

A GUIDE TO PRODUCT RECALLS: United States & European Union



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A Guide to Product Recalls: United States & European Union is not intended as legal advice and should not be interpreted as legal advice. We recommend you contact counsel for legal advice about your product recall needs.

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Introduction

We are pleased to present Squire Patton Boggs' A Guide to Product Recalls – United States & European Union.

As countries continue to open their borders to global trade and consumers purchase products sold in other countries via the Internet with greater frequency, product manufacturers and distributors are faced with not only increased global demand and heightened competition to produce more sophisticated products at, often, a lower cost, but also a maze of regulatory requirements.

In light of this dynamic global economy, manufacturers and distributors are also faced with the need to be more proactive and coordinated in their product recall efforts. Government consumer protection authorities are helping such recall efforts by developing sophisticated online product recall portals and other automated reporting tools.

In 2012, the Organisation for Economic Co-operation and Development (OECD) launched its global product recall portal to coordinate recall notifications between the United States (US) Consumer Product Safety Commission (CPSC), the European Union's (EU) Member States, which coordinate such efforts through the European Commission's (EC) Online Dangerous Product Notification Portal: Rapid Alert System (RAPEX), launched in 2004, and other countries around the globe.

In addition to facilitating cross-border recalls, the data captured by the OECD, CPSC and RAPEX have led to statistical and economic reports that may benefit manufacturers and distributors in product development, regulatory compliance and recall efficiencies:

- Deaths, injuries and property damage from consumer product incidents cost the US more than US\$900 billion annually.
- EU Member States and Iceland, Liechtenstein and Norway reported through RAPEX 2,435 notifications on consumer products posing health and safety risks in 2014. Injuries, chemical risks, choking and electric shock topped the list.
- At French borders, 25-30% of imported products do not comply with Continental Europe (CE) marking requirements.

We have developed this high-level, at-a-glance guide to help you consider how you can create an effective product recall program, so that, in the event of a product recall or inquiry by a governing regulatory agency, you can more confidently and effectively take the necessary steps and make the necessary communication efforts.

On behalf of Squire Patton Boggs' Global Products Liability Litigation Practice, I hope you find this a useful resource.

Sincerely,








Patricia E. Lowry

Leader, Global Products Liability Litigation Practice

About Our Authors

A Guide to Product Recalls: United States & European Union is a result of the collaborative efforts of several of our lawyers.

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A special thank you to the associates involved in this project, including Louise Roberts, Manchester; Marion Seranne, Paris; and Moritz Maassen, Frankfurt.



About Our Products Liability Practice

Our Products Liability Practice is internationally renowned for its successful defense of many of the world's largest companies in cases involving catastrophic bodily injury, property damage or economic loss allegedly caused by defective products, devices or exposure to toxic substances.

We handle products liability claims and recalls across numerous industries with a strong focus on:

- Highly regulated pharmaceuticals, over-the counter drugs, medical devices and healthcare products
- Automotive, including tires, seat belts and other vehicle safety systems
- Consumer and industrial products, including household appliances, food and beverages, building materials, and electrical equipment



We regularly represent clients as global, national and regional coordinating counsel on mass action, multidistrict litigation (MDL), cross-border and individual lawsuits. Our extensive experience and broad footprint allow us to provide clients with a unified defense and thorough insight into theories of liability, scientific and medical experts, the national plaintiffs' bar in the US and claimants' counsel in Europe, as well as judges and courtroom procedure in jurisdictions across the globe. In Europe we represent clients in all types of proceedings including criminal proceedings related to products liability matters and in Asia we advise clients on China's 2010 Tort Liability Law.

We represent clients as both trial lawyers and advisory counsel on their products liability needs, including regional and global product recalls.



Litigation Counsel

- Trial counsel
- Subject matter counsel, including:
 - Experts
 - Sales and marketing issues
 - Crisis management
- Global, national (including MDL) and regional coordinating counsel
- Regulatory counsel
- Settlement counsel
- Appellate counsel



Advisory Counsel

- Regulatory counsel
- Transactional due diligence
- Product recalls
- Corrective action programs
- Product licensing, acquisitions and sales
- Indemnity and insurance issues
- Disclaimers, instructions, warnings and warranties
- Market risk evaluation
- Compliance programs, investigations and Corporate Integrity Agreements
- US Foreign Corrupt Practices Act (FCPA) and UK Bribery Act



Competitive Differentiators

- Lead counsel in all areas of products liability defense.
- Successful products liability trial counsel.
- In-depth technical knowledge of products, and related medical, scientific, engineering and design principles.
- Extensive experience in false advertising, marketing and deceptive trade practice claims.
- Comprehensive defense of all aspects of whistle-blower, qui tam and False Claims Act allegations.
- Product recalls and preventative liability advice on warranties, warning labels and issues related to corporate transactions and mergers.
- Global reach – US, Europe, Middle East, Latin America and Asia Pacific.
- Representation before US, EU and national European regulatory and certification authorities that oversee consumer health and protection and product quality control.
- Extensive civil and criminal proceeding experience in Europe.
- Internationally recognized expertise, including trial lawyers who are Fellows in the American College of Trial Lawyers, and lawyers recognized in legal guides such as Best Lawyers, U.S. News & World Report's "Best Law Firms" survey, *Legal 500*, *Lawdragon 500*, *Leading Lawyers in America* and the *Guide to Product Liability Lawyers, Who's Who Legal*.

Approach

The best products liability defense is an effective risk management program. If, however, litigation is unavoidable we have the resources and experience throughout the US, Europe, Asia Pacific, Latin America and the Middle East to quickly respond to client needs and manage large, complex litigation that involves numerous issues, such as:

- Multiple related cases, parties and jurisdictions
- High-volume documents and depositions
- Severe time constraints
- Portfolio management

We excel at project and process management. We work with each client to develop an overall litigation strategy and work plan that accounts for the probability of taking the matter all the way to trial, the likelihood of success, the extent of discovery required and the possibility of alternative dispute resolution.

Depending on the scope of the products liability issue, we also can quickly leverage a network of external resources across the globe, including, partner law firms, for instance in Scandinavia, and dedicated crisis management and public relations resources to ensure seamless representation.

Finally, we utilize a number of technology resources to efficiently manage litigation including award winning eDiscovery tools that isolate material information quickly and cost-effectively, as well as client extranets.



Regulatory Insight

We collaborate with our regulatory lawyers around the world to keep apprised of new regulations that may impact our clients' product portfolios. If our clients are subject to litigation, our regulatory lawyers help us assess our clients' exposure before regulatory agencies, including:

- US Food and Drug Administration (FDA)
- Consumer Product Safety Commission (CPSC)
- US Department of Justice (DOJ)
- European Chemicals Agency (ECHA)
- European Medicines Agency (EMA)
- UK Medicines and Healthcare Products Regulatory Agency (MHRA)
- European Notified Bodies, including TÜV Rheinland
- Japan's Ministry of Health, Labour and Welfare (MHLW)

We pride ourselves in our ability to follow our clients' lead. Whether the facts demand an immediate settlement strategy or an aggressive defense, we provide practical and effective legal counsel. We develop a coordinated litigation, regulatory and public relations strategy designed to achieve clients' desired goals on all fronts.



GENERAL RECALL INFORMATION AND RECOMMENDATIONS

What Are Recalls and Market Withdrawals?

Recall

- A company's removal or correction of a marketed product that is in violation of federal or state law, and against which a government agency could initiate legal action.
 - Recalls are typically "voluntary" – conducted on a company's own initiative or at the regulator's request.

Market Withdrawal

- The removal of product that is below a company's standards or that corrects a minor or technical violation that would not be subject to legal action and that does not represent a public health hazard.

Preparing For a Product Recall – General Recommendations

Develop a Written Recall Policy and Protocol

- Recall plans should be reviewed by experienced recall and/or regulatory counsel.

Identify a Recall "Chain of Command"

- Recall coordinator and task force, with clearly defined responsibilities.
- Share recall protocol with the Chain of Command.

Implement Recordkeeping

- Product coding.
- Handling procedures that maintain product identity and traceability.
- Product complaints, warranty returns, insurance claims, lawsuits, etc.
- Maintain quality control and product distribution records

Conduct Internal Investigations

- Determine whether the problem/hazard is due to defect, misuse, or other factors.
- Determine how widespread the problem is.
- Determine the batches that contain the problem, the facility or product line that contain the problem or the supplier who caused the problem.

Practice

- Conduct periodic mock recalls.

Inform Consumer Regulatory Agencies

- Often within 24 hours of obtaining reportable information.
- Initial information needed by the government, regardless of country:
 - Description of problem or hazard - reason for recall;
 - Product identification (purpose, brand names, size and type of containers, lot and code numbers);
 - Amount manufactured and amount distributed;
 - Where distributed;
 - Number and types of consignees (including all sales to wholesalers, distributors, retailers, consumers); and
 - Other information requested by regulators, particularly if instances involved children.

Develop a "Corrective Action Plan"

- Identification of the product.
- Scope of recall:
 - How much of the product may have been affected?
- Depth of recall:
 - Who is affected: Distributor, Retailer, Consumer?
- Disposition of recalled product:
 - Does it require: Destruction, Correction, Recondition?
- Plan for replacement or reimbursement.
- Plan for public notification
 - Written recall notifications, phone notifications, press releases, social media, etc.
- Effectiveness checks and status reports.

Specific plan elements will be influenced by the nature of the product, hazard level, recall classification, extent of product distribution, etc.

Public Communications

- Depending on the severity of the problem/hazard communications can include:
 - A joint news release from the regulatory agency and the company.
 - Direct notice to consumers known to have the product – identified through registration cards, sales records, catalog orders, retailer loyalty cards, or other means.
 - Company website and blog, Facebook, Google, YouTube, Twitter, and other social media.
 - Paid notices in newspapers, magazines, social media.
 - Recall posters in stores, medical clinics, equipment rental locations, repair shops, etc.
- Some regulatory agencies may require their pre-approval of public communications.
- Involve legal counsel to review for accuracy and to preserve attorney-client privilege to greatest extent possible.

Product Recalls – Other Practical Considerations

Public Communications – A Delicate Balance

- Required notices generally must explain the reason for the recall and the hazard involved, but such statements may play poorly in front of a court.
- Saying too little may mean an ineffective recall.
- Efforts to control the message limit on damage to reputation of the company.
- Involve legal counsel to review for accuracy and to preserve attorney client privilege to greatest extent possible.

Coordination Of Regulatory Authorities

In both the US and the EU, national and regional regulatory authorities, such as the CPSC and the European Commission (EC) will coordinate, when appropriate, with other regulatory agencies both at the national and state levels.

US Agencies May Include

- Food & Drug Administration.
- National Institutes of Health (NIH)
- Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)
 - Federal agencies usually maintain contact information for corresponding state officials and will usually notify pertinent state officials.
 - Independent notification, however, may be required or advisable.

Managing Product Returns

- Stop shipments.
- Set up customer website and phone numbers.
- Coordinate with company's customer service center.
- Determine whether to repair, replace or destroy recalled defective products. Budget accordingly.
- Quarantine any remaining affected products within the company.
- Requests to dispose or destroy recalled products may be required of the regulatory agency.

Moving Forward

- Provide timely reports to the regulatory agency on the progress of the recall.
- How is the company upgrading its quality control or risk analysis procedures?
- How can the company's correction action procedure be improved?

Insurance Coverage

- Business interruption coverage.
- Product liability coverage.
- First-party property insurance.
- Directors and officers liability insurance.
- Errors and omissions insurance.

- State-level departments of health, consumer protection divisions or equivalent.

- Specific requirements may vary by state.

EU Agencies May Include

- "Competent Authorities" of each EU Member State, who oversee consumer product safety.
 - Communications about dangerous products is facilitated, in part by RAPEX, an online notification and communications portal, developed by the EC.
 - Cooperation of cross-border enforcement is further encouraged by Regulation EC No. 2006/2004
- Other national health and safety authorities.

CONSUMER PRODUCT RECALLS – UNITED STATES

Be Informed

- Be aware of provisions under the Consumer Product Safety Act (15 U.S.C. §§ 2051–2089), as well as any new US regulatory requirements.
- As products are being distributed more globally, US regulatory agencies are examining recall requirements and requiring manufacturers to maintain a recall plan.
- Such recall plans should be reviewed by experienced regulatory counsel.

Know Your Resources

- US Consumer Product Safety Commission (CPSC) is the governing consumer products regulatory authority in the US and works closely with other regulatory and government agencies.
- The CPSC website offers numerous resources on product recalls:
 - *CPSC Recall Handbook*, published March 2012, a comprehensive “how to” resource
 - Overview about the CPSC Fast-Track Program, which was developed in 1997 to quickly and efficiently remove potential hazardous products from the marketplace
 - Links to file product recalls: safeproducts.gov

Alert Agencies

- Inform the CPSC and other regulatory agencies if a problem/hazard is reported:
 - Within 24 hours of obtaining reportable information.
 - File report electronically through the CPSC website (SaferProducts.gov), by mail or telephone (+1 301 504 7520).

CPSC Fast-Track Recall Program

- Initiated in 1997, the CPSC’s Fast Track Recall Program was developed to quickly and efficiently remove potentially hazardous products from the marketplace.
- Companies must report potential product defects under Section 15(b) of the Consumer Product Safety Act
- Qualifying companies may benefit in several ways, including the CPSC expediting the review of technical information and recall documents.
- Full CPSC report in as described in 16 C.F.R. § 1115.13(d), recall plan and proposed notice to consumers are required to participate.
- Voluntary recall process must get underway within 20 days.
- CPSC Fast Track Recall Program Contact Information
 - Email: sect15@cpsc.gov
 - Tel.: +1 301 504 7520

Communications to the Public

- CPSC must approve public communications.
- Depending on the severity of the problem/hazard communications can include:
 - A joint news release from CPSC and the company.
 - Direct notice to consumers known to have the product—identified through registration cards, sales records, catalog orders, retailer loyalty cards, or other means.
 - Company website and blog, Facebook, Google, YouTube, Twitter, and other social media.
 - Paid notices in newspapers, magazines, social media.
 - Recall posters in stores, medical clinics, equipment rental locations, repair shops, etc.
- Involve legal counsel to review for accuracy and to preserve attorney client privilege to greatest extent possible.

Managing Product Returns

- Stop shipments.
- Set up customer website and phone numbers.
- Coordinate with company’s customer service and fulfillment center.
- Determine whether to repair, replace or destroy recalled defective products. Budget accordingly.
- Quarantine any remaining affected products within the company.
- Requests to dispose or destroy recalled products should be submitted in writing to recalledproductdisposal@cpsc.gov so that CPSC investigator can either witness disposal or make arrangements for other verification of destruction.

Moving Forward

- Provide timely reports to the CPSC on the progress of the recall.
- How is the company upgrading its quality control or risk analysis procedures?

CONSUMER PRODUCT RECALLS – EUROPEAN UNION

GPS Regulations

The European Parliament and the Council of the European Union established Directive 2001/95/EC more commonly known as the “Directive” or General Product Safety Regulations or GPS Regulations.

- Ensures that consumer products placed on the market in EU Member States are safe.
- Defines specific obligations and powers of Member States (Chapter IV).
 - Identifies “Competent Authorities” of each Member State who will oversee product safety compliance and collaborate with producers/distributors regarding of notifications, withdrawals, recalls.

RAPEX

Launched in 2004, RAPEX facilitates the rapid exchange of information between Member States and the EC on non-food products posing a serious risk to the health and safety of consumers.

Application of RAPEX

- Enables producers and distributors to notify Competent Authorities in each EU Member State through an online portal and automated RAPEX Recall Notification Form.
- Enables Competent Authorities of Member States to view and process such notifications and quickly communicate with one another.
- Stores completed notification forms in the RAPEX online database.
- Enables the EC to publish weekly reports on reported products posing a serious risk, as well as an annual report on country-by-country, product and injury statistics.

- Defines responsibility of product producers and distributors.
- Establishes guidelines for notification of dangerous consumer products to the Competent Authorities of Member States in accordance with Directive 2001/95/EC to follow:
 - Assessment of risk (slight to very serious) to vulnerability of consumers.
 - Notification procedure and forms.
- Establishes RAPEX to allow for rapid cross-border communication between Member States on dangerous products.
- Establishes cross-border enforcement and cooperation (CPC) framework and Regulation ED No. 2006/2004 to facilitate enforcement by national authorities.

RAPEX is best for notification of products sold and distributed across EU borders. If the product is sold and distributed only in one country, RAPEX may not be needed unless the producer/distributor and national authority believes such cross-border notification is necessary.

Required Information

- RAPEX Recall Notification Form or “GPSD business application”
 - Product information, hazards/risks, countries in which consumers may be exposed and plan of action.
 - Assessment of risk (slight to very serious) to consumers.
 - Criteria for classification of notifications according to urgency.

Responsibility and General Considerations

Who is Responsible for “Corrective Action”?

- Producers’ and distributors’ responsibilities for a recall vary on the circumstances and warrant a responsibility agreement created by the producer.
 - Products made in the EU and branded by the manufacturer
 - Responsibility lies with the manufacturer.
 - Products made in the EU and branded by the distributor
 - Shared responsibility between the manufacturer and the distributor.
 - Products made outside the EU and branded by the manufacturer
 - Responsibility is with the company that imports the product into the EU (manufacturer’s agent included).
 - The importer will generally need to involve the manufacturer in any corrective action.
- Products made outside the EU and branded by the EU distributor
 - Responsibility is with the distributor.
 - The distributor may wish to involve the manufacturer or his/her agent in any corrective action.
- Distributors, regardless of whether or not they take a leading role in the recall, should assist the producer in tracing the product and consumers and notifying consumers.

Other Steps to Consider in the EU

Who to Inform

- “Competent Authorities” of the EU Member States
- Consumers
- Internal staff members
- Key business customers, distributors and suppliers
- Any relevant market surveillance authorities

Producers and distributors should give the authorities some preliminary information about a product risk as soon as they are aware of it. If the overall risk is judged to be serious enough, notify local market surveillance authorities.

Timeline to Inform

- Each country may have its own timeline requirements to inform authorities and public.
 - In general, countries state that notification be “immediate.”
- Although there needs to be some priority in informing different audiences, they all need to receive the same message within a short time frame, especially if the risk is serious.

Technical Documentation

- To deal with product safety concerns, producers need to have easy access to all documentation relating to:
 - The design of their products (including material specifications), especially those concerned with product safety.
 - Any changes that have been made and the dates and/or the serial numbers or batch numbers of products they apply to.
- Many EU Directives require manufacturers to draw up technical files which demonstrate how the product conforms with the relevant requirements. If the manufacturer is outside the EU, the importer or the manufacturer’s representative needs to keep a copy of the file.
 - Keep technical documentation for a period of 10 years from the date of manufacture.

EUROPEAN UNION – COUNTRY-BY-COUNTRY GUIDANCE

United Kingdom

In the UK, there are extensive requirements that regulate the labelling, placing on the market, manufacture, distribution and post-marketing surveillance or recall of many products.

- The UK's General Product Safety Regulations 2005 (GPS Regulations), implements Directive 2001/95/EC on General Product Safety
 - The GPS Regulations apply to all products (new and second-hand) used by consumers.
 - The principal responsibility for day-to-day enforcement of the GPS Regulations lies with local authorities.

Main Duties of GPS Regulations

- Only place safe products on market
- Ensure product remains safe throughout its reasonably foreseeable period of use.
- Duty to notify enforcement authority of risks incompatible with general safety requirement.
 - Action taken to prevent risk and details of any Member States in which the product was marketed or supplied.

Duty to Recall a Product

- If placed supplied goods pose risks to consumer
 - Duty to notify enforcement authority.
 - Duty to co-operate with action taken to avoid the risks (e.g., product recalls).
 - Recall may be necessary if dangerous product already supplied to consumers.

Producer/Distributor Responsibility

- Use reasonable endeavors to organize return of product from consumers.
- Need method to identify safety issues and products subject to recall.
- Prohibition needed on sale of products subject to recall.

Failure to Comply

- Criminal liability for failure to comply with notice, and enforcement agency can conduct recall itself then bring civil proceedings for the recovery of its costs.

France

Duty to Recall a Product

- There is no duty to recall a product from the market.
 - However, all professional operators that put the product on the market (producer, importer, supplier etc.) have a duty to comply with the applicable safety guidelines.
 - Should the products present safety risks or consumer health and safety issues, the professional has to immediately notify the Competent Authorities of the risk.
- The measure taken by the Competent Authorities has to be proportionate to the risks created (i.e., warnings to products recall).
 - In the event of serious or immediate danger, the Direction Générale de la Concurrence, de la Répression des Fraudes (DGCCRF) may order the producer to recall the product.

Notify French Regulatory Authorities

- A RAPEX GPSD business application notification will automatically be forwarded to the relevant French authorities.
- Alternatively, it is possible to file the notification to the French authority, the DGCCRF.
- If online notification is unavailable, hard paper notification is required and should be addressed to the local authorities.
 - Use the Prioritaire – Fiche de Notification template

If applicable, once a national authority confirms the risk and the corrective measures, the notification will be conveyed via RAPEX to the EC and other countries participating in RAPEX.

Events of Serious or Immediate Danger

- The DGCCRF will issue a joint order (“arrêté conjoint”) to (i) recall of the product for exchange or modification or full or partial reimbursement and (ii) suspend the production when required.
 - Warnings can also be posted on the products (i.e., on the labels).
 - This order could also provide for the costs that would be incurred by the manufacturer, the supplier, the distributor, etc., to take associated safety measures.
 - The joint order for recall of the products can be taken for a period not exceeding one year.
 - Such orders may be renewed via the same procedure for further periods each not exceeding one year.
- The DGCCRF could hear the professionals concerned without delay and not later than 15 days after a decision to suspend has been taken.
- The French Regulator will require regular updates regarding the recall process or the corrective measures.

Reporting Timeframes and Methods

- Notification has to be made immediately (“immédiatement”) without any further precise time scale.
- The Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States could therefore be a non-mandatory guideline to define the concept of “immediately” (i.e., 10 days since it was reportable information, three days in this present case – serious risks).

Publicizing the Notification

- A public recall notification “Avis de rappels de produits” would be published on the following websites:
 - DGCCRF: <http://www.economie.gouv.fr/dgccrf/Securite/Alertes/Rappels-de-produits>
 - Product Recall Database (France): <http://www.rappelsproduits.fr>
 - Que Choisir Very Dangerous Product Recall Database (France): <http://www.quechoisir.org/rubriques/rub-produits-au-rappel>
- Recall letters may be sent to consumers/distributors.
- Notification may be done via radio or even sometimes TV.

Failed Recall

- There is no guideline defining specific recall/corrective actions.
- There is no direct sanction resulting from the delay in taking corrective action, in notification or the non-notification.
 - However, failure to comply is a breach of health and safety obligations, which can constitute a criminal offence and/or a civil fault.

Penalties

- Should someone be injured or die by the defective products several criminal sanctions could apply. These sanctions can range to €375,000 fine and imprisonment.
 - The maximum amount of a fine applicable to companies is five times that which is applicable to natural persons (companies’ legal representative), the two types of sanctions being cumulative.
 - Additional sanctions can also be ordered.
 - Potential civil liability penalties may include damages for the loss suffered because of the defective products.

Germany

Duty to Recall a Product

- According to ProdSG German *Produktsicherheitsgesetz*, Section 6 Para. 4 (Product Safety Act, ProdSG) the manufacturer must inform authorities immediately upon notice of a defect of a product which potentially poses a risk to consumers' health or safety.
 - In cases that qualify as "serious," according to the RAPEX classification, the deadline can be limited to three days.
 - The notification will enable the authorities to examine whether the risk is being controlled.

Notify German Regulatory Authorities

- File a RAPEX GPSD business application with the Regierungspräsidium Stuttgart.
 - Market surveillance agencies (Marktüberwachungsbehörden).
- The local Competent Authority of Member State of the company's place of business.
 - It is not clear whether this refers to the registered place of business or the business address of a company.

Reporting Timeframe

- Notification of the competent authority has to be carried out immediately upon notice of a defective product posing a risk to consumers' health or safety.

Public Notifications

- There is no law which requires authorities to publish information to the public.
- Nevertheless, authorities have to take the necessary steps to protect public safety.
- Such steps may include information directed to suppliers or dealers, and the issuance of warnings to the public.

Failed Recall

- There is no law, regulation or guideline that specifies a satisfactory recall rate.
- Authorities will order manufacturers to give information on the status of a recall on a regular basis.
- It is up to the authority on whether or not a recall has been handled satisfactorily. This depends on the risk and the product.

Penalties

- Non-compliance with product safety requirements, especially non-compliance with the ProdSG, can result in administrative or criminal law penalties or civil law claims
- Administrative penalties for not filing an immediate notification to the authorities can range up to €100,000.

Other Considerations

- Notification of a product recall is not mandatory in Germany.
 - Such measures can also be ordered by the Competent Authority.
- Recalls are not explicitly regulated in German law and there is little case law.
 - However, the German Supreme Court ruled that a recall has to be conducted when a simple warning is not sufficient to control the risk.
- Depending on the graveness of a risk such notification can either be a simple warning or a full product recall.

Spain

Duty to Recall a Product

- According to Royal Decree 1801/2003, 26 December, on products safety (the Act), manufacturers have a duty of recall when they discover or they have enough signs that a product is risky for consumers.

Recall Process

- Manufacturers must be aware of any claims and conduct the relevant sample test or any relevant measure in order to be informed once a claim is submitted with them.
- As soon as manufacturers are aware that there is a risk, they must proceed to recall the product.
- There is no specific regulation on how the recall should work, but the Act indicates that it is the manufacturer's decision to recall the product from the market or to recall it from specific consumers.

Duty to Notify

- There *is* a duty to notify Spanish regulators.
- If the product has been commercialized only in a certain region, manufacturers must inform the relevant regional authority.
- Spanish law establishes the duty to do anything to protect the consumers.
- Inform Spanish authorities to provide the maximum diligence.
- Producers are *obligated* to inform distributors and end users.
- If the product is commercialized in several regions, the producer/distributor should notify the authorities of the region where it is domiciled or to the Member State authority, if it is not domiciled in Spain.

Notify Spanish Regulatory Authorities

- File RAPEX GPSD business application is sufficient to meet the client's duty to notify Spanish regulators.

Public Notices

- Spanish law does not require any specific public notice.
- However, since Spanish law establishes the duty to do anything to protect the consumers, producers should post public notices in convenient and accessible places, such as newspaper publication, specific letter to a list of clients, etc.

PRODUCT RECALL RESOURCES

Global Consumer Product Recall Resources

The Organisation for Economic Co-operation and Development (OECD)

- Website: <http://www.oecd.org/>
- Tel.: +33 1 45 24 82 00
- Fax: +33 1 45 24 85 00
- OECD – Global Recalls Portal
 - Launched in October 2012, OECD’s GlobalRecalls portal brings together information on product recalls being issued in the US, Europe, Australia, Canada and other countries around the world.
 - *“For businesses, notably for product manufacturers, the portal will provide information that could enable them to move more swiftly to address a safety problem, thereby reducing the number of incidents causing injury, and the costs associated with them. This could lower the safety risks, which could, in turn, lower insurance costs for producers.”*
 - Global Recalls Portal Website: <http://globalrecalls.oecd.org/>

US Consumer Product and Recall Resources

US Consumer Product Safety Act (15 U.S.C. §§ 2051–2089)

- Web link to 15 U.S.C. §§ 2051–2089: <http://www.cpsc.gov/PageFiles/105435/cpsa.pdf>
- Summary of required recall Information in accordance with 16 C.F.R. § 1115.13(d):
<http://www.cpsc.gov/en/Business--Manufacturing/Recall-Guidance/Required-Report-Information/>
- Web link to US Government Publishing Office: Electronic Code of Federal Regulation (eCFR)
16 C.F.R. § 1115 – Substantial Product Hazard Reports: <http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=e87002093e6f4b96efbd75e4810a86ff&mc=true&n=sp16.2.1115.a&r=SUBPART&ty=HTML>
- Note: This link is updated almost daily.

US Consumer Product Safety Commission (CPSC)

- Website: <http://www.cpsc.gov/>
- Tel.: +1 301 504 7923
- Fax: +1 301 504 0124 and +1 301 504 0025
- CPSC Recall website: <http://www.saferproducts.gov/>

CPSC Recall Guidance

- Website: <http://www.cpsc.gov/en/Business--Manufacturing/Recall-Guidance/>

A good resource of handbooks on recall process, regulated products, notification types and other tips and tools for conducting recalls.

Link to the CPSC Recall Handbook, published March 2012

- Web Link to PDF: <http://www.cpsc.gov/PageFiles/106141/8002.pdf>
- Tel.: +1 301 504 7520

Overview about the CPSC Fast-Track Program

- Website: <http://www.cpsc.gov/en/Business--Manufacturing/Recall-Guidance/CPSC-Fast-Track-Recall-Program/>
- Email: sect15@cpsc.gov
- Tel.: +1 301 504 7520

European Consumer Products and Recall Resources

European Parliament and the Council of the European Union's Directive 2001/95/EC on General Product Safety Regulations

- Web link to the Directive 2001/95/EC also known as "GPSD": <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0095&from=EN>

EU's List of "Competent Authorities" of Member States in Charge of Receiving and Treating Notifications on Dangerous Non-Food Products (under GPSD 2001/95/EC)

- Web link to the Competent Authorities List: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/how_does_it_work/docs/rapex_appointed_authorities.pdf

EU's Regulation EC No. 2006/2004 on Cross-Border Cooperation and Enforcement of Product Recalls Between National Authorities of Member States:

- Web link to PDF: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R2006:20130301:EN:PDF>

European Commission (Health and Food Safety)

- Website: http://ec.europa.eu/dgs/health_food-safety/index_en.htm
- Tel.: +32 2 299 11 11

EC's Online Dangerous Product Notification Portal: Rapid Alert System for non-food (RAPEX)

- Website: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm
- Tel.: +800 67 89 10 11

RAPEX General Product Safety (GPSD) Business Application (for Recalls)

- RAPEX GPSD Business Application (All Languages) - <https://webgate.ec.europa.eu/gpsd-ba/index.do>
- RAPEX Business Application Form (English) - https://webgate.ec.europa.eu/gpsd-ba/pdf/GPSD_EN.pdf

EU Product Recall Booklet: Product Safety in Europe: A Guide to Corrective Action Including Recalls

- Web Link to PDF: http://ec.europa.eu/consumers/archive/cons_safe/action_guide_en.pdf

More in Depth EU RAPEX Notification and Recall Guidelines (in accordance with Article 5(3) of Directive 2001/95/EC):

- Web Link to PDF: http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/how_does_it_work/docs/rapex_op-guidelines_business_en.pdf

Other Links Referenced in the Guide

Section: European Union – Country-By-Country Guidance – UK

- UK's Official Website on Guidance for Product Safety for Manufacturers: <https://www.gov.uk/product-safety-for-manufacturers>
- UK's General Product Safety Regulations 2005: <http://www.norfolk.gov.uk/view/ncc048403>

Section: European Union – Country-By-Country Guidance – France

- DGCCRF (Direction Générale de la Concurrence, de la Répression des Fraudes): <http://www.economie.gouv.fr/dgccrf/dgccrf>
- DGCCRF List and Contact Information of Competent Authorities in France (by department): <http://www.economie.gouv.fr/dgccrf/coordonnees-des-DDPP-et-DDCSPP>
- DGCCRF (product recall database): <http://www.economie.gouv.fr/dgccrf/Securite/Alertes/Rappels-de-produits>
- DG CCRF Product Recall Priority Notification Sheet (Prioritaire Fiche de Notification) template: http://www.economie.gouv.fr/files/directions_services/dgccrf/securite/alertes/documents/formulaire_prof.pdf

Section: European Union – Country-By-Country Guidance – Germany

- *Regierungspräsidium* Stuttgart: http://www.rp-stuttgart.de/servlet/PB/menu/1007480_l1/index.html
- ProdSG German Produktsicherheitsgesetz, Section 6 Para. 4 (Product Safety Act, ProdSG): http://www.gesetze-im-internet.de/englisch_prodsg/index.html

Section: European Union – Country-By-Country Guidance – Spain

- Spanish Agency for Consumer, Food Security & Nutrition (AECOSAN): <http://aesan.msssi.gob.es/en/AESAN/web/home.shtml>
- Royal Decree 1801/2003, 26 December, RCL 2004\59: <http://consumo-inc.gob.es/novedad/pdf/SEGURIDAD.PDF>

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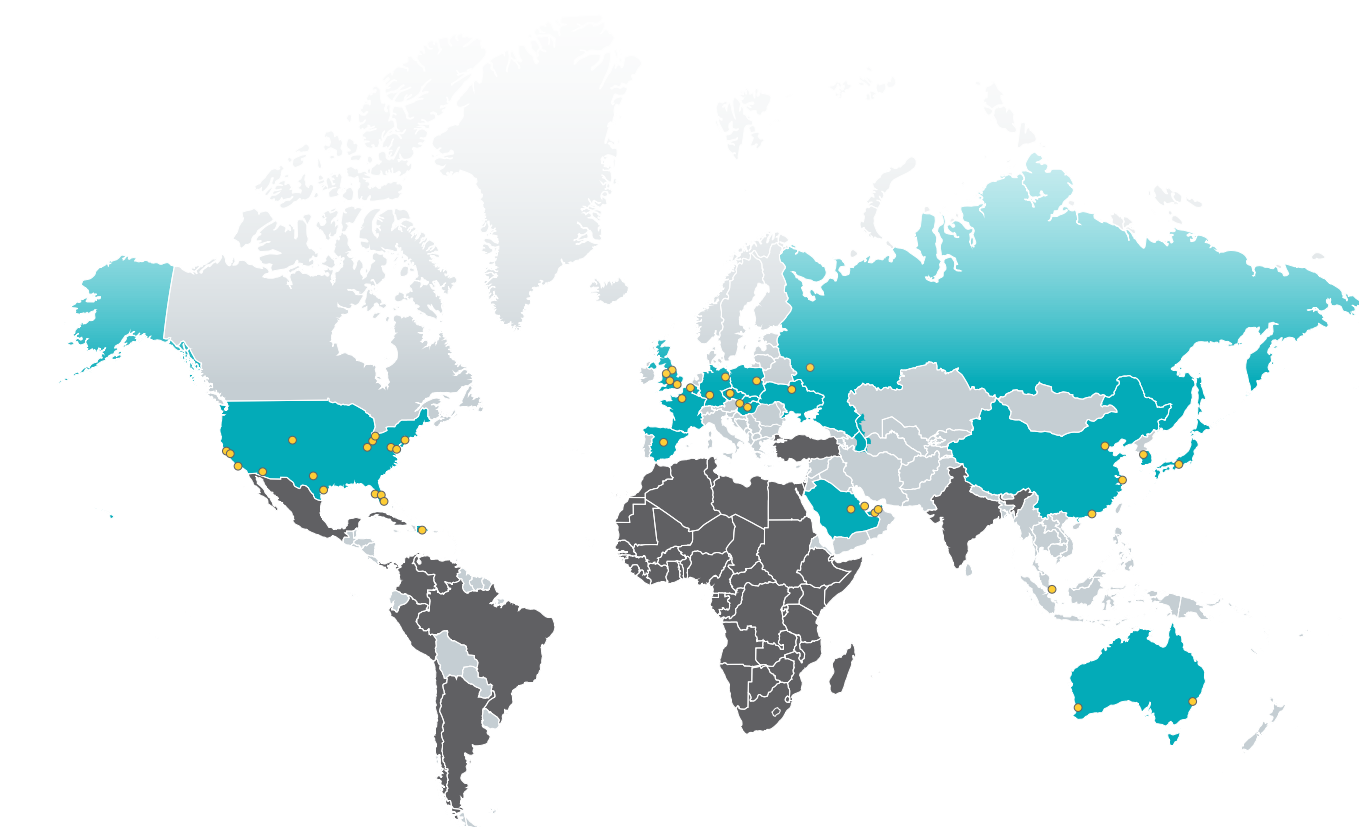
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■ Office Locations

■ Regional Desks and Strategic Alliances

