interruption losses."

Companies that underestimate or even ignore the possibility of a product recall do so at their peril. The costs can be substantial enough to jeopardise the balance sheet, and handling a recall can place unexpected pressures on the business – and its brands.

SECTOR

food & drink

Tighter regulation on labels for foods containing allergenic substances has led to more EU-wide food risk alerts in this area, with the overall number of reported risks rising. But despite the Cadbury salmonella scare and China's tainted milk, most food recalls are not safety-related

Notifications of food risks transmitted through the EU Rapid Alert System for Food and Feed (RASFF) rose by 5.8% in 2009, with a 17.7% per cent increase in follow-up notifications.

A total of 3,322 original notifications were transmitted through RASFF, of which 1,796 were market notifications, 1,484 border rejections and 42 news notifications (see panel, right). There were 578 market notifications classified as alerts, and 1,218 as information notifications. These original notifications gave rise to 4,767 follow-ups. However, after receipt of additional information, 21 alert notifications, 27 information notifications and 28 border rejections were withdrawn.

The presence of allergenic substances has become more important in reporting since the EU introduced rules on labelling, presentation and advertising of foodstuffs, which added a list of allergenic substances required to be mentioned on food product labels. Since then, the number of RASFF notifications has grown and the number of notifications related to allergens jumped well above 100 in 2009.

Although notifications relating to products sourced in China fell in 2009, it remains the largest source of notified products.

High impact recalls

- **2008** China's dairy industry suffered a major blow when it was discovered that melamine (which causes liver damage) had been illegally added to foodstuffs, including milk, to improve their apparent protein content. This resulted in the death of six babies and the hospitalisation of around 300,000 people.

The recall affected global companies that had bought milk products from China. The Chinese state news agency reported in July 2010 that food safety officials had seized further raw dairy materials contaminated with melamine, with some finished milk powder products also found to be tainted – the implication being that traders may have bought tainted milk that

KEY POINTS

The correct labelling of allergens in food products has become more significant as a result of new EU rules

Although the number of notified food products from China is falling, it is still the biggest source

Most food-related recalls involve labelling or packaging

should have been destroyed in 2008 to process and resell it.

- **2006** Confectionery company Cadbury recalled more than a million chocolate bars following fears of salmonella contamination at one of its UK plants. Reportedly, although the company suspected contamination in January, it did not alert the UK Food Standards Agency until June. Estimated recall costs for Cadbury Schweppes were £15m (€17.1m) in addition to £20m for new safety systems and a £1m fine.
- **2005** Premier Foods withdrew 470 products from stores across Europe following the discovery that they contained a carcinogenic industrial dye, Sudan 1. This recall is estimated to have cost the UK food industry alone £100m. Related products had also been shipped to India and Canada. Sudan 1 had been banned by the UK authorities in 1995 but some affected products had remained on the shelf.

Risk manager's comment

Paul Howard, head of insurance and risk management for Sainsbury's, says that most food recalls do not involve unsafe products. "Mistakes or sub-standard printing or wrapping can trigger a withdrawal or recall, but there may be nothing wrong with the product from a quality perspective. Customers

GUIDE TO EU FOOD RISK NOTIFICATIONS

Notifications reporting food risks to the RASFF fall into the following categories:

- **Alert notifications** – when a product presents a serious risk on the market or when rapid action is required. Alerts are triggered by the member of the network that detects the problem and has initiated the relevant measures, such as withdrawal/recall.
- **Information notifications** – when a food or a feed on the market of the notifying country for which a risk has been identified does not require rapid action.
- **Border rejection notifications** – when a food or a feed was refused entry into the EU for reason of a risk to human or animal health.
- **News notifications** – information related to the safety of food or feed that has not been communicated as an alert, information or border rejection notification, but which is judged to be of interest to the food and feed control authorities in the member states.
- **Original notifications** refer to one or more consignments of a food or a feed that were not previously notified to the RASFF.
- **Follow-up notifications** are follow-ups to an original notification.

might also complain that the taste of a product has changed, often because of the manufacturer having reduced the amount of hydrogenated fats and salt to make the product a healthier option."

SECTOR

toys

Toys are historically one of the biggest sources of recall, with those made in China vastly outnumbering those made elsewhere. But the blame shouldn't just lie at China's door – malpractice and negligence by European importers also has a part to play

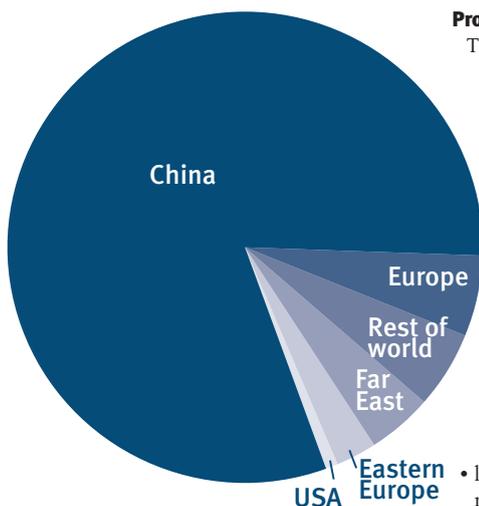
In 2009, toys was the product category most frequently notified through the RAPEX system, accounting for 472 notifications – 28% of the total. But, in the first six months of 2010, RAPEX reported that, while toy notifications remained at 28%, they had been overtaken by notifications for clothing, textiles and fashion items, at 30%.

StrategicRISK's own research, based on RAPEX weekly reports from the beginning of January to 17 September 2010, shows that the reporting figure for toys – 289 in the first six months of the year – rose to 357 during this longer period. Our findings also show that China was by far the greatest source of these unsafe toys, as the origin of 290 of the notified products. Set against this is the consideration that China is probably the largest toy manufacturing country in the world.

Fear of choking

Many toys are notified in connection with more than one potential risk, and the largest sources of complaints are in relation to potential choking on small or detachable parts, inclusion of chemicals prohibited by the EU's REACH (registration, evaluation, authorisation

RAPEX NOTIFICATIONS MADE (1 JANUARY – 17 SEPTEMBER 2010)



and restriction of chemicals) regulation in the product, and possible injury posed by the inherent nature of the product – for example, sharp edges.

With the increasing propensity for toys to simulate adult products has come greater focus on potential damage to hearing in connection with toy mobile phones. Dressing-up clothes too are closely scrutinised for risks associated with strangulation and suffocation. The inflammatory nature of some materials used continues to pose concerns. Interestingly, several of the notifications were related to actual or possible counterfeits of established products. Companies can undeservedly suffer reputational damage if a counterfeit product with their brand name is subject to a well-publicised recall.

The world's largest toymaker Mattel recalled around 21 million toys worldwide over five weeks in 2007, reportedly because of excessive levels of lead paint. The products were made in China and the recall substantially damaged Mattel's reputation. According to a Reuters report, Mattel's executive vice-president of worldwide operations, Thomas Debrowski, admitted that the "vast majority" of products recalled were "the result of a design flaw in Mattel's design, not through a manufacturing flaw in Chinese manufacturers".

Product quality progress

The European Commission's General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China (AQSIQ) is collaborating to resolve product quality issues in respect of Chinese-manufactured products. Traceability has been the biggest challenge in the operation of the 'RAPEX-CHINA' system in recent years. In 253 (25%) out of 1,007 RAPEX cases, AQSIQ was not able to find the responsible Chinese companies and thus could not adopt appropriate restrictive measures.

According to AQSIQ, this is likely to be for one of the following reasons:

- limited resources do not always allow national authorities to thoroughly

investigate the particular aspect of a case;

- the information about the Chinese companies submitted by the member states, is incorrect or inaccurate;
- the Chinese company denies its role in the production or export of a notified product and it does not keep any orders, contracts, invoices or other documents that could prove its involvement;
- change of address of the responsible Chinese company or bankruptcy; or
- the complexity of the multiple trade relations of the responsible Chinese authorities.

But reports also show malpractice by some European importers. Feedback received from AQSIQ suggests that some of the products subject to AQSIQ's investigations were manufactured by Chinese companies according to improper specifications provided by EU importers. And in many cases EU importers have not specified any safety requirements for purchased products, have not requested tests before shipping to the EU, or have not had products posing risks to consumers approved before shipping. "Both the Commission services and the member states should continue their efforts in informing companies with regard to the obligations of European product safety legislation," said RAPEX's 2009 annual report.

Most of the unsafe toys listed by RAPEX contravene the EC Toys Directive and EN 71. Good risk and quality management dictate that a companies looking to outsource toy production to China or elsewhere should not just assume their specifications are being met, but should routinely and randomly test imported products.

KEY POINTS

Notifications for counterfeit items can affect the reputation of the brand holder

Tracing Chinese companies responsible for products can be a major difficulty

Outsourcing to China demands routine and random specification checks

SECTOR

electrical goods

Contributing to more than 50 deaths a year in the UK, electrical products must be monitored carefully. And it's not just the threat of electric shock that is putting these products in the frame

Electrical appliances accounted for 138 notifications through the RAPEX system in 2009, 8% of the total. In the first six months of 2010, with 90 notifications they represented 9%. *StrategicRISK's* own research shows that there were 120 notifications in the period from 1 January to 17 September, with China the origin of 98 of the products listed – over 80%.

The most common risk for electrical products is unsurprisingly electric shock, often combined with the risk of fire. The UK Electricity Safety Council (ESC) says that every year more than 50 deaths and 100,000 injuries in UK homes are caused by electricity and electrical products.

However, two new risks are emerging, in connection with hearing damage and with ultra violet (UV) radiation. The European Commission's Directorate-General for Health and Consumers recently raised some particular concerns in connection with these and specific types of appliances.

Hearing fears

Issues relating to hearing damage have been raised in connection with personal music players. A conference on the risks of hearing loss from personal music players was held in Brussels in January 2009, bringing together the European Commission, EU member states, scientists, standard makers, industry, consumer organisations and other stakeholders to discuss what action should be taken to protect consumers.

Following the conference, a Commission decision (2009/490/EC) was adopted on 23 June 2009, which defines the safety requirements for personal music players in order to avoid the risk of hearing damage. In particular, the decision states that exposure to high sound levels must be limited in order to avoid hearing damage and that users must be provided with adequate warnings and information on the risks of hearing damage.

A mandate to develop new safety standards, based on the safety requirements in the decision, was subsequently sent to the European Committee for Electrotechnical Standardisation (Cenelec) on 28 September

2009. It is expected that the standards will be adopted by the end of 2011.

UV radiation under the spotlight

Consumers should also be aware of the potential risks associated with using sunbeds, according to the results of a market surveillance check of sunbeds and sunbed services, published in February 2010 by the European Commission.

Market surveillance authorities in 10 member states inspected more than 500 sunbeds at over 300 locations (mostly tanning salons and wellness centres) between September 2008 and September 2009, and found three main problems: UV radiation limits for sunbeds were violated in one in seven sunbeds made available at tanning services; consumer guidance, including on the hazards of UV radiation or prohibiting their use by under 18s was not provided; and there were insufficient warnings on the sunbeds themselves (for example, that UV radiation may cause injury).

Authorities are intensifying their work to ensure compliance with all relevant safety legislation, and the results of the 2008/09 check will feed into a follow-up project launched this year by authorities in 12 member states to train more inspectors and improve information to consumers. Authorities are also working more with the sunbed industry, which is itself developing training material for service providers such as tanning studios.

Commissioner in charge of health and consumer policy John Dalli said: "I am concerned that a high percentage of sunbeds and sunbed services were found not to respect

safety rules. This is an important health concern, since the incidence of skin cancer is doubling every 15 to 20 years. Competent surveillance authorities in the member states must ensure that these appliances are safe."

The Commission is co-financing a follow-up joint project, launched by member states, to support industry keen to develop training material and code of good conduct for tanning studios and information, especially to young consumers, and to discuss with member states the application of the product safety rules in the interest of consumer safety. The outcome of this project should be available at the end of 2011.

Website sweep

With so many consumers now buying goods online, last year enforcement authorities across Europe carried out an 'electronic goods sweep', checking websites selling electronic goods for compliance with EU consumer law. Six popular product categories were selected for the check, including personal music players, digital cameras and mobile phones. Since then, national authorities have followed up on problematic sites, requesting corrections and imposing sanctions when necessary.

Overall, of 369 websites checked, 310 sites (84%) now comply with EU-wide consumer rules, compared with only 163 sites (44%) in May 2009. Sanctions for confirmed breaches included fines and closure of websites. In terms of the main problems that were identified initially:

- 86% of the websites checked now display clear and accurate information as required by law (for example, on the right to return the product without giving a reason and on the legal guarantee period), compared with 64% in May 2009;
 - 94% of the websites checked now display clear and accurate information about the total cost (including delivery charges and all other extra costs), compared with 75% in May 2009;
 - 95% of the websites checked now provide the required trader details such as name, address and email, compared with 82% in May 2009.
- While the sweep focused mainly on trading aspects, the ESC has issued a guide on online buying for consumers, warning that products could be a cheap copy, of poor quality, or made to look like a well-known brand.

KEY POINTS

Users of personal music players must be made aware of potential dangers to hearing

A high percentage of sunbeds have been found to disregard safety rules, while skin cancer is on the rise

Websites selling electrical goods must adhere to strict guidelines

SECTOR

Clothing, textiles & fashion items

There has been a large rise in notifications for clothing over the past year, but could this be down to increased and enhanced surveillance efforts, focusing largely on chemical dangers in adult clothing, and cords and drawstrings on childrenswear?

According to EU reporting agency RAPEX, clothing, textiles and fashion items now lead the most frequently notified product categories (taking over from toys), accounting for 305 notifications (30%) in the first six months of 2010. In the whole of 2009, RAPEX reported 395 notifications for this category, so clearly this should be an increased area of concern for European clothing manufacturers and importers.

RAPEX attributes the significant increase in the number of these notifications mainly to enhanced market surveillance activities. In particular, it cites the adoption of Commission Decision 2009/251/EC on DMF2, a strong novel sensitiser found to have been used as an anti-mould treatment especially in shoes, some textiles and furniture.

A second, equally important factor leading to the prominence of this category in the findings of non-compliance was the launch of the joint market surveillance action on cords and drawstrings in children's clothing, which involved the participation of 11 member states.

Children's clothing safety initiative

European market surveillance authorities receive notifications of accidents where cords or drawstrings on children's clothes become entangled in bicycles, doors, car doors, or playground equipment, leading to severe injury or death. National accident statistics show that such accidents fall into two groups by age:

- younger children, where entrapment of hood cords in playground equipment such as slides result in fatalities; and
- older children, where cords and strings from the waist and lower hems of garments are trapped in moving vehicles, such as bus doors, ski lifts and bicycles, resulting in severe injuries or death from being dragged or run over by the vehicle.

The project launched to address this issue was carried out by surveillance authorities in

August 2008 and February 2010. They undertook 4,642 inspections, with particular focus on retailers, but also wholesalers, manufacturers and importers, of which 61 were done at EU borders together with customs authorities. A total of 16,300 garments were checked, and 2,188 did not comply with one or more of the requirements of the European safety standard. Almost 70% of the non-compliant garments were clothes for babies and young children.

The main aim of the project was to reduce the amount of unsafe children's clothing on the EU market, whether produced in Europe or imported. It resulted in many RAPEX notifications and corrective measures have been taken. As a result of this exercise, RAPEX is stressing that manufacturers, distributors, importers and retailers must ensure that cords and drawstrings in children clothes comply with the European standard EN 14682:2007 or provide an equivalent level of safety.

Key risks

Not surprisingly, in view of the above, the majority of notifications this year relate to childrenswear, while those that address adult clothing and household fabrics focus on chemical dangers – DMF2 and also potentially carcinogenic dyes.

Issues relating to the flammability of children's nightwear – once a common reason for recalling clothing – do not appear to be a problem now, at least within Europe. However, in other areas such as North America, Australia and New Zealand, this is still a concern. For example, in August 2010, there was a safety recall of children's pyjamas in Canada, the sleepwear having failed to meet design and flammability requirements under Canadian law.

Recent recalls include a UK nationwide recall in June 2010 for a range of baby clothing from supermarket chain Asda because of fears that it could pose a health risk. Following one complaint, the store

withdrew the clothing because transfers on the front became loose after washing, posing a choking risk to babies who could put it in their mouths. This followed a recall by the same retailer a month earlier, this time involving thousands of children's jeans, designed for under-fives, in case a child might choke on a loose button.

Reputational damage by association

Protecting brand value is an important issue for many European clothing producers who take stringent measures to protect the integrity and ensure the safety of their products. However, this is an area where counterfeit products abound, often originating in countries where safety standards are poor.

A widely publicised recall of a counterfeit 'brand name' product may have repercussions on the genuine producer if only because consumers may avoid buying the product because they are unsure they can identify the authentic article. To avoid being associated with a recall that is not of their making, such producers need to strictly enforce their policies relating to the sale of fake products, for example on auction sites.

KEY POINTS

Market surveillance investigating cords and drawstrings found over 7% of inspected garments did not meet European safety standards

Flammability of children's nightwear is no longer a common problem in Europe, but is still a concern in North America, New Zealand and Australia

Producers must enforce strict policies on fake products to avoid the knock-on effects of a recall on counterfeit items

SECTOR motor, make-up & medicine

Products with long supply chains and large-scale distribution, such as pharmaceuticals, are crying out for identification technology that can be applied across Europe in the form of barcodes or radio frequency tags. But these are expensive and many of the products are cheap

In addition to clothing, textiles and fashion items, toys and electrical appliances, the other two product categories most frequently notified through the RAPEX system for general consumer products in 2009 were motor vehicles (146 notifications, 9% of the total) and cosmetics (86 notifications, 5%).

Other categories not covered by RAPEX are food (see page 9) and pharmaceuticals.

It's worth noting that recall insurers do not cover all types of products. For example, Zurich Global Corporate doesn't write risks related to motor vehicles and pharmaceuticals.

Motor vehicles

In the period from 1 January to 17 September 2010, there were 134 product notifications in connection with motor vehicles. Potential risks mainly relate to injuries and, to a lesser extent, fire.

The recent worldwide Toyota recalls, affecting around 10 million vehicles, offer a grim lesson on the potential costs. In February 2010, US TV news channel CNN reported that it would cost an estimated \$2bn to repair accelerator pedals and brakes on recalled vehicles, but said that the total cost of the recall could be much higher, with more than 30 lawsuits initiated in the US at that time. In addition, the reputational damage could be significant.

Other substantial motor recalls include:

- Ford Motor's recall of 4.5 million cars in the US in 2009 for problems relating to faulty switches in cruise control – the largest single recall in Ford's history.
- Mazda Motor Corporation's decision in August 2010 to voluntarily recall 215,000 of its compact cars and minivans in the USA because of faulty power steering.

Cosmetics

In the first six months of 2010, cosmetics fell out of the top five categories for RAPEX notifications, replaced by childcare articles and children's equipment. There were 30 RAPEX notifications relating to childcare articles and children's equipment in the first half of 2010.

Between 1 January and 17 September this year, there were only 51 notifications relating

to cosmetics, suggesting the total for the year will be down. By far the greatest risk is in connection with chemicals used, although there were also cases of microbiological (bacterial contamination) risk.

Animal testing can produce a reputational backlash. In June, the European Chemicals Agency (ECHA) published a new practical guide to avoiding animal testing, stressing that it should only be undertaken as a last resort and asking companies to share data to avoid the need for duplicate testing.

Pharmaceuticals: Risk manager's comment

Simone Wray, risk manager at Lloydsparmacy and former chairman of the Institute of Risk Management, describes the procedures used in his organisation: "In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for the regulation of medicines used in health care, and the investigation of adverse effects. The MHRA issues safety warnings including drug alerts on defective medicine and product recalls in conjunction with the marketing authorisation holder responsible for placing the product on the market.

"There are four grades of notifications, ranging from the most serious, Class 1, where the product is subject to immediate recall and every patient has to be contacted immediately, to Class 4 where, for example, there may be a printing error on the pack, which may not require a recall. A recall can be initiated by the MHRA or the original drug manufacturer.

"Lloydsparmacy's sister distribution company, AAH Pharmaceuticals, holds the MHRA wholesale dealer's licence, which requires a system for recalls to be in place.

"As a customer of AAH, Lloydsparmacy would be immediately notified of a recall and this would then be managed by our superintendent pharmacist's team across our 1,700 locations. Ensuring compliance is essential, and it can be difficult in view of the scale of our operations and the fact that most recall work has to be done manually. Technology doesn't yet support product recall by providing batch numbers or

product codes, details of which don't pass beyond wholesale.

"While we can usually see if an item is in our stock, we have to do a blanket recall, then physically check each individual pack. The packs are then returned to AAH, which returns them to the manufacturer.

"As the largest pharmaceutical distributor in the UK, AAH has to communicate and manage two or three recalls a week. There has been a general increase in recalls year on year, mainly because of labelling and packaging issues. A Class 2 recall was recently initiated involving over 30 common lines from a single manufacturer that involved checking hundreds of thousands of boxes. Also, there is a very long supply chain. An original batch may be divided up and change hands several times before it gets to pharmacies for dispensing.

"The EU is looking at standardising 2D barcodes or radio frequency identification tags, but both solutions are expensive. And the solution would need to be common across Europe. While manufacturers might introduce barcode technology for the more expensive products, it's not likely that they'll do this for, say, a cheap bottle of aspirin.

"So recall is time-consuming and expensive. However, liability and the cost of recall are passed back to the manufacturer, which is why the group hasn't seen the need for product recall insurance. As a member of the British Association of Pharmaceutical Wholesalers, AAH has access to expertise to develop the processes to support the recall, track costs and charge them back. The residual risk, though, is whether reimbursement is received."

KEY POINTS

Children's products have replaced cosmetics in the RAPEX top five

A new European guide to avoiding animal testing in cosmetics is available

Most pharmaceutical recalls have to be done manually, with a long supply chain



**We have to make big
decisions every day.
Knowing Zurich is
protecting us,
we can make them
confidently.**

Zurich HelpPoint®

Global Directors & Officers coverage.

We provided a customized D&O policy to protect a major corporation's executives working in 75 countries. Knowing that we've been in business for more than 130 years and that our solution is in accordance with regulations everywhere they operate, their management has the confidence to focus on what's in front of them: running the company effectively. It's an example of how Zurich HelpPoint delivers the help businesses need when it matters most. To learn more about cases like this visit www.zurich.com/globalfinanciallines



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