Product Recall

Contributing editors

Jason Harmon, Alison Newstead and Devin Ross

2019

GETTING THE DEAL THROUGH

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Shook, Hardy & Bacon LLP

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Preface

Product Recall 2019

Tenth edition

Getting the Deal Through is delighted to publish the tenth edition of *Product Recall*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

Getting the Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Colombia and Mexico.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Jason Harmon, Alison Newstead and Devin Ross of Shook Hardy & Bacon LLP, for their continued assistance with this volume.

GETTING THE DEAL THROUGH

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Global overview

Alison Newstead and Harley Ratliff
Shook, Hardy & Bacon LLP

Product recalls continue to occur at an ever increasing rate. Barring rare cases of malicious tampering, each recall represents a breakdown of risk management, whether in design, manufacture or packaging, in communicating necessary information about the product's characteristics, or in foreseeing ways in which a product might be innocently misused.

High-profile recalls shine a powerful light on how damaging these failures can be – not just potential injuries for consumers and others at risk – but to the reputations of the companies responsible for the products and the value of their brands. The legal consequences are becoming increasingly damaging too. In 2015, the US Department of Transportation's National Highway Traffic Safety Administration imposed US$200 million in civil penalties – the largest in history – against a Japanese automobile parts manufacturer related to potentially defective airbags. A Japanese court sentenced four former senior executives at Mitsubishi Motors to three years' imprisonment (suspended for five years) for the death of a truck driver after covering up vehicle defects in one of the country's biggest safety scandals. In the United Kingdom in 2007, confectionery producer Cadbury was handed criminal fines totalling £1 million for breaches of food safety legislation that led to the recall of seven products in its chocolate range. In China, severe penalties were handed down in January 2009 after the contaminated baby milk scandal involving misuse of the industrial chemical melamine, including death sentences and life imprisonment for some of those responsible.

The difficulty of the challenge facing managers suddenly tasked with a product safety crisis has been compared by one leading commentator to driving a car backwards at speed with little warning. In most developed countries, the days are gone when companies could internalise the information about the known dangers in their organisations and quietly manage the problem with what has been called a 'silent recall' – the removal of existing stocks of defective products. Globalised markets, higher consumer safety expectations and tighter legislation have made the processes of crisis management considerably more transparent. As well as having to deal with notifying government officials, putting the supply chain into reverse, publishing warnings and managing the logistics of restocking and resupplying large numbers of customers, there is the public admission of failure to be faced, and the threat of mass tort actions as well as regulatory penalties. Managers can be forgiven for thinking when contemplating recalls that they are damned if they do, and damned if they don't.

Many large companies operating in major economies nevertheless still undertake only the most rudimentary recall planning. Where preparations are made, the emphasis is often limited to damage limitation for the brand and public relations strategies. Communications and government relations consultants have developed specialist units that can assist with these functions. There is no doubt that these are critical considerations, sometimes affecting the very survival of a business. The legal and insurance aspects of recalls are often less well anticipated and understood. The need to obtain experienced legal advice early on in product crises, however, has never been greater. As the following chapters amply demonstrate, there has been a rapid growth in regulatory oversight of product recalls. But at the same time, this has increased the diversity internationally in the laws governing questions such as when a product defect is deemed to require notification to national authorities, how that information is dealt with, and how prescriptive the procedures are for deciding on and managing the various steps to be taken after the need to address a defect has been identified.

United States

The most highly developed laws in this area are probably those found in the United States, whose Consumer Products Safety Commission (CPSC), which oversees more than 15,000 types of consumer goods, has steadily expanded its enforcement authority since its creation in 1972. In addition to the CPSC, the US enlists a host of other agencies, including the Food and Drug Administration (FDA), National Highway Traffic Safety Administration (NHTSA) and Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), to help enforce a myriad of sector-specific product safety laws.

The US overhauled its consumer protection laws when it passed the Consumer Product Safety Improvement Act of 2008 (CPSIA). Among other things, the CPSIA provided for uniform information in recall notices, enhanced powers for the CPSC to dictate how recalls or other corrective actions will be carried out and increased penalties for violations. These penalties include significant fines, possible imprisonment and forfeiture of assets, depending on the nature of the violation. The act also now permits the CPSC to share confidential product safety information with foreign governments and agencies.

The CPSIA also mandated the establishment of a public online hazards reporting database (www.saferproducts.gov). The database allows consumers to submit reports of safety risks or actual harm, as well as search for information on a variety of products and recalls. The CPSC transmits qualifying reports to manufacturers, which may then respond and provide comments to be posted alongside the reports. While the manufacturing industry has voiced concerns about false or inaccurate reporting, the CPSC insists that the database has safeguards in place to minimise these problems. In its first year, the database received reports from more than 6,600 consumers about products ranging from kitchen appliances to footwear to baby cribs. In 2012, in the first lawsuit of its kind, a federal district court in Maryland sided with a consumer product manufacturer and enjoined the CPSC from publishing a report it deemed to be inaccurate and misleading.

Europe

In Europe, the obligations of manufacturers and others in the supply chain were made clearer and more consistent across the EU member states by important revisions to the General Product Safety Directive taking effect from 2004. To promote traceability, Decision 768/2008/EC positively requires the name and address of manufacturers and importers of products placed on the market in the EU to be indicated on the products themselves, or where that is not possible on packaging or other documentation. Further, additional product safety and market surveillance requirements have been proposed in the European Commission's Product Safety and Market Surveillance Package (February 2013). These proposed revisions (due to come into force in 2015 but which have stalled) are discussed in detail in the European overview chapter.

The European Commission produces an annual report outlining trends in European consumer product recall activity. The most recent report indicates that, in 2017, there were 2,201 unsafe product notifications in the EU. China remains the country of origin of most unsafe products in Europe, with 53 per cent of unsafe products being notified

as originating in China. Continued work needs to be undertaken with the Chinese product safety regulator – the Administration for Quality, Supervision, Inspection and Quarantine (AQSIQ) – to prevent unsafe products being designed, manufactured and exported for sale in the EU. Good manufacturing processes, including quality control and post market vigilance, are being increasingly adhered to across the EU, which may account for the increased number of notifications.

Since 2008, the European authorities have been required to go even further to improve capabilities to meet more consistent minimum standards of market surveillance and enforcement by Regulation (EC) 765/2008 (which is part of a package of measures contained in what is known as the New Legislative Framework). The measures include stronger border controls to detect non-compliant products. These will be further strengthened once the Regulation on Market Surveillance of Products comes into force.

It would appear that the growth in European recalls will continue across the board, for consumer products, pharmaceuticals and medical devices and – more and more commonly – food.

Other regions

While the general trend is towards increased regulatory intervention in developed nations, the pace of change is different in other regions, especially Asia. Japan, for example, has had recall laws for a number of years, but it was only at the end of 2006 that it introduced binding rules for notification of 'serious product accidents' with defective consumer products to its authorities, and authorised the publication of this information by them. This threshold for notification – actual accidents – is much higher than in the US or Europe, which require there only to be a risk of injury, and only manufacturers and importers are subject to the duty. Japan has, however, increased its authorities' powers to dictate recall measures.

A number of international bodies exist with the objective of increasing the effectiveness of information sharing and joint enforcement, including the OECD's Committee on Consumer Policy (CCP), the International Consumer Product Safety Caucus, the International Consumer Product Safety and Health Organisation, the Product Safety Enforcement Forum of Europe and the Committee on Consumer Policy of the International Standards Organisation.

China remains the country of origin for the majority of recalled products in the EU. As a result, the EU, US and Japan have memoranda of understanding with AQSIQ for information sharing and cooperation in addressing problem products. The key issue of traceability of manufacturers of unsafe products in China continues to be a challenge for AQSIQ and the EU authorities. However, cooperation with Chinese authorities and businesses continues to be developed on an EU level. The 'Rapex-China' system, which allows for regular and rapid exchange of information between the EU and AQSIQ, has prevented various unsafe products from being exported to the EU. There are also other bilateral agreements, and protocols such as the US/EU guidelines for information exchange and on administration cooperation, and AUZSHARE, a computerised database on enforcement matters for Australian and New Zealand authorities.

Global trends

The direction of travel for international policy in this area can be discerned from the conclusions reached at a round-table meeting of regulators, business representatives and other stakeholders from around the world hosted by the OECD in October 2008. This concluded that there is a need for greater inter-governmental coordination and cooperation, harmonisation of product safety standards, a more proactive approach to product safety failures, an increase in resources available to regulators and a rapid international information exchange system to enable countries to notify each other about the presence of unsafe goods in markets. This was developed further by the OECD Working Party on Consumer Product Safety in 2011 when a web portal with a global inventory of product safety issues and events was established. The OECD's Global Recalls portal was launched in October 2012 and pools information on recalls and emergency alerts on a single website. Searches can be carried out for recalls of specific products and specific jurisdictions. Consumers also have the option of reporting a health and safety concern to the relevant regulatory authority, such as the European Commission or the US CPSC.

Currently, a significant international trend vital in the recall context is that of product traceability. In Europe, the PIP breast implant scandal added impetus to the EU's new regulatory framework for medical devices and in vitro diagnostic medical devices, which imposes more stringent standards regarding recall. Two new regulations strengthen the regulatory framework relating to medical devices including pre-market assessment of devices, post market surveillance and the transparency of data. The new rules will only apply after transitional periods of three years after entry into force for the Regulation on medical devices (May 2020) and five years after entry into force for the Regulation on in-vitro diagnostic medical devices (May 2022). Similarly, traceability features strongly in the proposals set out in the European Commission's Product Safety and Market Surveillance Package, adopted in February 2013 (but still awaiting approval). The legislation, if implemented, will see the replacement of the General Product Safety Directive with a new Consumer Product Safety Regulation, including increased requirements on manufacturers and importers relating to labelling products with their country of origin and enhanced obligations regarding contact information for the manufacturer and importer in order to be better able to identify parties throughout the supply chain.

Finally, readers interested in global trends in product safety and recalls and comparisons between national legal and enforcement regimes will find useful information in a study produced for the OECD's CCP entitled Analytical Report on Consumer Product Safety (DSTI/CP(2008)18/FINAL), and another report entitled Enhancing Information Sharing on Consumer Product Safety (DSTI/CP(2010)3/FINAL), both available at www.oecd.org.

European overview

Alison Newstead
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The success of the European market has led to increasing numbers of products moving freely across European borders. The result of this free movement is that the same products (and their inherent safety risks) are commonly found in many jurisdictions. A pan-European structure therefore needs to be in place to effectively manage any product safety issues that may arise.

The aim of European product safety legislation is to ensure that a consistent approach to the regulation of product safety issues is adopted across the EU. A uniform approach facilitates the smooth running of cross-border commercial activities and gives assurance to community citizens that effective measures are in place to ensure that the products they use in their daily lives are safe.

Laws governing product recall in Europe

In Europe, the laws governing the safety requirements that consumer (non-food) products must meet and the corrective action that needs to be taken by producers (and others) when a product poses a safety risk are set out in the General Product Safety Directive 2001/95/EC (GPSD). These requirements are implemented in each member state by way of national laws.

The main obligations prescribed by the GPSD are monitored and enforced by competent national authorities. However, there is an important overarching supervisory function played by the European Commission, which ensures that information obtained regarding unsafe products is disseminated quickly and efficiently throughout the EU.

The obligations set out in the GPSD apply to products intended for, or likely to be used by, consumers. Other similar regulatory regimes are in place for food products, pharmaceuticals and medical devices. In addition, Regulation (EC) 765/2008 on Accreditation and Market Surveillance (RAMS) contains extra provisions that apply to professional products covered by EU harmonisation legislation (eg, machinery, electrical goods). This means that member states – through their market surveillance authorities – should have powers not only to restrict the sale of non-compliant products but to order their recall as well. Thus recall powers are not limited to consumer products and may extend to products used for business purposes if they are subject to EU harmonised requirements. This European overview deals primarily with the current regime as it applies to non-food consumer products.

It should be noted that the current EU legislative framework was due to be revised in 2015 in response to the proposals set out in the European Commission's Product Safety and Market Surveillance Package, adopted in February 2013. The initial expected implementation date of 2015 was not achieved and, as at September 2018, 'country of origin' issues have still to be overcome. The Package, if implemented, will see the replacement of the General Product Safety Directive with a new Regulation on Consumer Product Safety (COM (2013) 78) and the introduction of a Regulation on the Market Surveillance of Products (COM (2013) 75). If implemented in their current draft form, these Regulations will have significant practical implications for those who manufacture, distribute or sell products within the EU. In particular, there will be additional obligations with regard to labelling, preparation of risk assessments, extended obligations to manufacturers, importers and retailers regarding notification of risks, penalties that are linked to the size of the business, increased scope of market surveillance provisions and additional obligations on national authorities with regard to investigations, in addition to explicit powers regarding recall.

Who are producers and what are their obligations?

Under the GPSD, producer is a term that encompasses manufacturers, first importers into the EU, 'own branders', and 'other professionals in the supply chain insofar as their activities may affect the safety of a product'. To this end, the reach of the GPSD's obligations is widely cast.

The GPSD sets out an obligation on producers to only place safe products on the market. In accordance with article 2(b) of the GPSD, a safe product is:

> *any product which, under normal or reasonably foreseeable conditions of use [...] does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:*
> - *the characteristics of the product [...];*
> - *the effect on other products [...];*
> - *the presentation of the product, the labelling, any warnings and instructions for its use [...];*
> - *the categories of consumers at risk when using the product, in particular children and the elderly.*

This definition may be expanded if the provisions of the proposed Regulation on Consumer Product Safety remain as drafted. The definition will additionally cover the appearance of a product and, in particular, where a product, although not foodstuff, resembles foodstuff and is likely to be confused with foodstuff owing to its form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics. (Thus incorporating the principles in Directive 87/357/EEC on dangerous imitations.)

In addition to the obligation to only place safe products on the market, producers are also obliged to provide information and warnings to consumers as to any inherent risks that a product may pose. Such measures commonly comprise instruction booklets containing safety advice and warnings or labels on the products themselves.

On an administrative level, producers also have to ensure that they have adequate systems in place to enable them to monitor and address any safety risks, and to take any appropriate action such as issuing warnings, or withdrawing or recalling the product from the market should a safety risk arise.

Specific requirements are set out as to traceability, requiring products or their packaging to bear details of the producer and the product reference or batch number. Consumers should therefore be able to easily identify and contact producers directly in the event that they experience a problem with a product. Product references (eg, model and serial number) or batch number information allow the producer to identify quickly and concisely which products may be affected and where they have been distributed. Such information is vital when addressing a potential safety risk: primarily in order to carry out risk assessment investigations on the correct products, and subsequently in order to embark on appropriate and effective corrective action, whether this is by way of new or additional warnings, withdrawal, recall or otherwise.

The new proposed EU Regulation on Consumer Product Safety significantly enhances traceability obligations. The Regulation sets out

increased requirements on both manufacturers and importers (the new proposed Regulation does not use the term 'producer' as defined in the GPSD) as to labelling products with their country of origin. There are also enhanced obligations regarding contact information for the manufacturer and importer and the ability to identify parties throughout the supply chain.

In order that producers are kept adequately informed of the risks that their products may pose, producers are also currently required to carry out sample testing on their products (where appropriate) and, if necessary, to keep a register of complaints. Sample testing has the obvious benefit of identifying potential safety issues before the products reach the market and a register of complaints is an ideal tool to monitor trends and carry out risk assessment investigations at an early stage. However, any internal register or list of complaints will only be useful if it is regularly reviewed and acted upon by producers. National authorities may also request access to any such register when considering whether appropriate and timely steps have been taken by a producer to address a safety problem. Authorities will not look kindly on those producers who have a record of an emerging potential safety risk, but have failed to act upon it.

The proposed EU Regulation on Consumer Product Safety, if implemented as drafted, sets out new obligations on manufacturers to prepare and retain technical documentation, including a documented risk assessment. Technical documentation that is used to put together the risk assessment must also be retained for 10 years and presented to the market surveillance authorities on request.

What are the obligations of distributors?

It is not just producers who are obliged to take positive action under the GPSD; distributors also play a key role in the supply chain and they therefore also have obligations to assist producers in ensuring that products are safe. Of course, the nature of a distributor's role and its contact with consumers is likely to vary from product to product, but the provisions of the GPSD make it clear that distributors should play an active role in monitoring product safety, by passing on information to producers and national authorities about product risks, maintaining appropriate documentation so that unsafe products may be traced, and cooperating with producers and competent authorities should any redress action need to be taken.

In addition to the current obligations, the proposed Regulation on Consumer Product Safety sets out additional obligations for importers to ensure that manufacturers have complied with their documentation and labelling obligations and to deal with non-compliance with obligations by other parties in the supply chain.

How is a notification of an unsafe product made to a national authority?

When a producer or distributor knows, or ought to know, that a product is unsafe, notification should be made immediately to the relevant authorities in each of the member states where the product has been marketed.

Notifications are usually made by way of a standard format and are commonly sent to national authorities by email, fax or post. There is also an option for EU businesses to use an online notification system called the 'GPSD Business Application' (see below).

In making a notification, details should be provided as to the product, the risk that it poses and the action that is to be taken to protect the consumer from that risk. If the product poses a serious risk, all member states will be notified through the RAPEX information system.

The Commission's outline notification form can be found on the European Commission's website. Each national authority will specify the exact information that it requires and will commonly revert to the party making a notification for further information, if necessary.

If a product poses a serious risk to health and safety, information given to the national authority must include details as to the authorities and companies receiving the notification, the party making the notification, the identity of the product or batch of products in question (and their country of origin), a full description of the risk that the products present, all available information relating to the tracing of the product, a description of the corrective action undertaken to prevent risks to consumers and details of companies in the distribution chain.

Part IV of the Commission's guidelines on the notification procedure and RAPEX sets out the standard notification form that is used by member states to make notifications to the European Commission. Producers should familiarise themselves with the content of this standard form and be ready to supply such information to their national authority if requested.

To make notification quicker and easier, the European Commission has set up an online notification procedure called the 'GPSD Business Application'. This allows producers or distributors to complete a single, centralised notification form online, which is then sent to all of the member states of the EU.

Any businesses that are established in the EU, or that have a representative in the EU, can use this online notification system. However, the traditional forms of notification (fax, email and post) are still accepted.

The portal through which online notifications can be made can be found on the European Commission's website. This portal includes a manual on how to complete the online notification process and sets out the form that needs to be completed by the party making the online notification.

Access to the information submitted to this online system is limited exclusively to the competent authorities in each member state and cannot be accessed generally by the public.

Who should make the notification?

The GPSD suggests that it is for the distributor, as well as the producer, to make the necessary notification to the national competent authority should a safety risk arise. In practice, however, it is accepted that it is commonly only the producer who makes the notification. This is generally for practical reasons; the distributor may well have passed all information to the producer as to possible safety issues (eg, via customer complaints), but it is unlikely to be equipped with the necessary technical information about the product to carry out the risk assessment process and decide whether a notification is necessary. As a result, notification is something that is commonly handled by the producer who has the relevant information, resources and expertise to hand. The duplication of notifications is not necessary. If a distributor or producer knows that all relevant information has been conveyed to the competent authority by the other party, then it is not obliged to repeat the notification.

When should a notification be made?

The GPSD states that notifications should be made immediately. Guidance from the European Commission suggests that notifications should be made 'as soon as the information on the dangerous product has become available and in the case of serious risk within three days and any other cases within 10 days in any event'. The member states have different interpretations as to what is considered to be immediate, although the drafting of the GPSD clearly suggests that investigations and notifications to competent authorities should not be unduly delayed.

In some cases, a producer may initially have scant information to enable it to commence a risk assessment and determine whether a notification is necessary. Practices differ in each member state, but in some circumstances, a producer may inform national competent authorities that a potential safety risk is being investigated and a decision as to formal notification will be made once risk assessments are complete. The Commission's view is that parties should not delay in submitting a notification because all information as to the potentially dangerous product has not been collected and reviewed. This is sometimes difficult to square with the need to carry out a thorough risk assessment and decide whether notification is required at all.

Under article 5(4) of the GPSD, producers and distributors are obliged to cooperate with their national competent authority in respect of any corrective action that is undertaken (whether voluntarily or as deemed appropriate by the national authority). The GPSD leaves it to the national authorities to establish procedures for cooperation and exchange of information, but commonly there is a continuing dialogue between the parties once notification has been made. The Commission expects national authorities to monitor the effectiveness of any corrective action and to ensure that additional measures including enforcement action are taken, if necessary.

Who are the national competent authorities?

The GPSD sets out the framework for each member state to establish or nominate national bodies to ensure that obligations under the GPSD are complied with and that information about safety risks is circulated

to the European Commission for onward transmission to other member states.

The GPSD specifically advocates that national authorities should have wide-ranging powers to ensure that adequate measures are taken to address product safety risks. These measures include a requirement to affix warnings to products, temporary bans on supply in order to carry out investigations, total bans on marketing of a product, withdrawal, recall and destruction. Nevertheless, any such measures that are taken must be proportionate and take into account the precautionary principle.

While the GPSD conveys wide-ranging powers to national authorities to ensure that adequate steps are taken to address the problems of unsafe products on the market, the idea of voluntary rather than formal action is advocated. In practice, responsible producers commonly embark on voluntary corrective action and fully cooperate with national authorities to ensure that they take measures that are both proportionate and acceptable to the national authorities. It is usually only where producers fail to take any action, or their action is not deemed to go far enough, or indeed where the producers cannot be identified, that national authorities call on these powers to deal themselves with products posing a risk.

If the new proposed Regulation on Market Surveillance of Products are implemented, national authorities will have enhanced obligations with regard to investigating the safety of products and sharing information with other authorities, including those outside the EU.

What about penalties for non-compliance?

The GPSD is not prescriptive as to the level of penalties that should be applied for failure to comply with obligations under the GPSD; it is left for national law in each member state to set out the penalties for infringement. Nevertheless, the GPSD is clear that such penalties should be 'effective, proportionate and dissuasive'. It should be noted, however, that the proposals in the Product Safety and Market Surveillance Package include an obligation on national authorities to take into consideration the size of the undertaking and whether previous infringements have been committed. Substantial organisations may therefore see considerably larger penalties than previously.

How is information in notifications conveyed between member states?

Although day-to-day monitoring and compliance with product safety obligations is carried out at a national level, the European Commission remains very much at the heart of the product safety network. The Commission takes an active role in the operation of a European network of national competent authorities and is the central point for transmission of information in notifications to all member states.

If steps are taken to restrict the placing of consumer products on a market, or there is a withdrawal or recall of a product from a national market, to the extent that the European Commission is not required to be notified through the RAPEX system (see below), the national competent authorities are required to notify the European Commission of the steps that are being taken in that territory, and the reasoning behind the particular action being adopted (the national authorities must also inform the Commission if the particular measures are modified or lifted).

It is then for the European Commission to forward the information contained in the notifications to the other national authorities for their information. A list of the 'National Contact Points' to whom information is disseminated by the Commission can be found on the Commission's website.

It is possible that, in some instances, a safety issue may only be concerned with one particular member state. In such circumstances, although notification to the relevant national authority is required, measures taken only need to be notified to the European Commission if there is information that the Commission may consider as of interest from a safety point of view, or if the action is taken in response to a new type of risk that the Commission may not have previously come across in other notifications.

What is the RAPEX system, when is it employed and how does it work?

Information as to unsafe non-food consumer products that do not pose a serious threat is exchanged between national enforcement authorities and the European Commission by way of the notification procedure. However, it is the RAPEX system that plays a key role in ensuring that information as to products that pose a serious threat, and the measures that are being taken to address this, can be disseminated and acted upon quickly throughout the European market.

There are currently 31 countries that participate in the European RAPEX system – all of the EU member states and the EEA/EFTA countries of Liechtenstein, Norway and Iceland.

RAPEX does not apply to products that are covered by specific and equivalent notification mechanisms established under other EU legislation such as food and feed (Regulation (EC) 178/2002), for which a separate EU information system exists – the Rapid Alert System for Food and Feed (RASFF). Separate alert systems are also in place for pharmaceuticals and medical devices.

When a producer has identified that a product poses a serious safety risk to consumers and steps are taken in conjunction with the national competent authority to address this risk (whether measures preventing, restricting or imposing conditions on the marketing or use of consumer products), notification is made immediately to the European Commission, via the national authorities and the National RAPEX Contact Point. Such notifications are made regardless of whether the measures are taken on a voluntary or compulsory basis. Any modifications to the action taken or decisions not to proceed or cease the corrective action are also notified to the Commission.

If a product poses a serious risk to the health and safety of consumers but, in addition, emergency action is required by the member states as the product in question poses a life-threatening risk, or there have been fatalities associated with the product, then the national authority will make the notification to the European Commission additionally stating that it requires emergency action.

On receipt of RAPEX information, the Commission is at liberty to carry out its own investigations and the member states are required to supply the Commission with information to the best of their ability in order that such investigations may be completed. In practice, such requests for further information are likely to be passed on directly to producers, who will need to be ready to provide the information requested.

If a product that poses a serious risk is limited to a single EU country, then the RAPEX system is not employed, but the general notification procedure is followed instead.

When notifications are received by the Commission through the RAPEX system, they are forwarded to all other member states, which in turn are obliged to inform the Commission immediately of any steps that are taken to address the risks within their territories.

Products that pose a serious risk and have been notified to the Commission are published each week on the Commission's website.

The weekly notifications set out the year and week of the notification, the notifying country, a description of the product (and a photograph, if available), the product's country of origin, the danger posed by the product, measures adopted by the notifying country, and details of other countries in which the products were found and measures taken.

There is also a search facility on the Commission's RAPEX website allowing users to search for previous notifications using keywords relating to the product, the risk it poses, or the country in which the notification was made.

How are serious risks identified?

In January 2010, new guidelines were published by the European Commission (Decision 2010/15/EU) that provide detailed assistance to national market surveillance authorities as to how to carry out risk assessments in respect of products and determine whether they pose a serious risk to health and safety.

The guidelines set out a risk assessment method whose aim is to assist market surveillance authorities (and thus producers) in each member state to take a uniform approach in determining whether a product poses a serious risk to the public interest, including health and safety. Previous risk assessment methods used (eg, the nomograph method, the matrix method and the method previously recommended by the Commission for the RAPEX system), were found to produce differing results. The 2010 guidelines were therefore intended to improve the risk assessment process, providing a standard approach to addressing the questions of hazard, probability and risk, without ruling out the use of other methodologies.

The guidelines are detailed and provide a step-by-step guide as to what steps should be taken, and what questions should be asked in order to build up a risk assessment. The guidelines look at the product, the hazard it poses, the category of consumers likely to be affected, injury scenarios, the severity of injuries, the probability of injury and a final determination of risk. Guidance is also given as to how to decide what corrective action is appropriate to address the risks identified.

The guidelines specifically state that the risk assessments should be documented 'describing the product and all the parameters you chose while developing it, the type(s) of consumer you chose for your injury scenario(s) and the probabilities with the underlying data and assumptions'.

In documenting how the risk assessment is carried out, producers should be able to give a reasoned explanation to national authorities as to the level of risk the product poses and to justify the corrective action proposed. By having a clear document of the risk assessment methodology, a producer will also then be able to easily update the risk assessment should new information come to light.

Failure to keep an accurate record of the approach adopted could lead to criticism by the national authority and make it difficult to challenge any different conclusions as to risks that the national authorities may reach, should they carry out their own risk assessment investigations.

The results of any risk assessment carried out by a producer or distributor are not binding on the national authorities and national authorities may come to a different conclusion from producers as to the risks that a product may pose and the action that should be taken. The national authorities work through the risk assessment procedure on receipt of any notification to assess whether the product poses a serious risk and a RAPEX notification is necessary, and what corrective action they consider producers and distributors should take. This assessment is checked by the National Contact Point before being submitted to the RAPEX system.

What are the current European recall trends?

Each year, the European Commission publishes an annual report on the operation of the RAPEX system, providing an overview of recall trends in the EU. The most recent annual report highlights a number of key trends for 2017.

Increase in unsafe products notified in the EU

In 2017, the number of unsafe product notifications increased slightly from 2016 to 2,201 notifications. This is not necessarily indicative of more dangerous products finding their way onto the EU market; businesses and regulators are becoming more 'safety vigilant'. Manufacturers and others in the supply chain are becoming ever more aware of – and responsive to – their regulatory obligations and, despite pressure on budgets, regulators also appear to be increasing efforts to identify unsafe products and ensure appropriate corrective action is taken. The new proposed Regulation on Consumer Product Safety may well prompt a rise in the number of unsafe products notified as vigilance levels increase throughout the supply chain.

The top five dangers reported were injuries, chemical risk, choking, electric shock and fire.

China remains the country of origin of most unsafe products

Fifty-three per cent of product alerts in 2017 originated from China. The continued high level in unsafe products of Chinese origin demonstrates that, in addition to current initiatives (such as RAPEX China), more work needs to be undertaken with the Chinese product safety regulator, AQSIQ, to prevent unsafe products being designed, manufactured and exported for sale in the EU.

Toys are the most commonly notified unsafe consumer product

Once again, toys represented the most commonly notified unsafe product in 2017 (29 per cent of notifications), followed by motor vehicles (20 per cent), clothing textiles and fashion items (12 per cent), electrical appliances and equipment (6 per cent) childcare articles and children's equipment (5 per cent) then other product categories such as jewellery, cosmetics and lighting. It is not surprising that toys are in the highest categories of notified products, not least due to the vulnerability of the intended user group and the potential for extreme damage to a manufacturer's brand reputation should an unsafe product cause injury to a child.

Worldwide cooperation

As products move globally and not just across EU borders, the European Commission has embarked on a number of initiatives with other countries to improve product safety for the benefit of citizens worldwide.

The most important of these initiatives is the links that the European Commission has with China. A memorandum of understanding signed between the European Commission and the Chinese product safety regulator, AQSIQ, in 2006 (and revised in 2008 and 2010), establishes a framework for cooperation and collaboration between the two authorities to ensure the safety of consumer products exported into the EU. A RAPEX China application has also been set up to forward RAPEX information to AQSIQ when notifications are made in respect of products of Chinese origin. Details are provided to AQSIQ as to products that have been identified as dangerous and withdrawn or banned from the EU market. AQSIQ then investigates in China and takes steps, where necessary, to prevent the further export of dangerous products. AQSIQ reports to the Commission on a quarterly basis as to follow-up action that has been taken as a result of these notifications.

In 2016, the European Commission marked its 10th year of working closely with China on unsafe product issues. A specific module on RAPEX has been created in order that the Chinese authorities may take action with manufacturers in their own jurisdiction and inform them of EU requirements quickly and effectively.

Bilateral cooperation also exists between the European regulators and the regulators in the US and Japan. Canada and the EU have also strengthened their cooperation by way of the EU–Canada Comprehensive Economic and Trade Agreement. Trilateral discussions and initiatives between Europe, the US and China also exist with a view to ensuring the protection of consumers on a global basis.

Argentina

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

In Argentina, product safety is regulated by several federal and local agencies. Overlapping authority among agencies may occur with respect to a particular product. Given the diversity of products and agencies regulating product safety, this chapter focuses on the four main agencies: the Consumer Protection Agency (CPA); the Domestic Trade Secretariat (DTS); the Drug, Food and Medical Technology, National Administration (ANMAT); and the Industry and Commerce Secretariat. The primary product safety regulations are:

- the Consumer Protection Law (CPL), as implemented by Executive Decree 1798/94, applies to any and all products sold to consumers. The CPL embodies (among other rules) legal principles applicable to consumers' safe use and consumption of products;
- the Argentine Food Code, which contains a broad range of rules applicable to food and beverages, including meat, dairy products, alcoholic beverages, soft drinks, dietary products and additives, among others;
- the Drug Law, which regulates the production, apportioning, import, export, storage and marketing of drugs, medical products and any product intended for medical treatment;
- the Civil and Commercial Code recently enacted, which contains general liability rules, including the obligation to prevent or aggravate any damage; and
- Resolution 808-E/2017 of the Domestic Trade Secretariat (Secretaria de Comercio) which incorporates to local regulation Resolution No. 4, passed on 6 April 2017 by MERCOSUR. This resolution contains the procedure set to alert and withdraw from local markets products and services considered potentially harmful or dangerous to the consumer.

Many other regulations have been issued by agencies with jurisdiction over certain products, such as the Ministry of Agriculture and the Ministry of Health, all of them governing the product safety of particular products.

2 What requirements exist for the traceability of products to facilitate recalls?

There are no specific regulations or requirements regarding the traceability of products for recall purposes. However, with regard to certain products, such as medicines, the applicable rules require the convenient storage of testing lots. Likewise, ANMAT recommends that drug manufacturers keep records of raw materials, parts providers and clients. ANMAT also requires local distributors and manufacturers of specific products to be part of the Medicine Traceability National System, which allows local authorities to detect any anomalies in the legal distribution of such particular products and helps in the recall process.

3 What penalties may be imposed for non-compliance with these laws?

The CPL provides for penalties applicable to suppliers who violate consumers' rights, including the right to safe consumption. These penalties include fines of up to 5 million pesos, seizure of products, closure for up to 30 days, being banned from providing products to the government for up to five years and loss of government benefits. Other rules authorise ANMAT, and most of the government agencies overseeing particular products, to seize products under their jurisdiction and apply fines. Agency-imposed penalties are administrative and can be challenged before higher authorities and the courts, or both. Criminal prosecution may also apply.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

Resolution 808-E/2017 DTS contains the rules governing the notification of products to government authorities. Such resolution provides that suppliers must notify the competent administrative authority and the CPA upon learning that a product is potentially dangerous to consumers. As different rules govern specific products and enable several government agencies to act, those rules may or may not contain notification provisions. For instance, ANMAT regulations require that suppliers inform the ANMAT authorities about voluntary recalls. Other agencies have not enacted notification rules for products under their jurisdiction.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

Reporting obligations begin upon suppliers' awareness of the risks that a product poses to consumers' and users' safety. In general terms, the CPL requires immediate notification both to the competent administrative authorities and consumers. Resolution 808-E/2017 DTS requires immediate notification both to the competent administrative authorities and the CPA. More specific regulations, such as those enabling ANMAT's activity, require immediate communication of a voluntary recall and give 72 hours for the filing of a full recall implementation plan with ANMAT.

6 To which authority should notification be sent? Does this vary according to the product in question?

The particular authority to which notification should be sent depends on the specific products in question. Note that overlapping authority among government agencies may occur. At a federal level, safety issues related to consumer products should be notified to the CPA. ANMAT should be notified when it comes to food, medical devices, drugs and cosmetics. Motor vehicle suppliers should notify the Domestic Trade Secretariat and farm products suppliers should report to the Department of Agriculture.

7 What product information and other data should be provided in the notification to the competent authority?

Each regulatory agency has its own requirements about what information manufacturers should provide, which depends on the type of product. Resolution 808-E/2017 DTS indicates that suppliers should report:

- information on the supplier issuing the recall (eg, name of the company, core business activity, fiscal identification, legal domicile, contact phone number, name of a contact person responsible for the recall process, equal information on local suppliers in MERCOSUR region, etc);

- product description including but not limited to the product name, brand, type, size, number of products included in the recall, lot numbers, serial number, manufacture date, expiry date, country from which the product was imported and manufactured, countries the product was exported to, pictures;
- region in which the product was sold;
- information on any significant incident involving the product, including judicial cases;
- description of the defect, identified risks of using the product;
- notification already provided to other agencies;
- actions already taken;
- press communications plan;
- recall plan or strategy; and
- destination of products when recalled.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

In order to ensure the adequate completion of recalls, most agencies require companies to file reports on the status of the recall and updates regarding safety issues. For example, ANMAT requires manufacturers to file weekly reports with relevant information about the implementation of recall actions, including any alerts addressed to consumers or the press, number of products already recovered, among others. Resolution 808-E/2017 DTS indicates that an update report should be filed at least every 60 days, and a final report should be filed with the results of the recall.

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

See question 3.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

Although trade and industrial secrets are protected, the right of manufacturers and distributors should be balanced with the consumers' right to detailed information on product risks. Hence, whether to seal or disclose sensitive information could be decided by the competent agency on a case-by-case basis. As in conflicting situations a government agency may be inclined to prioritise consumers' rights, manufacturers should not take it for granted that their sensitive information will be protected.

11 May information notified to the authorities be used in a criminal prosecution?

Effective prosecution stands as a priority when it comes to suspected criminal activities. Therefore, manufacturers should assume that the information they provide to government agencies may be used in a criminal investigation.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

When a company learns that its product is in violation of regulatory provisions, presents a threat to safety or creates a substantial risk of injury to consumers, the implementation of a corrective action should be considered. Although the decision to recall a product is voluntary, the competent agency can request or order that a recall be implemented.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Pursuant to section 4 of Executive Decree 1798/94, upon learning about a product risk to consumers, suppliers of goods and services should communicate immediately to the competent authority and to the consumer by plentiful advertising.

14 Are there requirements or guidelines for the content of recall notices?

According to Resolution 808-E/2017 DTS, the communication to local authorities should include:

- information of the supplier issuing the recall;
- identification of the product;
- description of the defect, risks and consequences of using the product;
- indications of areas where the product was distributed;
- information about action already taken to mitigate the risk;
- description of product related accidents occurred;
- media communication plan; and
- consumer contact plan.

Other rules may apply to specific products. ANMAT, for example, issued Resolution 1402/08, setting requirements for the recall of drugs, cosmetics, personal hygiene products and perfumes. Such guidelines require the publication of warnings through the press or through ANMAT's own communication resources (eg, a website).

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

Only ANMAT has indicated that publications of warnings should be done through its own communication and media resources.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

ANMAT guidelines provide that the agency will evaluate the recall process and deem it satisfactory when suppliers have completed all possible actions to ensure that most products have been retrieved and that all necessary actions to avoid its commercialisation and

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consumption have been taken. Such evaluation of satisfactory recalls would depend on the circumstances, such as how many products have been effectively recalled, the time period of the recall and the risk or danger of using the product, among others.

Resolution 808-E/2017 DTS provides that local authorities could request the supplier the extension of the recall process, indicating different courses of action.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

Resolution 808-E/2017 DTS indicates that suppliers must repair or replace recalled products..

18 What are the penalties for failure to undertake a recall or other corrective actions?

See question 3.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

Most government agencies do not have the authority to compel manufacturers to undertake a recall. However, most of those agencies can order the supply chain to halt marketing of a particular product. Agencies can also publish warnings and other information about product dangers. Administrative agencies also have the power to seize products and preventively close plants and warehouses. Agencies such as ANMAT and DTA can review recall plans and suggest changes or modifications to the plan. ANMAT can also design its own plan to audit manufacturers recalling products, issue its own warnings and resort to the courts when necessary for recall compliance.

20 Can the government authorities publish warnings or other information to users or suppliers?

Government authorities can publish warnings or other information to users or suppliers. ANMAT allows consumers to post incident reports online, while the CPA allows consumers to file claims against providers of goods and services through its website or by email.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

When the manufacturer or distributor does not act diligently, government authorities can organise a product recall. Government agencies can also issue warnings to consumers and the public, seize products and order the supply chain to halt marketing of a particular product. However, as a practical matter, when a government agency requests a supplier to initiate a recall, the supplier should consider complying to avoid sanctions and damage to its image.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

A supplier is usually not responsible for the costs related to government actions regarding safety issues or product recalls.

23 How may decisions of the authorities be challenged?

There are limited ways to challenge agency decisions. In any event, as the challenge procedure can be slow and burdensome for a supplier that has been the object of a restraining order (eg, prohibition on marketing certain products), the supplier can file a fast-track request, asking a court to stop the effects of an administrative decision. To prevail, the challenging supplier should demonstrate that the administrative decision is arbitrary.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

Most court precedents have found safety warnings, alerts and the recall itself to be an admission of liability. A court even considered a recall performed abroad as an admission of liability for a product marketed in Argentina.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

No discovery procedure is in force in Argentina. But, as a matter of Argentine procedural law, plaintiffs should set forth in the complaint, the relevant facts of the case and list the evidence to be produced. Hence, when a plaintiff is not aware of internal reports, or that an internal defect investigation has taken place, it is unlikely that the plaintiff will request the production of those documents as evidence.

Australia

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

Relevant legislation and responsible minister

Australia's product safety laws are found in both the common law and federal and state legislation. The main statutory provisions prescribing product safety requirements are contained in Parts 3-3 (Safety of consumer goods and product-related services) and 3-4 (Information standards) of the Australian Consumer Law (ACL). The ACL forms Schedule 2 to the Competition and Consumer Act 2010 (Cth) (CCA). The CCA commenced on 1 January 2011, replacing the Trade Practice Act 1974 (Cth) (TPA). The various state and territory fair trading legislation incorporates the provisions of the ACL, in an attempt to establish a single, national law concerning consumer protection and fair trading.

While the provisions of the TPA applied only to corporations engaged in trade and commerce, or interstate business ventures, the ACL effectively applies to individuals partnerships, businesses and corporations.

The product safety provisions of the ACL cover the:

- publication of public warning notices with regard to potentially dangerous goods (section 129);
- banning of unsafe goods (sections 109 and 114);
- making of product information standards (section 134);
- compulsory recall of unsafe goods (sections 122 to 127);
- notification to the authorities of voluntary recalls (section 128); and
- mandatory reporting requirements on suppliers of consumer goods and services (sections 131 and 132).

The federal minister responsible for consumer protection is the Minister for Small Business (the minister). The minister relies on the Australian Competition and Consumer Commission (ACCC) to monitor and audit the effectiveness of product recalls of general consumer goods. The ACCC is also responsible for the investigation, and prosecution, of breaches of the CCA.

Legislative safety requirements and powers of the minister

Under the ACL, consumer goods must comply with:

- relevant product safety standards (section 106); and
- relevant product information standards (section 136).

Under section 104 of the ACL, the minister is entitled to publish product safety standards where reasonably necessary to prevent or reduce the risk of injury to any person. These standards may include requirements as to:

- performance, composition, contents, methods of manufacturing or processing, design, construction, finish or packaging of the goods;
- testing of the goods either during or after the completion of manufacturing or processing; and
- the form and content of markings, warnings or instructions to accompany the goods.

Similarly, under section 134 of the ACL the minister is entitled to publish product information standards in respect of goods (not just consumer goods). These standards may set such requirements as:

- the content of information about goods;
- the provision of specified information; and
- the form and manner in which that information is to be disclosed.

Section 105 of the ACL allows the minister to declare all or part of a standard prepared or approved by Standards Australia International Limited or by a prescribed association or body to be a consumer product safety standard for the purposes of section 104. A similar provision exists in respect of information standards (section 135).

The ACL prohibits the manufacture, possession, control and supply (or offer of supply) of consumer goods that do not comply with safety standards (section 106). Goods that fail to meet these requirements may be subject to a compulsory product recall (section 122).

Under section 129 of the ACL, the responsible minister can declare goods to be unsafe where they are of a particular kind that will or might cause injury to any person, or a reasonably foreseeable use (including a misuse) of those goods will or may cause injury to any person. A notice declaring goods to be unsafe remains in force for 18 months. Thereafter, the minister may impose a permanent ban on the goods.

The compulsory product recall mechanism contained in the ACL is discussed in detail below.

Finally, the ACL has introduced a mandatory reporting requirement on suppliers of consumer goods and product-related services (sections 131 and 132). The supplier has two days to provide the written notification to the minister if it becomes aware of the death, serious injury or illness of any person and:

- considers that this incident was caused, or may have been caused, by the use or reasonably foreseeable misuse, of the goods or services; or
- becomes aware that a person other than the supplier considers that the incident was caused, or may have been caused, by the use or reasonably foreseeable misuse, of the goods or services.

In addition to the product safety provisions of the ACL, specific safety requirements and guidelines exist for certain types of products. For example:

- medicines and medical devices are regulated by the Therapeutic Goods Administration (TGA) under the Therapeutic Goods Act 1989 (Cth) (www.tga.gov.au);
- food must meet the requirements set out in the Australia New Zealand Food Standards Code (Food Standards Code). The Food Standards Code is developed and administered by Food Standards Australia New Zealand (a binational government agency deriving its power from the Food Standards Australia New Zealand Act 1991 (Cth)), and is enforced by the various state and territory health departments (www.foodstandards.gov.au);
- motor vehicles and motor vehicle parts are regulated by the Federal Department of Infrastructure, Transport, Regional Development and Local Government (www.infrastructure.gov.au/roads/motor/design/index.aspx);
- electrical and gas supply and products are regulated by state and territory electrical and gas regulators (www.erac.gov.au and www.gtrc.gov.au); and
- agricultural and veterinary products are regulated by the Australian Pesticides and Veterinary Medicines Authority (www.apvma.gov.au).

2 What requirements exist for the traceability of products to facilitate recalls?

While there is no general traceability requirement under the ACL, certain industry regulators impose such requirements. For example, lot numbers must be included on food packaging in accordance with standard 1.2.2 of the Food Standards Code.

3 What penalties may be imposed for non-compliance with these laws?

The criminal penalties for non-compliance with product safety requirements are contained in Part 4-3 of the ACL. Section 194 of the ACL makes it an offence to manufacture, possess or have control of, for the purposes of trade or commerce or supply (or offer to supply), consumer goods that do not comply with safety standards. A similar offence exists in respect of banned consumer goods (section 197). A body corporate that contravenes these sections is guilty of an offence punishable on conviction by a penalty not exceeding A$1.1 million. The maximum penalty for a person other than a body corporate is A$220,000.

A similar criminal penalty exists under section 203 where a person supplies goods in Australia in respect of which an information standard has been prescribed, and that person has not complied with the standard in relation to the goods.

The penalties for failing to undertake a compulsory product recall are discussed in question 18.

As an alternative to criminal prosecution, the ACCC may either issue infringement notices or pursue civil pecuniary penalties for contraventions of prescribed sections of the ACL. Section 134A of the CCA empowers the ACCC to issue infringement notices in situations where it has reasonable grounds to believe that a person has contravened certain provisions of the ACL including sections 106(1), (2), (3) or (5) (supply of consumer goods that do not comply with safety standards), 131(1) and 132(1) (mandatory reporting requirements) and 136(1), (2) and (3) (supply of goods that do not comply with information standards). In the explanatory memorandum for these amendments, it was stated that they were for use for 'relatively minor' or 'less serious' contraventions. The relevant penalties are set by section 134C of the CCA, and vary depending on the particular provision and the legal status of the person to whom the notice is issued. Penalties range from 600 penalty units (which may be issued to listed corporations in respect of certain provisions) to six penalty units (which may be issued to persons who are not a body corporate). Penalty units are set at A$210 (an increase from 1 July 2017 on the previous figure of A$180) by section 4AA of the Crimes Act 1914 (Cth), making the penalty range from A$1,260 to A$126,000. These are lower than the pecuniary penalties that might be awarded in court proceedings. Under section 134D of the CCA, compliance with an infringement notice is a bar to further proceedings (both criminal and civil) in relation to an offence constituted by the same conduct that constituted the alleged contravention. For more serious contraventions, section 224 of the ACL allows a court to impose a pecuniary penalty of up to A$1.1 million for body corporates, and up to A$220,000 for individuals who contravene certain provisions of the ACL including sections 106(1), (2), (3) or (5), 131(1), 132(1) and 136(1), (2) and (3). An action seeking recovery of a pecuniary penalty is a civil (see section 228), as opposed to being a criminal, action. As such, the ACCC need only prove the contravention to the civil standard (proof on the balance of probabilities) as opposed to the criminal standard (proof beyond reasonable doubt).

In addition to pecuniary penalty and infringement notice provisions, the ACCC has been empowered to seek orders disqualifying persons from managing corporations if the court is satisfied that the person has committed, attempted to commit or been involved in a contravention of sections 106(1), (2), (3) or (5), 131(1) and 132(1) or 136(1), (2) and (3) of the ACL (section 248 ACL). The ACCC may also issue public warning notices under section 223 of the ACL for suspected contraventions of the ACL.

In addition to the civil and criminal penalties that may be imposed for non-compliance with Australian product safety laws, if an individual suffers loss or damage as a result of non-compliance with these laws then they may recover damages under the ACL (section 236). In this regard, individuals are assisted by a series of 'deeming provisions' in the legislation. By way of example, under section 106(7), where:

- a person supplies consumer goods in contravention of this section by reason that the goods do not comply with a prescribed consumer product safety standard;
- another person suffers loss or damage by reason of a defect in, or a dangerous characteristic of, the goods, because of a reasonably foreseeable use (including a misuse) of the goods or because contrary to the safety standard he or she was not provided with particular information in relation to the goods; and
- the other person would not have suffered the loss or damage if the goods had complied with that standard, the person is taken for the purposes of the ACL to have suffered the loss or damage by the supplying of the goods.

Similar deeming provisions exist where an individual suffers loss or damage from consumer goods that have been banned (section 118(7)), or where an information standard exists for goods of a particular kind and that information standard has not been complied with (section 136(8)).

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

Australia introduced mandatory reporting requirements for suppliers of consumer goods on 1 January 2011. Pursuant to section 131 of the ACL, if a supplier becomes aware of the death, serious injury or illness of any person and considers that this incident was caused, or may have been caused, by the use or foreseeable misuse of the consumer goods, or becomes aware that a person other than the supplier considers that the incident was caused by the use or foreseeable misuse of the consumer goods, the supplier must provide written notification of the incident to the minister. Given the requirement of death or personal injury or illness, the existence of a serious safety defect in a product is not sufficient in itself to trigger the reporting requirement – there must be an incidence of death, serious injury or illness. Further, property damage alone is not a trigger of the mandatory reporting requirement – therefore a fire caused by a defective clothes dryer that solely damaged property would not be reportable.

In addition to the mandatory reporting requirements, section 128 of the ACL requires a person to give the minister notice within two days following a voluntary recall. The ACL contains no definition of 'recall', therefore there is a degree of imprecision. In practice, however, the regulator gives a very expansive definition to the term so that, for example, if a supplier voluntarily asks consumers to carefully dispose of or return defective goods for a refund or replacement, then that is regarded as a recall. The same applies if a supplier asks consumers or other suppliers to return the goods for some form of modification if a defect is safety-related.

It is worth noting that the recall notification obligations arising under the ACL relate only to instances where a product is recalled because:

- the consumer goods will or may cause injury to another person;
- a reasonably foreseeable use (including a misuse) of the consumer goods will or may cause injury to any other person;
- a safety standard for the consumer goods is in force and they do not, or it is likely that they do not, comply with the standard; or
- an interim ban, or a permanent ban, on the consumer goods is in force.

If a product is recalled for some other reason, it would not be subject to the ACL recall provisions.

The other means by which a corporation may be required to notify authorities of defects or injuries arises under section 133D of the CCA. Under this section, the minister or an inspector may give a disclosure notice to a supplier of consumer goods if the person giving the notice has reason to believe that:

- the consumer goods of that kind will or may cause injury to any person; or
- that a reasonably foreseeable use (including a misuse) will or may cause injury to any person, and that the supplier is capable of giving information, producing documents or giving evidence in relation to those consumer goods.

Once this threshold has been met, the minister has broad powers to require the corporation to furnish information, produce documents or give evidence (either written or oral).

There are also a number of industry-specific reporting requirements. By way of example, the Therapeutic Goods Act 1989 (Cth) establishes rigorous reporting requirements in relation to medicines and medical devices. Additional organisations which may need to be notified for specific product groups include:

- Food Standards Australia New Zealand (for food products);
- Department of Infrastructure and Regional Development and Local (for motor vehicles);
- Australian Pesticides & Veterinary Medicines Authority (for agricultural and veterinary products);
- state and territory electrical regulators (for electrical products); and
- state and territory gas regulators (for gas appliance products)

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

The criteria for determining whether notification is required under the mandatory reporting requirement are discussed in question 4. The obligation is triggered by awareness of a 'death or serious injury or illness' that was caused, or may have been caused, by the consumer good. Serious injury or illness is defined as 'an acute physical injury or illness that requires medical or surgical treatment by, or under the supervision of, a medical practitioner or a nurse (whether or not in a hospital, clinic or similar place)'. The ACL provides that the obligation does not apply in certain circumstances including where the supplier, or another person, is required to notify the death or serious injury or illness in accordance with a law of the commonwealth, a state or a territory that is a law specified in the regulations. An example of such a law is the Therapeutic Goods Act 1989 (Cth), which requires notification in relation to drugs and medical devices.

The time limit for mandatory notification under section 131 is within two days (not business days) of awareness.

In the absence of any intervention by a regulatory authority, the decision to commence a voluntary product recall is based upon common law criteria. Once a decision has been made to commence a voluntary recall, then the obligations set out in section 128 will apply. The specific obligations are discussed further below. Specific provisions also exist for the provision of information in the case of mandatory recalls. These are discussed further below.

6 To which authority should notification be sent? Does this vary according to the product in question?

The ACL formally requires notification of voluntary recalls of consumer goods (section 128) and mandatory product reports (section 131) to be submitted to the minister. However, in practice there is an expectation that notification will be given to the ACCC, which acts on the minister's behalf. Notification is also provided in the case of voluntary recalls to:

- the fair trading agencies in relevant states and territories; and
- where relevant, industry regulators such as the TGA (such notification often being required by law).

The ACCC has established an online portal for the provision of notifications under sections 128 (available at www.productsafety.gov.au/contact-us/for-retailers-suppliers/submit-a-recall) and 131 (available at www.productsafety.gov.au/contact-us/for-retailers-suppliers/mandatory-injury-report). Guidelines issued by the ACCC in relation to Product Safety Recalls provide that if a business cannot submit a recall notice using the online form, it should contact the ACCC on 1300 302 502.

7 What product information and other data should be provided in the notification to the competent authority?

A notification under section 131 must identify the consumer goods, and must include information about the following matters to the extent that it is known by the supplier at the time the notice is given:

- when, and in what quantities, the consumer goods were manufactured in Australia, supplied in Australia, exported into Australia or exported from Australia;
- the circumstances in which the death or serious injury or illness occurred;
- the nature of the serious injury or illness suffered by any person; and
- any action that the supplier has taken, or is intending to take, in relation to the consumer goods.

Notification of a voluntary recall under section 128 may be undertaken by way of a section 128 online form (which is available online at www.productsafety.gov.au/contact-us/for-retailers-suppliers/submit-a-recall). Persons can also choose to prepare their own notifications should they wish. To be considered sufficient, such a notification must state that the consumer goods are subject to recall, and:

- if the consumer goods contain a defect or have a dangerous characteristic – set out the nature of the defect or characteristic;
- if a reasonably foreseeable use or misuse of the consumer goods is dangerous – set out the circumstances of that use or misuse;
- if the consumer goods do not, or it is likely that they do not, comply with a safety standard for the goods that is in force – set out the nature of the non-compliance or likely non-compliance; and
- if an interim ban, or a permanent ban, on the consumer goods is in force – state that fact.

Other information that may be provided includes:

- a clear description of the product including the name, make, model and serial number, with a photograph or drawing if available;
- full contact details of the supplier;
- a statement of the hazard and the associated risk;
- dates when the product was available for sale;
- the number of products affected;
- where the product has been distributed and exported;
- the action that the corporation proposes to take (including copies of any proposed recall advertisements);
- what actions the other suppliers and consumers should take; and
- detailed information about using or storing the product.

Some industry bodies have their own notification forms. For example, defects in medicines are reported to the TGA using the medicine report form, while problems with medical devices are reported using a medical device incident report.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

There is an expectation that corporations will keep the ACCC informed of progress, developments and outcome following the implementation of a recall. Indeed, corporations that have conducted a recall can expect to be audited. Where the authorities have requested information from a corporation using a statutory provision such as section 133D of the CCA, there is a legal obligation to respond. Failure to respond can lead to the imposition of significant penalties.

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

Failure to provide notification of a voluntary recall is an offence punishable on conviction by a fine not exceeding A$3,330 for an individual, or A$16,650 for a body corporate (section 201). A similar offence exists in relation to a failure to comply with the mandatory reporting obligations (section 202). Both offences are offences of strict liability. Alternatively, the court may impose a pecuniary penalty for contravention of the section under section 224. Conduct of an individual in contravention of the requirement can also lead to the imposition of a disqualification order under section 248 (see question 3).

Refusal or failure to comply with a notice requesting information under section 133D of the CCA is an offence punishable on conviction by a fine not exceeding 200 penalty units (A$42,000) for a body corporate and 40 penalty units (A$8,400) for a person other than a body corporate (section 133F CCA). Should a person knowingly provide information in purported compliance with a section 133D notice that is false or misleading in a material particular, then that person is guilty of an offence punishable on conviction by a penalty of 60 penalty units (A$12,600) or imprisonment for not longer than 12 months, or both. The penalty for a body corporate is 300 penalty units, or A$63,000 (section 133G CCA).

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

Typically, when a corporation notifies information to the authorities there is not an expectation that it will be made public. However, the Freedom of Information Act 1982 (Cth) (the FOI Act) provides individuals with a legally enforceable right to obtain access to documents held by ministers and government agencies. This right to access is not

unlimited. Access to documents under the FOI Act is subject to prescribed exemptions such as documents evidencing confidential business affairs. Where such documents are requested by an individual, then the corporation to which the documents relate has a right to submit to the minister that the documents should be exempt from disclosure.

11 May information notified to the authorities be used in a criminal prosecution?

Pursuant to section 131(6), the giving of notice in accordance with the mandatory reporting requirement is not to be taken for any purpose to be an admission by the supplier of any liability in relation to:

- the consumer goods; or
- the death or serious injury or illness of any person.

Information, evidence or documents provided by an individual under, or obtained by the authorities in accordance with, section 133D of the CCA are not admissible in evidence against the person in any proceedings instituted by the person, or in any criminal proceedings, other than proceedings against the person for a contravention of a provision of section 133F or 133G. That is to say, it may only be used to prosecute an individual for one of the offences discussed in question 9. The provisions of section 155 of the CCA also need to be considered. This section entitles the ACCC to obtain information, documents and evidence in certain circumstances.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

The decision to undertake a voluntary safety-related recall is the responsibility of the supplier. Given the lack of statutory guidance, a corporation will make the assessment as to whether to recall a product in accordance with the common law.

Under the common law, manufacturers and suppliers of products owe a continuing duty to purchasers and users to prevent a product from causing harm, including after the product is sold. Although the case law in Australia is limited, it is reasonably clear that a manufacturer's common law duty of care may extend to a duty to recall in certain circumstances. Where there is a risk of injury connected with product use, the supplier should investigate the risk to determine whether the risk is substantial and causally related to the product. If there is a substantial risk and a plausible causal connection, the supplier ought to consider appropriate remedial action. In deciding what action to take, the supplier should have regard to the:

- magnitude of the potential harm involved;
- probability of such harm occurring;
- availability and effectiveness of alternative remedial action; and
- degree of knowledge in potential users of the potential harm.

If there is no relevant product safety standard or product information standard, it is sometimes a complex and difficult process in deciding whether to initiate a product recall.

In some cases proper analysis will reveal a problem or defect that is neither safety-related nor critical. In such cases, appropriate remedial action may involve no more than a routine service. However, where the problem or defect has potential safety-related consequences or may affect critical product performance, then the appropriate course is much more likely to be the initiation of a product recall.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

In the case of a compulsory product recall under section 122 of the ACL (discussed below in question 19), the responsible minister may require the corporation to publish warnings or other information to product users (see generally section 123). It is an offence to fail to comply with the requirements and directions contained in a notice issued under section 122.

The section 128 notification requirements for voluntary recalls are discussed above.

Further, where goods are recalled, either voluntarily or in accordance with section 122, a person who has supplied or supplies any of the recalled goods to another person outside Australia shall, as soon as is practicable, notify that person of the recall as well as any defect, dangerous characteristic, non-compliance with a product safety standard, or interim or permanent ban in respect of that good (sections 125 and 128(4)). A copy of that notice must also be provided to the minister who issued the recall notice within 10 days of giving the notice (sections 125(4) and 128(6)). Failure to provide such notice to the minister can result in either a criminal or civil penalty, or a disqualification order.

14 Are there requirements or guidelines for the content of recall notices?

The content of recall notices is not mandated by the ACL. However, companies are encouraged to use a standard hatched border with the safety triangle. A template is available for download at www.recalls.gov.au.

As to content, the ACCC recommends that recall notices contain a clear description of the product, including the name, the date when the product was sold, the potential risk and what action the consumer should take.

If the recall is a consequence of an identified breach of an ACL mandatory standard or ban, or of a hazard identified by the ACCC, the conduct of the recall should be negotiated with the ACCC.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The ACL does not expressly require the use of any particular medium by suppliers for the publication of product recalls or warnings. It does, however, expressly provide for the publication of public notices (such as safety warning notices) by the minister on the internet. Traditionally, recalls have been publicised in daily newspapers, and indeed there is an expectation that this will occur.

Additional methods of publication may be appropriate depending on the risk associated with using the product, where the product has been distributed, and the nature of the potential audience that needs to be notified. Additional forms of publication include:

- signs in retail outlets;
- issue of media releases to newspaper, radio and television;
- direct customer contact;
- radio and television advertisements;
- advertisement by retail flyers;
- publication through industry and community organisations;
- publication on a website; and
- publication in consumer magazines.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

No. But the regulator's expectations will depend on the particular circumstances and the nature of the product concerned.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

Where a compulsory recall has occurred (see question 19), section 123(1)(c) of the ACL empowers the minister to require the supplier to either repair or replace the good in question, or refund the purchase price. The standards of repair and replacement are governed by section 124.

Sections 54 and 55 of the ACL require a manufacturer to compensate a consumer who has suffered loss or damage from a good that is either not reasonably fit for the disclosed purpose (and for any purpose for which the supplier represents that it is reasonably fit), or not of acceptable quality. Further, under section 58 of the ACL, manufacturers are under an obligation to provide repair facilities for consumer goods.

18 What are the penalties for failure to undertake a recall or other corrective actions?

Under section 199 of the ACL, if a person fails to undertake a compulsory recall or other corrective action in accordance with a notice under subsection 122 then they have committed an offence with a maximum penalty of A$1.1 million for a body corporate and A$220,000 for an individual. Similarly, under section 224, a civil pecuniary penalty of A$1.1 million for a body corporate and A$220,000 for an individual may be imposed by a court for failure to undertake compulsory recall or corrective action, while the ACCC may issue infringement notices under

Update and trends

According to a recent statement by Australia's consumer product regulator, the ACCC, 'faulty products continue to cause injury and harm to thousands of Australians with more than 4.5 million items recalled by suppliers in the period' July 2017 to June 2018. This has led to increasing focus on mandatory reporting obligations and product recalls for safety-related issues. It has also led the ACCC to suggest that there is need in Australia for a general safety provision of a kind that is seen in European Union countries.

There continues to be a strong correlation between enforcement action taken by the ACCC, product recalls and claims for compensation by consumers against manufacturers frequently commenced by way of class actions. There have now been several instances where regulatory action has led to the commencement of class actions. There have also been many instances where product recalls have triggered class action claims. These developments have added to the product liability risks for consumer product manufacturers and suppliers in Australia.

section 134C of the CCA. Finally, the ACCC may seek disqualification orders under section 248 of the ACL (see question 3).

In addition to the criminal and civil penalties that may be imposed upon conviction for non-compliance with a product recall order, if an individual suffers loss or damage as a result of non-compliance with such an order then they may recover damages under the ACL (section 236). In this regard, individuals are assisted by the 'deeming provisions' contained in section 127(3). These provisions are similar to those discussed in question 3 with regard to general product safety laws.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

Under section 122 of the ACL, the responsible minister can order a compulsory recall of a consumer good if it will or may cause injury to a person, and where it appears that the supplier has not taken satisfactory action to prevent the goods from causing injury. Section 122 creates a regime for the compulsory recall of goods in certain circumstances. Subject to meeting the administrative requirements contained in the CCA (discussed below in question 23), a product recall (or other remedial action) can be mandated in circumstances where a person supplies consumer goods and any of the following applies:

- it appears to the responsible minister that the goods are goods of a kind that will or may cause injury to any person;
- it appears to the responsible minister that a reasonably foreseeable use (including a misuse) of such goods will or may cause injury to any person;
- a safety standard for such goods is in force and the goods do not comply with the standard;
- an interim ban, or a permanent ban, on such goods is in force; and
- it appears to the responsible minister that one or more suppliers of such goods have not taken satisfactory action to prevent those goods causing injury to any person.

The steps that may be required are discussed below in question 21.

The penalties for failing to comply with a compulsory recall are discussed above at question 18.

20 Can the government authorities publish warnings or other information to users or suppliers?

In the case of a compulsory recall, the minister can require the publication of warnings and other information to users and suppliers under section 123 of the ACL. Similarly, copies of recall notices are published on the Australian recalls website (www.recalls.gov.au).

Under section 129 of the ACL, a responsible minister may publish a written notice on the internet containing one or both of the following:

- a statement that consumer goods of a kind specified in the notice are under investigation to determine whether the goods will or may cause injury to any person, or a reasonably foreseeable use (including a misuse) of those goods will or may cause injury to any person; or
- a warning of possible risks involved in the use of consumer goods of a kind specified in the notice.

This is in addition to the power to publish notices imposing either an interim ban (section 109) or permanently banning goods (section 114), the requirements for which are discussed in question 1.

Australian authorities generally work with suppliers within the framework of the Australian voluntary recall system in order to convey information and notices regarding product safety and product recall.

The Product Safety Australia website provides a facility for members of the public to report apparently unsafe products to either the ACCC or the relevant state and territory regulators (see www.productsafety.gov.au/content/index.phtml/tag/ReportAnUnsafeProduct#toc1). The online form for such reports requires the provision of personal information to enable the authorities to follow up with the individual making the report. These reports are made to the regulators directly and are not published on the website.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Yes. As discussed above, the Australian system of product recall is primarily voluntary, with reserve compulsory powers. Under section 122 of the ACL, the minister can compel a corporation to conduct a mandatory recall in prescribed circumstances. These are discussed in detail in question 19.

Once the minister has formed the view that action is required in relation to a product, a notice is issued under section 123 requiring the supplier to do any or all of the following:

- recall the goods within a specified time;
- disclose to the public or to a class of persons specified in the notice in the manner and within the period specified in the notice one or more of the following:
  - the nature of the defect in, or a dangerous characteristic of, the goods identified in the notice;
  - the circumstances, being circumstances identified in the notice, in which a reasonably foreseeable use or misuse of the goods is dangerous; or
  - procedures for disposing of the goods specified in the notice; and
- inform the public or a class of persons specified in the notice that the supplier undertakes to do whichever of the following the supplier thinks is appropriate:
  - except where the notice identifies a dangerous characteristic of the goods, repair the goods; replace the goods; or
  - refund a person to whom the goods were supplied (whether by the supplier or another person) the price of the goods.

The compulsory product recall provisions apply to goods intended to be used or likely to be used by a consumer. Where no supplier is known to the responsible minister, then the minister may require the regulator to undertake one or more of the steps above (with the exception of the provision of repair, replacement or refund).

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

It is unclear whether the costs incurred by the government authority are recoverable from the producer or other responsible party. However, if successful legal proceedings are brought by the authorities against a corporation, the corporation will be liable to pay the authorities' legal costs in prosecuting the matter under Australia's 'costs follow the event' rule.

23 How may decisions of the authorities be challenged?

Pursuant to section 132(1) of the CCA, the minister must issue a proposed ban notice before imposing an interim ban or a permanent ban on consumer goods or product-related services of a particular kind. Section 132A(1) requires the minister to issue a proposed recall notice before issuing the recall notice for goods of a particular kind.

The minister must publish on the internet a draft version of the proposed notice, along with a summary of the reasons for the proposed issue of the notice. This notice must include an invitation to any supplier

of the product to request a conference with the ACCC. A person must be given at least 10 days to notify the ACCC that they wish to hold a conference in relation to the proposed ban or recall. However, the notice period may be dispensed with if it appears to the minister that consumer goods or product-related services of a particular kind create an imminent risk of death, serious illness or injury.

If a conference is requested, the ACCC must appoint a date, time and place and provide written notice to that effect to the minister (and each person who notified the ACCC of their request to attend a conference). As soon as is practicable following the conference the ACCC must by notice in writing to the minister make recommendations as to whether a ban notice or recall notice should be published. A copy of this recommendation must be given to all suppliers who were present at the conference. The ACCC's recommendation is not binding; however, the minister is under a statutory duty to have regard to such recommendation, and where the minister decides to depart from it there is an obligation to set out the reasons in a written notice published on the internet.

If a person is aggrieved by the decision of either the ACCC or the minister then it is possible, in certain circumstances, to institute proceedings for such administrative law remedies as are conferred and governed by the Administrative Decisions (Judicial review) Act 1989 (Cth).

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

The mere act of publishing a safety warning or product recall notice is not, in and of itself, an admission of liability (see *Courtney v Medtel* (2003) 126 FCR 219). However, whether there is an admission of liability will depend on the material that is published, the words that are used and the relevant context. Similarly, the provision of a mandatory notification under section 131 of the ACL is not to be taken for any purpose to be an admission of any liability in relation to the consumer goods, or the death or serious injury or illness of any person. As with the publication of a recall notice, there is no reason why the contents of a notification could not be construed as an admission of fact.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Under the court discovery processes, a party is obliged to discover – that is to identify and allow the other party to access – all documents in its possession, custody or power that are relevant to a matter in issue in the proceedings. Documentary discovery occurs at the pretrial stage so that all documents relevant to the case are disclosed by the parties before the hearing commences.

The obligation to give documentary discovery extends to documents that are no longer in the parties' possession, custody or power, but that were previously.

Documents that are relevant to a case include those documents on which the party relies; documents that adversely affect the party's own case; documents that affect another party's case; documents that support another party's case and documents that the party is required by relevant practice direction to disclose.

All discovered documents must be listed and the parties' lists sworn and exchanged. Parties are entitled to inspect each others' documents and if desired, copy them, save for those in relation to which a claim for legal professional privilege has been advanced.

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

There are various EU rules and regulations on certain food and non-food products. Many of these European directives and regulations are structured as follows.

The EU directives and regulations specify basic safety requirements. European norm-organisations set detailed technical norms. There is no legal requirement to adhere to those norms. If, however, a product is produced in accordance with the technical norms it is presumed that such product is in accordance with basic safety requirements. If a product is not produced in accordance with the technical norms, the producers have to prove that the product is nevertheless in accordance with basic safety requirements.

For those products that are not within the scope of the EU regulations on certain food and non-food items, the EU has enacted the European Product Security Directive. This Directive is not directly applicable. Thus the Austrian legislature has enacted the Austrian Federal Act on Protection Against Dangerous Products 2004 (the Product Safety Act).

Under the Product Safety Act, a product is deemed to be safe when, provided that it is put to its proper or any reasonably foreseeable use, it harbours no dangers or dangers of such a low level as is acceptable for human safety with a view to its use and to safeguarding a high level of protection. The meaning of 'use' includes the period of service and, where applicable, its start-up, installation and maintenance requirements.

In evaluating safety, consideration is primarily given to:

- consumers (consumer categories), including, without limitation, children, older or disabled people who are exposed to a higher risk by the product when it is used as reasonably foreseeable;
- the product's properties, in particular its composition, design and finish, packaging, the conditions for its assembly and its behaviour when maintained, stored and transported;
- its effect on other products when its use jointly with other products can be reasonably foreseen; and
- its layout, presentation, labelling, its instructions for use and operation if any, instructions for its maintenance, storage and disposal, and any other data or information given by the manufacturer or importer.

A product is deemed to be dangerous when it does not meet the safety requirements as stated above. The capacity to achieve a higher degree of safety or the availability of other products that are less dangerous, however, is insufficient reason to consider a product to be dangerous (section 4 of the Product Safety Act).

2 What requirements exist for the traceability of products to facilitate recalls?

Under the Product Safety Act, manufacturers and importers have to take measures that are suitable and appropriate to, if necessary, withdraw the products from the market, giving reasonable and effective warning to consumers and, if so required, recalling the products from their customers (section 7, paragraph 2 of the Product Safety Act).

Within the scope of their business activities vendors have to contribute to monitoring the safety of the products marketed, especially by passing on indications of any danger that may be posed by the product, by keeping and making available documentation required to trace products and by cooperating with measures by the manufacturers and competent authorities to avoid any danger. Within the scope of their business activities, they should ensure efficient cooperation with other marketers, consumers and authorities (section 7, paragraph 2 of the Product Safety Act).

To enable traceability, the product or its package must report the producer's name and address or, insofar as it is not based in the European Economic Area, the name and address of the EU representative or the importer. Moreover, unambiguous product identification information must be provided on the product or package.

3 What penalties may be imposed for non-compliance with these laws?

There are civil, criminal and administrative repercussions if a manufacturer, importer or vendor fails to comply with product safety legislation.

Under Austrian tort law, anyone can lodge a claim for damages, if the non-compliance led to harm. The Austrian Product Liability Act even provides for a non-fault-based liability of the producer or importer of a defective product. Claims based on the Product Liability Act can be lodged if a person is killed, suffers an injury to his or her body or health, or if any tangible property other than the product itself is damaged because of the defect of a product (deductible by €500). Austrian tort law does not provide for punitive damages.

There is a possible administrative fine of up to €25,000. For the first violation, the fines are significantly lower than that (eg, €2,500), thus they do not provide an adequate incentive to comply with product safety regulations.

Under Austrian law, corporations can be held criminally liable (ie, be fined severely) if a 'decision-maker' (eg, board member) committed a criminal offence him or herself or under certain preconditions, if an employee committed a criminal offence (eg, if a decision-maker facilitated the criminal offence by not acting with the necessary due diligence).

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

Once a product has been brought into circulation, producers, importers and vendors are required to inform the competent authority if they become aware of (or are made aware of) hazards their product poses to the consumers. Manufacturers and importers have to take measures that are suitable and appropriate for the product to enable them to recognise any dangers that may be posed by such products and take appropriate action to avoid such dangers. Vendors have to contribute to monitoring the safety of the products marketed, especially by passing on indications of any danger that may be posed by the product, by keeping and making available documentation required to trace products and by cooperating with measures by the manufacturers and competent authorities to avoid any danger within the scope of their business activities.

Within the scope of their business activities, they should ensure efficient cooperation with other marketers, consumers and authorities. There are special rules for high-risk goods.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

Any situation where a product does not meet the safety requirements under the Product Safety Act (see question 1) has to be reported to the competent authority. Notification about such hazardous products has to be made promptly (section 7, paragraph 4 of the Product Safety Act). In cases of serious danger (ie, any severe danger that requires rapid action on the part of the authorities even when it has no direct effect), there are special rules on inter-agency cooperation, temporary action to avert danger by the supervisory bodies (eg, seizure, ban on marketing, application of warning signs, etc) and (higher) fines.

6 To which authority should notification be sent? Does this vary according to the product in question?

The notification has to be sent to the 'responsible authorities'. The responsible authorities are the state governors and the Federal Minister for Work, Social Affairs, Health and Consumer Protection. There are special rules for high-risk goods (eg, medical products).

7 What product information and other data should be provided in the notification to the competent authority?

All necessary information to judge the character and severity of the threat caused by the defective product should be provided. For high-risk products, there are special rules and regulations.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Authorities have to be provided with updated information about risks and a response to their enquiries in a timely manner.

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

Under Austrian tort law, anyone can lodge a claim for damages, if the non-compliance led to damages. However, claims for property damage cannot be based on violations of the reporting obligations, since the Product Safety Act's scope of protection does not include property but only bodily harm.

Failure to comply with reporting obligations may also result in administrative penalties up to €3,000. For the first violation, the fines are significantly lower than that (eg, €300) thus they do not provide an adequate deterrence.

Under Austrian law, corporations can be held criminally liable (ie, be fined severely) if a 'decision-maker' (eg, board member) committed a criminal offence him or herself or under certain preconditions, if an employee committed a criminal offence (eg, if a decision-maker facilitated the criminal offence by not acting with the necessary due diligence).

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

Under the Austrian rules on public confidentiality, commercially sensitive information that has been notified to the authorities is protected from public disclosure.

11 May information notified to the authorities be used in a criminal prosecution?

Yes, any information disclosed to the authorities may be used in a criminal prosecution. The Austrian constitution also provides for a duty of inter-agency cooperation. This duty to cooperate applies to cooperation between authorities and the public prosecutor's office.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

In case of a defective product, the necessary response depends on the nature of the defect. A recall is not always necessary.

The Austrian product liability and product safety law distinguishes four types of product defects:

- Construction defects are defects inherent to the design of the product. In the whole line of the product, every piece is flawed. Construction defects can lead to a recall obligation if the safety of the consumer would be insufficiently provided for by only informing the public.
- Production defects affect only a certain piece of a line of products owing to an error in the production process. Product recalls will usually not be necessary in such a case, since the number of flawed products will be small if the design of the product as such is up to code.
- Instructional defects are errors in a product's manual. The product as such is not faulty, only the manufacturer's instructions for using it. In such a case, it will usually be enough to inform the consumers on how to use the product correctly in order to avoid danger.
- Development defects are defects that could not be discovered prior to the circulation of the product because of insufficient scientific knowledge leading to the inability of the manufacturer to realise that the design of the product could lead to safety hazards. Therefore, a development defect is usually simply a construction defect that the manufacturer cannot be held liable for because it was impossible to avoid at the time the product was put into circulation. However, the same rules apply, which means a product recall is necessary if the consumer's safety would be put at risk without it or if a warning is not sufficient to control the risk.

Up to this point, there is no detailed statute or case law providing for a clear differentiation between cases where a corrective action is sufficient and cases where a product recall is necessary. In our experience, it is advisable to err on the side of caution.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

As stated above, there is no general regulation that states what corrective and protective actions have to be taken by the manufacturer in the event the product is found to be dangerous. However, the competent authority (see question 6) can undertake certain measures to ensure that the public is shielded from unnecessary danger, if the consumer's safety requires it. In some cases, an obligation to enclose improved instruction manuals may suffice; in other cases, other steps (including a product recall) may be necessary.

14 Are there requirements or guidelines for the content of recall notices?

In the event a defective product is under the scope of the EU Rapid Alert System for dangerous non-food products, the EU provides for an application generating the necessary report.

In non-EU cases, the information that has to be provided generally is:

- the name of the recalled good;
- the names of the manufacturer, importer and vendor;
- the reason for product recall;
- the intended plan (eg, the customer is asked to return the product in exchange for a full refund); and
- preferably a picture of the recalled product (see guideline regarding food product recall provided by the Austrian Agency for Health and Food Safety).

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The Product Safety Act speaks of 'suitable media' as a place to publish warnings and notices about recall actions but there is no legal definition. Product recalls are published on the website of the Austrian Agency for Health and Food Safety, a private company owned by the state. Information about product recall will also usually be found at supermarkets or other stores that sold the defective products.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There are no laws or regulations specifying after what time period a recall is deemed to be satisfactory. If the product recall is published in compliance with the guidelines and measures taken by the competent authority, the manufacturer will have fulfilled its recall obligations.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

Yes, generally speaking, a producer or other supplier has to repair or replace defective products, subject to the applicable statute of limitations. The consumer's claim is to be lodged against its contractual party (eg, the vendor). The vendor then has a recourse claim against its contractual partner (eg, importer).

18 What are the penalties for failure to undertake a recall or other corrective actions?

There are civil, criminal and administrative repercussions if a manufacturer, importer or vendor fails to comply with product safety legislation.

Under Austrian tort law, anyone can lodge a claim for damages, if the non-compliance led to damages. The Austrian Product Liability Act even provides for a non-fault-based liability of the producer or importer of a defective product. Claims based on the Product Liability Act can be lodged if a person is killed, suffers an injury to his or her body or health, or if any tangible property other than the product itself is damaged because of the defect of a product (deductible by €500).

Claims based on violations of recall obligations can be lodged under normal tort law if the manufacturer is not liable according to the Product Liability Act, specifically in the case of damages owing to development defects (see question 12).

Austrian tort law does not provide for punitive damages.

There is a possible administrative fine of up to €25,000. For the first violation, the fines are significantly lower than that (eg, €2,500) thus they do not provide an adequate deterrence.

Under Austrian law, corporations can be held criminally liable (ie, be fined severely) if a 'decision-maker' (eg, board member) committed a criminal offence him or herself or under certain preconditions, or if an employee committed a criminal offence (eg, if a decision-maker facilitated the criminal offence by not acting with the necessary due diligence).

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

To the extent that the safety requirements are not complied with by marketers, the authorities can take government action directed at marketers or, if necessary to avert any danger, at any other person. Such measures can include, without limitation:

- requirement to add or improve instructions for use or to attach identification elements on the package or product;
- requirement to attach to the product a warning against dangers and directions for behaviour to avert them as are appropriate to reflect the urgency of averting such dangers;
- requirement to publish warnings or other urgent information in a manner and by media suitable for the market categories concerned;
- orders and prohibitions with regard to promotional measures for products;
- specification of certain quality requirements (eg, safety precautions), in particular by declaring national or international standards to be fully or partially binding;
- requirement to furnish proof of compliance with specified testing requirements;
- prohibitions or limitations on the marketing (eg, with regard to specified categories of persons or the type of distribution);
- prohibitions or limitations on export (eg, with regard to a destination);
- requirement to promptly withdraw from the distribution chain any product or batch of products already placed on the market and, if necessary, its destruction under suitable conditions; and
- obligation to carry out a prompt and efficient recall of a product or product batch already marketed from consumers, if necessary, publication of such recall scheme in media suitable for the market categories concerned and, if necessary, the destruction of such product or product batch under suitable conditions.

The measures referred to above are to be taken by way of an ordinance and can thus be enforced. Nevertheless, to the extent that reasonable measures for danger aversion can be obtained on a voluntary basis, such procedure is to be given preference.

In cases of grave danger, temporary action to avert danger can be taken by the authorities, if:

- the product has been found to pose a danger to human life or health either by an expert opinion prepared by a domestic or foreign accredited testing body or an authorised civil engineer;
- there is reasonable suspicion that the use of a product constitutes an imminent danger to human life or health;
- marketing of a product is manifestly inconsistent with any measure decreed under section 11 of the Product Safety Act; or
- the product has already been subject to a measure in a state party to the EEA Treaty and such measure was notified within the scope of a RAPEX procedure based on Directive 2001/95/EC on general product safety.

Any temporary action within the meaning of the above list has to be directed to averting imminent danger, with due regard to be given to a high level of protection for consumer safety. For such purpose, the most restrained means still effective to meet the purpose should be used at all times.

Any products subject to temporary action are to be left in the business or storage rooms and, if possible, should be sealed or labelled so as to ensure that they cannot be changed without breaking the seal or label. The person previously authorised to handle the products should be notified in writing by the supervisory body of the consequences under criminal law that may result from moving or changing the products or from breaking the official seal.

20 Can the government authorities publish warnings or other information to users or suppliers?

Yes (see question 19).

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21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Yes (see question 19).

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Yes.

23 How may decisions of the authorities be challenged?

The decisions taken by the authorities are taken by way of an ordinance and can thus be challenged in Austria's administrative courts.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

Under Austrian tort law, the damaged party has to prove that the damage incurred was caused by a defective product and that the defendant is liable for the damages incurred. While the publication of a safety warning or a product recall will be seen as an admission that a product was defective, it does neither prove that damages were caused because of that defect nor does it prove any wrongdoing on the part of the defendant.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Austrian law on civil procedure does not provide for a discovery phase. However, if criminal proceedings are pending, victims have a right to inspect the criminal proceedings' files and thus can gain access to vital information.

Brazil

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

The basic law governing the safety requirements that products must meet is the Consumer Protection Code (CDC), which rules all relations regarding the production and placement in the market of products and services, and subsequent acquisition and use of them by consumers. The CDC sets forth that suppliers cannot place in the market products or services that are extremely harmful or hazardous to consumers' health or safety (article 10). A supplier that acknowledges the danger of products or services after placing them in the market must immediately inform the authorities and consumers (first paragraph of article 10). The Justice Ministry issued Ordinance 487/2012 in order to regulate the procedure for recalls in Brazil.

2 What requirements exist for the traceability of products to facilitate recalls?

Ordinance 487/2012 provides that suppliers should provide detailed descriptions of product or services, containing information for their identification (eg, brand, type, lot, series number, chassis, start and end date of manufacture, picture, etc), as well as geographic distribution of the harmful products or services.

3 What penalties may be imposed for non-compliance with these laws?

Non-compliance with the laws for protection of consumers may subject the supplier to administrative, civil or criminal penalties.

If the public authorities for consumers deem that the supplier violated the provisions of the CDC, they may initiate a procedure for verification of violations and application of penalties that can be accumulated or not, such as:

- fines;
- product seizure;
- destruction of the product;
- cancellation of product registration at the competent authorities;
- prohibition on product manufacture;
- suspension of product or service supply;
- temporary suspension of the activity;
- revocation of concession or permission for use;
- cancellation of permit for the establishment or activity;
- total or partial closing down of the establishment, work or activity;
- administrative intervention; or
- imposition of counteradvertising.

The public authorities can apply fines of up to 9.8 million reais, in accordance with the severity of the infraction, the advantage obtained and the economic status of the supplier.

A criminal investigation also can be started to ascertain criminal responsibility of anyone who contributed to the lack of mandatory communication, for late communication or for insufficient mandatory communication. According to the CDC, failure to inform the competent authorities or withdraw harmful or hazardous products from the market will lead to a penalty of six months' to two years' imprisonment, and a fine.

Without prejudice of administrative and criminal penalties, civil actions before the courts may be started in order to compel the supplier, whether jointly or severally, to answer for property or moral damages caused to consumers in connection with defective products.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

In order that they are subject to notification to government authorities and recall, products or services have to be introduced in the consumer market and extremely harmful or hazardous to consumers' health or safety. The supplier should communicate the fact forthwith by publicity releases to the competent authorities and to consumers. The recall campaign can be spontaneously started by the supplier or upon the request of the competent authorities.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

The main criterion is that the product must be 'extremely harmful or hazardous' to consumers' health or safety. The CDC does not define the meaning of the expression and the interpretation will depend on a case-by-case analysis. In theory, the product may not be considered 'extremely harmful or hazardous' for risks deemed normal and foreseeable as a result of their nature and regular use, neither for potential risks that are already known and duly informed by suppliers. However, again, the analysis will have to be on a case-by-case basis.

As regards the time limits for the notification, the supplier is obliged to inform the public authorities and consumers by publicity releases immediately (ie, as soon as the defect is discovered and the supplier has become aware of the anomaly) regarding the hazard.

6 To which authority should notification be sent? Does this vary according to the product in question?

Article 2 of Ordinance 487/2012 states that the supplier has to send notification to the Department of Protection and Defence of the Consumer (DPDC, an entity related to the Ministry of Justice), the state, Federal District and municipal authorities for the protection of the consumer (known as Procons), and the competent rule-making and regulatory authority.

The authority to which notification must be sent varies depending on the product in question. There are economic activities that are regulated by public authorities in Brazil that are competent for the registry, surveillance and monitoring of quality and safety of products and services. Therefore, if the supplier activity is regulated by the state, the supplier will have to notify the authority it is subjected to.

7 What product information and other data should be provided in the notification to the competent authority?

The supplier should inform the competent authorities regarding the potential hazardous or dangerous product or service in writing. The report to the authorities must contain the following information:

- particulars of the product or service provider;
- a detailed description of the product or service to the extent necessary for its adequate identification;

- a detailed description of the defect, coupled with technical information necessary to clarify the facts, as well as the date (day, month and year) and means by which the hazardous or dangerous condition was detected;
- a detailed description of the risks and their implications;
- the quantity of potentially defective products or services, and the number of consumers affected;
- the territory covered by the potentially defective products and services introduced into the consumer market (per Brazilian state), and the countries to which those products and services were exported;
- a report on the actions already taken as well as on those being proposed to cure the defect and remedy the risk;
- a description of any accident related to the product or service defect, if applicable;
- the media communication plan;
- the consumer service plan; and
- the template notice of risk to consumers.

Depending on the product or service being recalled, there may be other data or measures that should be provided, as determined by the rule-making and regulatory authorities.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

The supplier should provide the DPDC, Procons and the pertinent rule-making or regulatory authority with the following information:

- periodical recall status reports (with a maximum interval of 60 days between them), stating the quantity of products or services repaired or withheld from the market, including those in stock, and the respective allocation at state level; and
- a final recall status report, stating the number and percentage of consumers affected, in an overall manner and per federative unit, as well as the reasons and measures to be adopted vis-à-vis the percentage products or services not withheld or repaired, also informing how consumers were advised about the risk.

In addition, the competent authorities are allowed to, at any time, request additional or supplementary information and data related to those listed in question 7, so as to verify the efficacy of recall procedures.

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

Failure to comply with reporting obligations may incur the administrative, criminal and civil penalties described in question 3.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

The law does not set out any protection from public disclosure of commercially sensitive information that has been notified to authorities. Nevertheless, the supplier may inform the public authorities of which information is commercially sensitive, and request them not to disclose the sensitive information.

11 May information notified to the authorities be used in a criminal prosecution?

Yes. There is no rule that prevents authorities from using the information in a criminal prosecution.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

The criteria for determining when a matter requires product recall or other corrective actions are described in question 5.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

The requirements for determining when a matter requires product recall or other corrective actions are described in question 4.

14 Are there requirements or guidelines for the content of recall notices?

The supplier, beyond the notification to competent authorities, must immediately inform consumers about the dangers of the product and service placed in the market by publicity releases. The publicity releases should provide clear and accurate information about:

- the product or service, to the extent necessary for its identification;
- the defect verified, its risks and implications;
- the preventive and corrective measures that consumers must take;
- the measures to be taken by the provider;
- contact information and place of consumer service;
- information on the free-of-charge condition of the recall; and
- other information intended to protect the safety of consumers with regard to the product or service concerned.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The supplier should communicate the fact forthwith by publicity releases to the competent authorities and to consumers. The publicity releases should be divulged in the press, on radio and television, at the expense of the supplier of the product or service.

The supplier may use direct and individual communication to consumers, along with publicity releases. Nevertheless, such individual communications will not release the supplier from making collective announcements.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

Yes. The supplier has to prepare a plan to deal with consumers that should be notified to the authorities and contain the following:

- the service channels available to consumers;
- the places and times of service;
- the average duration of services; and
- the contingency plan and estimated period for full remedy of all products or services concerned.

The supplier will also have to send to the competent authorities periodical recall status reports stating the quantity of products or services repaired or withheld from the market. A final recall status report shall also be sent to the authorities, stating the number and percentage of consumers affected, in an overall manner and per federative unit, as well as the reasons and measures to be adopted vis-à-vis the percentage of products or services not withheld or repaired.

Based on these reports, the DPDC and the regulatory authority may establish, separately or cumulatively, an extension or expansion of recall measures, at the supplier's expense, upon evidence that recall results were unsatisfactory.

The termination of the period for the recall does not prevent the supplier from the correction or replacement of the defective product or service. The supplier will be obliged to repair or replace the product or service, without any cost to the consumer, as long as the product is on the market.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

The supplier is obliged to repair and replace recalled products or services without any costs to consumers. In the event the correction or replacement of the defective product is impossible, the supplier must reimburse consumers.

In addition, the supplier may have to offer additional compensation where the consumers prove that they suffered further property or moral damages from the use of the defective product or service.

18 What are the penalties for failure to undertake a recall or other corrective actions?

Failure to comply with reporting obligations may incur the administrative, criminal and civil penalties described in question 3.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

The competent authorities can serve notice to suppliers to provide information on defective products or services and request the start of the recall campaign. Any supplier that does not carry out a recall, does so insufficiently or does so outside of the time limit set by the law, may be subject to administrative procedure started by the competent authorities for application of the administrative penalties described in question 3, without prejudice to civil and penal sanctions.

As a rule, the supplier is responsible for establishing the actions to be taken to repair or replace defective products or services that are extremely harmful or dangerous to consumers. Once the corrective actions are defined, they have to be notified to the competent authorities.

20 Can the government authorities publish warnings or other information to users or suppliers?

Yes. Article 10, paragraph 3 of the CDC says that: 'Whenever the federal government, states, Federal District and municipalities learn that products or services are hazardous to the health or safety of consumers, they shall inform consumers of the matter.'

Some regulatory authorities and public authorities for the protection of consumers (such as the DPDC and Procons) have communication channels on their websites or offer a telephone number so that the public can report incidents regarding products or services. Generally, whenever an incident is reported, the competent authorities start an administrative procedure in order to investigate the causes of the incident and ask the supplier to provide clarifications.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

The law does not provide for this possibility. As a rule, the recall must be carried out by the supplier.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

The law provides that recall expenses are the full responsibility of the supplier. The supplier will have to bear the expenses for recall even if the authorities order the extension of the period or scope of the recall. Therefore, if government authorities incur any expenses in relation to the product recalls, they may request recovery of the expenses.

23 How may decisions of the authorities be challenged?

The authorities' decisions may be challenged by administrative appeal, whenever possible, or by the filing of a lawsuit before the judiciary. Article 5, XXXV of the federal Constitution sets out that 'the law shall not exclude from review by the judiciary injury or threat to a right'.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

Yes. Publication of safety warnings and product recalls are likely to be viewed by the civil courts as an admission of liability for defective products.

The supplier may be held liable for the incidents suffered by consumers in connection with a defective product before, during or after the recall. While there are products on the market that have problems that led to the call, the supplier will be responsible for prompt repair, at no cost to consumers, even if the recall campaign stipulates a deadline for its closure.

The Third Panel of the Superior Court of Justice has already maintained the lower court of appeals' decision that considered, among other peculiarities of a particular case, that the supplier should be held liable because it publicly recognised a product defect by promoting a recall (Special Appeal 1.010.392-RJ, Reporting Justice Minister Humberto Gomes de Barros). In this decision, the Superior Court also understood that non-compliance with the recall by the consumer does not remove the liability from the supplier.

In the CDC system, the liability is strict (regardless of culpability) as a rule. There is no relevance whether it comes out of a contractual or non-contractual relationship. As a general rule, the consumer may file an action against all those involved in the chain of production. Those who are not directly responsible will have right of recourse against the responsible party. Only under specific foreseen situations in the law will the supplier not be held liable.

According to the CDC, there are two types of liability in connection with defective products: liability from the product itself, and liability related to a flaw in the product's quality or quantity.

The first type of liability is related to the idea of a consumption accident. The consumption accident takes place when the deviation goes beyond the defective product and reaches consumers physically or psychologically, affecting their health and safety.

The supplier may not be held liable for the accident of consumption only when it shows that it did not place the product on the market, that, although it did place the product on the market, the defect does not exist, or there is exclusive culpability of the consumer or a third party separate from the chain of production.

The supplier may also not be held liable if it can prove that the defectiveness of the product and scope of the recall was not the direct cause of the property or moral damages suffered by the consumer, and being considered by Brazilian courts.

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The responsibility of the supplier for damages caused by defective products may also be completely excluded if the supplier can show that it succeeded in repairing or replacing 100 per cent of the defective products by means of the recall.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Yes. Communications, internal reports, investigations into defects or planned corrective actions can be disclosed through court discovery processes to claimants in product liability actions.

According to the Brazilian Civil Procedure Code, the judge, ex officio or at the request of a party, will stipulate the evidence required for judgment on the merits. Thus, the judge can order that the party of the action or a third party (ie, person separate from the proceeding) must disclose the document in its possession. The document must be individualised and relevant for the discovery procedure.

As general rule, the party or third party cannot refuse to present the document, except in specific situations, such as:

- the disclosure may result in the publication of facts that they should keep confidential, in the line of duty or under the work-product doctrine;
- there are other serious reasons which, at the discretion of the judge, would justify the refusal to disclose; and
- there is a legal provision justifying the refusal to disclose.

If the person refuses to present the document without any lawful reason and is a party to the action, the judge will hold as true the facts which the party sought to prove by means of the document.

In the event the document is presented to the judge, it will be attached to the action case records and, as a rule, anyone will be able to analyse it. This is so because the Brazilian Federal Constitution says that all procedural acts must be public. Nevertheless, the judge will apply secrecy in any actions whenever the public or social interest would so require.

China

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

The PRC Product Quality Law
The PRC Product Quality Law was promulgated by the Standing Committee of the PRC National People's Congress on 2 February 1993, to commence operation on 1 September 1993 and was amended by it on 8 July 2000 and 27 August 2009. Products mentioned in the law include products processed and manufactured for the purpose of marketing, except for military products. According to the provisions of the law, producers and sellers are responsible for product quality.

Obligations of producers
Producers will be responsible for the quality of the products they produce. Products should meet the following requirements:

- products will be free from any unexpected dangers threatening the safety of people and property (if there are state standards or trade standards for ensuring the health and safety of lives and property, the products should conform to such standards);
- products will have the property they are stated to have, except for cases in which there are explanations about defects in the properties of the products; and
- products will tally with the standards prescribed or specified on the packaging and with the quality specified in the instructions for use or shown in samples.

Further, the marks on the products or the packaging should be accurate and include a certificate of quality inspection. For products that have a time limit for use, a date of production, a period for safe use or the date of the product becoming ineffective should be specified clearly in a conspicuous position on the product. Products that may cause harm to persons or injure the safety of persons and property because of improper use should carry warning marks or warnings written in Chinese. For products that are easily broken, inflammable, explosive, toxic, corrosive or radioactive and products that cannot be handled upside down in the process of storage or transportation or for which there are other special requirements, the package thereof should meet the corresponding requirements, carry warning marks or warnings written in Chinese or guidelines for handling.

Obligations of sellers
Sellers should implement the system of examination and acceptance of goods procured, verifying the product quality certificates and other marks and should adopt measures to maintain the quality of products for sale.

Sellers should not:

- sell any product that has been withdrawn by order of the state and thereby prohibited from being sold, or products that have expired or deteriorated;
- falsify the place of origin or falsify or use the names and addresses of other producers;
- falsify or use quality marks such as certification marks and fine quality marks; and
- adulterate the products for sale, or present fake ones as genuine or shoddy ones as good or substandard ones as standard.

The PRC Law on Protection of Consumer Rights and Interests (2013 Amendment)
The PRC Law on Protection of Consumer Rights and Interests was promulgated by the Standing Committee of the PRC National People's Congress on 31 October 1993, commencing operation on 1 January 1994. The law was amended on 25 October 2013.

The law stipulates the rights of consumers and the obligations of business operators related to product safety.

Rights of consumers
Consumers will, when purchasing and using commodities or receiving services, enjoy the right of the inviolability of the safety of their person and property. Consumers should have the right to demand that business operators supply commodities and services up to the required standards of personal and property safety.

Obligations of business operators
Business operators should guarantee that the commodities and services they supply meet the requirements for personal or property safety. As to commodities and services liable to harm persons or property, business operators shall give the consumers accurate explanations and clear warnings, and shall explain or indicate the correct ways of using the commodities or receiving services as well as the methods of preventing damage.

Business operators should, upon discovery of defects of the commodities or services they supply that are liable to cause harm to persons or property, immediately report to the administrative departments concerned, inform consumers, stop production and sales, and adopt measures, such as alert, recall, harmless treatment and destruction, to prevent damage. Where recall measures are taken, the operators will be liable for the consumer's necessary expenses caused by commodity recalls.

The PRC Tort Law
The PRC Tort Law was issued by the Standing Committee of the National People's Congress on 26 December 2009, commencing operation on 1 July 2010.

According to the provisions of the law, manufacturers, sellers and third parties such as carriers or warehouse operators are responsible for various aspects of product quality.

Obligations of manufacturers are:

- where a defective product causes any harm to another person, the manufacturer shall assume liability under tort law; and
- where any defect of a product is found after the product is put into circulation, the manufacturer should take such remedial measures as warning consumers or carrying out a recall operation in a timely manner. The manufacturer who fails to take remedial measures in a timely manner, or take sufficient and effective measures, and has caused any harm will have liability under the tort law.

The obligations of sellers are:

- where a product with any defect caused by the fault of a seller causes any harm to another person, the seller shall assume the tort liability;

- where a seller can neither specify the manufacturer of a defective product nor specify the supplier of the defective product, the seller shall assume the tort liability; and
- where any defect of a product is found after the product is put into circulation, the seller should take such remedial measures as warning and recall in a timely manner. The seller who fails to take remedial measures in a timely manner or take sufficient and effective measures and has caused any harm shall assume the tort liability.

The obligations of third parties are:
- where any harm is caused to another person by a defective product and the defect is caused by the fault of a third party, such as carrier or warehouse worker, the manufacturer or seller of the product that has paid the compensation should be entitled to be reimbursed by the third party.

Rights of the victim are:
- where any harm is caused by a defective product, the victim may require compensation to be made by the manufacturer of the product or the seller of the product;
- where the defect of a product endangers the personal or property safety of another person, the victim shall be entitled to require the manufacturer or seller to assume the tort liabilities by removing the obstruction or eliminating the danger; and
- where a manufacturer or seller, knowing of any defect in a product, continues to manufacture or sell the product and the defect causes a death or any serious damage to the health of another person, the victim shall be entitled to require the corresponding punitive compensation.

Besides the three basic laws above, there are regulations in effect in China related to the recall of specific product categories, such as automotive products, medical drugs, medical devices, food, children's toys and railway equipment. These are:
- Regulations on the Administration of Recalls of Defective Automotive Products (Decree No. 626 of State Council, promulgated by it on 22 October 2012 and commencing operation on 1 January 2013);
- Measures for the Implementation of the Regulation on the Administration of the Recall of Defective Auto Products (Decree No. 176 of General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), promulgated by it on 27 November 2015 and commencing operation on 1 January 2016);
- Administrative Measures for Drug Recalls (Decree No. 29 of the State Food and Drug Administration (SFDA), promulgated by it and commencing operation on 10 December 2007);
- Administrative Measures for Medical Device Recalls (Decree No. 29 of SFDA, promulgated by it on 25 January 2017 and commencing operation on 1 May 2017);
- Provisions on the Administration of Food Recall (Decree No. 98 of SFDA, promulgated by it and commencing operation on 27 August 2007);
- Administrative Measures for Food Recalls (Decree No. 12 of the State Food and Drug Administration, promulgated by it and commencing operation on 11 March 2015);
- Provisions on the Administration of Children's Toy Recalls (Decree No. 101 of General Administration of Quality Supervision, Inspection and Quarantine, promulgated by it and commencing operation on 27 August 2007); and
- Measures for the Administration of Recall of Defective Railway Special Equipment (Decree No. 23 of the Ministry of Transport, promulgated by it on 11 November 2015 and commencing operation on 1 January 2016).

On 21 October 2015, the AQSIQ issued the Measures for the Administration of the Recall of Defective Consumer Goods, which commenced operation on 1 January 2016. Nine types of electronics and 11 children's products that are manufactured in China or imported into China and then sold in China are covered by the measures. If any other consumer goods that have not been listed in the catalogue need to be recalled, the measures may apply. The measures do not apply to tobacco and tobacco products, motor vehicle products, civilian aircraft, civilian vessels, food, pharmaceuticals, cosmetics, medical instrument products, pesticide products and other products specifically provided by laws or regulations.

On 22 March 2018, the original AQSIQ (which has been incorporated into the newly created State Administration for Market Regulation, under the 2018 institutional reforms delivered by the State Council) issued the Rules on Recall of Defective Imported Consumer Goods which commenced operation on the same day. Under these new Rules, importers are responsible for the recall of defective consumer goods imported by them when recall responsibilities are triggered.

Further, China has been enacting the administrative regulations for defective product recalls, implementation regulations of the Law on Protection of Consumer Rights and Interests, and provisions on the administration of household appliance product recalls – the three drafts have been published for public consultation, but the formal versions have not yet been issued.

According to the finalised draft of the Implementing Regulations of the Law on Protection of Consumer Rights and Interests issued by the State Council on 16 November 2016, provisions have been included as regards mandatory obligations for the recall of detective products by operators, producers and importers. The inclusion of these provisions in these implementing regulations, illustrates the importance of this area to the Chinese government.

2 What requirements exist for the traceability of products to facilitate recalls?

According to the Regulations on the Administration of Recalls of Defective Automotive Products and the Implementation Measures, producers should establish and maintain records on the design, manufacturing, labelling, inspection and other aspects of automotive products:
- relevant documents on the design, manufacturing, labelling and inspection of automotive products and relevant quality control information;
- information on the manufacturers of the safety-related parts of automotive products and the design, manufacturing and inspection of automotive parts; and
- information on the production batches of automotive products and information on technical changes.

Producers should also preserve the names, valid certificate numbers, contact addresses, telephone numbers, purchase dates, vehicle identification codes and other information on car owners concerned in the initial sale of automotive products. These records should be maintained for not less than 10 years.

Producers should file the following information with the product quality supervision department of the State Council for their records:
- the basic information about the producer;
- information about automotive products, technical parameters and information about the initial owner of automotive products;
- information as to repair, replacement or return owing to faults in the automotive products that endanger personal and property safety;
- information on recalls implemented outside China;
- technical service notification and announcements; and
- other information required by the product quality supervision department of the State Council.

The information filed by producers should be updated within 20 working days if there are any changes.

Operators selling, renting and repairing automotive products must establish and maintain records on the models, specifications, vehicle identification numbers, quantity, whereabouts, purchasers, leasing and repair, among others, of the automotive products they deal in, and the records must be maintained for not less than five years.

According to the Administrative Measures for Drug Recalls, drug producing enterprises, management enterprises and the entities using such drugs must establish and maintain complete records of sales to ensure the traceability of drug sales.

According to the regulations for food recall, food producers must accurately record and store the information about raw and supplementary materials procurement, production and processing, storage and transport, sales and product identification, among others, in the production chain, and retain records on consumer complaints, incidents

of food-borne diseases and food contamination incidents, as well as archives about the disputes over food hazards.

According to the Provisions on the Administration of Children's Toy Recalls, producers must strengthen children's toy production and sales information management and establish and perfect the relevant information files. Sellers must improve information management for the stock and sale of children's toys and properly keep files of consumer complaints.

3 What penalties may be imposed for non-compliance with these laws?

According to the above basic laws, an enterprise producing or selling products that do not conform to the state standard or the specific trade standard for ensuring physical health and safety of persons and property will be:

- ordered to stop production and sale;
- the products illegally produced and sold will be confiscated;
- a fine of up to three times the value of the products illegally produced or sold will be imposed upon the producer or seller;
- where there are illegal proceeds, such proceeds will be confiscated; and
- if the circumstances are serious, the business licence will be revoked.

These are administrative penalties. If the case is serious enough to constitute a crime, criminal responsibility will be investigated.

According to the Measures for the Administration of the Recall of Defective Consumer Goods, the producers who carried out recall of defective consumer goods as required are not exempted from liability.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

The Regulations on the Administration of Recalls of Defective Automotive Products and the Implementation Measures require the dealers and automotive product part manufacturers to report to the AQSIQ information on potential defects in automotive products of which they have been informed, and notify the manufacturers. In addition, the producers informed of the potentially existing defects in automotive products must immediately organise investigation and analysis, and truthfully report the results to the AQSIQ.

According to the Administrative Measures for Drug Recalls, a drug management enterprise or entity using drugs that finds a potential safety hazard with the drug it is selling or using must promptly stop selling or using the drug, notify the drug producing enterprise or supplier, and notify the pharmaceutical supervisory and administrative departments.

According to the Administrative Measures for Medical Device Recalls, medical device operators and users, finding that medical devices they are selling or using may be defective, should report such findings to their local SFDA department. Those users which are also medical institutes should also report their findings to their local health supervision departments. Medical device producers should report any medical device adverse event information collected by them to their local SFDA. Further, agents designated by an overseas manufacturer of imported medical devices in China are required to promptly report relevant information regarding the recall of medical devices that are only carried out outside China to the SFDA.

According to the Provisions on the Administration of Food Recall, food producers must promptly notify the provincial or municipal qualitative inspection authority about information concerning food safety hazards, including consumer complaints and events related to food safety hazards, and must not conceal or attempt to falsify the facts concerning their food that endangers human health.

According to the Provisions on the Administration of Children's Toy Recalls, producers must notify information including consumer complaints, product injury accidents, product damage disputes and product recalls abroad to the quality and technical supervision authority.

According to the Measures for the Administration of the Recall of Defective Consumer Goods, the manufacturers or importers shall also report to the AQSIQ information on the product recall implemented outside China.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

For automotive products, under the following circumstances, notification is required if:

- the manufacturer confirms that some defect exists in its automotive products;
- the seller, leaseholder or repairer finds some defect exists in the automotive products; or
- the seller, leaseholder or repairer receives consumer complaints that some defect exists in the automotive products.

The manufacturer must notify product defects within five working days from the defect being confirmed.

Further, according to the Measures for the Administration of the Recall of Defective Consumer Goods, the AQSIQ will strengthen the building of the expert database for the recall of consumer goods, select national product quality inspection institutions and laboratories with statutory qualifications to provide technical support for the administration of the recall of consumer goods.

6 To which authority should notification be sent? Does this vary according to the product in question?

For general products, including food, drugs and medical instruments, the notification should be sent to the State Administration for Market Regulation (which includes the former AQSIQ and SFDA). For railway special equipment, the notification should be sent to the national railway bureau, under the Ministry of Transport.

7 What product information and other data should be provided in the notification to the competent authority?

Automotive product manufacturers need to complete a report detailing:

- information on the manufacturer:
  - name of enterprise;
  - enterprise address, email address, telephone number, fax number and website; and
  - contact telephone number, fax number and email address;
- information on the recalled vehicle:
  - brand;
  - vehicle model;
  - design;
  - model number;
  - production dates;
  - VINs affected;
  - engine numbers affected;
  - vehicle frame numbers affected;
  - vehicle type;
  - shape of vehicle body; and
  - photograph;
- characteristic information of the defective vehicle model:
  - number of recalls and the total sales of this vehicle model;
  - production year and vehicle model information of the vehicle involved in the recall; and
  - total number of potential vehicle recalls;
- description of the defect:
  - system the defect belongs to and its location;
  - causes of the defect;
  - potential results caused by the defect, and explanation of potential hazards and their severity;
  - warning information from vehicles before and when the defect occurs, such as abnormal alarms and warning lights;
  - if the defective parts were bought from another manufacturer, the details of the manufacturer (name, address, contact method, etc) and its manager or legal representative;
  - summary of defect, including, without limitation, number of defect reports, accidents, casualties and claims made; and
  - date or report of defect evaluation (attached if necessary);
- description of defect analysis:
  - manufacturer's methods of defect elimination (attached if necessary);

- main differences between the parts used to repair and the recalled parts;
- how and when the defect of the products involved in the recall was corrected in the course of production; and
- schedule of recall illustrating the schedule of recall and potential problems during the implementation of the recall.

Sellers, leaseholders and repairers of automotive products need to complete the following report:

- information on the seller, leaseholder or repairer:
  - name of enterprise;
  - enterprise address, email address, telephone number, fax number and website; and
  - contact telephone number, fax number and email address;
- information on the vehicle:
  - brand;
  - vehicle model;
  - design;
  - model number;
  - vehicle type; and
  - shape of vehicle body;
- characteristic information of the defective vehicle:
  - production date;
  - VIN code;
  - engine number; and
  - frame number;
- description of the defect:
  - system the defect belongs to and its location;
  - causes of the defect;
  - results caused by the defect, number of defective vehicles, accidents, casualties, explanation of potential unreasonable hazards and their severity; and
  - warning information from vehicles before and when the defect occurs, such as abnormal alarms and warning lights.

Drug quality problems and adverse drug reactions should be provided in the notification to the competent authority, according to the Administrative Measures for Drug Recalls. Details are not listed in the Measures though.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

According to the Regulations on the Administration of Recalls of Defective Automotive Products and the Implementation Measures, where a manufacturer becomes aware of any potential defects in its automotive products, it should immediately organise investigation and analysis, and report the investigation and analysis results to the AQSIQ, and where the AQSIQ carries out a defect investigation, the manufacturer should cooperate with the defect investigation by providing relevant information, products and special equipment that are necessary for the investigation. Operators and automotive product part manufacturers should report to the AQSIQ information on potential defects in automotive products which they have been informed of, and notify the manufacturers.

According to the Administrative Measures for Drug Recalls, when pharmaceutical supervisory and administrative departments investigate potential drug safety hazards, the drug manufacturers must provide assistance. Drug-handling enterprises and the entities using the drug must cooperate with the investigation by the manufacturers or the pharmaceutical supervisory and administrative departments related to drug safety hazards, and provide relevant materials.

According to the Administrative Measures for Medical Device Recalls, any medical device operators or users that fail to perform their reporting obligations will be fined between 5,000 and 30,000 yuan; if serious consequences result, relevant Medical Device Business Licences can be withdrawn or cancelled.

According to the Provisions on the Administration of Food Recall, food producers and sellers must cooperate with investigations into food safety hazards organised by the provincial quality supervision departments, and must not refuse on the ground that the food passed any compliance examinations.

According to the Provisions on the Administration of Children's Toy Recalls, producers and sellers must cooperate with defect investigations organised by the provincial quality supervision departments, and provide relevant materials for the investigations.

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

According to the Regulations on the Administration of Recalls of Defective Automotive Products, the producers concealing the recall will be ordered again by the authority to correct. Those failing to correct will receive fines of 1 to 10 per cent of the value of the defective automotive products. Any illegal income will be confiscated and relevant operating licences will be cancelled by the authority issuing the licences in the most serious situations. Further, the producers or operators who do not cooperate with the defect investigations carried out by the product quality supervision department will be ordered to go through correction procedures. Those failing to correct will be given fines of between 500,000 to 1 million yuan. Any illegal income will be confiscated and any relevant licences can be cancelled in the most serious cases.

According to the Measures for the Implementation of the Regulation on the Administration of the Recall of Defective Auto Products, if the manufacturer did not file the investigation analysis results as required, nor fail to correct this within the given time limit, a fine of between 10,000 and 30,000 yuan will be imposed. And if the automotive part manufacturer did not cooperate with the defect investigation, or failed to correct this within the given time limit, a fine of between 10,000 and 30,000 yuan will also be imposed.

According to the Administrative Measures for Drug Recalls, if drug-handling enterprises or the entities using the drug fail to report a defect, they will be fined between 1,000 and 50,000 yuan. If serious consequences are caused, the licence-issuing department will withdraw such entity's drug supply certificate or other licence.

According to the Provisions on the Administration of Food Recall, if the food producer refuses to cooperate with an investigation of food safety hazards organised by the quality supervision departments, it will be warned and ordered to rectify the situation within a required time limit. If it fails to rectify the situation within such time limit, it will be fined up to 20,000 yuan.

According to the Provisions on the Administration of Children's Toy Recalls, if the producer refuses to cooperate with the defect investigations organised by the quality supervision departments, it will be warned and ordered to rectify the situation within a required time limit. If it fails to rectify the situation within such time limit, it will be fined up to 20,000 yuan.

In addition to the administrative penalties listed above, anyone violating the regulations and constituting a crime will be held criminally responsible.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

The Regulations on the Administration of Recalls of Defective Automotive Products state that if staff engaging in the supervision and management of defective automotive products carry out one of the following acts violating the Regulations, they will be punished:

- using the information, products and special equipment provided by producers or operators for a purpose other than technical inspection and identification necessary for defect investigation; and
- disclosing the parties' business secrets or personal information.

According to the Measures for the Administration of the Recall of Defective Consumer Goods, the AQSIQ should keep the information obtained from manufacturers and operators confidential, and shall not use such information for other purpose than technical detection and identification. AQSIQ officials who disclose business secrets or personal information shall be punished.

11 May information notified to the authorities be used in a criminal prosecution?

No provisions in product recall regulations stipulate that information notified to the authorities cannot be used in a criminal prosecution. According to China's constitutional principles, all entities and citizens

have an obligation to cooperate with the criminal investigation and relevant evidence collection. Thus, the conclusion is that information notified to the authorities may be used in a criminal prosecution.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

Automotive products
According to the Regulations on the Administration of Recalls of Defective Automotive Products and the Implementation Measures, when the defect exists in sold automotive products, the defective products must be recalled.

Definition of defect
Defect refers to a failure to comply with national standards or industry standards regarding security of personal and property safety that universally exist in the automotive products of some batch, model or category caused by design, manufacturing or labelling, and other unreasonable hazards endangering the safety of people and property.

Principles of judgement of defect of automotive products
A defect exists where:
- during usual operation there are situations that do not accord with the technical regulations and national criteria related to automotive safety, through examination by the inspection bodies;
- design or manufacturing defects have caused personal injury or property damage, to the vehicle owners or others; or
- defects might cause personal injury or property damage under certain conditions, through testing, experiments and in theory, although the defects have not caused personal injury or property damage to the vehicle owners or others.

Drugs
According to the Administrative Measures for Drug Recalls, when potential safety hazards exist in the drugs on sale, the defective drugs must be recalled.

Definition of potential safety hazard
A potential safety hazard refers to an unreasonable hazard related to drugs that endangers human health and safety of life because of research and development, and production.

Evaluation of potential safety hazard
In evaluating the harm that could be caused by a drug, the following can be taken into account:
- hazardous effects on the main users;
- hazardous effects on special users, especially high-risk groups, such as the elderly, children, pregnant women, persons with hepatic and renal dysfunction, surgical patients, among others;
- severity and emergency of the hazard; and
- results of the hazard.

Medical devices
According to the Administrative Measures for Medical Device Recalls, defective medical device products mainly include products that:
- may endanger human health and safety in normal use;
- do not meet the mandatory standards, or the registered technical requirements; and
- do not meet the relevant provisions on medical device quality management and lead to unreasonable risks.

Food
According to the Provisions on the Administration of Food Recall, unsafe food must be recalled.

Definition of unsafe food
Food that has caused or might cause hazards, including:
- food that is contaminated in some manner, food that has passed on disease or food that is hazardous to human health;
- food that includes ingredients that may cause health hazards to particular groups, but this is not marked on the food labels and instructions or is marked incompletely or unclearly; and
- other unsafe food stipulated by relevant laws and regulations.

Investigation of food safety hazards
Investigations into:
- whether the food meets the requirements of food safety laws, regulations or criteria;
- whether the food includes non-food ingredients, includes non-food chemicals or describes non-food as food;
- the type and number of the main consumers of such food; and
- the amount, batch or category of the food in which safety hazards exist, its distribution channels and how widely distributed the product is.

Evaluation of food safety hazards
Investigations into:
- food that is contaminated in some manner, food that has passed on disease or food that is hazardous to human health, or is potentially hazardous;
- the effects on the main consumers;
- the severity and emergency of the hazard; and
- short-term and long-term results of the hazard.

Children's toys
According to the Provisions on the Administration of Children's Toy Recalls, children's toys in which a defect exists must be recalled.

Definition of defect
Defect refers to unreasonable hazards that universally exist in the same batch, model or category of children's toys and endanger the safety of persons and property because of design, production or instructions.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Automotive products
According to the Regulations on the Administration of Recalls of Defective Automotive Products and the Implementation Measures, once the manufacturer confirms that a defect exists in its automotive products and decides to implement an initiative recall, it should:
- promptly make a recall plan and file it with the appropriate departments for records;
- promptly and effectively notify the importers, sellers, leaseholders, repairers and vehicle owners about the defect, potential damages and its prevention measures and recall plan;
- notify the sellers to stop selling the defective automotive products, and notify the importers to stop importing;
- set up hotline numbers, reply to enquiries and publish information about the defect on websites designated by the appropriate department for public search;
- make the recall notice, file it with the appropriate department, notify the sellers, leaseholders, repairers and vehicle owners and start to implement the recall plan within one month of the date of filing the report with the appropriate department; and
- file a final report with the appropriate department within one month of the completion of the recall.

Drugs
According to the Administrative Measures for Drug Recalls, once the drug producer decides to or is ordered to recall the defective drugs, it should:
- make a recall plan and organise implementation;
- notify the drug-handling enterprises – entities using the drug to stop selling and using within 24 hours (first grade recall), 48 hours (second grade recall) or 72 hours (third grade recall);
- file the investigation evaluation report and recall plan with the SFDA for records within one day (first grade recall), three days (second grade recall) or seven days (third grade recall) after starting the drug recall;
- report the progress of the drug recall to the SFDA within one day (first grade recall), three days (second grade recall) or seven days (third grade recall);

- make detailed records related to the disposal of recalled drugs and report it to the SFDA;
- destroy the drugs, which must be done under the supervision of the SFDA; and
- evaluate the effect of recall, and file a final report to the SFDA after completing the recall.

Medical devices

According to the Administrative Measures for Medical Device Recalls, once a medical device is determined to be defective after investigation and evaluation, the producer should:

- immediately decide to implement a recall and issue product recall information to the community;
- notify operators and users within one day (first grade recall), three days (second grade recall) or seven days (third grade recall), once a product recall decision is made;
- immediately file a report as to a medical device recall event with its local SFDA and then file an investigation and evaluation report and the recall plan, within five working days;
- amend recall plans as required by the SFDA, arrange for the implementation of them and regularly report the implementation to the SFDA as per the recall plan;
- make detailed records related to the disposal of recalled medical devices and report to the SFDA; and
- evaluate the effects of a recall action within 10 working days of completion of the recall, and file a final report with the SFDA.

Food

According to the Provisions on the Administration of Food Recall, when food is confirmed to be unsafe food that should be recalled, the food producer should:

- promptly stop producing and selling the unsafe food;
- notify the sellers to stop selling and consumers to stop buying within one day (first grade recall), two days (second grade recall) or three days (third grade recall);
- file a food recall plan with the quality supervision department within one day (first grade recall), two days (second grade recall) or three days (third grade recall);
- file a periodic progress report related to the food recall with the quality supervision department every three days (first grade recall), seven days (second grade recall) or 15 days (third grade recall);
- keep recall records, including batch numbers, amounts, portions, reasons and results of the food recall;
- file a final report with the quality supervision department within 15 days from the due day of the food recall;
- promptly implement non-toxic processing of the unsafe food, and destroy the food that should be destroyed; and
- keep detailed records related to the processing of the recalled food.

Children's toys

According to the Provisions on the Administration of Children's Toy Recalls, when children's toys are confirmed to be defective, the producer should:

- promptly stop producing and selling the defective toys;
- announce the defect in the toys to the public;
- notify sellers to stop selling and consumers to stop buying;
- file a recall plan with the quality supervision department for records; and
- file a final report with the quality supervision department within 15 days of the due date of the recall.

14 Are there requirements or guidelines for the content of recall notices?

The recall notices should include the existing defects, emergency methods to avoid harm and the measures taken by the manufacturer to eliminate the defects.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The producers implementing the recall should publish information 'in a way that is convenient for the public' and inform the owners of automotive products with defects, for emergency disposal methods', and measures taken by producers to eliminate defects, through newspapers, websites, broadcasts and TV, within five working days of filing the recall plan with the authorities. They should also accept public consultation through the hotline and network platform.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

No, there are no PRC laws, regulations or guidelines specifying targets or a period after which a recall is deemed to be satisfactory. In practice, the recalling enterprise sets targets in the recall plan, which needs to be approved by the competent authority.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

The regulations related to product recalls do not stipulate specific measures for recalls. In practice, they are included in the recall plan set up by the recalling enterprise, and need to be approved by the competent authority.

However, according to the PRC Product Quality Law, producers will be responsible for compensating people for damage caused by defects, which means that the producer must offer compensation if the product defects cause personal or property damage. The compensation includes the following:

- if bodily injury is caused by the defect, the party responsible shall pay for medical expenses and nursing expenses during medical treatment and the lost income because of absence from work;
- if the bodily injury has resulted in disability, the party responsible will also be responsible for the expenses for self-supporting equipment, living allowances, compensation of the disabled person and the living expenses necessary for those being supported by the disabled person;
- if death has resulted, the party responsible will pay the funeral expenses, compensation and the living expenses necessary for those who had been supported by the victim;
- if the product defect causes damage to property, the party will be responsible for restoration or compensation; and
- if victims sustain other major losses, the party responsible must compensate the losses.

18 What are the penalties for failure to undertake a recall or other corrective actions?

According to the Regulations on the Administration of Recalls of Defective Automotive Products, producers that fail to implement the recall as per the recorded recall plan will be ordered by the authority to take corrective action. Those failing to correct will receive fines of between 500,000 and 1 million yuan. Any illegal income will be confiscated and relevant licences may be cancelled by the authority issuing the licences in the more serious cases. The regulations also state that producers refusing to recall after being ordered to do so will be ordered again by the authority to correct this. Those failing to correct this will receive fines of between 1 and 10 per cent of the value of the defective automotive products. Any illegal income may be confiscated and relevant licences may be cancelled by the authority issuing the licences in the most serious cases.

According to the Administrative Measures for Drug Recalls, if the drug producer finds potential safety hazards associated with the drug but does not recall the drug actively, it will be ordered to recall the drug, and be fined triple the value of the drug that should be recalled; if severe results are caused, the department that issued the drug approval will withdraw the certificates of approval of the drug and may even withdraw the producer's drug manufacturing certificate. If the drug manufacturer refuses to recall the drug when the relevant authority orders it to do so, it will be fined three times the value of the drug that should be recalled; if severe results are caused, the department that issued the drug approval will withdraw the certificates of approval of the drug, and may even withdraw the producer's drug manufacturing certificate.

According to the Administrative Measures for Medical Device Recalls, if a medical device producer refuses to undertake a recall, the SFDA must instruct the party concerned to make a correction and confiscate the medical devices illegally manufactured, operated or used. If the value of the medical devices illegally manufactured, operated or used is less than 10,000 yuan, a fine of between 20,000 and 50,000 yuan can be imposed; if the value is more than 10,000 yuan, a fine of

more than five times but less than 10 times the value can be imposed; in serious cases, production can be ordered to be ceased and business licences may be withdrawn or cancelled.

According to the Provisions on the Administration of Food Recall, if a food producer fails to undertake a recall, it will be given a warning and ordered to correct the issue within a specific time limit; if it does not correct the issue within the required time limit, it will be fined up to 30,000 yuan.

According to the Provisions on the Administration of Children's Toy Recalls, if the manufacturer fails to undertake a recall, it will be fined up to 30,000 yuan.

According to Tort Law of the People's Republic of China, if any product defect is found after the product is put into circulation, the manufacturer or seller must issue a warning and recall it in a timely manner. If the manufacturer or seller fails to take remedial measures in a timely manner and has caused any harm, the manufacturer or seller can be liable under the tort law.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

The authorities (the State Administration for Market Regulation and other relevant departments) are entitled to send the manufacturers a notification on a compulsory recall, notifying the manufacturer to recall designated products and requiring it to submit a recall plan within a time limit.

The detailed product recall action plan needs to be drafted by the manufacturers as mentioned above and then to be amended as per the advice given by the authorities until it is approved by them. The authorities are also entitled to enter the production and business place of the producers and operators for on-site investigation, to check and copy relevant information and records, and to gain an understanding of the potential defects existing in products from relevant entities and individuals.

Further, the certification authority is entitled to suspend or return the certificate for compulsory certification of products, and customs is entitled to stop going through import declaration procedures for defective products produced outside China's borders.

20 Can the government authorities publish warnings or other information to users or suppliers?

According to the Measures for the Administration of the Recall of Defective Consumer Goods, where the AQSIQ determines there is a high risk that certain consumer goods are defective, and might cause serious personal injury or property damage, according to the defective information analyse and evaluation results, but the recall cannot be carried out as per the measures, owing to uncertainty about their origin or de-registration of their manufacturers, the AQSIQ will issue a consumption warning.

According to the Provisions on the Administration of Food Recall, the SFDA may publish food safety information and consumption warning information under the following circumstances or take other actions to avoid damage:

- the food producer concealed food safety hazards deliberately, or it should have recalled but did not;
- food safety hazards are extended or repeated owing to the faults of the food producer; and
- potential safety hazards are found in food that may cause harm to human health and safety, during administrative supervision or selective examination.

In China, the authorities usually accept claims or complaints by phone, email or mail – usually the claims or complaints are not made public before investigation and verification though, so as to avoid confusion.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Government authorities usually do not organise a product recall by themselves; they instead guide, coordinate and supervise the recall, while the recall is actually carried out by the producer.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

According to the Regulations on the Administration of Recalls of Defective Automotive Products, producers should bear the costs for eliminating defects and all necessary costs for transporting defective automotive products.

Other regulations do not refer to the cost issues.

23 How may decisions of the authorities be challenged?

Producers denying the products are defective may file an opposition with the AQSIQ within 15 working days from receipt of a notice requiring recall from the AQSIQ, and provide evidence. The AQSIQ will organise the experts who are not related to the producer to demonstrate the evidence, and carry out technical detection or identification to the products if necessary.

Further, if the producer considers that its lawful rights and interests have been infringed by the authorities or their personnel, they can file a complaint with the higher authorities, or appeal to the court, according to the PRC Administrative Reconsideration Law and Administrative Procedure Law.

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Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

Theoretically, yes. According to the Measures for the Administration of the Recall of Defective Consumer Goods, the recall actions implemented by producers will not exempt them from liability to pay compensation if the defective product causes actual damages to consumers.

When a product is recalled, consumers will not need to prove the defect existed in the product through tests, but just need to prove the facts of damage caused by the defective product, which accords with the legal principle that consumers should be given more protection.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Theoretically yes, if the court discovery processes are started. According to the Provisions of the Supreme Court on Evidence in Civil Procedures, if the necessary evidence refers to commercial secrets or the party is not able to collect such evidence by itself, the party can apply to the court for evidence collection by the court. Also, according to the PRC Civil Procedure Law, refusing or obstructing a court investigation or obstructing the collection of evidence may lead to the court not only ordering the relevant entity to perform its obligation but also imposing a fine on said entity.

Whether it is necessary for the court to approve the application and start the processes depends on the court itself.

Colombia

Daniel Arango and Mauricio Moreno
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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

The basic laws governing the safety requirements that products must meet are:

- Law 9/1979 (Sanitary Measures Statute – SMS), which contains the general rules and principles mainly governing products that might entail significant health risks, such as food, medical and cosmetic products; and
- Law 1480/2011 (Consumer Protection Statute – CPS), which contains the general rules and principles governing consumer's safety. According to the CPS, an 'unsafe or defective product' is one which does not offer the reasonable safety standard that any person is entitled to, due to the product's design, manufacturing, construction, packaging or information. A product that does not meet the safety requirements stablished in technical and sanitary regulations is legally presumed unsafe.

Specific rules and requirements are usually adopted through technical and sanitary regulations issued by different government agencies – mainly ministries and sometimes superintendencies – depending on the nature of the product. Most of those requirements are compiled and monitored by the two main supervisory agencies on product safety: the National Institute for Medicine and Food Surveillance (INVIMA) and the Superintency of Industry and Commerce (SIC).

2 What requirements exist for the traceability of products to facilitate recalls?

There are no prior requirements for the traceability of general products, although the notification to the SIC of defects discovered in products must include the product reference and lot number, date of import or production and, if possible, dates and places in which the product was available for sale and number of defective units. Therefore, keeping track of this data might facilitate a potential notification and recall plan.

3 What penalties may be imposed for non-compliance with these laws?

Non-compliance with product safety laws may result in criminal, civil and administrative penalties.

Criminal penalties may be imposed for the sale or distribution of defective alimentary, medical or prophylactic products (article 372 Criminal Code). Criminal penalties range from fines (up to 1,500 monthly minimum wage – as of 2018, 1.171 billion pesos) to prison (up to 12 years). In any case, if the defective product damages someone's property or causes bodily injury or death, the person responsible for these criminal offences may be prosecuted according to the Criminal Code.

As for civil sanctions, the manufacturer and retailer are jointly and severally liable for bodily injury, death and material damages caused by defective products and for the failure to comply with the duty to notify the SIC of defects discovered in products manufactured or sold by them.

Government agencies, such as the SIC and the INVIMA, may also impose administrative penalties for the non-compliance with these laws and regulations, such as fines, temporary or permanent closure of commercial establishments, prohibitions to manufacture or sell certain products, order to destroy defective products, product confiscation, among others.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

Any member of the chain of production, distribution or retail who finds out that any kind of product manufactured, distributed or sold by them has a defect that may cause or has caused damages, must notify SIC as further described below (article 19, CPS and Decree 679/2016). In the case of medical products, INVIMA must also be notified (article 26, INVIMA Resolution 1403/2007). Notification to other government agencies might be required, depending on the product concerned.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

Notification is required whenever the defect may cause or has caused an incident with adversely affects the health, life or safety of people. Notification must be filed within the three calendar days after learning of the defect, which is deemed to have happened once the producer, distributor or retailer:

- has been informed by a consumer or any other member of the chain of production, distribution about the unreasonable risks that the product poses;
- learns that the product might not comply with any safety requirements established in technical and sanitary regulations;
- learns that the product does not offer the reasonable safety standard that any person is entitled to, due to the product's design, manufacturing, construction, packaging or information;
- learns that the product might pose a safety risk according to scientific or technical knowledge, or that the product does not comply with safety requirements established in international technical standards;
- learns of the existence of an investigation regarding the product defectiveness; or
- notifies other countries' authorities of the defects.

6 To which authority should notification be sent? Does this vary according to the product in question?

Regardless of the type of product, the SIC should always be notified (article 19, CPS and Decree 679/2016). In the case of medical products, the INVIMA must also be notified (article 26, INVIMA Resolution 1403/2007). Notification to other government agencies might be required, depending on the product concerned

7 What product information and other data should be provided in the notification to the competent authority?

The notification to the SIC should include:

- identification of the product by:
  - name under which the product has been marketed and sold;
  - type of product;
  - reference and lot number;
  - import and production date;
  - dates during which the product has been sold;

  - number of defective units; and
  - places where the product has been sold.
- picture of the product;
- a description of the action plan;
- a description of the defect and its risks;
- the number and description of reported damages or victims;
- the most relevant distributors and retailers of the product, along with contact information for their representatives;
- a description of the corrective actions that have been and will be taken; and
- the procedure designed to return the product and refund its price, as well as its expected results.

It should be noted that the SIC might request further information.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

There are no specific obligations to provide the SIC periodic updates after initial notification, although it is advisable to do so. SIC may request updates and ask for clarifications, which must be attended within their set deadlines, unless there are reasonable grounds to ask for extensions.

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

Although no criminal offences specifically referred to a failure to report, if the non-reported product causes damage to property, personal injuries or death, the person responsible for these criminal offences may be prosecuted according to the Criminal Code.

The CPS provides for a joint and several liability between those that fail to comply with reporting obligations and the manufacturer, for injuries and other damages caused by defective products.

The SIC may also impose administrative penalties for the non-compliance with these laws, such as fines, temporary or permanent closure of commercial establishments, prohibitions to manufacture or sell certain products, order to destroy defective products, product confiscation, among others.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

In general terms, any person can access administrative records and files, although sensitive information is protected from public access. It is advised to specify and mark commercially sensitive information and specifically request that measures be taken to prevent public disclosure.

11 May information notified to the authorities be used in a criminal prosecution?

There are no laws forbidding the use of the information notified to the authorities in criminal prosecution. Besides, any public authority that learns of a possible occurrence of a criminal offence must immediately report it to the competent authorities.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

There are no set criteria for determining whether a product recall is required or other corrective actions are sufficient. Any member of the chain of production, distribution or retail that finds out that any kind of product manufactured, distributed or sold by him or her has a defect that may cause or has caused adverse effects on health, life or safety of people must take 'appropriate measures' to prevent damages. Appropriateness might depend on the type of product and defect (eg, a lack of safety warnings or instructions may be corrected by publicising said warning or instructions, with no need for recall).

Additionally, the producer and importer should:

- suspend production and dispatch of the product until corrective measures are adopted;
- notify the distributors and retailers about the defect, request them to stop selling the product until corrective measures are adopted and direct them to isolate and mark the defective products within their control; and
- notify consumers about the defect by appropriate means.

Update and trends

The SIC has played an active role in reporting obligations and the implementation of recall or other action plans. Under its wide supervisory powers, the SIC will usually request information from manufacturers, distributors and retailers and check for its consistency, carry out unannounced inspections and follow up on the action plans. The SIC will usually require manufacturers, distributors and retailers to directly post their reports of defective product and action plans on the web portal launched in July 2017 (http://seguridadproducto.sic.gov.co).

Distributors and retailers must also:

- suspend distribution and sale of the product;
- request the producer and importer the information to be provided to the consumers; and
- notify the consumers about the defect and the action plan by appropriate means.

The producer must either destroy or repair the defects of the isolated and recalled products.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Distributors and retailers must try to establish direct contact with the users and inform them about the defect and the action plan. If such contact is not possible, a press release must be published in a media outlet with an intensity and frequency that is consistent with the sales volume, the number of consumers and the way in which the product was marketed.

In July 2017, the SIC launched a web portal to publish product warnings and action plans (http://seguridadproducto.sic.gov.co/). In the web portal, consumers can check reports of defective products, as well as the details of the recall or action plan implemented by manufacturers and sellers. Although there is no legal requirement for producers, importers, distributors and retailers to directly post their reports on the web portal, the SIC will usually require them to create an account and post any relevant information once a notification notice has been filed with the SIC.

As for the recall requirements, the producer or importer must design the procedure to recall and isolate the defective products, as well as bear the associated costs.

14 Are there requirements or guidelines for the content of recall notices?

Recall notices to the SIC, as well as any other preventive or corrective plan, must contain the information mentioned in question 7.

As for public recall notices, there are no specific requirements. The required information that should be uploaded to the web portal mentioned in question 13 contains:

- identification of the product;
- name under which the product was sold;
- type of product;
- identification of the producer, importer or brand used; and
- description of the defect and its associated risks.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

A 'suitable' media outlet must be used. Suitability is assessed considering the sales volume, the number of consumers and the way in which the product was marketed.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There are no targets or periods after which a recall is deemed to be satisfactory. However, the SIC may determine a desired result, set a deadline to achieve it and make recommendations to do so.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

The producer must either destroy or repair the defects of the isolated and recalled products. If the product is destroyed, the consumer may choose between a product replacement and a price refund.

18 What are the penalties for failure to undertake a recall or other corrective actions?

The penalties for failure to undertake a recall or other corrective actions are described in questions 3 and 9.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

The SIC has wide powers in product safety matters. Under the CPS, it may order any measure that is necessary to avoid consumer damages. The most usual compelling powers include successive fines, temporary closure of commercial establishments, as well as prohibitions to manufacture and distribute the product. Although the producer, importer, distributor or retailer has a certain flexibility to design the proposed action plan, the SIC might request further actions or specify how certain actions should be taken.

20 Can the government authorities publish warnings or other information to users or suppliers?

Both the SIC and the INVIMA can publish warnings to users and suppliers. In July 2017, SIC launched a web portal for the disclosure of product warnings and action plans (http://seguridadproducto.sic.gov.co/). The SIC must publish information about any reports on defective products and will usually direct producers, importers, distributors and retailers to do the same. Members of the public cannot directly post remarks or reports of incidents, but they can check reports of defective products, as well as the details of the recall or action plan implemented by manufacturers and sellers and request the SIC to take action.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

The SIC will initially compel producers, importers, distributors and retailers using the powers mentioned in question 19. Although under Colombian law there is no specific power to do so, if those powers are ineffective, the SIC can organise a product recall and implement other corrective actions under its wide powers and duties in product safety matters.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Under Colombian law, recall and other corrective actions expenses must be borne by the members of the production and distribution chain. Therefore, any reasonable costs incurred by the government authorities may be recovered from the party that fails to comply with product safety obligations.

23 How may decisions of the authorities be challenged?

The affected party may request the authority to reconsider its decision and file a judicial claim to annul it and compensate any damages arisen from the annulled decision. The judicial review complaint should be filed within four months of the date on which the decision was officially notified (or from the date that a motion to reconsider the decision was declined) and the claimant has the burden to argue and prove that the decision, its basis or its procedure violate constitutional or legal rules or principles.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

There are no specific evidentiary rules that consider or prohibit the publication of a safety warning or a product recall as an admission of liability for defective products. Publication of safety warnings and product recalls should be weighed and assessed by the courts along with all the relevant evidence to determine whether liability for defective products arises. It might be viewed as a piece of evidence of the existence of the defect, but the claimant would still be required to prove damages and causation.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Those kind of documents may be disclosed through court discovery processes in product liability actions, excluding the ones under professional secrecy, such as the lawyer-client privileged communications.

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

The main rules regarding product safety are found in the Product Safety Act, which implements EU General Product Safety Directive 2001/95 (Directive 95/2001 EC). The Product Safety Act applies to consumer products and products that under foreseeable circumstances could be used by consumers, although they might not be intended for them.

Further to this, the Danish Working Environment Act contains rules regarding the health and safety of workers as well as rules about products used in the work process.

The Danish rules on product liability are also relevant and can be found in the Product Liability Act and through principles developed in case law. Whereas the Product Liability Act only governs consumer products, the product liability developed through case law also governs commercial products and generally has a wider field of application, and these rules therefore work in tandem when it comes to establishing the basis of a claim for damages where a defective product has caused damage.

It is also possible to find numerous sector-specific rules regarding specific types of products. Many of these sector-specific rules stem from the EU and have been implemented in Denmark. Examples of such rules can be found within the areas of electrical products, food, drinks, cosmetics, toys, etc. However, it is important to note that unless otherwise stated, the rules regarding specific types of products are supplemented by the Product Safety Act.

2 What requirements exist for the traceability of products to facilitate recalls?

It is required that a manufacturer takes the necessary steps to avoid a product posing a danger to consumers, such as warning the consumer in an effective way, withdrawing or recalling a dangerous product. In taking such steps, the manufacturer may place relevant product information on the product or its packaging, including a reference number, product identity, the name and address of the manufacturer, etc. If the manufacturer can secure an effective recall in other ways without marking the products, this will be sufficient. From both a legal and commercial point of view, marking the products in a way that is sufficient to locate and identify a batch of defective products is always recommended since sufficient product identification combined with a procedure of locating the whereabouts of a defective batch of products can go a long way in limiting the number of people exposed to the risk of the defective products and the costs and efforts needed to ensure effective recall.

Manufacturers that have not produced the product themselves, for example, a representative in Denmark, must, when relevant, keep the documentation necessary to trace the product. This documentation must be kept during the expected lifetime of the product, although no longer than five years from the end of the financial year in which the product was marketed.

Distributors must also take part in the product supervision by supplying information to the manufacturer and the authorities about risks related to the product and by storing and supplying the documentation necessary to trace the product (eg, the date of purchase and the contact information of the seller involved in previous stages of sale and marketing). This information must be kept during the expected lifetime of the product, although no longer than five years from the acquisition by the distributor of the product.

Further to this, a number of sector-specific rules regarding the traceability of products exist. Examples of such sector-specific rules can be found within the areas of food, drinks and pharmaceuticals.

3 What penalties may be imposed for non-compliance with these laws?

Generally, non-compliance can be sanctioned in two ways. First, fines may be administratively imposed under the Product Safety Act. In order for fines to be imposed under the Product Safety Act, the act provides that for some offences breach of the rules must be intentional, while in other cases gross negligence or the mere existence of a breach is sufficient. Distributors and manufacturers do, however, often voluntarily take the necessary steps to cooperate with the authorities.

Second, it is possible to sanction an offence by imprisonment according to more general provisions of the Danish Criminal Act. If a product poses a threat to humans, and the manufacturer or distributor nevertheless sells (or tries to sell) the product, he or she may be convicted of endangering other people's lives, and can, in serious cases – for instance, if the contamination of the product is sought to be hidden – receive a prison sentence of up to 10 years.

Further to this, sector-specific rules allow for administratively imposing penalties, for example, within the areas of food, drinks, pharmaceuticals, toys, etc.

The size of the fines depends on what rules have been breached. Factors influencing the size of the fines under the Product Safety Act are, among others, the number of accidents, whether there have been repeating offences and the revenue of the firm breaching the rules.

From a commercial point of view, the most serious way of sanctioning non-compliance with product safety laws is for the authorities to issue injunctions with a requirement to warn the consumer, remedy the circumstances that have resulted in the danger, destroy, withdraw or recall the product, or take these measures themselves. See question 19 for further information.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

According to the Product Safety Act, both the manufacturer and the distributor have an obligation to inform the enforcement authority (in most cases the Danish Safety Technology Authority (DSTA)) about consumer products that are considered not to be safe. The information about the dangerous product can come from internal investigations, reports, known accidents, product complaints, etc. Further to this, the manufacturer must seek out information on the risks related to the consumer products. This can be done in several ways, including by performing random tests, processing complaints and by notifying the distributors about the product surveillance in order to give them a better basis for assessing and reporting risks and accidents.

The distributor takes part in the product surveillance by passing on information about the risk related to the product to the manufacturer

and the authorities and by keeping the information necessary to track the origin of the products.

Apart from the notification about the dangerous product, both the manufacturer and the distributor must notify the authorities about the measures taken to avoid risks.

There is no general set of combined rules that applies to products, and the relevant rules regarding such products must therefore be found within the sector-specific legislation. These rules will, generally, apply to both consumer and non-consumer products. Examples of such sector-specific rules are within the areas of food, drinks and pharmaceuticals.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

According to the Product Safety Act, if a product is considered to be unsafe, a notification must be sent to the DSTA immediately. A product is safe when there is no risk, or only a limited and acceptable risk, for consumers, when the product is used under normal and predictable circumstances, and within the expected lifetime of the product. A product is generally considered safe when it is manufactured according to health and safety requirements. There is a presumption that the product is safe when it is manufactured according to Danish health and safety regulations incorporating certain European standards. If no such health and safety regulations exist the safety of the product is assessed based on the actual circumstances.

The assessment of whether or not a notification is sent immediately will depend on the concrete circumstances of the case.

6 To which authority should notification be sent? Does this vary according to the product in question?

The question of which authority the notification should be sent to depends on the product in question. However, if the notification is sent to the wrong authority, there is a general obligation for the Danish authorities to pass on communications to the relevant authority.

Notifications according to the Product Safety Act must be sent to the DSTA, which also coordinates the information exchanged through the European RAPEX system. Notifications may also be sent electronically via the Product Safety Business Alert Gateway on the European Commission's website.

Other authorities are responsible for sector-specific notifications:

Food and drink

The appropriate authority to contact in a recall situation is the Danish Veterinary and Food Administration. The Danish Veterinary and Food Administration ensures that the recall is published on its website.

Outside ordinary opening hours, it is possible to contact the Food Guard.

Pharmaceuticals

The appropriate authority to contact when discovering a problem with pharmaceuticals is the Danish Medicines Agency. Outside ordinary opening hours, an emergency number can be reached.

7 What product information and other data should be provided in the notification to the competent authority?

The information requested reflects Appendix I to Directive 95/2001 EC. Based on the information, it must be possible to identify the product. Therefore, information must be provided about the risk of the product, who may have bought the product, where it is sold, how many products have been sold, the measures taken to avoid risk from occurring and generally information that can help trace and recall the product.

If the information necessary cannot be found with the manufacturer or distributor, the authorities can, among other things, perform tests and collect samples of the product or components thereof without payment.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

As described in question 4, both distributors and manufacturers have an obligation to monitor the products and notify the DSTA if the products are considered not to be safe. Distributors and manufacturers are also under an obligation to cooperate with the authorities to the greatest extent possible.

The authorities may also demand information about any preconditions or measures taken and the result of such. Further to this, the authorities may demand any information and documents they may find necessary irrespective of whether or not the information is considered commercially sensitive.

The DSTA will usually follow up on recalls and in this respect urge the manufacturer to provide updated information about the measures taken and the status of the recall. If the circumstances of the case then prove to be unsatisfactory, the manufacturer must take new steps to secure a satisfactory recall.

The authorities may also, if necessary, without a court order, gain access to the premises or transport facilities of a distributor or manufacturer in order to obtain information, documents, and such like.

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

Failure to comply with the obligation to report is penalised with a fine. In rare cases, imprisonment can be the result. For more information, see question 3.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

According to the Product Safety Act, the authorities have an obligation to, when possible, disclose information to the public about the risk related to dangerous products, the measures taken, how to identify the product, how the consumer should act, among others. The authorities may only disclose commercially sensitive information if this is necessary to protect the health and safety of consumers. If the health and safety of the consumer can be secured without disclosing such information, the authorities may not disclose it.

The authorities in Denmark are under a general obligation to provide certain information related to specific cases. As a general rule, access to such information does not include certain types of commercially sensitive material. In cases where documents or the like contain both commercially sensitive and non-sensitive information, access can be given to the non-sensitive information.

11 May information notified to the authorities be used in a criminal prosecution?

It is highly probable that the information gathered by the authorities will be used in a criminal prosecution.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

If a product is considered to be unsafe (see question 5), the manufacturer must take the necessary precautions to avoid the product posing a risk to consumers. This could be anything from warning the consumer in an effective way to a complete withdrawal or recall, depending on the circumstances of the case. It is not possible to lay down specific legal criteria for determining when a given action is appropriate, but some guidance may be found in 'Product Safety in Europe – A Guide to Corrective Action Including Recalls'. Generally, both the manufacturer and the authorities are to assess the situation from a principle of proportionality and from the present, specific risk. A complete recall is, however, considered the last resort, and irrespective of the measures taken the manufacturer may not continue to market an unsafe product.

Food and drink

Recalls of food and drinks are mainly governed by EC Regulation 178/2002. A recall is generally necessary if there is suspicion that the product does not comply with the food safety requirements.

Pharmaceuticals

It is possible for the Danish Medicines Agency to demand a recall of pharmaceuticals in a number of cases, for example, if the therapeutic effect is lacking, the risk of the product outweighs the benefits, the product does not have the correct qualitative or quantitative composition and so on. The response time of the Danish Medicines Agency is divided into three classes:

- class 1: potentially life threatening – immediate action;
- class 2: can cause sickness or improper treatment – action within 24 hours; and
- class 3: others, no patient risk – action within two to three working days.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Publishing warnings is just one of several possible actions to be taken in case of a dangerous product. If a product is considered to be unsafe, the manufacturer has an obligation to take the necessary steps to avoid the product posing a risk to the consumer. This is usually done by warning the consumer, withdrawing or recalling the product. The method used will depend on the circumstances of the case, but it is important that the actual measure taken prevents the product from posing a risk to the consumer.

To ensure the effectiveness of the measures taken, manufacturers are advised to place relevant product information on the product or its packaging, for example in the form of a reference number, batch number or the like (see also question 2).

Further to posting warnings about dangerous products, the manufacturer must generally give the consumer the information necessary to estimate the risk of using the product. This information can be given in the form of warnings, instruction manuals, information in the store, and such like. It is not important how this information is conveyed, but that it is conveyed in an appropriate manner considering the circumstances.

14 Are there requirements or guidelines for the content of recall notices?

The DSTA has not issued its own guidelines. However, the DSTA refers to the Corrective Action Guide, issued by a group of organisations through the EMARS project and funded by the European Commission, which contain guidelines and suggestions on how a recall notice should be drafted. This guide can be found on the DSTA's website (www.sik.dk), but are non-binding and can be deviated from if another procedure is considered to be at least as effective.

Generally a recall notice should:

- be at least one A4 page;
- have a heading containing the Danish word for 'warning' or 'xx manufacturer warns' and which tells what kind of product is involved and the problem the notice concerns;
- contain a photo of the product (minimum half an A4 page) that represents the product in as identifiable a way as possible; and
- be short, informative and precise, and say something about the problem, the danger, how to react, where to get more information and the date of the notice.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

Information about recalled products will be made available at www.sik.dk. Even after a successful recall, the products can be found in an archive on the DSTA's website with information about the product.

Regarding advertisements in the media, there is no list of media that should be used. The actual media to be used will be the result of a dialogue between the DSTA and the manufacturer and will be based upon the manufacturer's knowledge of the sale of the product and how to most effectively reach the consumers affected. It is, however, the manufacturer's responsibility to ensure that all consumers are reached.

If the parties cannot come to terms, the DSTA will as a minimum require that the notice is advertised in national media.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

No targets and no specific time period exist after which a recall is deemed to be satisfactory. The DSTA will, however, usually follow up on recalls and if the circumstances of the case prove to be unsatisfactory, the manufacturer must take new steps to secure a satisfactory recall.

Update and trends

The DSTA monitors and investigates the market for defective and unsafe products in Denmark and the authorities have constant and significant focus on the market for electronic devices and toys. Investigations carried out by the DSTA have recently resulted in a series of product recalls within these particular business sectors. In order to help businesses in general (ie, not only electronic and toy businesses) to comply with applicable product safety regulation, and hence avoid defective and unsafe products being placed on the market, the Market Surveillance Council has launched a guidance website. This website lists the relevant rules for a wide range of product categories that products must comply with and the relevant public authorities for the products concerned. The website can be found at www.virk.dk.

Moreover, the Danish parliament has recently enacted a new Gas Safety Act and five associated executive orders that seek to modernise and simplify the rules and requirements concerning gas installations, plants and equipment. A novel feature is that the executive orders contain certain minimum safety standards as opposed to detailed product specific requirements that businesses must comply with. The aim is to give businesses as much freedom as possible as to how they wish to comply with applicable law without putting the general security level at risk.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

An obligation to repair or replace the product cannot be inferred from the Product Safety Act.

The Danish Sale of Goods Act governs the obligations of the manufacturer and distributor to repair or replace the goods. An unsafe product is generally considered to be non-conforming and will entitle non-consumers to avoid the contract, claim a proportionate price reduction or, in some cases, claim damages.

Consumers can demand repair, redelivery of a conforming product, a price reduction or they can avoid the contract. If the seller offers to repair or deliver a conforming substitute product, the buyer cannot avoid the contract or demand a price reduction. Further to this, the buyer cannot claim redelivery or a repair of the product if this is impossible or imposes disproportionate costs on the seller. The rules regarding consumers cannot be derogated from in a negative manner, while the buyer and seller in non-consumer contracts can make alternative arrangements.

According to the Danish Sale of Goods Act, a notice of must generally be given within reasonable time and ultimately within a two-year period of the goods being handed over to the buyer. However, in situations where a public authority has issued an injunction to recall or destroy a product (not withdraw), the time bar is not applicable, and the rules in the Danish Statute of Limitations will apply instead. The point in time at which the non-conformity claim becomes statute-barred will then depend on the actual circumstances, but can be as long as 10 years.

If a recall is completed voluntarily, the two-year time bar will probably still apply and will thus limit the sellers' liability for goods.

18 What are the penalties for failure to undertake a recall or other corrective actions?

See question 3.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

If the manufacturer or the distributor fail to take actions or the actions taken prove to be insufficient, the authorities can issue an injunction against a manufacturer, or someone who has been involved in marketing or selling the product, to warn the consumer, remedy the circumstances that have resulted in the danger, or to destroy, withdraw or recall the product, etc.

The authorities are able to take the above-mentioned measures themselves and thereby, to a certain extent, act on behalf of the person who introduced the dangerous product on the market. This possibility

exists if that person does not take the necessary steps himself or herself, including taking due actions, or does not follow a ban or an injunction from the authorities. Before the authorities resort to such measures, they must make an assessment of which measures are necessary to use in the actual case.

In situations where it is not possible to trace the person who introduced the product on the market, the authorities may also act on behalf of this person and can post warnings, destroy the product, secure a recall or a withdrawal and so on.

20 Can the government authorities publish warnings or other information to users or suppliers?

The authorities have the competence to issue warnings, complete recalls and withdrawals, among others, regarding specific products if the person who introduced the product onto the market fails to take appropriate measures or where it is not possible to trace the person who introduced the product onto the market. To the extent that the relevant authority becomes aware of a general problem regarding a specific type of product, it may post warnings, safety guidelines and such like on its website in a general attempt to prevent accidents relating to a specific product group. There is, however, no official website where members of the public can post remarks or reports of incidents, but it is always possible for a member of the public to notify the authorities of a specific problem or finding.

Upon receiving such reports, the authorities will act upon it when relevant and may initiate recall, withdrawal or warning proceedings according to the procedures described in this chapter.

Several authorities will publish lists of recalled products on their website and also store them in an online archive for a period of time.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

See question 19.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

If the authorities organise a product recall according to the Product Safety Act, the costs incurred by the authorities can be recovered from the party on behalf of whom the authority is acting.

23 How may decisions of the authorities be challenged?

As a general rule the decisions made by the authorities according to the Product Safety Act cannot be challenged to a higher administrative authority. Authorities overseeing sector-specific regulation can, however, also use the Product Safety Act to issue injunctions and such like and the relevant minister has the authority to issue general rules regarding the possibility of challenging sector-specific decisions. Some sector-specific rules give the option to challenge decisions according to the relevant law.

According to the Product Safety Act, if the authorities have issued a ban or an injunction according to specific provisions of the Product Safety Act, the addressee can demand to have the ban or injunction tried by the courts if he or she makes a request to the relevant authority within three months after being informed of such. If the addressee makes such a request, the authority will then have the ban or injunction tried by the courts without undue delay. The court can decide that a request suspends the ban or injunction.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

It seems highly plausible that the courts will see a safety warning as an admission of the product being defective, and if the plaintiff can prove that there has been an injury caused by the defect, this will in most cases result in liability.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

It is possible that information sent to the authorities can be disclosed to the public.

According to the Product Safety Act, the authorities must, when possible, disclose information to the public about the risk related to dangerous products, the measures taken in an actual case, how to identify the product, how the consumer should act, etc. The authorities may, however, only disclose commercially sensitive information if this is necessary to protect the health and safety of the consumer.

Furthermore, it is possible to request information from public authorities, but the access to such information does, as a general rule, not include commercially sensitive material. If a document or the like contains both commercially sensitive and non-sensitive information, access can be given to the non-sensitive information (see also question 10).

When product liability actions are tried by the Danish civil courts, the Danish civil procedural law applies. However, the procedural law rules do not provide for court discovery processes as known in common law countries, and the principle of proceedings is therefore applicable. This means, as a general rule, that no party is compelled to disclose certain information or documents. It is, however, possible for the court to direct that the opposing party or a third party provide certain information upon request. In addition to this, information as described may be disclosed due to the authorities' obligation according to the Product Safety Act to release information about the risk related to dangerous products, the measures taken in an actual case, how to identify the product, how the consumer should act and such like (see also question 10).

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

Consumer products
The General Product Safety Regulations 2005 (GPSR) require that producers shall not place products on the market unless they are safe and provided with appropriate warnings and instructions for use. Producers must also monitor the safety of their products after they have been placed on the market. The duties are essentially the same as those provided for in the EU General Product Safety Directive 2001/95/EC (GPSD).

Distributors (ie, others in the supply chain) are required to help ensure compliance with safety requirements, including participating in monitoring of the safety of products on the market by passing on information about risks.

Commercial products
The UK currently has separate legislation (not derived from the EU) covering the safety of products intended for commercial use, principally section 6 of the Health and Safety at Work Act 1974 (HSWA) which is enforced by the Health and Safety Executive (HSE). Manufacturers, importers and other suppliers are required to ensure, so far as is reasonably practicable, that the products are safe and without risks to health at all times when they are being used or maintained. They must also arrange for the carrying out of appropriate testing and examination to ensure products are safe. The market surveillance powers of the HSE will be extended when the proposed EU Product Safety and Market Surveillance Package comes into force. The new proposed Regulation on Market Surveillance of Products (COM (2013) 75) will apply to consumer and commercial products and provides increased and new powers to market surveillance authorities. The regulation was due to come into force in 2015. However, continued resistance by industry to certain provisions contained in the package have seen the entire proposal stall.

Sector-specific safety legislation
Numerous regulations govern particular types of products, for example, food, pharmaceuticals, medical devices, machinery, electrical items, vehicles and toys. Often these regulations implement European directives and legislation will be similar to that of other European member states.

The European Commission's Product Safety and Market Surveillance Package, adopted in February 2013, sets out increased obligations for manufacturers, importers, distributors and national authorities to improve the safety of products on the EU market and strengthens market surveillance activities. These proposals (in the form of a new Regulation on Consumer Product Safety (COM (2013) 78) and a new Regulation on Market Surveillance of Products) were expected to come into force in 2015. However, the implementation of the regulations has been delayed, particularly as a result of concern of stakeholders regarding the proposal that products be labelled with country of origin. Further details are set out in the European overview chapter.

Code of Practice on Consumer Product Safety Related Recalls and other Corrective Actions
In 2018, the Code of Practice on Consumer Product Safety Related Recalls and other Corrective Actions (PAS 7100: 2018) was published by the Department for Business, Energy & Industrial Strategy (BEIS). It came into effect 7 March 2018. This PAS (Publicly Available Specification) takes the form of guidance and recommendations for businesses and regulators. The PAS is designed to help manufacturers, importers and distributors prepare for any product safety issue that might arise with their products. Part 1 is intended for businesses and covers monitoring, risk assessment, notification and corrective action, with the emphasis on the preparation of a product safety incident plan (PSIP). A helpful flow chart on managing a typical corrective action (which includes a full product recall) is found at Figure 1 of the PAS.

2 What requirements exist for the traceability of products to facilitate recalls?

Requirements for traceability of consumer products are that products should be supplied with details of the producer's name and address and the relevant product reference or batch marking. There are no generic requirements for commercial products' traceability.

Some sector-specific legislation contains more detailed requirements. For example, the General Food Regulations 2004 and the Food Safety and Hygiene Regulations 2013 (which give effect to European Regulation (EC) 178/2002) contain requirements for extensive traceability systems throughout the supply chain. Traceability of products also features in legislation for pharmaceuticals (Human Medicines Regulations 2012 (SI 2012/1916)) and medical devices (Medical Device Regulations 2002 (SI 2002/618)) as part of required vigilance systems. In terms of vehicles, in accordance with the Driver and Vehicle Standards Agency (DVSA) Vehicle Safety Defects and Recalls: Code of Practice (2013), the UK Driver and Vehicle Licensing Agency (DVLA) will assist in tracing vehicle owners.

Additional obligations as to traceability requirements are set out in the proposed Regulation on Consumer Product Safety. This Regulation sets out a specific requirement for traceability of certain products (including electronic traceability) which, owing to their specific characteristics or specific conditions of distribution or usage, are susceptible to bear a serious risk to the health and safety of consumers. There are also proposed obligations to label the country of origin on the product, its packaging or the documentation accompanying the product. The new proposed Market Surveillance Regulation (which applies to commercial and consumer products) requires economic operators to make available any documentation that the market surveillance authorities require, including information that enables the precise identification and tracing of products.

PAS 7100 recommends that a PSIP should include a product and customer traceability plan (4.4.2). The PAS states that the extent of traceability information required and the form it should take should be determined on the basis of risk (see question 5). As per general product safety regulations and product sector specific regulations, this traceability information should identify:

- the producer or manufacturer of the item;
- the general product identifier (eg, model reference); and
- a specific identifier for the product or series of products (eg, serial number, batch reference, date of manufacture).

PAS 7100 also states that the design process should consider what form the traceability information should take, where it should be positioned on the product and the best way of including this information so that it remains legible after use. Consideration should be given to the durability of markings to enable them to withstand general wear and tear and, where appropriate and practical, fire and water damage. Where the product contains parts, components, sub-assemblies, among others, that are likely to play an important part in the safety of the final product, these too will need traceability information to be included about them. This will allow cross-checking against complete products and also spare parts held in stock or made available to third parties.

Providing the information on the product itself is required wherever possible, since packaging is normally discarded.

3 What penalties may be imposed for non-compliance with these laws?

Consumer products

The UK does not have a system of administrative fines. Penalties are dealt with in the criminal courts. Offences are mostly based on strict liability, but may be subject to a defence of due diligence. The principal penalty for offences committed after 12 March 2015 is an unlimited criminal fine.

Provision also exists for suppliers or others who are natural persons (as opposed to corporations) to be imprisoned for up to 12 months, although this is rarely used. Criminal proceedings are brought in most cases against the corporate entity that is responsible for manufacture or supply of the product in the UK. Directors, senior executives and other individuals can also be prosecuted personally where they are responsible for a contravention by a corporation, although cases are uncommon. The possibility also exists for a criminal, corporate or individual manslaughter prosecution.

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

Penalties for offences in relation to food and drink products have no upper limit set by the relevant legislation. In 2007, chocolate-maker Cadbury was fined a total of £1 million for breaching food safety laws in a salmonella outbreak that affected more than 40 people. Penalties may well now increase with the introduction of definitive sentencing guidelines in February 2016.

The authorities may also apply to the courts for an order for the forfeiture (ie, seizure) of consumer products that are dangerous, and these goods will be destroyed unless the courts direct otherwise.

Various other enforcement powers are available to the authorities that do not require them to first obtain court orders, including suspension notices (which require the temporary suspension of supply or marketing of products that are suspected of contravening product safety requirements, while tests and other investigations are carried out); and requirements to mark (notices requiring clear and comprehensive warnings to be marked on products of their risks, or to make products' marketing subject to prior conditions). See also withdrawal notices, requirements to warn and recall notices below. Recipients of such notices are entitled to appeal against them.

Products for commercial use

Penalties for contravention of safety requirements relating to commercial products under the HSWA are unlimited criminal fines (for offences committed after 12 March 2015). There are also provisions whereby individuals can be convicted of offences (eg, directors and officers of a corporation responsible for a product) for up to two years. Other enforcement powers are also available to the HSE (see question 19).

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

Consumer products

The GPSR require producers or distributors to notify the enforcement authorities if they know that a product they have placed on the market or supplied does not comply with the general safety requirement. Although the obligation to notify applies to producers and distributors, in the UK the authorities' approach is that notification by one of them is sufficient.

In general, the requirements concern notification of information concerning defects or newly discovered risks, irrespective of whether any incident, injury or damage has yet occurred.

PAS 7100 highlights that the PSIP should emphasise the legal duty to notify the relevant market surveillance authority and allocate responsibility for timely notification (see question 5). Distributors' notification responsibilities, within the limits of their activities, are also listed in the PAS.

Commercial products

There are currently no UK statutory requirements requiring notification to the authorities of defective products for commercial use. (See, however, the rules referred to in question 5 for specific sectors.)

Where products have been tested or certified by a third party, it is possible there may be a contractual obligation incorporated into the agreement requiring the manufacturer or its representative to inform the body concerned. This body may in turn inform the authorities.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

Consumer products

The criterion for notification is simply that a consumer product is known to have risks that are incompatible with the general safety requirement – namely, that it is not safe. It is not necessary for there to have been an incident involving personal injury or property damage. 'Isolated circumstances or products' do not need to be notified. The new proposed Regulation on Consumer Product Safety also makes an exemption from notification 'if the manufacturers, importers or distributors can demonstrate that the risk can be fully controlled and cannot anymore endanger the health and safety of persons'.

The UK government has published guidance on when notification is appropriate (Notification Guidance for Producers and Distributors (DTI, September 2005)). This refers to the European Commission's methodological framework for assessing risk contained in its published Guidelines for the Notification of Dangerous Consumer Products (2004) for the purposes of the GPSD. However, these risk-assessment guidelines have been superseded by Decision 2010/15/EU, which sets out revised risk-assessment guidelines. These guidelines are often referred to as the 'RAPEX guidelines'. The aim of the 2010 RAPEX guidelines is to provide a practical and transparent risk-assessment method for use by member states' competent authorities when they assess risk in non-food products. The risk-assessment methodology looks at the product itself, the product hazard, the abilities and behaviour of the consumer (in particular vulnerable consumers), injury scenarios, the severity and probability of injury and the determination of risk. The number of products supplied or users potentially affected is not a relevant consideration for notification, although it may be taken into account in determining what action to take to address the risk.

Use of the methodology set out in the RAPEX guidelines is recommended in PAS 7100. The Nomograph methodology is also recognised, as it can be used to supplement the RAPEX methodology and is applied by some market surveillance authorities.

The obligation under the GPSR is to notify the authorities 'forthwith' (or immediately) upon knowing a product is unsafe. The UK government guidelines advise that in practice this means making a notification as soon as possible, and no later than 10 calendar days of a risk assessment or obtaining other information showing the product is unsafe. Further, where there is a serious risk, the notification should be made no later than three days after the information has been obtained. PAS 7100 confirms that notification should not be delayed because the business is not yet in a position to provide all of the required information. In this case, the additional information should be provided as it becomes available.

Food and drink

Obligations to notify the Food Standards Agency (FSA) and relevant local authority of unsafe food and drink products are governed by Regulation EC/178/2002 on General Food Law (article 19) and the Food Safety and Hygiene Regulations 2013. A food business operator must notify the authorities if it considers or has reason to believe that food it has placed on the market may be injurious to health. (See the FSA's Guidance Notes for Food Business Operators on Food Safety, Traceability, Product Withdrawal and Recall, 2007).

Pharmaceuticals
Notification obligations are incorporated into manufacturers and wholesale dealers' licences and marketing authorisations. The holder of a manufacturer's licence has a duty to notify the Defective Medicines Report Centre (DMRC) (a unit of the Inspection, Enforcement and Standards Division of the Medicines and Healthcare Products Regulatory Agency (MHRA)) immediately once investigations have identified a defect that could result in recall or other restrictions on supply. Manufacturers who make a notification after a recall has commenced will be in breach of the Human Medicines Regulations 2012 (SI 2012/1916). The DMRC can be contacted for advice prior to a recall being undertaken. For guidance see: A Guide to Defective Medicinal Products (MHRA, 2014) and guidance on the website of the European Medicines Agency, www.emea.europa.eu.

Medical devices
The medical devices directives require vigilance systems which include reporting to the Medicines and Healthcare Products Regulatory Agency (MHRA) by the manufacturer or its authorised representative of malfunctions or deteriorations in a device, inadequacies in labelling or instructions for use that might lead or have led to a patient's or user's death or serious health effects and any technical or medical reasons for a systematic recall of the devices.

The MHRA's Directives Bulletin 3 – Guidance on the Operation of the EU Vigilance System in the UK (September 2008) provides interpretation and guidance on notification of different types of incidents. The European Commission also provides up-to-date guidance in document MEDDEV 2.12-1 Rev 8 (2013). Notification should be immediate upon the defect being known. The guidance contains guidelines on time limits ranging from two days to 30 days depending on the seriousness of the issue.

It should be noted that, on 5 April 2017, two new European Regulations on medical devices were adopted and entered into force on 25 May 2017:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; and
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

The new regulations strengthen the regulatory framework relating to medical devices including the pre-market assessment of devices, post market surveillance and the transparency of data. The new rules will only apply after transitional periods of three years after entry into force for the Regulation on medical devices (May 2020) and five years after entry into force for the Regulation on in vitro diagnostic medical devices (May 2022). The Commission has indicated that it will be reviewing its guidance documents over the next few years to take into account the new regulations.

Motor vehicles
Supplemental to the general consumer product laws above, the DVSA's Vehicle Safety Defects and Recalls: Code of Practice (2013) applies to all vehicles (private and commercial). It requires notification to the DVSA by manufacturers of vehicle or component parts, importers, distributors or concessionaires of 'safety defects' (defined as a failure because of design or construction that is likely to affect the safe operation of the product without prior warning to the user and may pose a significant risk to the driver, occupants and others). The DVSA's Code of Practice and Manufacturers' Guide to Recalls in the UK Automotive Sector (April 2014) advocates early notification of alleged safety defects, even when all the information usually supplied on the official notification form is not available.

6 To which authority should notification be sent? Does this vary according to the product in question?

For most consumer products, the appropriate authority for notifications in England and Wales is the Trading Standards Department of the local government authority for the area in which the manufacturer's or supplier's business is based. For contact details, see www.tradingstandards.gov.uk. If the product is also supplied in other EU member states, one single notification can be made to the European Commission, via its Business Application portal. All relevant national authorities will be informed.

Other authorities responsible for sector-specific notifications are the FSA (www.food.gov.uk), the DVSA (www.gov.uk/government/organisations/driver-and-vehicle-standards-agency) and the MHRA (www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency).

These authorities may forward the information notified to them to the EU authorities for the purposes of RAPEX, RASFF (Rapid Alert System for Food and Feed) or other rapid alert systems in Europe for pharmaceuticals and medical devices, or for the purposes of information-sharing systems pursuant to other EU legislation.

7 What product information and other data should be provided in the notification to the competent authority?

The information to be notified for consumer products generally is the nature of the defect, the action being taken to prevent risks to consumers and the details of other EU member states in which the product is known to have been supplied or marketed. The reporting form for general consumer products is available from the UK Department for Business, Energy and Industrial Strategy (BEIS) (www.gov.uk/government/organisations/department-for-business-energy-and-industrial-strategy). Different forms are available for specific products from the FSA, MHRA and DVSA.

PAS 7100 states that the notification must include information on any action taken to reduce risk to consumers and, in the case of serious risk, must provide the following:

- information enabling a precise identification of the product or batch of products in question;
- a full description of the risks the products presents; and
- all information relevant for tracing the product.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Where it has only been possible to provide incomplete notification data within the time limits, updated information should be provided as soon as possible thereafter. There is a duty on producers and distributors to cooperate with the authorities in taking action to avoid risks to consumers. The authorities also have formal enforcement powers to require the provision of additional information and records if they require it in order to investigate a breach of product safety legislation or to decide whether to use their enforcement powers to, for example, serve safety notices. Failure to provide information requested may be an offence. Market surveillance authorities will have new and expanded powers under the proposed EU Regulation on Market Surveillance of Products. The draft regulation requires economic operators to make available on request any documentation or information that the surveillance authorities require.

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

The penalty for failing to properly notify the appropriate authority of a defective consumer product is an unlimited criminal fine or up to three months' imprisonment (for an individual producer or distributor or, for example, a director of a corporation) or both.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

There is limited protection for commercially sensitive information. The authorities are obliged to make available to the public information on the identity and risks associated with a defective product, and the measures taken to avoid the risk. There is no obligation on the authorities to disclose information that is covered by professional secrecy, unless its disclosure is necessary to protect the public.

Under the Freedom of Information Act 2000 (FOIA), any person may request information from the authorities on a product safety matter. The original provider of the information has no right to prevent its disclosure. The authorities have discretion as to whether to release

information that is provided in confidence or which could prejudice a person's commercial interests.

The FOIA recognises that in many circumstances it may be inappropriate for a public body to disclose the information that it holds. The FOIA therefore contains a number of exemptions that protect information from potential disclosure. Of particular relevance to product safety notifications and recalls are those exemptions relating to 'investigations', 'law enforcement' and 'information provided in confidence'.

Information provided compulsorily under consumer protection legislation obligations may be protected from disclosure by provisions of the Enterprise Act 2002. (This extra protection does not extend to information originally provided voluntarily.) Disclosure of the information to a claimant for the purposes of civil proceedings may nevertheless be permitted.

11 May information notified to the authorities be used in a criminal prosecution?

It is likely that the information obtained by the authorities will be relied upon if there were criminal proceedings or other enforcement action. There is no bar to the information being used as evidence. In some cases, it might amount to an admission of an offence.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

The GPSR provide that a producer of consumer goods must be prepared to take 'appropriate action' to deal with unsafe products including, where necessary to avoid risks, withdrawal from the supply chain, warnings to consumers or (as a last resort) recall from consumers. No legal criteria are laid down in these regulations for determining what action is appropriate in any given circumstances. Published codes of practice for recall will be relevant, including the Consumer Safety in Europe Corrective Action Guide (2012). The GPSR incorporate the 'precautionary principle' (see EU COM (2001) 1), which may justify the action even where the risk cannot be determined with sufficient certainty.

PAS 7100 highlights that – as per the RAPEX risk assessment methodology referred to above – risk can be classified into one of four basic levels: serious, high, medium and low. 'Serious risk' normally requires immediate action, 'high risk' normally requires rapid action and 'medium risk' normally requires some action, while 'low risk' does not generally require action for products on the market but it may require changes to the design of the product, or to manufacturing or quality control processes.

Commercial products

For commercial products, the duty in section 6 of the HSWA may comprise taking reasonably practicable steps to recall or modify products if this is necessary to prevent risks of injury. Again, there are no specific legal criteria to determine thresholds of risk requiring such precautions.

The common law of negligence is also relevant as it may comprise a duty to take reasonable steps to warn users or to prevent use of consumer or commercial products until they can be modified or replaced. This duty may apply even where the risk arises only where the product is incorrectly maintained or used.

Food and drink

The criteria for recall or other action are contained in article 19 of Regulation (EC) 178/2002 on General Food Law. Article 19 requires the withdrawal of foodstuffs from the supply chain if there is any non-compliance with the food safety requirements, to inform consumers of the reason for the withdrawal, and recall from consumers 'if necessary . . . when other measures are not sufficient to achieve a high level of health protection'.

Pharmaceuticals

The MHRA's Guide to Defective Medicinal Products (2014) refers to article 117 of Directive 2001/83/EC, which specifies under what circumstances a recall may be required. A medicinal product should be withdrawn if:

- it is harmful under normal conditions of use;
- it lacks therapeutic efficacy;
- qualitative and quantitative composition of the product is not as declared; or
- the controls on the product or the ingredients have not been carried out or some other obligation relating to the granting of the market authorisation is not fulfilled.

The MHRA uses an international classification system for medicine recalls:

- class 1: the defect presents a life threatening or serious risk to health;
- class 2: the defect may cause mistreatment or harm to the patient, but it is not life-threatening or serious; and
- class 3: the defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the marketing authorisation or specification.

'Class 4 drug alerts' also exist where there is no threat to patients or no serious defect likely to impair product use or efficacy. These usually cover minor defects, for example, in packaging or printed materials. The extent and urgency of the recall will generally be discussed and agreed with the MHRA using these criteria.

Medical devices

The MHRA adopts the EU term 'field safety corrective action' (FSCA) to embrace recall and related warnings. Guidance on determining the need for a recall is contained in the MHRA's Directives Bulletin No. 3 – Guidance on the Operation of the EU Vigilance System in the UK (2008), which refers to risk assessments being carried out in accordance with the international standard BS EN ISO 14971. The European Commission's MEDDEV 2.12/1 Rev 8, sets out guidance on the medical device vigilance system, including field safety corrective action.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Under the GPSR, it is primarily for the manufacturer of a consumer product to determine whether a product is unsafe (and thus requires notification to the enforcement authorities) and what corrective action is appropriate in the particular circumstances (eg, warnings, withdrawal or recall). The authorities in the UK largely rely upon manufacturers voluntarily taking the appropriate corrective action. Should an enforcing authority not be satisfied with the approach taken by a manufacturer or other responsible party, it is likely to voice its concerns and informally request that additional corrective action be taken. The GPSR require the authorities to act in a manner proportionate to the seriousness of the risk and to encourage and promote voluntary action by manufacturers and distributors. The authorities nevertheless have powers to impose requirements (see question 19).

14 Are there requirements or guidelines for the content of recall notices?

UK legislation does not generally set out specific requirements or guidelines for the content of recall notices. However, PAS 7100 identifies the following elements that a corrective action announcement should always contain:

- a clear heading that draws attention to the announcement containing the words 'Important Safety Warning' and a description of the corrective action – for example, product recall;
- a clear description of the hazard and associated or potential safety risk;
- product identification details such as brand, bar code, colour, size (and where possible model, batch or serial number);
- a photograph of the product;
- details of when and where the product was available for sale;
- a description of the action required by the consumer;
- details of arrangements for any proposed exchange, refund or repair; and
- a website address and freephone number for further information.

PAS 7100 also states that, if possible, additional information to ensure consumer safety (eg, 'Stop using immediately', 'Unplug and do not use') should also be included.

Update and trends

The Office for Product Safety and Standards
In January 2018, the UK government announced the creation of a new national oversight body called the Office for Product Safety and Standards (OPSS), which has been tasked with identifying consumer risks and managing responses to large-scale product recalls and repairs. The announcement was part of the government's response to the Working Group on Product Recalls and Safety established in 2016. In addition to providing support and advice for local authority Trading Standards teams, the OPSS will coordinate work across local authorities where action is needed on a national scale and will ensure the UK continues to carry out appropriate border checks on imported products once the UK leaves the European Union.

The new OPSS covers general consumer product safety (ie, non-food products). It will not cover vehicles, medicines and medical devices or workplace equipment as these are covered by other agencies. It will also not cover construction products that are subject to separate review. One of the first tasks of the OPSS has been to work with the British Standards Institute to provide guidance on product recalls and corrective action – this was the genesis of the creation of the PAS as discussed above. The OPSS will have a budget of about £12 million a year when fully operational.

Brexit
A recent Briefing Paper from the House of Commons Library on Product Safety and Recall emphasises that the current legal framework will not change until exit negotiations between the UK and the EU are finalised, but notes that Brexit will have an impact on the existing body of law relating to product liability and safety.

The UK has implemented the GPSD via the GPSR and the expectation is that the GPSR will remain in force after Brexit, under the European Union (Withdrawal) Bill 2017–19 albeit with a different constitutional basis.

In addition, recall notices should be clear, concise, factual and easily understandable. Graphics should be used where possible as English may not be the first language of some of the target audience. PAS 7100 suggests that a 'checker tool' in online messages and web pages to assist consumers can also be useful.

Annex G of PAS 7100 contains visual examples of product recall notices, with recommended content and display features. Figure G3 sets out a notification using social media.

Some bodies (such as the British Retail Consortium) have also drawn up product recall guidelines, which outline the key elements that should be included in notices to suppliers, notices for the trade press or the general public. Examples of notices can also be found in Product Safety in Europe: A Guide to Corrective Action Including Recalls (Prosafe, etc).

For medical devices, there is a template for 'Field Safety Notices' – see MEDDEV 2.12/1 Rev 8 (Annex 5).

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

There is no prescriptive list of the media that must be used to publish or communicate warnings or recalls to suppliers or users, albeit that PAS 7100 contains a list of example communication channels that could be used. The method selected should relate to the assessed levels of risk, the mechanisms available, the affected product type and the target group of consumers likely to be affected. Producers can convey messages, for example, by local or national newspapers or advertisement in specialist magazines, letters to suppliers and end users (eg, using warranty records), web-postings, email or text messages, use of social media, posters at the point of sale, communications to installers or maintainers, store loyalty schemes or a mixture of each of these or other approaches.

A plan of the proposed action has to be submitted to the relevant regulatory authority as part of the notification process. If the enforcing authority does not consider the approach to communication of information to users and others to be adequate, additional or alternative forms of corrective action can be requested.

In some sectors, there will be involvement by the regulator in the chain of communication. For vehicle recalls, the DVLA can address and send letters directly to registered vehicle owners. The FSA (for food) and the MHRA (for medicinal products and medical devices) can also publish their own alerts.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There are no set targets or time periods at which a recall is deemed to have been successfully completed – albeit a recall can never be completely closed unless 100 per cent of products are accounted for. Enforcing authorities are likely to request update reports as to the success rate of any corrective action that is taken. The enforcing authority may require additional measures to be adopted, including repeat recall notices if they consider the response to corrective action to have been unsatisfactory.

The government has previously published success rates of recalls for different types of product based on the percentage retrieved of the overall numbers sold. See Product Recall Research (DTI, 2000). In 2014, Electrical Safety First produced a report, Consumer Voices on Product Recall, suggesting that the 'success rate of recalls is rarely more than 10 per cent to 20 per cent'. However, it is questionable whether some of the data accurately represents typical outcomes of recalls in practice. For example, because of the ability to trace vehicle owners directly through the DVLA, vehicle recalls often have much higher success rates in recall than other product sectors.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

There is no positive obligation on a producer conducting a recall to offer to repair, replace or pay compensation as part of its corrective action programme. Practices vary but, unless the items in question are of low value or perishable, manufacturers generally tend to offer repair or replacement products.

Rights of recovery for any loss or damage relating to the product simply ceasing to be usable will largely be against the seller from whom the consumer directly purchased the products (unless he or she has suffered injury or property damage when a claim in that regard against the manufacturer or importer into the EU may be made). Whether or not the seller can obtain recourse for the costs of repair or replacement and such like, from the manufacturer or others in the supply chain is an issue that will be determined by reference to the terms of the relevant supply contracts.

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

Commercial products
Subject to the express or implied terms governing quality in the contract of sale, the owner of a commercial product that has been recalled may be able to reject the product, if not already accepted, and reclaim the purchase price as well as additional losses incurred. More usually though the owner will be deemed to have accepted a product already in use, and the owner's rights will consist of a claim for damages for breach of warranty against the immediate seller. The damages would comprise the loss to the owner flowing directly and naturally resulting in the ordinary course of events from the breach of warranty.

In the event of the immediate seller being liable to the owner, the seller may, depending on the relevant contractual terms, be able to recover the losses from others in the supply chain.

18 What are the penalties for failure to undertake a recall or other corrective actions?

See question 3.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

Consumer products

The enforcing authority may serve withdrawal notices to prohibit a person from supplying a product without the authority's consent. The notice may also require the person on whom it is served to take action to alert consumers to the risks that the product presents. If a product is already on the market, such a notice may only be served in circumstances where the action of the producer or distributor concerned is considered to be unsatisfactory or insufficient. The authorities also have power to serve a 'requirement to warn'. This can dictate the form and manner of publication warnings to consumers.

Recall notices may be used in situations where the enforcement authority has reasonable grounds for believing that a product is dangerous and that it has already been supplied or made available to consumers. Such notices require the person on whom they are served to use reasonable endeavours to organise the return of the product from consumers. Such notices can only be used by enforcing authorities in situations where other voluntary action would not suffice to prevent the risks posed by the product and the action taken by the person on whom the notice is to be served is deemed to be inadequate or insufficient, unless the risk is serious and deemed to require urgent action.

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

Commercial products

The HSE is empowered to issue enforcement notices in respect of unsafe products. An 'improvement notice' may be used to require a manufacturer or other supplier to provide warnings or safety information. A prohibition notice may be used to stop the supply of a product. It is doubtful that such notices can require the recall or modification of a product. In cases of serious danger, the HSE may seize products.

The European Commission's proposed Regulation on Market Surveillance of Products extends beyond consumer products, allowing enforcing authorities to deal with potential product risks, irrespective of the intended end user. The draft Regulation provides for market surveillance authorities to carry out risk assessments and to inform 'economic operators' (manufacturers, distributors, importers) of the corrective action that must be taken and the period in which it must be taken.

20 Can the government authorities publish warnings or other information to users or suppliers?

It is common for the authorities to publish alerts about unsafe products (see question 15). Generally this will be done in association with manufacturers or others responsible for recalls, and will reiterate warnings and other advice issued voluntarily by them. However, the authorities are not permitted to issue press releases or call for a recall or other action unless they do so in cooperation with manufacturers or other responsible persons, or they act within the limits and procedural frameworks of the GPSD, RAPEX or other European notification frameworks and the enforcement powers above (*R v Liverpool City Council*, *Ex parte Baby Products Association* (1999), The Times, 1 December).

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Where an enforcement authority has been unable to identify any person on whom to serve a consumer product recall notice, or the person on whom such a notice has been served has failed to comply with it, then the authority may itself take such action as could have been required by a recall notice. In accordance with the proposed EU Regulation on Market Surveillance of Products, when a product (consumer or commercial) is considered as a serious risk by a market surveillance authority, it is obliged to take all necessary measures and may do so without requiring the economic operator to take corrective action first or providing the opportunity to be heard beforehand. This includes, ultimately, recall. As per the current position, if a product poses a risk and the economic operator cannot be ascertained or does not take appropriate corrective action, the market surveillance authority can take 'all necessary measures', including recall.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Enforcing authorities may recover any costs or expenses they reasonably incur in carrying out the actions stipulated in a consumer product recall notice and which have not been complied with by the person on whom the recall notice was served. Apart from this, administrative and other costs are not recoverable. In any proceedings for forfeiture of products, or for criminal prosecutions for the original supply of unsafe products, the court will generally order the parties to pay the authorities' legal and other costs.

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

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23 How may decisions of the authorities be challenged?

A special process exists whereby, before a consumer product recall notice is issued, the recipient is first permitted seven days in which to request the authority to obtain independent advice on whether a recall is necessary. A scheme for these purposes exists under the auspices of the Chartered Institute of Arbitrators. Use of this scheme is, however, extremely rare.

Public law remedies may also be used to challenge the actions of enforcement authorities through court proceedings known as judicial review. This may be appropriate where, for example, an authority has acted outside the scope of its statutory powers, has failed to observe the correct procedural requirements or where its decision can be shown to be wholly irrational.

A person on whom an enforcement notice has been served and a person having an interest in a product in respect of which a safety notice (other than a consumer recall notice) has been served may apply to a court within 21 days for an order to vary or set aside the terms of the notice. A person on whom a recall notice has been served may, before the end of the period of seven days beginning with the day on which the notice was served, apply for an order suspending the effect of the notice.

The current procedural requirements differ for commercial products, in that appeals against HSE improvement notices and prohibition notices are dealt with by the employment tribunals.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

It is very likely that a claimant claiming for injury or property damage will plead that a recall notification and associated warnings amount to admissions of there having been a defect in relation to the product. It will be a question of fact in each case whether the defect existed in the claimant's particular product. It is, however, a matter for the court to determine whether any defect was actually present if the defendant argues that the recall action was purely precautionary. Even where this is established, the claimant will still need to prove the defect caused his or her loss, and that any prior recall or warnings would have been acted upon so as to avoid the loss. (See *Coal Pension Properties Ltd v Nu-Way Ltd* [2009] ECWA 824 (TCC).) See also the ECJ decision in *Boston Scientific Medizintechnik GmbH and Others* (2014) which held, inter alia, that where a product belongs to the same group or production series of products which had a potential defect, such a product may be classified as defective. There was no need to show that the product in question had such a defect. Furthermore, in relation to the question of whether a risk of failure could constitute a defect, the court held that for products that carry a high risk (such as pacemakers) the potential lack of safety would constitute a defect.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Disclosure of documents is generally required by procedural rules in the courts of England and Wales, and parties may be required to reveal documents that assist their opponents' cases. The usual rules as to document discovery apply to any documents (including electronic documents) that are created in the course of investigations, notifications to the authorities and recall communications. However, communications with lawyers and documents created for actual or contemplated litigation purposes may be protected from disclosure by legal privilege.

France

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

The basic French laws governing the safety requirements that products must meet are:

- Act No. 83-660 of 21 July 1983 (published in the Official Journal (JORF) of 22 July 1983, page 2,262);
- consolidated versions of the Decrees 2004-670 of 9 July 2004 and 2008-810 of 22 August 2008 (published in the Official Journal No. 0196 of 23 August 2008, page 13,238 text 13 and JORF No. 159 of 10 July 2004, page 12,520) implementing Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety (General Product Safety Directive) in France;
- consolidated versions of the Decrees 2016-301 of 14 March 2016 and 2016-351 of 25 March 2016
- Act No. 2017-203 of 21 February 2017, ratifying Decrees No. 2016-301 and 2016-351; and
- special acts in force that also govern specific fields; there are, for example, specific provisions within the Public Health Code (CSP), concerning safety requirements regarding drugs and public health, etc.

Decree No. 2004-670 of 9 July 2004 and 2016-301 of 14 March 2016 and Decree No. 2016-351 of 25 March 2016 are integrated into the Consumer Code under Title II, Book IV.

Article L421-3 of the Consumer Code creates a fundamental right to safety for consumers:

> *Products and services must, under normal conditions of use or under other circumstances that may reasonably be foreseen by the professional, offer the safety that can legitimately be expected, and must not be a danger to public health.*

Article L421-1 et seq of the Consumer Code also define other obligations for professionals in connection with this general product safety obligation, including the obligation to provide information, the follow-up obligation and the obligation to notify.

The safety requirements apply to any professional, that is to say the 'producer' and the 'distributor' (article L421-1 of the Consumer Code):

- 'producer' means the manufacturer of the product, the manufacturer's representative and other professionals in the supply chain, as far as their activities may affect the safety properties of a product; and
- 'distributor' means any professional in the supply chain whose activity does not affect the safety properties of a product.

2 What requirements exist for the traceability of products to facilitate recalls?

French law has set up requirements to ensure the traceability of products to facilitate recalls:

- article L423-2 of the Consumer Code introduces a follow-up obligation for the producer who accordingly has to take measures in order to control, follow up and be informed about risks that its products might present, for example, by organising their traceability (by indicating, on the product or its packaging, the producer's identity and address, as well as the product reference or the batch of products to which it belongs);
- article L412-1 of the Consumer Code insists on the requirement of taking measures to ensure the traceability of products and foods; and
- French case law requires the organisation of the traceability of products based on the precautionary principle (decision of the French Administrative Supreme Court of 29 December 1999).

3 What penalties may be imposed for non-compliance with these laws?

The Consumer Code does not stipulate specific penalties for non-compliance with the obligations regarding the safety of products set forth in article L421-3 et seq (ie, the obligations to provide information, to follow up and to notify). However, the government does want the professionals to be aware of their responsibilities and also wants to promote collaboration between them and the authorities.

Nevertheless, there can be civil or criminal penalties if non-compliance with one of these provisions leads to harm to a consumer. In this case the professional may be held liable in both civil and criminal jurisdictions and may be sentenced by the civil courts to remedy the damage caused to the victim. Furthermore, a person who has misled or tried to mislead his or her contracting partner about the nature, origins or risks inherent in the use of the product (deception) is punishable by a fine of €300,000 and up to two years' imprisonment (articles L441-1 and L454-1 of the Consumer Code).

There are no administrative penalties in the case of non-compliance with these laws.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

The obligation to notify government authorities (or other bodies) of defects discovered in products, or known incidents or property damage, results from the General Product Safety Directive and was implemented in article L423-3 of the Consumer Code.

According to article L423-3 of the Consumer Code, the professional responsible for marketing a product has to inform the competent administrative authorities as soon as he or she notices that a product does not comply with the general product safety requirements provided by article L421-3.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

Criteria applied for determining when to notify a defect

According to article L423-3 of the Consumer Code, the professional has to notify government authorities (or other bodies) of defects in products, or incidents, as soon as he or she knows that the product he or she has put on the market does not comply with the requirements laid down in article L421-3 of the Consumer Code (general safety obligation).

The Commission's decision of 14 December 2004 sets out guidelines for the notification of dangerous consumer products to the competent authorities of the member states by producers and distributors

(the guidelines) in accordance with article 5(3) of the General Product Safety Directive. This is the reference document for the application of the provisions of the General Product Safety Directive concerning notification of dangerous consumer products to the French competent authorities by producers and distributors.

These guidelines set out the notification criteria that apply to France and read as follows:

- the product is understood to be intended for, or likely to be used by, consumers (article 2a of the General Product Safety Directive);
- article 5 of the General Product Safety Directive applies (unless there are specific provisions established by other community legislation);
- the product is on the market;
- the professional has evidence that the product is dangerous according to the general product safety directive, or that it does not satisfy the safety requirements of the relevant community sectoral legislation applicable to the product concerned; and
- the risks are such that the product may not remain on the market.

Time limits for notification

According to article L423-3 of the Consumer Code, the professional has to notify the competent administrative authorities of the incident immediately. No precise time limit is defined within the national provisions.

The guidelines for the notification of dangerous consumer products in France (commission's decision of 14 December 2004) provide two time limits:

- a company must inform the competent authorities as soon as the relevant information has become available, and in any case within 10 days from when it has reportable information, even while investigations are continuing, indicating the existence of a dangerous product; or
- when there is a serious risk, companies are required to inform the authorities of the situation no later than three days after having obtained notifiable information.

6 To which authority should notification be sent? Does this vary according to the product in question?

According to the ministerial order of 9 September 2004 concerning the application of article L423-3 of the Consumer Code, notifications (pursuant to article L423-3) should be sent to one of the three authorities. Depending on the product in question, the competent authority is one of the following:

- the Directorate for Road Safety and Traffic: notification must be provided from car manufacturers and their distribution network when vehicles and equipment sold under the manufacturer's brand are concerned;
- the Directorate General for Food: notification must be provided when food products are concerned, which includes animal food, animal food products or human food. All notifications regarding food products that are not included in these categories (such as additives, aromas, etc) are to be submitted to the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF); and
- the DGCCRF: the DGCCRF receives any other notifications that do not fall under the auspices of the Directorate for Road Safety and Traffic or Directorate General for Food referred to above.

7 What product information and other data should be provided in the notification to the competent authority?

According to article 2 of the Ministerial Order of 9 September 2004, the following information should be provided in a notification to the competent authority:

- the date of notification;
- the name and address of the professional or company providing the notification, as well as those of its suppliers and the professionals who have been supplied with the product;
- the product's description (particularly its name, brand, batch number, volumes involved, etc);
- the description of the danger and the measures taken by the professional; and
- any other information that could be useful to the authorities.

Notification forms can be found on the DGCCRF's website: www.economie.gouv.fr/dgccrf/Securite/Rappel-de-produits/Signalement-des-produits:

- for non-food products, the notification form is available from: https://webgate.ec.europa.eu/gpsd-ba/index.do; and
- for food products that fall under the auspices of the DGCCRF, the notification form is available from: www.economie.gouv.fr/files/files/directions_services/dgccrf/securite/alertes/documents/formulaire_prof.pdf.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

There is no explicit obligation under French law (the Consumer Code) to provide authorities with updated information about risks. The professional's obligation to inform, as laid down in articles L423-1 and L423-2 of the Consumer Code, only concerns the obligation to provide the consumers with information that enables them to assess the risks inherent in a product.

However, French controlling officials, listed in article L511-3 of the Consumer Code, have investigatory powers, and the professionals must respond to their enquiries (article L512-8 et seq).

It should be emphasised that this new article (amending the old article L215-1) has significantly reduced the number of authorities that are entitled to investigate and note professionals' infractions: only the officers of competition law, consumption and fraud control have that power from now on.

Article L512-5 of the Consumer Code authorises those officials to enter business premises, and premises in which a service is being provided. Moreover, this new article gives them the power to exercise their mission on the public highway.

They can also require to be provided with all information allowing them to determine the specifications of the products or services or to estimate whether the product or the service is dangerous (article L512-8 et seq of the Consumer Code).

The Sanitary Surveillance Institute (IVS), created in 1998, and whose task is, in the case of a threat to public health, to inform the public authorities of the origin of the threat and to take appropriate measures to avert the danger, can also request that a person communicate any information in his or her possession relating to serious threats to human health (article L1413-5 of the CSP).

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

See question 3.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

Article 11 of the Criminal Procedure Code specifies that the procedure during an inquiry is secret.

In accordance with this fundamental principle, the officials and employees of the competent authorities have to respect professional confidentiality. Despite the provisions of article 11 of the Criminal Procedure Code, article L512-22 of the Consumer Code does, however, allow the disclosure of confidential information where doing so would avert the risk of serious and immediate danger to the health and safety of consumers.

Therefore, commercially sensitive information that has been communicated to the competent authorities is not in all circumstances protected against public disclosure.

11 May information notified to the authorities be used in a criminal prosecution?

Information notified by professionals to the authorities can be completed by means of inquiries or hearings before the competent authorities that are in charge of the investigation and assessment of breach of the legal provisions regarding product safety (indeed, the professionals have to provide them with all information related to the product and its potential danger (see question 8)). For this reason, information notified by the professionals to the authorities and completed during the inquiries may be used in a criminal prosecution when a breach of the legal provisions regarding product safety has been noted.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

According to article L412-1,II of the Consumer Code, a product recall can be ordered by decree of the French Administrative Supreme Court for modification or full or partial reimbursement or exchange if the products do not comply with the general safety obligations defined in article L421-3.

Under the provisions of article L521-17, a recall can also be ordered by ministerial order in cases of a 'grave or immediate danger' and if the products do not comply with the general safety obligations defined in article L421-3.

According to article R422-1 of the Consumer Code, these decrees and ministerial orders are made after consulting the National Agency for Safety of Medicine and Health Products (ANSM, formerly the AFSSAPS) and the Agency for Food, Environmental and Occupational Health & Safety (ANSES, formerly the AFSSA) in matters relating to their responsibilities.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

According to the provisions of the Consumer Code, two kinds of measures can be taken if products do not comply with the statutory safety requirements: permanent measures and temporary or urgent measures.

Permanent measures

Article L412-1 of the Consumer Code specifies that the government may order, by decree of the French Administrative Supreme Court, that products shall be recalled or withdrawn from the market for the purpose of modification or exchange if the products do not comply with the general safety obligation defined in article L421-3. This article also allows for determination of the different ways in which products or services are to be prohibited or regulated if they do not comply with the general safety obligation.

Temporary or urgent measures

Orders

In the case of serious or imminent danger in connection with the provision of a service, and if the products do not comply with the general safety obligation defined in article L421-3, the administrative authorities can take urgent measures and suspend the provision of a service for a period not exceeding three months (article L521-23 of the Consumer Code).

A recall can also be ordered pursuant to the provisions of article L521-17 by ministerial order (in case of serious or immediate danger in connection with the provision of a service and if the products do not comply with the general safety obligation defined in article L421-3). The representative may also order the destruction of the product or the suspension of the provision of a service as well as the publication of warnings.

Injunctions

Article L521-18 allows the competent ministries to issue two kinds of administrative injunctions (an injunction for the product to be adapted so as to be compliant with the safety provisions and an injunction for inspection by an authorised testing institute in order to rule out any danger).

14 Are there requirements or guidelines for the content of recall notices?

There are no express requirements in French law for the content of recall notices. However, the decrees or orders must specify:

- the measure that has been taken;
- the duration of that particular measure (in the case of a temporary measure); and
- the conditions under which the costs incurred by the execution of this measure are borne by the professional.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The communication of warnings or recalls to professionals and suppliers is made by decrees and orders.

The communication of warnings or recalls to users may be carried out by:

- information campaigns issued by the administrative authorities;
- publication of guidelines by the administrative authorities (for example, in the field of risk prevention for blood products and for pharmaceuticals obtained from blood, the Minister for Employment and Social Affairs published guidelines for patient information); and
- information on recalls in the press (for example, in the periodical Que Choisir managed by a consumer association), on television or on the internet.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

French law does not specify targets or a period after which a recall is deemed to be satisfactory.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

The civil courts will sentence the producer or other suppliers to repair or replace recalled products or offer other compensation.

If the producer cannot prove that the end-user used the product despite being informed of the recall, he or she has to indemnify the victim.

18 What are the penalties for failure to undertake a recall or other corrective actions?

The penalties for failure to comply with decrees or ministerial orders ordering recalls or other corrective actions are as follows:

- a failure to comply with a decree taken in accordance with the provisions of article L412-1 of the Consumer Code is punishable by a fine defined in the decree; and
- a failure to comply with a ministerial order taken in accordance with the provisions of article L521-17 of the Consumer Code is punishable by a fine of €1,500 for an individual and of €7,500 for a corporate entity. The dangerous product can also be confiscated (article R532-1 and R452-4 of the Consumer Code).

There are also product-specific criminal consequences. For products whose intended use relates to health, there are special provisions in the CSP (article L5451-1 et seq).

These impose a criminal fine of €150,000 or a sentence of up to two years' imprisonment on a person who:

- continues trading despite a banning order;
- does not comply with any sales restrictions; or
- fails to withdraw the product from the market or to pass on warnings or the relevant instructions for use.

Similarly severe provisions apply to foodstuffs. In this regard, failure to comply with a withdrawal order may satisfy the definition of 'fraudulent misdescription' of goods for sale (falsification). The falsification occurs by creating the false impression that a product is marketed as complying with standards when it does not.

Merely offering for sale such fraudulently misdescribed foodstuffs or animal food constitutes fraudulent misdescription and carries the same sentence. If the misdescribed substance is harmful to human or animal health or if the offence is committed by an organised group, it is punishable by a criminal fine of €750,000 and a sentence of up to seven years' imprisonment (article L451-2 of the Consumer Code).

There are also general criminal law consequences. Three criminal offences may be committed in connection with a failure to withdraw unsafe products from the market or a failure to warn consumers of possible risks with those products:

- involuntary manslaughter;
- negligent bodily harm; and
- endangerment.

The elements of the offence of endangerment are satisfied if:
- the person concerned owes a duty to ensure the safety of the product;
- the violation of this duty creates the risk of death, mutilation or permanent disability;
- this risk is immediate;
- another person is exposed to this risk; and
- the breach of the duty to ensure safety was intentional (article 223-1 of the Penal Code).

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

In order to have manufacturers or others in the supply chain undertake a recall or take other corrective actions, the authorities may undertake investigations or take preventive measures:
- they may undertake investigations at workplaces between 8am and 8pm (article L512-5 of the Consumer Code);
- they may take test samples (article L512-23) or gather all kinds of information necessary in order to get to know the product's properties (article L512-8 et seq of the Consumer Code);
- they may request the transmission of different kinds of documents and information regarding the products (article L512-8 et seq of the Consumer Code); and
- they can even order the closing down of the entire firm or of parts of the firm manufacturing the product (article L521-5 of the Consumer Code).

The authorities can also take permanent or temporary measures (see question 13) and:
- order that products shall be recalled or withdrawn from the market (article L412-1 of the Consumer Code);
- order the destruction of the dangerous product (article L412-1 of the Consumer Code);
- suspend the fabrication, the importation, the exportation or the marketing authorisation of a product for a fixed time period, limited to a maximum of one year (article L521-17 of the Consumer Code); and
- order the publication of instructions for use and safety precautions (article L521-17 of the Consumer Code).

In the case of the manufacturers' non-compliance with these measures, the authorities may also apply specific penalties provided for by French law (fines, etc) (see question 18).

The authorities can also use the media (information campaigns, information on recalls in the press) in order to compel manufacturers to undertake a recall or other corrective actions (see question 15). The impact that the promulgation of such information has on consumers is very useful for the authorities with regard to obtaining the manufacturers' compliance with the ordered measures.

20 Can the government authorities publish warnings or other information to users or suppliers?

The ANSM must inform, if necessary, the public by any media, and notably by broadcasting health messages or recall notices on any product that represents a danger to human health (L5312-4 of the Public Health Code).

Finally, the IVS may warn the Minister for Health Affairs about any threat to public health.

The government authorities' websites also provide facilities for members of the public to post remarks and report incidents.

The website of the ANSM also provides a special form to report undesirable effects of a medicine.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Pursuant to the provisions of articles L412-1 and L521-17 of the Consumer Code, the government authority can organise a product recall where a producer or other responsible party has not already done so.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

The costs incurred by the government authorities in relation to product safety issues are recoverable from the producer or other responsible party.

This results from decisions of the Administrative Supreme Court as well as from the provisions of the Consumer Code. Article L412-1, II (2) regarding decrees of the Administrative Supreme Court and article L521-17 regarding ministerial orders stipulate that the decrees or ministerial orders indicate the conditions under which the costs associated with the safety measures pursuant to a decree or ministerial order are to be borne by the professional. However, the professionals often challenge the obligation to bear these costs.

23 How may decisions of the authorities be challenged?

Decrees of the Administrative Supreme Court may be challenged before the administrative courts, setting aside an administrative decision on the grounds that such a decree is ultra vires; submitting that there were no safety regulations for the product in question or that the product complies with European safety provisions.

The banning or suspension order in the case of imminent danger issued by the prefect or by the competent minister is a unilateral administrative act that can also be challenged by claiming ultra vires.

The opinions issued by the Consumer Safety Commission cannot be challenged before the administrative courts, because of their advisory nature and the fact that they are not regulatory decisions. The same applies for the opinions of the ANSES and the IVS.

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Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

The publication of a safety warning or a product recall is likely to be viewed by the French civil courts as an admission of liability for defective products, or at least as an indication that the product is defective.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

In product liability actions, communications, internal reports or investigations into defects may be disclosed by the producers to claimants in order to prove that:

- their product is not defective (and that any damage is caused by the conditions of use of the product); or
- the defect results from a third-party product that has been supplied and incorporated into the end product.

Germany

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

German law does not recognise a basic codification regulating general product safety requirements for each and every product. In lieu thereof, the German Federal Court of Justice has ruled as a general principle – which is based on German Civil Code tort law – that a product must meet the safety standard that the affected business area (consumers or specific entrepreneurs) may reasonably expect from such products. The user (and bystander) should be protected from dangers arising from a product that is used in a regular manner, but also from dangers that arise from (predictable) misuse. The court thus has developed a legal framework based on general German tort law that may oblige manufacturers to conduct a recall or, as a less severe means, rework products in the field or utter a warning.

There exist several specific regulations for specific products (machines, pharmaceuticals, medical products, cosmetics, toys, foodstuffs, etc). Among these are EU directives that must be transposed into national law before they apply as well as EU regulations and national statutes. In contrast to EU directives, EU regulations are classified as a primary source of law, which means they apply directly and have to be interpreted the same way in all member states of the EU. EU directives, however, may be transposed into national law in different ways in different member states, thus leading to a different level of protection from product risks.

The EU General Product Safety Directive (2001/95/EC), which came into force on 15 January 2002, composes a central set of standards of product safety. It was transposed into German law through the Product Safety Act (ProdSG), which has been in force since 1 April 2004 under a different name, the Equipment and Product Safety Act. Its last recast (which merely adapted terms and definitions) came into force on 8 September 2015. The revised version transposes 13 EU directives and one decision into national law to prevent inconsistencies between national law and EU law.

The German Product Liability Act, which has been in force since 15 December 1989, is less important for recall situations, as it primarily addresses a manufacturer's or importer's duty to compensate harm suffered from product risks.

2 What requirements exist for the traceability of products to facilitate recalls?

German law does not recognise duties regarding traceability of products in general. Only products carrying a very high degree of risk for society such as pharmaceuticals and medical devices are subject to detailed regulation on their traceability. Cars can usually be traced back to the current owner owing to the detailed legal requirements of car registry. Apart from that, it is common in certain industries (such as the automotive industry) to contractually require suppliers to secure traceability of their products. Besides, manufacturers may have an own interest in securing traceability of their products as it may affect their recall costs insurance coverage and recall costs in general

Besides traceability issues, several regulations deal with the labelling of products. With regard to consumer products, the ProdSG contains a detailed comprehensive body of legislation that aims to enable the consumer to identify the manufacturer. To enable traceability, the product or its package must display the producer's name and address or, insofar as it is not based in the European Economic Area, the name and address of the EU representative or the importer. Moreover, unambiguous product identification information must be provided on the product or package.

3 What penalties may be imposed for non-compliance with these laws?

If a product is found to be unsafe, different fields of law may be touched. Administrative penalties – because of constitutional requirements – are statutorily regulated and their extent depends on the product in question: for example, even minor breaches of duties such as incorrect labelling that prevents traceability of pharmaceuticals may result in penalties of up to €25,000. Other statutes, such as the German cosmetics regulation, refer to the German Food and Feed Code and its penalty system of up to €100,000. Besides financial penalties, the authorities are entitled also to withdraw permission to do business in severe cases.

The most prominent regulation on administrative penalties undoubtedly is the ProdSG. It includes a range of monetary fines from €1,000 to a maximum of €100,000. The system that provides for a certain range of penalties is very much similar to the regulation in other pieces of legislation as it allows authorities to consider peculiarities of a case. Basically, a fine can be imposed for every single illegal act in the context of the applicable legislation. The exact amount of the fine, however, is at the discretion of the competent authority and litigable in courts. Whether a fine is adequate or not mainly depends on the quality and severity of the offender's breach of duty, the grade of its culpability as well as special circumstances (eg, repeated offence or recklessness).

Compared to other, especially common law jurisdictions, German law merely provides for limited claims of injured persons. The injured person will have a claim for compensation of the damages caused by an unsafe product. Such damages include material (eg, loss of profit) and immaterial (eg, damages for pain and suffering) aspects. However, German law does not recognise punitive damages. Any breach of duty regarding traceability is unlikely to have an effect on the damages amount. Under special circumstances, competitors might have a claim under the regulations of fair trade.

The most severe penalties for a company's board arise from criminal law. While board members generally may be imprisoned if an unsafe product leads to bodily harm or death of third persons, such sanction is imposed quite seldom. It can only be imposed if board members or executive employees acted at least negligently in manufacturing, marketing or not recalling an unsafe product. In most cases, the prosecutions' accusations will be confined to negligent conduct and result in a fine. However, if board members or executive employees acted voluntarily in producing unsafe products and human beings were harmed, as, for example, in the matter of defective silicone breast implants, ineffective cancer medication or in marketing non-marketable food such as in the EHEC disease or the dioxin crisis, a term of imprisonment for up to 15 years may be imposed. The exact penalty depends on the peculiarities of the case and the impact the product risks had on third persons. In principle, such penalties can also be imposed in connection to breaches of traceability duties and violation of recall duties – for example, if a manufacturer knew about life dangers arising from its products and nevertheless did not conduct a recall.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

There is no general provision that requires informing government authorities in cases where a defect is discovered in products, but special regulations, inter alia for medical devices, pharmaceuticals and foodstuffs, may oblige the manufacturer or importer to immediately inform authorities of a (potential) defect.

The ProdSG (as the main piece of legislation to provide for administrative action) is, inter alia, applicable to, consumer products and provides special duties for the manufacturer, importer and retailer. The manufacturer for example has to examine and collect consumer complaints and notify the competent authorities immediately when it fears a risk to health or safety of consumers on a reasonable basis of information. This notification must be issued immediately, without delay. This obligation will not only come into effect when the producer, representative or importer is positively aware of a defect in a product, but also at the point in time when it knew – or should have known, according to the present information or his or her experience – that the product posed a risk to health and safety.

Furthermore, the notification should include a list of actions that have already been taken to avoid the risk at hand and will be taken in the future in order to prevent government authorities from taking their own action. In order to encourage the obliged parties to notify the authorities the notification may not be used as a basis for administrative fines or for penal prosecution.

Notifying the authorities does not terminate the manufacturer's duty to conduct a recall for which it is solely responsible. The notification will only enable authorities to examine whether the risk is being controlled appropriately or whether there is a need for further administrative action. Although the authorities might be entitled to conduct a recall of an unsafe product by their own means, it is unlikely they will do so as long as the manufacturer is taking sufficient steps to control the risk (hence the list of action already taken and the forecast of planned action as explained above).

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

The criteria for determining whether a notification is necessary vary depending on the category of the product. The higher the risk to human beings, the more demanding the requirements to notify government authorities are. If, inter alia, pharmaceuticals or medical products or possibly lethal products are concerned, the knowledge of a (possible) product defect will very likely lead to a notification duty under the ProdSG. In general and for most products, a notification will require a product defect and a risk to health and safety of human beings.

The German Federal Court of Justice has developed a tort law duty that a manufacturer is obliged to monitor the market and examine customer complaints in order to assess whether there exists a product defect. The intensity of such monitoring measures depends on the category of the product and its possible impact. If a manufacturer has reasonable and reliable knowledge that some product defect causes a hazard to health and safety of human beings, the authorities will most likely have to be notified. If just minor risks result from the product, the manufacturer may decide not to notify the authorities. Either way, the manufacturer alone carries the risk of a misjudgment, thus is well advised to seek legal and technical advice.

If a manufacturer decides to notify the authorities, this notification has to be carried out expeditiously.

6 To which authority should notification be sent? Does this vary according to the product in question?

Although the ProdSG mentions the term 'market surveillance agency', such an agency does not exist; rather the term abstractly describes an administrative body that carries out the tasks imposed onto the 'market surveillance agency'. A German federal notification authority does not exist.

It is only in special areas, such as medical devices or pharmaceuticals where there are special federal agencies that must be notified such as the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). In cases of unsafe cars or car parts, the German Federal Office for Motor Traffic (KBA) needs to be notified.

When products are concerned, where no special federal agency is appointed as the market surveillance agency, the notification will have to be sent to the competent authority in the state where the defective product is located. Thus, the notification procedure depends on the particular state that is affected and the respective state legislation. For example, in the state of North Rhine-Westphalia, the district council is the responsible authority. The state of Hamburg imposed the administrative duties pursuant to the ProdSG onto the department for consumer protection.

Alternatively, notifications can be sent to the Federal Agency of Labour Protection and Labour Medicine, which is the agency that must inform the other state authorities as well as RAPEX (notification procedure to notify the European Commission of product risks).

7 What product information and other data should be provided in the notification to the competent authority?

The information the manufacturer must include in the notification is only regulated in special fields of law. The information is listed in online data sheets that the manufacturer has to fill in.

In general, there is no legislation stating exactly what product information has to be sent to the authorities. If the competent authority does not provide an online notification system, the manufacturer should consider providing information on the following topics:

- brand;
- information as to which product class the product belongs;
- product name;
- model description;
- EAN codes (European article number) or other means of Identification;
- product description;
- production period;
- customers and customer addresses (if known);
- distribution channels;
- description of the hazard and circumstances when it may occur;
- description of the risks to health and safety as well as probability of occurrence;
- description of already known harms and accidents;
- text of recall or warning (if sufficient);
- information channels used in order to inform customers (especially if consumers);
- recall measures that have already been taken; and
- success rates (reached and expected).

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Stipulations defining communication after notification exist in special pieces of legislation (eg, for medical devices or pharmaceuticals). In general, the authorities will include a requirement to be kept updated once the recall has been finalised, or at least be informed in a certain time frame.

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

The authorities may fine the manufacturer. The amount depends on the applicable piece of legislation. The fines are rather low and range from €10,000 to €25,000. If the manufacturer does not comply with reporting obligations, authorities might come to the conclusion that the manufacturer is a continuing danger to the market. Further steps (even closing the business) can be taken by authorities, again depending on the peculiarities of the case and the risk at hand.

Additional penalties, such as imprisonment or (personal) fines for board members under criminal law, are possible. The maximum sentence is imprisonment of one to five years. These further consequences under criminal law as well as damages under civil law require causal personal injury to human beings that could have been prevented had the manufacturer appropriately notified the authorities.

Update and trends

The decisive product recall judgment of the Federal Court of Justice in 2008 has not yet been followed by another decision of similar importance. While the Federal Court of Justice in 2008 was given the opportunity to outline some important aspects regarding the necessity of recall or (just) a warning towards business customers, it did – not even obiter – define which requirements (and limits) exist in terms of recalls of consumer products. Since in its 2008 decision the Federal Court of Justice came to the conclusion that – owing to the circumstances of the case – a warning is sufficient, it did not need to decide on subrogation issues. Thus, the question as to which subrogation claims – and on which legal basis – exist, is still merely subject to discussions in German legal literature. There is no case on the horizon that might give the Federal Court of Justice the opportunity to develop its views on product recalls.

While 'Dieselgate' is an ongoing issue and Volkswagen is fighting several battles worldwide (eg, against US authorities, litigation pursuant to customer complaints), it has made one thing pretty clear from a German recall view perspective: the German Federal Office for Motor Traffic (KBA) has taken a very soft approach towards the industry in recent years. Now in 2018, the KBA has ordered several recalls (eg, against Daimler) as it found evidence that other OEMs had made changes to the engine management depending on whether it was worked in test runs or not. Since it is safe to say 'Dieselgate' was by far the biggest scandal in German industrial history and followed by large media coverage and negative public echoes, the KBA and other surveillance authorities will probably take a harsher approach against manufacturers and retailers in the future.

While it is not exactly a recall issue, the introduction of group litigation becoming effective from 1 November 2018 onwards is to some extent driven by recall and large warranty cases. It has been common sense in Germany that litigation has to take place between 'two adversaries', and that has even been the case when a multitude of similar cases (factual or legal) needed to be decided. German legislators have still not followed the US or Australian way of launching 'big style' mass tort litigation, but limited the new law to the possibility that certain groups of claimants may ask a higher regional court to determine certain facts and legal questions that the group members can rely upon for their own litigation. The new law follows an 'opt-in' system, thus only favouring those who decided to become a group member.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

The authorities are bound by law to protect public safety. Generally, the authorities will neither need to obtain nor share commercially sensitive information with the public. If such conduct indeed should become necessary to protect third parties from imminent or severe danger, authorities certainly are entitled to do so but they have to thoroughly evaluate and assess the impact on the manufacturer. If the authorities did not act adequately, the manufacturer may be entitled to compensation.

11 May information notified to the authorities be used in a criminal prosecution?

Despite a particular regulation in the ProdSG that the notification may not be used in criminal prosecutions, this regulation explicitly only includes the notification and not additional correspondence. Thus, authorities are not allowed to pass the notification to prosecutors.

However, it is mandatory for the prosecution to investigate potential breaches of duty that might endanger public safety. When authorities order a recall officially, the prosecution could investigate the case. If it does, it is likely that it will use all investigation means legally allowed, and that includes searching and seizure of files both in the hands of the manufacturer as well as in the authorities' possession.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

Product recalls and the requirements for a successful recall are not statutorily regulated in Germany and very little case law exists on product recalls. In the past, the courts mainly had to assess whether recourse claims of the manufacturer against the supplier of the defective product or product part causing the recall were indeed founded. The German Federal Court of Justice ruled in 2008 that a recall has to be conducted when a mere warning is not sufficient to appropriately control the risk. If it is to be assumed that a consumer will not appropriately act on a mere warning, a (free-of-charge) recall of defective products might be necessary, irrespective of the existence of contractual warranty claims. Such severe measure, however, will merely have to be taken if a certain risk to the health or safety of the user or bystanders exists. In a second step, suppliers affected by an OEM recall should not necessarily accept costs for free-of-charge replacement of suspect parts outside contractual warranty since safety risks are usually entirely remedied upon dismantling the suspect part. The free-of-charge replacement thus may only be considered where a mere dismantling of a suspect part would lead to a significantly lower success rate of the recall. This question will usually arise in consumer products recalls. A free-of-charge replacement thus is not a mandatory legal requirement pursuant to German tort law, but may have an impact on whether certain recall measures are sufficient or not.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

A distinction must be made between warnings and recalls by authorities on the one hand and private entities on the other.

The requirements for warnings and recalls invoked by the authorities are to be found in the ProdSG and other special regulations. The authorities will have to take appropriate measures if they have reason to suspect that a product is defective and dangerous. However, they have to cease such measures once the manufacturer will have proven that the necessary steps to eliminate the product risks in question have been taken or that the risk assessment was wrong and the true risk level does not justify the measures taken.

Special areas such as medical devices or pharmaceutical liability recognise special regulations regarding the exact time to publish warnings and when to conduct a recall. Generally, a recall will be necessary when there is a danger to human beings and a warning will not be sufficient to eliminate the danger.

14 Are there requirements or guidelines for the content of recall notices?

Statutory regulations covering the content of recall notices do not exist, although guidelines for special products such as medical devices do exist. Generally, it is up to the manufacturer's discretion what actions it will undertake and which content the recall information contains. The recall notice must be coherent. It is to be issued in a way that – depending on the group of customers – enables the average customer to understand the content and importance of the recall notice. Moreover, the notice itself must inform about the danger of the product on the one hand and about the circumstances of its return on the other.

If a manufacturer decides to use retrofitting or upgrades in order to eliminate a product defect, it has to make sure that the instructions for such retrofitting or upgrade are absolutely clear (eg, by use of pictures, pictograms and descriptions). As a general rule, the more complicated the installation of a retrofitting or upgrade is, the less suitable it is for an installation by the customer him or herself; the manufacturer will bear all risks arising from a wrong installation, especially the risk that the danger at hand is not eliminated.

In any case, the manufacturer has to minimise the risk and must try to inform any potentially concerned person of the recall.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

With the exception of special areas of law, there are no statutory requirements that regulate the exact media to be used in a recall scenario. Since the manufacturer has to take adequate and effective steps to minimise the risk to public safety, it has to evaluate the probability and severity of harm to human beings. If courts evaluate the media use to not have been sufficient, the manufacturer's board might face criminal charges as well as claims for indemnification.

Thus it seems safest to make extensive use of different kinds of media such as the internet (manufacturer's own web presence, YouTube and social media channels such as Facebook, Instagram, Twitter, etc), TV and radio while at the same time limiting damage to the company's public image. The use of media, however, strongly depends on the relevant customer group (eg, parents, elderly people, certain professions or online recreational activities).

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There is no law, regulation or guideline that specifies a satisfactory recall rate. The authorities will order the manufacturer to forward information on the status of a recall on a regular basis (eg, every week or month). Then it is up to negotiations with the authorities if they regard a recall to have been satisfactory, which to a large extent depends on the severity of the risk, occurrence probabilities and the product in question. While a recall ratio of 85 to 90 per cent of consumer products is quite high, it could be deemed not sufficient for medical devices or automotive products. Experience shows that authorities have taken a significant amount of cars out of service because consumers did not react to the recall campaign at the expected rate.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

In case of a direct contractual relationship between a manufacturer and an end customer, the manufacturer will have to replace the defective good free of charge as long as affirmative defences against contractual claims (especially warranty claims) do not exist. If merely a component is defective, warranty claims will include dismantling and reinstallation costs. Since last year's edition, the German parliament has made a new law that came into force on 1 January 2018. It basically extended claims for dismantling and reinstallation costs – that only consumers were entitled to – to business customers without the need to prove negligent conduct on the seller's side. Furthermore, it facilitated subrogation against suppliers with regard to dismantling and reinstallation costs.

The general limitation on sales contracts is two years.

There is no existing German case law that states that a producer or manufacturer has to repair or replace goods free of charge if there are no contractual warranty claims. However, given that a manufacturer will have to make sure that a product risk will definitely be eliminated, it will have to repair or replace its product when the end user is a consumer and there is a likelihood that the consumer otherwise will continue to use a defective and hazardous product. A duty to replace or recall defective products may not arise if a warning is deemed sufficient to eliminate the risk, warranty claims have elapsed and it is safe to assume that the customers (eg, business customers) will not continue to use the defective products. Thus, replacement of suspect parts is not required in order to conduct the recall itself, but it is a question of whether the recall has been effective or not.

18 What are the penalties for failure to undertake a recall or other corrective actions?

If the circumstances require a recall of a defective product, the manufacturer is seen as having violated its duty to maintain public safety. As a consequence, the manufacturer will have to bear all claims of persons harmed by the product if their damages are caused by the manufacturer's failure to undertake a recall or other (appropriate) corrective actions. Such claims can contain material as well as immaterial damages.

In cases of personal injury, the manufacturer will face criminal charges. If a court finds that the board members had knowledge or should have known that a recall was the only appropriate means of eliminating a danger, it could even assume intentional conduct. In case of death of a person, the penalty could be imprisonment for up to 15 years.

Authorities are legally allowed to impose fines from €10,000 for refraining from taking corrective actions and up to €100,000 for refraining from undertaking a product recall irrespective of the injury of persons.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

Authorities are legally allowed to issue a variety of remedial or corrective orders. Among the protective or remedial measures they may take are product quality tests, public warnings, distribution prohibitions, a recall or destruction of the product. Since the ProdSG belongs to the area of law for the prevention of hazards, authorities must abide by certain principles (required by constitutional law) such as suitability and reasonableness of the measures taken.

However, the primary focus of public and civil laws for controlling and eliminating a product risk are the manufacturer, importer and distributor. If they have taken the appropriate steps to control a product risk, authorities will have to very carefully assess whether authoritative action is indeed necessary.

20 Can the government authorities publish warnings or other information to users or suppliers?

As mentioned before, German authorities are entitled to take a wide variety of measures to avoid and eliminate product risks. That includes issuing information to suppliers or dealers and issuing warnings to the public in respect of substantial product risks in cases where the producer, importer or distributor did not take appropriate action in time.

Consumers will find warnings and information concerning other remedial measures on government websites, and there are certain sites that feature the opportunity to post online reports or remarks. The authorities would be potentially liable in civil law – even if public liability is difficult to establish – for any unlawful content to the extent it caused damages to a private person or entity.

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21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

The authorities may order a product recall if no less severe measure is sufficiently suitable to fully control a specific product risk (eg, amended warnings or additional labelling). Since the authorities need to follow the test of reasonableness in principle, as a first step they are usually bound to order the manufacturer, importer or distributor to recall the product. In the event the addressee does not comply with the order or the product poses a serious risk to the health or safety of human beings on the basis of a reasonable risk assessment, the authorities may not only be legally allowed to, but even have an obligation to, conduct or organise a recall themselves.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

As a matter of general principle in public law for the prevention of hazards, costs for authoritative action incurred in the lawful control or elimination of risks in lieu of the responsible party may be recovered from this party by way of administrative order. However, the expenses should have been reasonably incurred for suitable and necessary parts of the corrective actions, which is litigable in court.

23 How may decisions of the authorities be challenged?

The competent authorities in cases of prevention or elimination of product risks are state authorities. This means that legal procedures differ from state to state. In some states, it is mandatory within the regulatory framework to challenge the decisions of authorities by an objection which must be addressed to the authority that has issued the decision. During the course of proceedings, either the issuing or supervisory authority may affirm, amend or even reverse the initial order. If the administrative bodies fully stand by or partly confirm their decision, the affected party can file public law litigation in the administrative court system, which may comprise trial and tiered appeal processes.

As some states abolished the need for administrative review proceedings, immediate public law litigation before the court is allowed in these states.

The formal challenge as well as litigation generally has a suspensive effect; however, the administration may order the immediate enforceability of the challenged order, in which case such enforceability itself may be subject to administrative or judicial review.

In cases of utmost urgency, manufacturers or others who are affected by directives from authorities have the opportunity to initiate accelerated litigation to seek a temporary order or preliminary injunctive relief. Within this summary process, the judicial examination focuses on the matter of urgency. The administrative court will assess whether the interests of the affected party or public interests are to prevail in the context of the extent and severity of the product risk. In practice, this kind of accelerated process is quite usual in Germany.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

The administrative order does not have any prejudicial effect on any potential civil law obligation or dispute. The intention of the legislation in respect of the laws on prevention of hazards is to avoid or mitigate product risks to the public and consumers in particular, and to grant the government decisive and extensive measures to protect public safety. Subject to the risk assessment of the authorities, issuing warnings or conducting a recall may be unrelated to a specific manufacturer of an affected family of products, or unrelated to specific products of the total production lots. There may be no way to identify defective products of a larger production series within reasonable time and expense. The distribution chain may not be immediately known, and authorities may act on preliminary and incomplete information. Thus, warnings or recalls simply may have an impetus that does not help a potential plaintiff in litigation.

The civil law liability (product liability) is determined by the requirements of the applicable tort and strict liability regimes and will require that the claimant provides, among other things, evidence that the product was defective and caused the alleged damage.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

German civil procedure law does not recognise any kind of discovery process or a pretrial discovery phase in general. As a consequence, neither party has procedural pre-litigation means to compel the opposing party to either disclose any type of documents or records. This is in consideration of the 'principle of provision', meaning that the parties to a litigation need to fully state their case and provide evidence for all disputed facts; the principle of disposition is to put the proceedings into the hands of the parties themselves and the parties decide what facts and documents to provide from their side. Under certain limited circumstances (but only within the confines of a trial), the court may order a party to provide specific documents it deems to be decisive.

In product liability litigation, therefore, the plaintiff needs to provide evidence of the defect and causation, at least, without recourse to any records that may be in possession of the other party. However, civil procedure law recognises certain rules that may partly relieve the plaintiff from the burden of proof or even reverse it.

In contrast to civil procedure, criminal courts and prosecutors are indeed entitled to force disclosure of internal information of the manufacturer (eg, by seizure). For this reason, claimants sometimes initiate criminal investigations against potential defendants before suing them in civil litigation, as the German law of civil proceedings recognises a right to access records of the prosecution as long as a legal interest exists.

Greece

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

The basic legislative documents that set out the Greek legal framework on product safety are Ministerial Decision Z3/2810/14 of December 2004 (MD), which implemented EU Directive 2001/95/EC on General Product Safety (GPSD) and Law 2251/1994 on Consumers' Protection (usually referred to as the Consumers' Law, as amended many times and in force today after being codified in 2018 – Law No. 2251), which, inter alia, implemented EU Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products (as amended by EU Directive 99/34/EC, the PL Directive). The above legal framework is supplemented by Regulation (EC) No. 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, in force as of 1 January 2010.

The General Secretariat of Trade and Consumer Protection of the Ministry of Economy and Development is the central competent authority regarding producers' compliance with the product safety rules (the General Secretariat).

The above-mentioned basic legislative documents supplement the provisions of the legislation on various specific product categories, where the latter does not cover certain matters, such as the description of the powers of the competent authorities on safety issues.

A product is safe if, under normal or foreseeable conditions of use, including its expected lifespan, it does not present any risk, or it presents only a minimum risk that is considered acceptable and compatible with a high level of protection for consumer safety and health (article 2b of the GPSD and the MD and article 7, paragraph 3, Law No. 2251).

There are various provisions for specific product categories, including the following.

Toys
Common Ministerial Decision 3669/194/2011 (Government Gazette Bulletin (GGB) 549/B/2011), implemented EU Directive 2009/48/EC on the Safety of Toys. The competent authority is the First Directorate of Industrial Policy, of the General Secretariat of Industry, of the Ministry of Economy and Development (the Industry Secretariat).

Childcare products
Ministerial Decision Z3-818 (GGB 1395/B/2009). Competent authorities are the General Secretariat and the local prefectures.

Low-voltage products
Common Ministerial Decision 51157/2016 (GGB 1425/B/2016), implemented EU Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits. The competent authority is the Fourth Directorate of the Industry Secretariat.

Power sockets and plugs
Ministerial Decision 529/28-1-2000 (GGB 67/B/2000), as amended by Ministerial Decisions 4822/17.3.2000 (GGB 352/B/17-3-2000) and 8991/14-5-2003 (GGB 643/B/2003). The competent authority is the Fourth Directorate of the Industry Secretariat.

Pressure products and systems
Ministerial Decisions B10451/929/88 (GGB 370/B/1988), 12479/F17/414/91 (GGB 431/B/1991), 14165/F17.4/373/93 (GGB 673/B/1993), 20769/6285/94 (GGB 977/B/1994), 14132/618/01 (GGB 1626/B/2001), 16289/330/99 (GGB 987/B/1999) and 12436/706/2011 (GGB 2039/B/2011). The competent authority is the Third Directorate of the Industry Secretariat.

Boilers
Presidential Decree 335/93 (GGB 143/A/1993) as amended by Presidential Decree 56/95 (GGB 46/A/1995) and Royal Decree 277/63 (GGB 65/A/1963). The competent authority is the Third Directorate of the Industry Secretariat.

Machines
Presidential Decree 57/2010 (GGB 97/A/2010), as amended by Presidential Decree 81/2011 (GGB 197/A/2011), which implemented EU Directive 2006/42/EC. The competent authority is the Third Directorate of the Industry Secretariat in collaboration with various other directorates.

Means of personal protection
Ministerial Decisions 4373/1205/93 (GGB 187/B/1993), 8881/94 (GGB 450/B/1994) and B.5261/190/97 (GGB 113/B/1997). The competent authority is the First Directorate of the Industry Secretariat.

Equipment for explosive works
Ministerial Decision B17081/2964/96 (GGB 157/B/1996). The competent authority is the Fourth Directorate of the Industry Secretariat.

Plastic tubes
Ministerial Decisions 14013/32/327/83 (GGB 597/B/1993) and 10347/32/176/93 (GGB 432/B/1993). The competent authority is the Second Directorate of the Industry Secretariat.

Structural construction products
Presidential Decree 334/94 (GGB 176/A/1994) and various Ministerial Decisions specifying the provisions of such PD. The competent authority is the Second Directorate of the Industry Secretariat.

Pleasure yachts
Ministerial Decision 4841/F7B/52/97 (GGB 111/B/1997). Competent authorities are the Third Directorate of the Industry Secretariat and the Ministry of Economy and Development.

Elevators
Ministerial Decisions 9.2/32803/1308/97 (GGB 815/B/1997) and 15085/593/03 (GGB 1186/B/03). Competent authorities are the following Directorates of the Industry Secretariat, namely, the Third Directorate and the Supporting Directorate for Industry.

Bio-extinguishers
Presidential Decree 205/01 (GGB 160/A/2001). The competent authority is the National Organisation for Medicines (EOF).

Air fresheners
Ministerial Decision Y1/1880/01 (GGB 1018/B/2001). The competent authority is EOF.

Anti-smoking products
Ministerial Decision Y3d/515/94 (GGB 137/B/1994). The competent authority is EOF.

Cosmetics
Ministerial Decision 3a/132979 (GGB 352/B/2005), which implemented Cosmetics EU Directive 76/768/EEC, and various other Ministerial Decisions issued subsequently to specify its provisions. The competent authority is EOF.

Chemicals (including industrial raw materials, industrial products and candles)
Ministerial Decisions Y1b/7723/94 (GGB 961/B/1994), 378/94 (GGB 705/B/1994), which implemented EU Directive 67/548/EEC, and 265/02 (GGB 1214/B/2002), which implemented EU Directives 1999/45/EC and 2001/60/EC. Competent authorities are EOF and the State's General Chemical Laboratory of the Ministry of Economy and Development, depending on the specific product.

Vehicles and parts for vehicles
Various legislative documents. The competent authority is the Ministry of Economy and Development.

2 What requirements exist for the traceability of products to facilitate recalls?

There is no specific regulation for traceability purposes. Only general provisions exist, giving the authorities broad discretion to ensure that traceability is guaranteed.

In general, each product has to be duly labelled and identified and must, therefore, include information about its producer, namely, the name of an individual or the business name of a legal enterprise, and the address of the registered office. Accordingly, each product has to bear the specification of the product type or category, and, if applicable, its series or batch number. The product must further be labelled, which means that it must bear the information enabling the evaluation of risks connected with its use, or any other information relating to product safety. Such data must be stated directly on the product, on an attached leaflet or even on the packaging, in a visible and legible manner. The information must be stated at least in Greek. This enables a consumer to duly identify the product, its series and its producer.

Distributors must participate in the procedure of monitoring the safety of products they put in the market and to this end cooperate with the producers and the competent authorities, mostly conveying information regarding the dangers of the products and providing the necessary documents that can establish the products' origin.

The producers of certain categories of products must be able to identify the products' distributors if it is necessary to determine a group of consumers who might have obtained the defective product.

As far as food and medical products are concerned, lot numbers, manufacturer's serial number and respective date of production must be included on packaging.

3 What penalties may be imposed for non-compliance with these laws?

According to article 13a of Law No. 2251 (as amended by Law No. 4512/2018), subject to the stipulations of the Criminal Code and the Rules Regulating the Market of Products and the Provision of Services (Law No. 4177/2013), the following civil and administrative sanctions may be imposed by a decision of the competent minister, acting either ex officio or after a complaint filed, namely:

- recommendation for compliance within a specified deadline as well as an order to stop the infringement and refrain from it in the future;
- a fine of between €1,500 and €1 million. The maximum amount of the fine may be doubled if more than three fines are imposed on a distributor; or
- if more than three fines are imposed on a infringer, the minister may order the temporary closure of his or her business for a period ranging from three months to one year.

Imposed sanctions may be generally readjusted by a joint ministerial decision.

A special set of sanctions may be imposed on the infringers that do not respond to consumers' complaints per the provided proceedings.

Further, the competent minister has the authority, considering the nature and graveness of the violation, as well as its general repercussions on the consumer public, to publicise, through the press or any other means available, the sanctions imposed and the restraining measures taken with regard to the circulation of a product in the market.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

If producers or distributors become aware that any of their products present dangers to consumers, they must notify the General Secretariat immediately, without delay, and any other competent authority depending on the type of the product at issue, for the prevention of any danger and hazard to consumers.

The notification is made in a form provided by the competent authority and has to include information to identify the product, a complete description of the defect or the risk involved with the usage of the product, information to locate the product in the market, a description of the actions taken by the producer or distributor and actions that should be taken by consumers to prevent any further risk.

If the product has been marketed outside Greece as well, the procedure under the RAPEX notification system may be followed. The system allows the almost simultaneous transfer of information on dangerous products within the EU. Respective procedures apply especially to food and medicines.

The notified authorities may request additional information, the submission of relative documents or measures to be taken by the producer or distributor.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

The safety of the product in question determines any notification needed (see question 1).

The following criteria are monitored from the point of view of risks to consumers' safety and health protection (article 7, paragraph 3, Law No. 2251 implementing the GPSD), namely:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product; and
- the categories of consumers at risk when using the product, in particular children and the elderly.

The producer may be informed about the danger of a product by any appropriate means. The producer may find out that the product is not safe because of his or her own inspections and tests or on the basis of initiatives from consumers, insurance companies, distributors or governmental bodies. In any case, it is necessary to notify the competent authority as soon as the producer establishes such risk.

EC Decision 2004/905/EC sets out guidelines for the notification by producers and distributors of dangerous consumer products to the competent authorities of the member states (the Guidelines) in accordance with article 5, paragraph 3 of the GPSD.

The Guidelines (Annex, section 3) set out the notification criteria, which are as follows:

- the product is understood to be intended for, or likely to be used by, consumers (article 2a of the GPSD);
- article 5 of the GPSD applies (unless there are specific provisions established by other EU legislation);
- the product is on the market;
- the professional has evidence that the product is dangerous according to the GPSD, or that it does not satisfy the safety requirements of the relevant community sectoral legislation applicable to the product considered; and
- the risks are such that the product may not remain on the market.

The Guidelines provide that the notification shall be made without delay and specify the deadline for making notifications in terms of days. Accordingly, in cases of serious risk, companies are required to inform the authorities without delay, in no case later than three days after obtaining information and in any other case within 10 days.

There are only minimal differences in the preconditions and time framework for notification for various specific product categories.

6 To which authority should notification be sent? Does this vary according to the product in question?

In general, notifications must be made to the competent authority as is stipulated in question 1. The authorities to which the notification should be made vary according to the product.

Further to the authorities mentioned in question 1, we examine below two important categories of products.

Food

For food products, the competent authority is the Hellenic Food Authority (HFA), established in 1999. The HFA is supervised by the Ministry of Rural Development and Food.

The HFA's principal aims are to take all the necessary actions to ensure that food produced, distributed or marketed in Greece meets the standards of food safety and hygiene as described by the national and European legislation. The HFA also acts as the national contact point of the European Union regarding the management of the Rapid Alert System for Food and Feed (RASFF) and for the Codex Alimentarius Commission (of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO)) and it is the local point of the European Food Safety Authority (EFSA).

Medicines

For medicines and sanitary products and equipment, EOF (see question 1) is the competent authority. EOF was established in 1983 and is supervised by the Ministry of Health. EOF's mission is to ensure public health and safety with regard to the following products, marketed in Greece:

- medicinal products for human and veterinary use;
- medicated animal foods and food additives;
- foodstuffs intended for particular nutritional uses and food supplements;
- biocides;
- medical devices; and
- cosmetics.

Within the framework of its mission, EOF, in cooperation with the European Union, performs the following tasks:

- evaluates and authorises new, safe and efficient health-related products;
- monitors the post-marketing product's quality, safety and efficiency;
- monitors product manufacturing procedures, clinical studies and the marketing of products in order to ensure compliance with good manufacturing, laboratory and clinical practice, as well as with the existing legislation regarding the marketing, distribution, commercialisation and advertising of the products;
- develops and promotes medical and pharmaceutical research; and
- provides health scientists, competent authorities, and the general public with objective and useful information regarding medicines (for human or veterinary use) and other relevant products, in order to ensure their rational use and assess their cost-effectiveness.

7 What product information and other data should be provided in the notification to the competent authority?

In accordance with the provisions of the Guidelines (Annex, section 5), the notification must include at least the following:

- details of the authorities and resellers or distributors notified;
- details of the producer and distributors;
- details of the contact person regarding the notification;
- details of the product, including the category of the product, product's brand or trade name, product's model, barcode or CN tariff, product's country of origin and a photograph or description of the product;
- description of the hazard and of the possible health or safety damages and conclusions of the risk estimation and evaluation carried out;
- a record of accidents; and
- details of corrective actions taken, including the type, the scope and the duration of actions and precautions taken and the identification of the responsible company.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Greek legislation does not expressly regulate the obligation to provide authorities with updated information on risks. However, the obligation falls within the general scope of safety regulations that stipulate that all products on the market must be safe and if a product becomes unsafe, the producer or distributor has to take all appropriate measures to meet all possible risks.

Taking into consideration that a notification to the authorities is made according to an initial assessment of the product's hazard, the authorities will have to be kept informed of the results of any ongoing research in order to be updated and monitor the case.

Moreover, according to the provisions of Law No. 2251, the competent authority may request information from the producer or the distributor and can set a deadline, within which the information must be given to it.

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

See question 3.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

In general, information containing commercial or industrial secrets should not be disclosed to the public by the notified authorities.

The competent authorities should make available to the public information in relation to the notified product and the risk from its usage but they should prevent the disclosure of information containing commercial or industrial secrets, unless such disclosure is necessary to protect the public.

Moreover, any third party may request the issue of an order granting access to the files of the case kept by the competent authorities, including commercial or industrial secrets, from the public prosecutor. Such a request may be granted if the applicant proves a lawful interest for this.

Thus, notified commercially sensitive information is not always protected against public disclosure.

11 May information notified to the authorities be used in a criminal prosecution?

There is no specific provision in Greek legislation. In general, information obtained by the authorities may be used in criminal proceedings.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

There are no specific provisions regarding the criteria according to which a product recall or other corrective actions are determined. The producer or distributor of a defective product must take any measure to eliminate possible hazard from that product's use, as soon as any defect comes to his or her attention. These measures may vary and can

Update and trends

Greek authorities have been quite active in using the RAPEX procedure. Based on official data from the past years, the General Secretariat made the following notifications: 2017: 18; 2016: 50; 2015: 14; 2014: 63; 2013: 70; 2012: 82; 2011: 69; 2010: 159; 2009: 153; and 2008: 129.

Consumer awareness appears to be low. Very few consumer organisations are actively focusing on challenging abusive general terms and conditions.

Consumer reports and complaints are filed with the General Secretariat. There is no official data available for 2017. A total of 6,370 complaints were filed in 2016. Since October 2013, complaints may be filed at any time through the new General Secretariat's webpage, at www.1520.gov.gr. Besides the online filing, the General Secretariat operates a call centre.

Further, during recent years, competent authorities have intensified market controls regarding unsafe products. Specifically, the fines imposed by the General Secretariat in the past years amounted as following: in 2017: €1.016 million; in 2016: €1.943 million; in 2015: €2.2314 million approximately; in 2014: €1.485 million approximately; and in 2013: €4.875 million approximately.

Law No. 2251 has been amended several times. The most significant changes introduced in the past regarding product liability and safety and product recall issues were enacted by Law No. 3587/2007 and Law No. 4177/2013. In 2018, Law No. 2251 was extensively amended by Law No. 4512/2018 (articles 100 to 111 and 126) and by virtue of the same, ministerial decision No. 5338 of 17 January 2018 was issued, codifying Law No. 2251 with effect as of 18 March 2018. Topics related to product recall affected by the latest revision of Law No. 2251 are:

- a narrrower definition of 'consumer' (see below);
- the regulatory authorities and their enforcement duties;
- the funding of consumers' associations; and
- the administrative proceedings and sanctions that may be imposed (articles 1a.1, 7, 10, 13a and 13b, Law No. 2251).

The definition of 'consumer', before the above 2018 revision of Law No. 2251, was extremely broad and included any natural or legal person or entity without legal personality that was the end recipient and user of products or services, as well as any guarantor in favour of a 'consumer' (but not for a business activity) (previous article 1, paragraph 4a, Law No. 2251); moreover, the definition had been further expanded by case law to cover persons that used the products or services not only for private use but also for business use. As of 18 March 2018, this extended definition was narrowed and 'consumer' is now only considered a natural person acting for purposes not falling within a commercial, business, handcraft or freelance activity (new article 1a, paragraph 1, Law No. 2251).

include warning notifications, retrospective instructions to consumers, invitations for servicing or updating of the product in order to become safe or notifications recalling the product.

A product recall is an action taken in the event that no other measure would eliminate the danger. The recall may be either initiated by the producer or distributor of the product or ordered by the competent authority.

A guide containing information on determining when a recall or another corrective action is required, according to the Guidelines, is provided by the EU at http://ec.europa.eu/consumers/cons_safe/action_guide_en.pdf.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Producers and distributors are obliged to market only safe products. If they fail to do so, they are obliged to take any appropriate measure without delay and as soon as possible in order to prevent any hazard to consumers. Both the producer and the distributor have this obligation.

It is the producer and the distributor of a product who must determine whether it is defective and, accordingly, whether the authorities need to be notified thereon. The above persons must define the measures to be taken.

The competent authorities retain their powers to impose additional measures ensuring the safety of users.

14 Are there requirements or guidelines for the content of recall notices?

See question 7.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

Greek legislation does not provide for specific media to be used for the warnings or recalls. Any type of publicity that can accomplish the scope for the elimination of the danger may be used. The competent authority may request more extensive publication than the publication used by the producer or distributor, depending on each case.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

Greek legislation does not provide for such targets or periods.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

Article 6, paragraphs 2 to 4 of Law No. 2251 provide (in conformity with the PL Directive) that a producer responsible for the defect is regarded the manufacturer of a finished product or of any raw material or of any component, as is any other person who presents him or herself as a producer by putting his or her name, trademark or other distinguishing feature on the product. Moreover, any person who imports a product within the EU for sale, leasing or hire or any form of distribution will be responsible as a producer. Where the producer of the product may not be identified, each supplier of the product will be treated as its producer unless he or she provides the injured person with information on the identity of the producer or of the person who supplied him or her with the product. The same applies to the supplier of imported products when the importer's identity is unknown, even if the producer's identity is known.

According to Law No. 2251 (article 6, paragraphs 1, 6 and 7), the producer must compensate the consumer for any damage incurred to the latter because of defects of his or her product. Damage includes the following:

- damage owing to death or physical injury; and
- damage or destruction, because of the defective product, of every asset of the consumer, apart from the defective product itself, including the right to use environmental goods, on condition that the loss from such damage or destruction exceeds €500, and on the condition that by nature they were destined to be and were actually used by the injured person for his or her personal use or consumption.

Damages for moral harm or mental distress may also be due based on the above regulation.

Further, and by virtue of article 540 of the Greek Civil Code, the buyer (in general and not only a consumer) is entitled either to demand the repair of the defective goods he or she purchased or their substitution (on the condition that such substitution or repair does not imply excessive and unreasonable cost for the seller), or to require a price reduction or to rescind the contract for sale of goods, unless the defect or the lack of conformity of the goods sold with any agreed qualities is minor. Additionally, according to the general provision of article 914 of the Greek Civil Code, whoever acts unlawfully and by default causes damages to another party is obliged to compensate the injured party.

Moreover, both Law No. 2251 and the Greek Civil Code regulate the provision by the seller of a product guarantee. In short, where such a guarantee was provided and the defect is detected and noticed within the guaranteed period, the producer or distributor is obliged either to repair or replace the product at issue. By the recent revision of 2018, Law No. 2251 was redrafted as to the applicable guarantees in

the sale of consumer goods (new articles 5 and 5a, Law No. 2251). In short, Law No. 2251 categorises the guarantee to:

- a mandatory, two-year free, statutory one (which may be reduced up to one year for used products); and
- an additional, optional, commercial one provided against payment or, exceptionally, or for free under detailed regulation.

Regarding prescription, Law No. 2251 provides that claims against the producer or the other persons liable for defective products are prescribed three years after the consumer became aware of the damage or should have been informed about the damage, the defect and the identity of the producer. Ten years after the product is put onto the market, the rights of the consumer are time-barred (article 6, paragraph 13, Law No. 2251).

The general limitation period within which a buyer, being a consumer or not, must exercise his or her rights from a contract for the sale of goods is two years. Tort claims are subject to a five-year limitation period starting from the day the victim became aware of the damage and the person liable to compensate him or her. The same action or omission may constitute breach of a contract and tort under requirements. Lastly, the general limitation period applying to claims is 20 years. Claims for unjust enrichment fall within this period.

18 What are the penalties for failure to undertake a recall or other corrective actions?

See question 3.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

Authorities may request the producer, the distributor or any supplier to take specific preventive or corrective actions. To that extent, they may also define the time frame within which the scope of such actions should have been accomplished. If the obliged party fails to comply with and satisfy such requests, the competent authority may impose fines (see question 3).

Products that present or may present serious dangers to the safety and health of consumers when used in conditions that are normal or predictable may be revoked or withdrawn, as a precaution, by the competent authority. The procedure, the terms and conditions for the revocation, withdrawal or disposal under terms, destruction and any other relevant topic, are regulated by a decision of the Minister of Development or by a joint decision of him or her and by any other competent minister.

20 Can the government authorities publish warnings or other information to users or suppliers?

Government authorities may publish warnings or other information to users or suppliers where a producer or other responsible party has not already done so. See question 19. There are no rules whereby the same authorities may issue informal information or notices outside the above-mentioned established regulatory scheme. Further, Greek authorities' websites do not provide a facility for the public to post remarks or reports of incidents. However, since May 2009, the website of the European Commission (https://webgate.ec.europa.eu/gpsd-ba/) provides for the GPSD Business Application, which is an online application that businesses can use instead of traditional methods, such as email or fax, to submit their notifications on dangerous products to national authorities; using this application, businesses can also notify all member states at the same time.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Yes. Government authorities may organise a product recall where a producer or other responsible party has not already done so. See question 19.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Yes. If it is the authority that carries out the required product recall, it will be entitled to claim the relevant costs incurred by the responsible party that did not comply with its obligations. Apart from the product recall costs, other administrative costs are not recoverable.

23 How may decisions of the authorities be challenged?

The ministerial decisions mentioned in question 19 must be served on the interested party. A quasi-judicial proceeding before the minister against those decisions is provided for, within an exclusive period of 30 days as of the above service. The minister has to issue his or her decision within an additional exclusive period of 60 days and the minister's decision may be challenged within a further period of 60 days of his or her decision being served on the interested party.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

Without prejudice to all necessary proceedings, including evidence production, which must take place before a court, the publication of a safety warning or a product recall is likely to be viewed by the civil courts as an admission of liability for defective products, or at least as an indication that the product is defective.

It is useful to note that, before a civil court, the consumer (claimant) has only to prove the defect of the product, the damage caused by it and the causal link, whereas proof of the absence of fault lies on the producer (defendant) under an adverse burden of proof rule established by case law to facilitate claimants.

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25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

A product liability action, being a private law dispute, is tried exclusively by civil courts. There is a general duty of truth but each litigant may only submit to the court the evidence being favourable to support his or her case.

The Greek Code of Civil Procedure does not provide for discovery within the meaning of the common law concept. However, a consumer (claimant) may request from the court – upon certain conditions – an order that the defendant (producer or distributor) files and discloses documents in his or her possession relevant to support the claim, which, however, must be clearly specified by the claimant. Thus, communications, internal reports and the like may be – at least in theory – disclosed in product liability actions. In practice, however, owing to the very strict prerequisites imposed by case law on the claimant regarding the specification by him or her of the requested documents, the success of such disclosure petition must be regarded as an exception.

Hong Kong

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

In Hong Kong, there is no specific legislation that governs product liability and consumer protection. Instead, general safety requirements of products are governed by various legislation and common law and to pursue a product liability claim, one must rely on existing laws of contract, tort and statutory duty.

The main legislation governing the safety requirements for consumer goods (those ordinarily supplied for private use or consumption) is the Consumer Goods Safety Ordinance (Cap 456). It does not apply to goods specified in the Schedule to the Ordinance, which include food, water, pleasure craft and vessels, motor vehicles, gas, electrical products, pesticides, pharmaceutical products, traditional Chinese medicines, toys and children's products and any other goods the safety of which is controlled by specific legislation.

For specific goods, the other legislations include the Toys and Children's Products Safety Ordinance (Cap 424), the Public Health and Municipal Services Ordinance (Cap 132), Pharmacy and Poisons Ordinance (Cap 138), Antibiotics Ordinance (Cap 137), Electricity Ordinance (Cap 406), Dangerous Goods Ordinance (Cap 51), Nuclear Material (Liability for Carriage) Ordinance (Cap 479) and the Chinese Medicine Ordinance (Cap 549), among others.

2 What requirements exist for the traceability of products to facilitate recalls?

To facilitate recalls of consumer goods ordinarily supplied for private use, section 9 of the Consumer Goods Safety Ordinance (Cap 456) requires the Commissioner of Customs and Excise to have a reasonable belief that the goods do not comply with an approved standard or a safety standard or safety specification established by regulation; or for which a safety standard has not been approved, are, or may be, unsafe; and there is a significant risk that the consumer goods will cause a serious injury. Provided that these criteria are fulfilled, the Commissioner may serve on a person a notice requiring the immediate withdrawal of those consumer goods from being supplied and the retrieval of those items already supplied.

3 What penalties may be imposed for non-compliance with these laws?

For criminal liability, section 6 of the Consumer Goods Safety Ordinance (Cap 456) provides that any person who supplies, manufactures or imports unsafe goods is committing an offence and is liable to a fine, imprisonment or both. A person who supplies, manufactures or imports into Hong Kong consumer goods that do not meet general safety requirements or the approved standard, will be liable to a fine, imprisonment or both. Section 28 provides that a person who is found guilty under this offence is liable to a fine at level 6 (HK$100,000) and to imprisonment for one year on the first conviction, and to a fine of HK$500,000 and to imprisonment for two years for subsequent conviction. If such offence is a continuing offence, that person is liable to an additional fine of $1,000 for each day during which it is proved to the satisfaction of the court that the offence has continued.

Legislation for consumer goods in Hong Kong does not provide for civil liability. Compensation can be claimed only by way of legal action in tort or contract. The Sale of Goods Ordinance (Cap 26) and the Control of Exemption Clauses Ordinance (Cap 71) supplement the protection offered by common law regarding compensation claims for breach of contract. In respect of tort claims, a person who manufactures and sells an article owes a duty of care in its production and design. The claimant will be required to prove the reasonableness of an inference to be drawn that the defendant was negligent and this negligence caused the harm including personal injury or damage to property.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

The Consumer Goods Safety Ordinance imposes a statutory obligation to warn. Section 7 of the Ordinance provides the Commissioner with the power to serve a notice to require a person, at his or her own expense and by his or her own arrangement, to publish a warning that the consumer goods may be unsafe unless steps specified in the notice are taken.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

A matter requires notification as long as the Commissioner reasonably believes that the consumer goods are unsafe in certain circumstances.

6 To which authority should notification be sent? Does this vary according to the product in question?

The sending of notification varies according to the product in question.

For food products, reports or complaints may be referred to the food trader, who should immediately notify the Food and Environmental Hygiene Department.

For pharmaceutical products, reports or complaints may be referred to the licensee, who should then report the problem to the Department of Health by filling out a Pharmaceutical Product Problem Report Form (Part 1). Serious problems that may lead to the recall of products must be reported to the Department of Health within 24 hours of receipt of the complaint or report for investigation.

7 What product information and other data should be provided in the notification to the competent authority?

The product information and other data provided in the notification vary according to the product in question.

For example, for pharmaceutical products, the Pharmaceutical Product Problem Report Form (Part 1) should be filled out when notifying the authority. Information in relation to the details of the problem (ie, reporting company's contact details, source of complaint, description of the problem, etc) and details of the product (eg, product registration number, manufacturer details, importer details, etc) should be included.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Under the Consumer Goods Safety Ordinance, there is no obligation to provide authorities with updated information about risks. However,

there is an obligation to respond to their enquiries. Section 10 of the Consumer Goods Safety Ordinance provides that the Commissioner may require the manufacturer, importer or supplier to test certain consumer goods in the form and manner the commissioner specifies.

However for food products, the traders must conduct follow-up action by providing a progress report at regular intervals at the request of the Department. After food recall is exercised, the trader should submit a final report within a specified time frame determined by the Department. As for enquiries, the Department may assess the adequacy of the food trader's action. For example, whether a prompt announcement of recall or prohibition of supply or import through the media was made, whether convenient and adequate locations for return of the food was made, and whether proper record of the recalled food is kept by the traders.

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

Section 28 provides that a failure to comply with a notice served by the Commissioner is an offence. A person who is found guilty under this offence is liable to a fine at level 6 (HK$100,000) and to imprisonment for one year on the first conviction, and to a fine of HK$500,000 and to imprisonment for two years for subsequent conviction.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

No.

11 May information notified to the authorities be used in a criminal prosecution?

Yes.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

The criteria for product recall differ depending on which product is in question as the government authorities have issued different practice guidelines for specific types of product.

For private consumer goods, the criteria for product recall is satisfied when the Commissioner has the reasonable belief that the consumer goods do not comply with an approved standard or for which a safety standard has not been approved, are or may be unsafe and there is a significant risk that the consumer goods will cause a serious injury.

There are similar recall requirements for electrical products and goods under the Electricity Ordinance (Cap 406) and the Public Health and Municipal Services Ordinance (Cap 132), respectively.

The Chinese Medicine Ordinance (Cap 549) was revised in 2018 and it now empowers the Director of Health to serve Chinese medicine safety order for recall of Chinese herbal medicine, proprietary Chinese medicine and intermediate products when the Director has the reasonable beliefs that the products are sold without the required licence or in breach with the licensing conditions, are dangerous or injurious to health or are unfit for use by human.

For voluntary recalls, the government issued guidelines to facilitate voluntary recall of certain products, such as consumer goods and toys and children's products.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

The Consumer Goods Safety Regulation (Cap 456A) requires any warning or caution in respect to the safe keeping, use, consumption or disposal of any consumer goods to be given in both Chinese and English languages. The warning or caution must be legible and placed in a conspicuous position on the goods themselves, on any packaging containing the goods (and may be a label securely fixed to the package or a document enclosed within the package).

In the Electrical Products (Safety) Regulation (Cap 406G), section 11 allows the Director of Electrical and Mechanical Services to serve on the supplier a written notice requiring the supplier to notify the purchasers about the hazardous effects in the product, accept a return of the product, and refund the purchasers any sum paid for the product, provided that a receipt for the product is returned.

14 Are there requirements or guidelines for the content of recall notices?

Yes, for certain goods. For example, the Pharmaceutical Products Recall Guidelines, published recently in 2016, provides that where a recall on a pharmaceutical product is initiated, required information may include details of the problem (eg, contact information of the person reporting the problem, nature of the problem, number of similar report received, etc), details of the product (eg, active ingredients, dosage form, batch number(s), date manufactured, etc), and health hazard evaluation and proposed action (eg, type of hazard, availability of alternative product, etc). The Recall Guidelines for Chinese Medicine Products, revised recently in 2018, provides that where a recall on Chinese medicine is initiated, required information may include details of the problem and the concerned hazards, the advice not to supply or use the products, and details of the product (eg, name, type and registration number of the product, etc).

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The media for information dissemination may take the form of a press release, letter addressed to the concerned parties, paid advertisement in the media, public announcement and putting up posters.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

No.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

No, but usually they will provide a full refund of the goods.

18 What are the penalties for failure to undertake a recall or other corrective actions?

According to section 2 of the Consumer Goods Safety Regulation (Cap 456A), a failure to comply with the requirements of a warning will result in a fine at level 6 and imprisonment for one year on first conviction and, for subsequent conviction, to a fine of HK$500,000 and to imprisonment for two years.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

Under section 9 of the Consumer Goods Safety Ordinance (Cap 456), the Commissioner may exercise under a reasonable belief his or her option to serve a recall notice requiring the recall of consumer goods and may decide the manner and extent reasonably possible. The power of authorities to compel manufacturers and suppliers to undertake a recall is also provided in specific legislation. For example, section 30 of the Food Safety Ordinance states that the Director may make an order to direct that any food supplied be recalled and may specify the manner and period in which the recall is to be conducted.

20 Can the government authorities publish warnings or other information to users or suppliers?

Yes. Warnings and other information published to users or suppliers are frequently found on the websites of relevant governmental authorities or the Consumer Council (or both). The Consumer Council issues consumer alerts for both services and products, the power of which is granted under section 5(2)(d) of Consumer Council Ordinance (Cap 216). Other relevant governmental authorities that publish warnings include the Centre for Food Safety, the Transport Department and the Drug Office, among others.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Yes. Voluntary recalls made by the government authorities are a common occurrence, especially in the pharmaceutical sector. Other than reports or complains made by the referral of manufacturers, wholesalers, retailers, hospital pharmacies, research institutes, medical practitioners, dentists and patients, recalls may also be initiated as a result of testing of samples of pharmaceutical products initiated by the manufacturers and by the Department of Health. For overseas pharmaceutical products, recall may be initiated by the local or overseas health authorities or from information received directly from such authorities.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Yes. Section 33 of the Consumer Goods Safety Ordinance states that the court or magistrate may order the person convicted or any other person having an interest in the destroyed or altered consumer goods to reimburse the government chemist for any costs associated with testing the consumer goods and the Commissioner for any expenditure that has been or may be incurred by him or her that is in connection with any seizure or detention of the consumer goods.

23 How may decisions of the authorities be challenged?

To challenge the decisions of the authorities, section 13 of the Consumer Goods Safety Ordinance states that a person may, within 14 days after the decision or action of the Commissioner, deliver to the Commissioner a notice of appeal stating both the substance of the matter and the reasons for the appeal. It is important to note that an appeal against a decision of the Commissioner does not suspend the decision, unless decided otherwise by the Commissioner.

After receiving the notice of appeal, the Commissioner will forward it to the Secretary. The Secretary will then appoint members to an Appeal Board panel that will hear the appeal.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

The court will give considerable weight to the publication of safety warnings or a product recall when considering liability for defective products.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Yes. Order 24, Rule 1 of the Rules of High Court (RHC) states that both parties to the action must discover documents which are or have been in their possession, custody or power relating to matters in question in the action. However, the court has the power to limit the extent of such discovery on the application of any party (Order 24, Rule 2(5) of the RHC).

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

In Italy, the regulation governing product safety is Legislative Decree No. 206 of 6 September 2005 (the Consumer Code), implementing both the General Product Safety Directive (Directive 2001/95/EC) and the Product Liability Directive (Directive 85/374/EEC).

The provisions laid down in the Consumer Code apply to those products that are not covered by specific sector legislation (eg, toys, machinery, pharmaceuticals and food). The Consumer Code also complements the provisions of sector-specific legislation, where this does not cover certain matters as, for instance, in relation to the powers of the relevant government authorities in charge of safety issues.

Under the Consumer Code, manufacturers must manufacture and market only safe products. The Consumer Code gives a generic definition of a safe product, which essentially reflects the definition given in Directive 2001/95/EC. According to the Consumer Code, a safe product is one that, under normal or foreseeable conditions of use, including duration, does not present any risk or only minimum risks considered acceptable and compatible with a high level of protection for consumer safety and health.

The safety of the product is generally assessed in accordance with:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any warnings and instructions for its use and any other indication or information regarding the product; and
- the categories of consumers at risk when using the product, in particular children and the elderly.

In any event, the possibility of obtaining a higher level of safety or a safer product is not, in itself, sufficient reason to identify a product as unsafe or hazardous.

Manufacturers that know or ought to know, on the basis of the information in their possession and in their capacity as professionals in their field, that a product they have placed on the market exposes consumers to risks that are incompatible with the general safety requirements must adopt measures commensurate with the characteristics of the product they supply and to the relevant risk, and among other things:

- adequately and effectively inform consumers of the risks the product might pose;
- take appropriate action including withdrawal from the market, if necessary; and
- immediately inform the competent authorities of the member states of such risks, giving details, in particular, of the actions taken to prevent damages for consumers.

Since many hazardous situations are recognised by manufacturers only as a result of an aggregated assessment of individual communications received from different distributors, in many cases the role of the distributor in ensuring compliance of the products with the applicable safety requirements is crucial.

Pursuant to the Consumer Code, distributors must comply with essentially the same obligations as the manufacturers. In particular, distributors should not supply products which, to their knowledge or based on their assessment, in accordance with the information in their possession and in their capacity as professionals in the field, do not comply with the specified safety requirements.

In any event, the distributors should:

- within the scope of their respective activities, contribute to monitoring the safety of the products placed on the market, especially by passing on information on product risks; and
- cooperate with producers and the competent government authorities in order to avoid the continuation of the risks and provide the documentation necessary for tracing product origin for 10 years from the date of distribution of the product to consumers.

The main legal framework that manufacturers and distributors should take into account to identify how to fulfil the obligations to the market or maintain only safe products on the market are the guidelines adopted by the European Commission in relation to safety issues.

In particular, Decision 2010/15/EU, issued pursuant to article 11 of Directive 2001/95/EC, establishes guidance for the management of the RAPEX system (the EU rapid alert system for dangerous non-food consumer products) and for notification, and represents the fundamental framework to which manufacturers and distributors must refer in assessing the level of risk posed by a product and filing the notification form accordingly.

Following public consultation on the revision of the current legislation regarding safety products, the European Commission proposed a new Product Safety and Market Surveillance Package, consisting of a proposal for Regulations on Consumer Product Safety and a proposal for Regulations for Market Surveillance of Product, intended to replace the relevant provisions of the General Product Safety Directive, as well as non-legislative documents. The proposals are currently awaiting the Council's position.

2 What requirements exist for the traceability of products to facilitate recalls?

Where there is a risk to public health, allowing prompt access to the relevant product traceability information and the ability to quickly locate the products represent the most important issues of any recall procedure. In fact, the easier the product traceability phase, the more successful the withdrawal or the recall of the product will be.

The Consumer Code simply requires manufacturers to be able to trace the specific product, but does not provide for any special requirement; as a matter of fact, with the exception of some products, such as food and pharmaceutical products that are regulated by special provisions, the requirements for product traceability in general are essentially those dictated by the best European business practice in the field of product safety.

In very general terms, the most common ways to trace products are batch numbers or barcodes or both at each level of product hierarchy and step in the supply chain. Manufacturers and distributors should also keep records of consumer purchases in order to detect product allocation more quickly.

In the case of safety problems caused by a component delivered by a supplier, it is necessary to identify the supply reference number appearing on the components fitted in the product.

3 What penalties may be imposed for non-compliance with these laws?

According to the Consumer Code, placing dangerous products on the market or violating a ban issued by a government authority to market a product declared dangerous is punishable with imprisonment for up to one year and a fine ranging from €10,000 to €50,000. If a more serious crime is also involved (ie, injury or manslaughter), the relevant criminal provisions will also apply. Indeed, the Consumer Code does not provide for the application of any disqualification order (and the like) for the directors who fail to take steps to ensure that the products they sell or manufacture comply with mandatory product safety standards or are responsible of other trade practices breaches.

In connection with possible criminal liability, any Italian public prosecutor can commence an investigation regarding the unsafe nature of a given product provided that product is distributed or used within the Italian territory. In carrying out product safety investigations, public prosecutors may adopt measures such as the preventive seizure of technical documents to assess the technical qualities, performances or risks connected to any given product and, should it be found that the products may pose serious risks to public health, the seizure of that product throughout the Italian territory.

Furthermore, failure to comply with the measures ordered by the competent Italian authorities can be sanctioned with fines from €10,000 to €25,000. Failure to cooperate with authorities in carrying out checks on products and in acquiring information and samples thereof can be sanctioned with a fine ranging from €2,500 to €40,000.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

Manufacturers or distributors that have discovered a defective product should notify government authorities by providing a full description of the risks that the products in question present supported by the results of the tests and research carried out, details of the hazard and possible health or safety damage and conclusions on risk assessment.

Notification is not required in cases where the problems concern a functional quality of the product, not its safety, and in cases where the manufacturer has been able to take immediate corrective action.

In order to avoid a proliferation of notifications to government authorities regarding the same product, those parties of the supply chain that know that the relevant authorities have already been informed and have all the information concerning the product are not subject to notification.

It is important to point out that, in the event a product has been marketed in several member states and poses a serious risk for the safety of the consumers, manufacturers or distributors may decide to notify only Italian authorities if Italy is the country in which they are established rather than informing all the relevant authorities of the countries in which the product has been marketed, leaving the Italian authority to decide on whether to inform the other member states' authorities through RAPEX-ICSMS.

In any event, manufacturers or distributors that only inform the authority of the country where they are located should always provide this authority with available information regarding the other countries where the product has been marketed. After the notification has been sent, the government authority may require additional information, the submission of documents or may require further measures to be taken by the manufacturers or distributors. Usually Italian authorities require manufacturers to file any documents that show that the product has been manufactured in line with the relevant standard regulations (eg, certification that the product is in line with the ISO standard level and so on).

Since the introduction of the 'Business Application' system in May 2009, it is possible to monitor the status of the notification in each country by informing online, at the same time, the competent authorities of the recall campaigns carried out.

Should any accident occur, manufacturers have to provide the relevant authority with an account of the accident and a technical description to help the authorities to understand the level of the risk connected with the product and to evaluate the reliability of the assessment of said risk, as well as the measures adopted by manufacturers or distributors.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

According to the provisions laid down in the Consumer Code, notification to government authorities is mandatory for manufacturers or distributors when the products pose risks for consumers that are incompatible with the general safety requirements.

When deciding whether a notification is required, manufacturers must assess both the probability of health and safety damage occurring and their likely severity, taking into account the factors that may affect the level of risk, such as the type of end-users. If, for instance, the product is likely to be used by children or the elderly, the level of the risk to be notified should be set at a lower level. In any event, the decision to notify should not be influenced by the number of products on the market or by the number of people who could be affected by the same, as these factors may be taken into account merely in evaluating the type of action to be taken to sort out the problem. If the overall level of risk is considered to be low depending both on the severity and likelihood of the possible health or safety damage, then manufacturers are not required to make any notification.

A methodological approach for facilitating risk assessment, as well as the filing of the notification form, is suggested in the guidance provided by Decision 2010/15/EU, which clarified that the severity of the risks is based on a balanced combination of probability and seriousness of damage.

In any event, the decision to file a notification remains – to some extent – at the discretion of the manufacturer.

When the notification is required or appropriate, the manufacturer should inform the relevant authorities 'without delay' and in any event within the terms indicated in appendix 3 to the guidelines (ie, within 10 days of reportable information becoming available), in spite of investigations continuing on the products. If the risk connected to a given product is serious, manufacturers are required to inform the authorities 'immediately' and, in any case, no later than three days of their having obtained the information.

6 To which authority should notification be sent? Does this vary according to the product in question?

When a product presents risks for consumer health, notification has to be sent to the relevant authority depending on the product in question.

In Italy, the contact point for all safety issues, as well as for adopting the RAPEX system, is the Ministry of Economic Development. The notification should also be filed with the relevant authority according to the product at issue. If the product has been sold in several countries, the Ministry of Economic Development – upon a discretional evaluation of the risks connected with that product – will decide whether to forward all the information concerning the product to the other EU authorities through RAPEX. It is important to note that the Ministry of Economic Development and the relevant authority that is competent for the product in question operate independently. This means that any action or measure that manufacturers or distributors decide to take may be differently evaluated by the aforesaid authorities. In particular, the government authority in charge of monitoring the safety of certain products may require the manufacturer – based on its own experience – to adopt additional measures to those discussed and approved with the Ministry of Economic Development.

7 What product information and other data should be provided in the notification to the competent authority?

Manufacturers or distributors must provide authorities with the following details:

- contact details of the authority to which notification is sent;
- identification of the companies notified and their role in the marketing of the products;
- details and reference of the manufacturers or distributors or both;
- information enabling a precise identification of the product or batch of products in question (brand or trademark model, name,

barcode CN tariff, country of origin, description of the product and its photograph);
- a full description of the risk that the products pose;
- details of the hazard and possible health or safety damage and conclusions on the risk assessment carried out;
- records of accidents; and
- a description of the actions taken to prevent risks to consumers and identification of the company responsible for the execution of aforesaid actions, their scope and duration.

In case of a serious risk or where the product has been distributed in several member states, the companies completing the notification form must also provide:
- a list of manufacturers, importers or authorised representatives further divided by member state and their relevant details;
- a list of distributors or retailers divided by member state; and
- the number of products held by each member of the supply chain.

The aforesaid information may take a long time to be collected. In any event, in case of a serious risk, manufacturers are required to provide government authorities with the information at their disposal without delay, while reserving completion of the form as soon as the data concerning the supply chain has been gathered.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

The Consumer Code does not contain any specific section concerning the obligation to provide authorities with updated information; this obligation is implied in the scope of safety regulations that stipulate that all products on the market must be safe products and if a product becomes unsafe, the manufacturers or distributors have to adopt any measure necessary aimed at consumer safety risk prevention.

Furthermore, it must be understood that any safety procedure is necessarily a continuous process, which means that an initial assessment of the level of risk related to a given product may vary in light of results of new analyses, research or events occurring in the course of the adoption of the same safety measures. The relevant authorities must be informed when knowledge of any development of the case arises in order to evaluate if the original evaluation of the risk and the measures taken remain effective. In any event, it has to be remembered that authorities have extensive powers against manufacturers and distributors and they may also request – at any time – the supply of updates on the development of the case.

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

Failure to comply with reporting and updating obligations exposes manufacturers and distributors to pecuniary (administrative) fines.

However, manufacturers and distributors may also be sanctioned under criminal law should they fail to report to the authority any information capable of affecting the risk assessment originally submitted to the authority itself and the effectiveness of the measures taken accordingly.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

As a general rule, commercially sensitive information should not be disclosed to the public by the public authorities. In any event, pursuant to the general transparency rule of Law No. 241/90, access to certain pieces of information collected by a public authority has to be guaranteed to all persons having a relevant interest, including those who bring or defend a legal claim. This means that any consumer alleging to have suffered damage because of a given defective product may request that the government authority provides authorisation to examine the papers filed by manufacturers or distributors. The authority will decide to accept or reject – even in part – the request (which has to be duly founded) to access information and the authority's decision can be challenged before the court.

Should a consumer file a request before the government authority to access the papers provided by the manufacturer concerning the recall proceedings, the manufacturer would be informed by the authority of this request and it would be entitled to challenge the request in court.

Update and trends

Particularly worthy of note and to date the most relevant case in terms of product recall litigation in Italy relates to the aftermath of the affair internationally known as 'Dieselgate'. After the recall of the vehicles involved on the part of the manufacturer, an Italian consumer association promoted two class actions in the name of the purchasers of said vehicles for breach of contract and unfair commercial practices, claiming compensation in the amount of approximately 15 per cent of the purchase price of the vehicles for each class member. Both class actions have been declared admissible and the trials are now pending. According to the press, more than 95,000 people have exercised their right to opt-in the actions and the aggregate value of the cases is reported as around €400 million, likely making them among the biggest class actions in Europe.

11 May information notified to the authorities be used in a criminal prosecution?

Any information notified to the authorities may be used in a criminal prosecution, both in favour of or against the manufacturer and/or distributor. For instance, in case the manufacturer is able to prove that, at the time of the offence, it had already warned consumers about the risks connected with the product and yet the injured party had freely decided to ignore the warning and use the dangerous product, this information may be used in order to reduce the extent to which the manufacturer may be held liable.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

In order to determine which corrective action is needed it is necessary to assess the risk that the product poses to consumers. Risk assessment usually takes places according to the following steps:
- identification of the hazard, with details of the nature and cause of the hazard, the total number of products affected and who could be affected by the hazard;
- an estimate of the level of risk, which depends on both the severity of the possible injury to those using the product and the probability of injury; and
- assessment on the acceptability of the risk for consumers.

Should the overall assessment of the above-mentioned elements present a serious level of risk, the measures to be taken usually consist of the recall of the product put on the market.

However, deciding what action is needed may also depend on the actual possibility of adopting a specific measure in that case, as well as on the success rate of that action in previous similar cases.

In any event, it is up to the government authority to require the specific corrective action it deems appropriate to the case at issue.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Publication is one of the corrective actions that can be adopted by the manufacturer, or be ordered by the government authority, in cases where the product may pose risks for consumer health. The same is not directly required by law even though, in cases where the risk is serious and the traceability of the product is not possible or cannot be easily and quickly carried out, a press release may appear to be the most effective and sometimes the only suitable safety measure in order to preliminarily inform consumers of the risk related to a product.

14 Are there requirements or guidelines for the content of recall notices?

Requirements regarding the content of the recall notices may be found in 'Product Safety in Europe', which is a voluntary guide to corrective action including recalls drawn up by the most important consumer and professional associations with the support of the European Commission. This guide not only indicates the general requirements

that a recall notice may contain but also provides some useful examples.

In any event, pursuant to the European Product Safety Guidelines, the safety warning must be clear, concise and easily understandable. The warning must draw the attention of consumers, for example, by using 'important safety wording'. The wording must also contain:

- product identification details;
- a clear description of its defectiveness;
- details of potential safety risk;
- information on the type of corrective action proposed and any refund or replacement offered;
- clear instructions on how to deal with the product; and
- a website address or hotline for further information.

Usually, when manufacturers publish a safety warning in the press, the same should be published at least in one of the major national newspapers and, if necessary, depending on the allocation of the product, in a newspaper having significant local circulation.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The specific media used to publish warnings or recall messages depends on several factors, including, without limitation, the level and the kind of geographical spread of the risk; the number and the type of consumers involved; and the timing.

Timing is certainly the key factor pushing the manufacturer to adopt a particular measure rather than another. In case of serious risks, Italian government authorities always suggest a manufacturer issues a press release.

In any event, warning communications can be given by using different methods:

- consumer telephone services such as an information line or free lines;
- point-of-sale information (leaflets);
- radio, TV news and consumer programmes or advertising;
- press service; and
- websites.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

Neither the Consumer Code nor the relevant guidelines provide for a specific target or periods after which a recall is automatically deemed to be satisfactory. In general, targets should be set in line with the seriousness of risk related to the product, the end users of the products and the possibility of contacting individual consumers. In several cases, in order to evaluate the result of a recall procedure, and to assess whether it may be considered satisfactory, it may be necessary to discuss the issue with the relevant authorities.

By and large, it can be said that if the product recalled from the market does not pose a serious risk to the health of consumers, the government authorities may consider satisfactory a recall plan through which it would be possible to withdraw only a small proportion of products, if the manufacturers or distributors have adopted all possible measures to inform consumers of the risks. Even in this case, it is in any event advisable to subsequently provide the authorities with the relevant solutions adopted to avoid subsequent production presenting the same problems.

On the contrary, if the risk connected with the product is serious and, in particular, if an accident has occurred, the government authority may consider the recall satisfactory only in cases where practically every single unit has been withdrawn or accounted for.

In several cases, this may be materially impossible. In such event, should a serious risk exist for public health, then the government authority may decide to inform the public prosecutor's office, in order to impose the seizure of each unsafe unit still on the market.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

The Consumer Code contains no specific obligations in this regard, also because its core purpose is consumers' safety, while all aspects concerning the possibility to claim compensation for damages arising from defective products and breach of the sales contract are governed by the Civil Code.

Leaving aside possible complaints or claims (for breach of contract, in tort or both) that consumers may bring against the manufacturer or distributor, approaching consumers and offering them some compensation or replacement may increase the success of a recall. In fact, the success of any recall procedure is at least partly based on consumers' cooperation, as the manufacturer cannot force them to give the product back.

18 What are the penalties for failure to undertake a recall or other corrective actions?

Failure to undertake a recall or other corrective actions aimed at keeping dangerous products off the market is punishable by up to one year imprisonment, provided that no more serious offences are perpetrated (typically, injury or manslaughter), since in this event the relevant criminal provisions will also apply.

Monetary penalties may also be applied.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

Pursuant to the Consumer Code, the relevant authorities must take all measures necessary to ensure that products on the market are safe. For this purpose they are entitled to indicate all the measures they deem appropriate and they can also order product recall from consumers and the destruction of the product itself.

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20 Can the government authorities publish warnings or other information to users or suppliers?

The Consumer Code provides that the relevant authorities should encourage and instruct manufacturers to voluntarily take all the safety measures necessary in a specific case.

Therefore, all the safety measures, including warnings, are usually published by manufacturers with the supervision of the competent authorities.

In the event that the authority finds that the manufacturer has not adopted sufficient measures to protect consumers, especially when the risk is serious and immediate and information to consumers is duly required, the authority may order a manufacturer to publish warnings or directly arrange for publication.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

In general, it can be said that the approach favoured by the authorities is for voluntary resolution of the problems connected with the products. This means that it is rare that the aforesaid authority will issue measures without the cooperation of the manufacturers or distributors.

However, in some serious cases requiring very urgent action, the competent authority may decide and act upon a recall, where the producer or other responsible party has not yet done so. This action will be managed with the help of the judicial authority and the police.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Any costs incurred by the relevant authority in relation to product safety issues are recoverable from the producer or manufacturer and, when this is not possible, from the distributors.

23 How may decisions of the authorities be challenged?

The decisions rendered by the relevant authorities are immediately enforceable, but such decisions may be challenged and provisional stay of their enforcement may be required before the competent regional administrative first-instance court, the TAR.

On a request for urgent measures, the TAR usually renders its decisions in a few days.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

In general, the publication of a safety warning or a product recall is likely to be viewed as an admission of liability for defective products; however, this does not mean that, should a litigation arise, the manufacturer or producer will always be condemned for the defectiveness of its products.

The Consumer Code provides for the possibility of a reduction in and exclusion of compensation, respectively:

- in the event of contributory negligence on the part of the injured party, referring to article 1227 of the Italian Civil Code for the determination of the extent of the reduction in compensation. This may occur in cases where the consumer has been duly informed by the manufacturer of the risk but he or she voluntarily decided to ignore the warning; and
- when the injured party was aware of the defect in the product and the danger deriving therefrom and still voluntarily exposed him or herself thereto. The exclusion of liability only operates in the event that the defect was recognisable or evident and, in such a case, liability on the part of the manufacturer or producer is excluded.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Italian law does not provide for US–style discovery proceedings, in which each party can access its counterpart's entire internal documentation. Indeed, under certain conditions, during a civil proceeding the party might require the judge to order the other party to file and exhibit – in the course of the litigation – certain documents, which must be expressly and specifically identified by the requesting party. In light of the above, from a strict procedural point of view, communications, internal reports and the like would not be fully disclosed in product liability actions.

In any event, as noted in question 10, it has to be pointed out that the injured party may have access to the documents filed by the manufacturer before the governmental authority in the recall proceedings, and consequently be in a position to file material evidence before the civil court.

Furthermore, should a criminal investigation be started, as is normal when physical injuries are reported, the public prosecutor, while carrying out the investigations, has extensive power to collect all documents belonging to the manufacturer that he or she deems appropriate, including all the papers relating to the product. These documents will be available to the injured party during the course of the criminal proceedings.

Therefore, from a practical point of view, it is possible – and in some cases usual – that the injured party may acquire overall knowledge of the papers relating to the defective product.

Japan

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

The Consumer Products Safety Act (Act No. 31 of 1973, as amended) (CPSA) generally applies to all kinds of products sold in Japan and accidents caused by products within Japan. Further to the CPSA, some specific products are also regulated in part by the following laws:

- electrical appliances by the Electrical Appliances and Materials Safety Act (Act No. 234 of 1961, as amended);
- gas appliances by the Gas Business Act (Act No. 51 of 1954, as amended); and
- combustion appliances (eg, gas stoves) by the Act on the Security and Transaction of Liquefied Petroleum Gas (Act No. 149 of 1967, as amended).

Other products, however, are regulated exclusively by the following laws instead of the CPSA. Some examples are:

- automobiles by the Road Tracking Vehicle Act (Act No. 185 of 1951, as amended) (RTVA);
- medicines, cosmetics and medical appliances by the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (formerly known as the Pharmaceutical Affairs Act) (Act No. 145 of 1960, as amended) (ASSCC); and
- food, additives and the like by the Food Sanitation Act (Act No. 233 of 1947, as amended) (FSA).

An outline of the CPSA in English is available on the website of the Ministry of Economy, Trade and Industry (METI) (www.meti.go.jp/policy/consumer/seian/shouan/contents/shouanhougaiyo-e.pdf).

2 What requirements exist for the traceability of products to facilitate recalls?

The Household Goods Quality Labelling Act requires that information, including the name of the product's manufacturer, importer and so on, be labelled on certain consumer products. This requirement helps consumers to properly identify the product and the parties responsible therefor, and facilitates the lodging of reports and the making of claims by consumers where appropriate.

In relation to consumer products, the safety level of which may deteriorate after a period of use, the CPSA requires the manufacturers and importers (hereinafter, manufacturers) of such products to prepare a list of the product holders based on the information provided by such holders (CPSA, article 32-11(1)).

Under the ASSCC, authorised holders of products composed of biological products should keep the records of their assignees (ASSCC, article 68-7(1)).

The FSA requires that food business operators endeavour to keep records of all necessary information, such as the identities of buyers (FSA, article 3(2)). Although the laws do not link such lists and records with the product recall programme, product traceability supported by such systems is seen to be helpful in the actual recall process.

3 What penalties may be imposed for non-compliance with these laws?

All these laws have penalty provisions for non-compliance. Under the FSA, a person producing food or additives that do not conform to the requisite standards risks imprisonment with (or without) work for not more than two years or a fine of not more than ¥2 million, or both (FSA, article 72). In addition, a prefectural governor may rescind the business approval, prohibit the business from operating in whole or in part, or suspend the business for a specified period (FSA, article 55).

Under the CPSA, a person selling designated products (see question 19) that do not meet the requirements stipulated by law risks imprisonment with (or without) work for not more than one year or a fine of not more than ¥1 million, or both (CPSA, article 58(1)). In addition, the competent minister may prohibit such a person from affixing labels pursuant to CPSA, article 13 on specified products for a period of no more than one year as designated by him or her (CPSA, article 15). In such cases, given that the affixation of labels is required under the CPSA, the effect of this prohibition is such that the person must not sell or display the same products for sales purposes.

Furthermore, publication of a product recall is in itself a type of penalty, as the publication usually includes the name of the manufacturer of the product and this can damage the manufacturer's reputation.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

If a manufacturer is made aware of any serious accident caused by a product, it is required by the CPSA, article 35(1) to report it to the relevant authority. It is assumed, however, that retailers will report such knowledge to the manufacturers or importers of the product. Recently, the METI has established an online version of the reporting system on its website (www.meti.go.jp/product_safety/form/index.html) (Japanese only). If the accident caused by a product is not serious or it is clear that the accident is caused by something other than a product, it should be reported to the National Institute of Technology and Evaluation (the NITE, one of the independent administrative agencies in Japan).

Furthermore, under article 63-3(1) of the RTVA, automobile manufacturers must notify the Ministry of Land, Infrastructure and Transportation (MLIT) of any defects discovered in the design or manufacturing process. This notification must be made before any necessary remedial measures are taken.

The ASSCC requires manufacturers of medicines, cosmetics and medical devices to notify the Minister of Health, Labour and Welfare (MHLW) if they initiate a product recall or are made aware of any adverse effects caused by such medical products or devices (ASSCC, articles 68-10(1)).

The FSA requests food business operators to endeavour to prevent public health hazards by taking any necessary measures appropriately and immediately, such as providing central or local government with the records of retailers they have supplied (FSA, article 3(3)).

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

Under the CPSA, a matter requires notification where it constitutes a 'serious product accident', namely, an incident that satisfies the criteria provided for under the Ordinance for the Enforcement of the CPSA (Act No. 48 of 1974, as amended). These criteria relate to the danger posed by, and the type of, the accident, and, in so doing, target accidents involving serious actual or potential danger (CPSA article 2(6)).

Under the Ordinance for the Enforcement of the CPSA (Cabinet Office Ordinance of the reporting of a serious accident caused by a product required by the CPSA, No. 47 of 2009 (the CPSA Cabinet Office Ordinance)), the reporting of a serious accident caused by a product required by the CPSA article 35 should be submitted to the relevant authority, within 10 days of the date the reporter came to know of the accident, in the prescribed form described in question 7 (CPSA Cabinet Office Ordinance article 3).

The Ordinance for Enforcement of the ASSCC (Ordinance of the Ministry of Welfare (the MOW, predecessor of the MHLW), No. 1 of 1961 (the ASSCC Ordinance)) requires a manufacturer to report to the MHLW as soon as it initiates a product recall programme (ASSCC Ordinance article 228-22(1)).

6 To which authority should notification be sent? Does this vary according to the product in question?

The relevant authority to which the notification should be sent depends on the product as follows:

- consumer products, electric appliances, gas appliances and combustion appliances to the Consumer Affairs Agency (CAA);
- medical products, cosmetics and medical devices to the MHLW;
- automobiles to the MLIT; and
- food, additives and the like to the CAA.

In addition to notifying the relevant authority, as required by law, it is highly recommended that other relevant authorities and local governments are notified as well.

7 What product information and other data should be provided in the notification to the competent authority?

Article 3 of the CPSA Cabinet Office Ordinance, which refers to the CPSA article 35(1), requests that the notification be made in the prescribed form (Form I) and contain the following information:

- name of the product, brand, number of models and the country of production;
- details of the human injury or injuries;
- situation of the accident (ie, facts, causes, measures taken to prevent future accidents, contact person or organisation that conducted the investigation and the holder of the products);
- date that the supplier reported the accident, and the background to such reporting;
- place of the accident;
- period and total volume of production, imports and distribution;
- company name and address of the product manufacturer or importer; and
- relevant industry association.

RTVA article 63-3(1) and ASSCC Ordinance article 228-22(1) also set forth information to be provided to the relevant authority.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Under article 51-2 of the Ordinance for Enforcement of the RTVA (Ordinance of the Ministry of Transport, No. 74 of 1951 (the RTVA Ordinance)), manufacturers must update information about risks every three months until remedial measures are completed.

The CPSA does not impose an obligation on manufacturers to update information, but manufacturers are expected to keep the relevant authorities updated regarding the status of the product recall programme.

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

Manufacturers that fail to report or who submit false reports in violation of the CPSA article 35(1) may be ordered by the relevant authority to establish systems to collect information on serious product accidents, if this is regarded as necessary by the relevant authority (CPSA article 37). Violation of these orders risks imprisonment with (or without) work for not more than one year or a penalty of ¥1 million, or both (CPSA article 58(v)).

Manufacturers that fail to report or that submit false reports in violation of the RTVA article 63-4(1) risk imprisonment with (or without) work for not more than one year, a fine of not more than ¥3 million, or both (RTVA article 106-4(3)).

A person producing food or additives who fails to report or who submits false reports in violation of the FSA article 28(1) risks a fine of not more than ¥500,000 (FSA article 75(2)).

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

In cases where the competent minister receives a report in accordance with CPSA article 35(1), or otherwise comes to know of the occurrence of a serious product accident, if he or she finds it necessary to prevent serious danger to general consumers, he or she will, in principle, make a public announcement of information such as the name and type of the relevant consumer product, the details of the accident, and so on, so as to minimise the dangers associated with the use of said product. However, commercially sensitive information will not necessarily be disclosed in such announcements (see question 20).

As a general rule, administrative organisations should disclose administrative documents upon request (Act on Access to Information Possessed by Administrative Organs, Act No. 42 of 1999, as amended (AAI)). Administrative documents are defined in the AAI; however, the AAI excludes several kinds of information from disclosure (AAI article 5). Such information includes confidential business information which if disclosed could have a harmful effect on the competitive position of a certain business entity. Commercially sensitive information is assumed to be generally covered by this category; however, the AAI also sets out a category for absolute disclosure if disclosure is necessary for the protection of life, health, livelihood and property (AAI article 5(ii)). In the context of product recall, most of the information provided by manufacturers is likely to fall within the scope of absolute disclosure. It is uncertain whether such commercially sensitive information can be kept undisclosed.

11 May information notified to the authorities be used in a criminal prosecution?

As a general rule, information that is acquired through an administrative procedure may not be used in a criminal investigation. The CPSA expressly sets out the rule that on-site inspections conducted by the relevant authority may not be regarded as criminal investigations (CPSA article 41(12)).

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

Any person engaged in the manufacture or import of consumer products must, in cases where there is an accident affecting the consumer products that he or she manufactured or imported, investigate the cause thereof; and, if he or she finds it necessary to prevent the occurrence and increase of danger already posed, endeavour to recall said consumer products or otherwise take measures to prevent the occurrence of danger or an increase in a danger already posed (CPSA article 38(1)). Retailers of such products are required to cooperate with the manufacturers' hazard-preventing measures (CPSA article 38(2)).

Under the RTVA, the applicable criteria are the 'security standards' stipulated in articles 40 to 46. The security standards vary in accordance with the type of automobile. Detailed criteria are also provided in the 'Security Standards for the Road Tracking Vehicle' (Ordinance of the Ministry of Transport, No. 67 of 1951). Product recall is expected if automobiles are found to violate the security standards; manufacturers and importers are required to report to the MLIT once such product recall programme is put into force (RTVA, article 63-3(1)).

Update and trends

On 13 June 2018, a law to amend the Food Sanitation Act (FSA) was promulgated. Among the several amendments that were made, set out below are the two important amendments in relation to product recall:

Collection of information regarding health hazard caused by food containing specific substances (article 8 of the amended FSA)
For the purpose of preventing health hazards, business operators who deal with food products containing specific substances requiring special precautions are obligated to report it to the prefectural authorities when any health problem is, or likely to be, caused by such a product. This amendment was made in response to the recent increase in health hazards caused by health foods. For example, in the last three years, there was a rapid increase in the number of cases where the health of women was severely affected due to the intake of supplements containing Pueraria mirifica, which was advertised as effective in enhancing beauty. The substances subject to this regulation is not specified yet. It will be specified by the MHLW after discussions at relevant commissions and implementation of the public comment process. According to the MHLW, such substances will include alkaloid and hormone-like substances.

Reporting system for food recall (article 58 of the amended FSA)
When a business operator voluntary recalls its food product which violates the FSA, it is required to report such recall to a prefectural governor. According to recently received information, the number of food recalls was about 1,000 a year even though there has been no obligation to report food recalls so far. As a result, information of recall was not centralised. After the enforcement of this amendment, the reported recall information will be consolidated on the MHLW's website through prefectural governors.

The first amendment above will be enforced by a date specified by a Cabinet Order within a period not exceeding two years from the day of promulgation (ie, 13 June 2018), whereas the second amendment is likely to come in to force in three years from that day.

As explained above, most of the criteria are quite abstract and manufacturers and importers are not specifically instructed to initiate a product recall programme. However, a product recall programme is generally accepted as one of the most typical 'hazard-preventing measures', and manufacturers and importers are therefore expected to implement such a programme.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Most of the laws and regulations order manufacturers to take necessary measures to collect information on accidents caused by their products, to provide such information properly to general consumers and to prevent a hazardous situation being caused by a product (eg, CPSA, articles 34(1) and 38(1)). Such necessary measures are assumed to include the publication of information as well as the conduct of a product recall programme. In addition, under the ASSCC, manufacturers and sellers are required to dispose, recall, stop selling, inform about defective products and take any other necessary measures (ASSCC, article 68-9).

14 Are there requirements or guidelines for the content of recall notices?

There are requirements for the content of recall notices in several laws and regulations. The Request for Providing Information Regarding the Accident, Caused by Consumer Products, etc (Notification by Director General for Commerce and Distribution Policy, No. 1 of 2015) applies to products regulated by the CPSA. The ASSCC is also supplemented by the Medicine Recall Notice (Notification by the Pharmaceutical and Food Safety Bureau, Notification No. 1121-10 of 2014).

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The laws and regulations do not stipulate any obligatory media or communication measures that must be taken to announce a recall programme. In practice, since manufacturers must report accident information and the initiation of a product recall programme to the relevant authorities, such information is forwarded to and uploaded on the websites of non-profit consumer information centres, which are affiliates of the authorities. The relevant authorities may also announce the accident at a press conference, if regarded as necessary.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There are no specified targets or any particular period after which a recall will be deemed satisfactory.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

As previously explained, the laws and regulations do not provide for any mandatory repair programme. Manufacturers generally choose measures that will best prevent hazardous situations or product deterioration. In addition, government authorities are likely to provide guidance or instructions. Apart from administrative responsibility, a producer or supplier will also be subject to civil liability for any defective products provided to consumers. See question 24.

18 What are the penalties for failure to undertake a recall or other corrective actions?

When a person violates an order of article 39(1) of the CPSA (as mentioned in question 19), that person will be punished by imprisonment with (or without) work for no more than one year or a fine of not more than ¥1 million, or both (CPSA, article 58(iv)).

Under the RTVA, manufacturers who find that their automobiles do not meet the legally requested requirements must report to the MLIT (RTVA, article 63-4(1)). If the manufacturer makes a false report, they will be charged and punished with imprisonment with (or without) work for no more than one year or a fine of up to ¥3 million, or both (RTVA, article 106-4(iii)). In 1999, a major truck and bus manufacturer was found to have failed to report a product defect and conduct a product recall. Accordingly, several employees in charge of product security were penalised with one and a half years' imprisonment (with probation for three years) (Yokohama District Court, judgment on 13 December 2007; affirmed by Tokyo High Court, judgment on 2 February 2009).

In addition, the representative directors each received a penalty of ¥200,000 due to violation of the RTVA, article 63-4(1) (Tokyo High Court, judgment of 15 July 2008, affirmed by the Supreme Court, judgment on 9 March 2010).

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

The manufacturers or importers of consumer products may be ordered by the relevant authority (a hazard prevention order under CPSA, article 39(1)), and to the extent necessary, to recall products where:

- serious accidents have occurred;
- the lives or wellbeing of general consumers have been placed in serious danger or the occurrence of such danger is considered to be imminent; or
- the relevant authority finds it necessary to prevent the occurrence or increase of any type of danger.

If a recall is carried out in an unsatisfactory way, a hazard prevention order or an on-site inspection order (as described below) will be executed.

The METI can produce a list of designated products that are deemed highly likely to cause danger to general consumers as a result of their structure, material or usage, etc (CPSA, article 2(2)). The METI may order the manufacturer to take all necessary measures to improve methods of manufacture, import or inspection of the specified products where it finds that such manufacturers fail to conform to

the requirements outlined in the CPSA Cabinet Office Ordinance (the Order for Improvement).

The relevant authority may, when necessary, enforce the CPSA by:

- ordering a person engaging in the manufacture, import or sale of the products or a business operator transacting specified maintenance products, to report on the status of its business (CPSA, article 40(1)); or
- sending officials (or the NITE on behalf of officials) to enter the offices, factories, workplaces, stores or warehouses of a person engaging in the manufacture, import or sale of the products, or a business operator transacting specified maintenance products and to conduct an inspection of products, books, documents and other items (CPSA, article 41(1)).

If the relevant authority has asked its officials to conduct an on-site inspection but some products are found to be extremely difficult for them to inspect on site, the authority may order the owner or possessor to submit them for inspection to the relevant authority within a designated period (CPSA, article 42(1)).

20 Can the government authorities publish warnings or other information to users or suppliers?

When relevant, the authority can publicly announce its orders and information to users and suppliers (CPSA, articles 36(1) and 39(2), RTVA, article 63-2(4), etc). Public announcements are made through press releases on the website of the CAA (www.caa.go.jp), which does not provide a facility for members of the public to post remarks or reports of incidents. Under the CPSA, information that should be included in such a public announcement comprises:

> *the name and type of the consumer products pertaining to said serious product accidents, the details of the accidents and any other matters that contribute to avoiding the dangers associated with the use of said consumer products (CPSA, article 36(1)).*

However, other information, including but not limited to details about the relevant manufacturer, current status of the accidents, periodical reports from the relevant manufacturer, among others, is also included in the public announcement.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Under the ASSCC, article 70(2), the MHLW and prefectural governors, after ordering necessary measures to be taken by the responsible parties under the ASSCC, article 70(1), may dispose of or recall or take other necessary measures if it is immediately necessary or if such responsible parties fail to observe the orders imposed upon them.

However, there is no provision that allows government authorities to conduct a complete product recall programme.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

There is no such provision.

23 How may decisions of the authorities be challenged?

Any administrative disposition imposing an obligation on parties can be challenged under the Administrative Case Litigation Act (Act No. 139 of 1962, as amended). This is provided, however, that the same has not been previously challenged in court.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

Safety warnings do not have any legal standing as admissions of liability. However, in practice, such warnings are likely to be seen by the civil court as strong evidence in establishing the liability of defective products.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Even though the Code of Civil Procedure (Act No. 109 of 1996, as amended (the CCP)) does not provide for full discovery, the court may order that documentary evidence be provided to a party upon the other party's request (CCP, article 220). Although the document-holding party may refuse to provide such documents on the grounds that they are irrelevant to the facts of the case, many of the documents are assumed to be relevant to product liability in actual product liability actions.

Notwithstanding the above, the document-holding party may still refuse to submit a document prepared exclusively for use by the holder thereof (CCP, article 220(iv)(d)).

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

The Framework Act on Consumers and the Framework Act on Product Safety are the basic laws governing the safety requirements for products.

The Framework Act on Consumers, as the general law applying to all consumer products, obliges the government to stipulate standards of safety, indication of manufacturer and advertisement that must be complied with by producers and sellers of products, and sets forth the obligation of business operators to report product defects, and the voluntary and involuntary recall system. The obligation of the government to stipulate standards of safety, indication and advertisement under the Framework Act on Consumers is specified in the individual laws such as the Food Sanitation Act, the Electrical Appliances Safety Control Act, the Quality Control and Safety Management of Industrial Products Act, the Motor Vehicle Management Act and the Pharmaceutical Affairs Act, and each law regulates the standard of product safety, the recall system, etc by product category.

The Framework Act on Product Safety, as the law applying to the finished products, regulates protection of consumers in connection with products, such as the investigation of product safety, the voluntary recall system and the involuntary recall system.

2 What requirements exist for the traceability of products to facilitate recalls?

In Korea, individual laws for each item regulate traceability of production history or trade records of the relevant products. In the case of food products, the Food Sanitation Act, through the Food History Trace and Management Framework, requires that the relevant information is recorded and managed by each of the production, processing and sale stages so that in case there is an incident relating to food safety, its cause can be traced and necessary measures can be taken (subparagraph 13 of article 2 of the Food Sanitation Act). In the case of products distributed through electronic commerce transactions or mail orders, it is stipulated that the business operator must preserve the history of transactions for a certain period of time and provide its customers with a method to easily inspect and preserve their transaction history (article 6 of the Act on the Consumer Protection in Electronic Commerce, etc).

With respect to the indication of manufacturer on product containers or packages, the Act on Fair Labelling and Advertising sets forth the information that must be included in the label and advertisement. The individual laws, such as the Health Functional Foods Act and the Management of Drinking Water Act, stipulate that customers be informed about who is responsible for the recall of the products by providing the specific standard of indication for a certain product.

3 What penalties may be imposed for non-compliance with these laws?

In case of violation of the relevant obligations, the aforementioned laws impose certain penalties.

For example, the Framework Act on Consumers stipulates that those who do not implement the involuntary recall order or the corrective order regarding violation of the standard of indication from the competent authorities may face up to three years in prison and a maximum of 50 million won in fines, and that those who do not implement the product defect reporting obligation or violate the standard of safety may be fined up to 30 million won.

The Framework Act on Product Safety stipulates that those who do not implement the involuntary recall order from the competent authorities may face up to three years in prison and a maximum of 30 million won in fines and that those who do not implement the product defect reporting obligation may be fined up to 30 million won.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

Under the laws related to consumer protection, the obligation of the business operator to report on product defects is divided into the defect information reporting obligation and the incident reporting obligation.

The defect information reporting obligation is an obligation for a manufacturer or a distributor of products (the 'business') to report to the head of the central administrative agency upon discovery of material product defects that would harm the life, body or property of consumers (article 47(1) of the Framework Act on Consumers and article 13(1) of the Framework Act on Product Safety). Upon receiving such report, the head of the central administrative agency can issue advice for recall and destruction of the products or issue an order for recall and destruction of them.

The incident reporting obligation is an obligation for the business to report to the head of the central administrative agency upon the occurrence of a death, an injury that will take four weeks or more to heal completely, a fire or an explosion attributable to products, or of repetitive accidents by the same product (article 13-2 of the Framework Act on Product Safety).

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

The 'material defect' that triggers the defect information reporting obligation means a defect lacking safety conventionally expected in the course of manufacturing, indication of design, distribution or provision of products, which cause or could cause a death, an injury or disease that will take three weeks or more to heal completely or food poisoning of more than two people (article 47 of the Framework Act on Consumers and article 34 of the Enforcement Decree of the same act). The business must file a defect report to the head of the competent central administrative agency within five days from the date of the discovery of a material defect of products, etc (article 35 of the Enforcement Decree of the Framework Act on Consumers).

The incident reporting obligation is triggered upon the occurrence of a death, an injury or disease that will take four weeks or more to heal completely, a fire or an explosion because of products, or of repetitive accidents by the same product. The business must file an incident report to the head of the competent central administrative agency within 48 hours from the time of the discovery of such incident (article 13-2 of the Framework Act on Product Safety and article 14-2(4) of the Enforcement Decree of the same act).

6 To which authority should notification be sent? Does this vary according to the product in question?

The business is required to make a defect report or an incident report to the central administrative agency (article 47 of the Framework Act on Consumers and article 13 and 13-2 of the Framework Act on Product Safety), and the competent central administrative agency varies according to the relevant product. For example, automobile defects should be reported to the Minister of Land, Infrastructure and Transport while agricultural machinery defects should be reported to the Minister of Agriculture, Food and Rural Affairs, and defects of other general products having no competent authorities should be reported to the Minister of Trade, Industry and Energy.

7 What product information and other data should be provided in the notification to the competent authority?

A defect report made by the business to the competent central administrative agency should be in the form of a document, and the defect report must include:

- the name, address and contact information of the business;
- the names of the products and the date of the manufacture or furnishing thereof;
- the contents of the serious defect and the danger or injury;
- the time and process that the business became aware of the serious defect; and
- the personal information of affected consumers, if any (article 35 of the Enforcement Decree of the Framework Act on Consumers).

When the business makes a defect report in accordance with article 13(1) of the Framework Act on Product Safety, he or she must report on the name, trademark, type, grade and title of the relevant products, and the item number and the date of the manufacture of the relevant products.

When a business reports on an incident that already took place in accordance with article 13-2(1) of the Framework Act on Product Safety, the business needs to submit to the head of the competent central administrative agency the incident report including:

- the name, trademark and model name of the relevant products;
- the contents of the incident and the date and place of the incident;
- the number of sales and the sales period; and
- the period of manufacture and the number of manufactured products (article 14(2) of the Enforcement Decree of the Framework Act on Product Safety).

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

The Framework Act on Consumers and the Framework Act on Product Safety do not stipulate any obligation to regularly update information about risks. However, when the risks of the products increase or a new defect of the products is discovered and the business becomes aware thereof, the defect information reporting obligation is triggered under the Framework Act on Consumers and the Framework Act on Product Safety.

Under the Framework Act on Consumers, when there is any reasonable ground to suspect the safety of products, the head of the central administrative agency can have any public official under his or her control enter the places of business to conduct an inspection (article 77(2) of the Framework Act on Consumers), and consumer organisations and the Korean Consumer Agency can request the business to provide information necessary for consumer protection. In this case, the business must comply with such request unless there exists any justifiable cause (article 78 of the Framework Act on Consumers). Under the Framework Act on Product Safety, if an accident causes or is likely to cause danger or harm to consumers owing to any defect in products, the head of the central administrative agency can request the relevant business to submit information associated with the accident (article 15 of the Framework Act on Product Safety).

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

If the business fails to make a report on any material defect in products or make a false report, it will be punished by a fine for negligence of up to 30 million won under the Framework Act on Consumers, and by a fine for negligence of up to five million won under the Framework Act on Product Safety (article 86(1)3 of the Framework Act on Consumers and article 27 of the Framework Act on Product Safety). The business that fails to make a report on any incident related to products will be punished by a fine for negligence of up to 30 million won (article 27 of the Framework Act on Product Safety).

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

The head of the central administrative agency who received a defect report will not disclose the fact of report on the defect until the matter of whether the defect of the products in question exists or not is confirmed (article 35(4) of the Enforcement Decree of the Framework Act on Consumers). Therefore, the fact of report on the defect is not publicly disclosed unless the defect in question is confirmed to be true.

The Framework Act on Product Safety imposes confidentiality obligation on public officials regarding any information they have obtained from a product safety investigation, a defect report, an incident report and documents requested, and prevents the disclosure and private use of confidential business information by imposing criminal sanctions against a person that discloses any confidential information breaching the law (article 23(2) of the Framework Act on Product Safety).

11 May information notified to the authorities be used in a criminal prosecution?

Under the Framework Act on Product Safety, the head of the central administrative agency can establish a product safety information network for gathering and managing the details of product safety investigations, information on recommendations for recall and orders for recall, and information reported by a business, and has to share such information with the heads of other relevant central administrative agencies (article 16(2) of the Framework Act on Product Safety).

Under the Criminal Procedure Act and the Act on the Performance of Duties by Police Officers, the investigation agency can require a public organisation to provide information or make a report on necessary matters regarding an investigation (article 199(2) of the Criminal Procedure Act and article 8(1) of the Act on the Performance of Duties by Police Officers), and therefore the investigation agency can be provided with information on defects and safety investigations by the heads of the relevant central administrative agencies and use the information for its investigation.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

Under Korean laws, the recall system is divided into the voluntary recall and the involuntary recall. Under voluntary recall, a business voluntarily takes measures such as recalling its products (article 48 of the Framework Act on Consumers and article 13(1) of the Framework Act on Product Safety). Under involuntary recall, the government compels a business to recall and destroy its products and, depending on the level of urgency and the defect of product, it is divided into a recommendation for recall and an order for recall (article 49 and 50 of the Framework Act on Consumers and article 10 and 11 of the Framework Act on Product Safety).

The Framework Act on Consumers and the Framework Act on Product Safety stipulate the general provisions regarding the requirements for recall, and the individual laws such as the Automobile Management Act and the Food Sanitation Act stipulate the requirement for recall of each item. Generally, a product that is distributed in the market and causes or is likely to cause danger or harm to the life, health or property of consumers owing to any defect in the manufacture, design, description of the product or technical or structural characteristics of the product is subject to a recommendation for recall (article 10 of the Framework Act on Product Safety). The head of a central administrative agency can order a business to carry out a recall when the business fails to comply with the order for recall, when the results of safety inspection show that relevant products present any risk to safety, or when there are reasonable grounds to acknowledge the risk of the relevant product (article 11 of the Framework Act on Product Safety).

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Under the Framework Act on Consumers, if a business that has received the recommendation for recall refuses to comply with it without justifiable reason, the head of the central administrative agency can publish the fact that the business has received such recommendation (article 49(4) of the Framework Act on Consumers). Also, the head of the Consumer Safety Center can publish about the matters relating to the safety of products and such like if necessary (article 52(2)2 of the Framework Act on Consumers).

Under the Framework Act on Product Safety, if a business on receipt of a recommendation fails to comply with such recommendation or if a business received the order for recall, the head of the central administrative agency can publicly announce that fact. Also, in cases where a product safety investigation is conducted, the head of the central administrative agency can publish the results of the investigation (article 10(2), 11(4) and 15(2) of the Framework Act on Product Safety).

14 Are there requirements or guidelines for the content of recall notices?

When a business receives the order for recall, the head of the central administrative agency can publicly announce this through newspapers, broadcasting systems or the Safety Korea website (www.safetykorea.kr), and the publication can include the name and serial number of the products, the reason and contents of the order, the company name, the name of the representative and other matters deemed necessary for protection of consumers by the head of the central administrative agency (article 7 of the Enforcement Decree of the Framework Act on Product Safety).

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

Under the Framework Act on Product Safety, the head of the central administrative agency can make public announcements of recall through newspapers, broadcast systems or product safety information networks. Public announcements of recall are usually made on the website of Safety Korea, and the Korea Consumer Agency posts information about recall on the Consumer Injury Surveillance System (www.ciss.go.kr).

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

The consumer-related acts do not stipulate the specific guideline for the method or period of a recall. However, under the Framework Act on Consumers and the Framework Act on Product Safety, the business that completed the order for recall has to report the results of such recall including the contents and results of the order, the measures for the prevention of recurrence of danger or injury and a plan for disposing of products for which the recall has not been completed yet (article 38(6) of the Enforcement Decree of the Framework Act on Consumers and article 10(3), 11(2) and 13(2) of the Framework Act on Product Safety).

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

In the case of the involuntary recall, the head of the central administrative agency can recommend or order the business to recall, destroy, repair, exchange, refund, repair, or to prohibit the manufacture, import, sale, provision of the product, or to take other necessary measures (article 10(1) of the Framework Act on Product Safety). In the case of the voluntary recall, the business can decide appropriate measures by itself and report the recall plan but the head of the central administrative agency can request for additional measures. In the case of a recommendation for recall and an order for recall, the business has to submit the report on the planned measures such as recall, and the head of the central administrative agency can request for additional measures when the plan is deemed to be unsatisfactory (article 14(3) of the Enforcement Decree of the Framework Act on Product Safety). In practice, the implementation of both the voluntary recall and the involuntary recall generally involves the recall of the relevant product and the exchange of the relevant product for a new one.

18 What are the penalties for failure to undertake a recall or other corrective actions?

The business that fails to comply with the order for recall under the Framework Act on Consumers will be punished by imprisonment for not more than three years or by a fine not exceeding 50 million won (article 82 of the Framework Act on Consumers). If the business fails to comply with the order for recall under the Framework Act on Product Safety, it will be punished by imprisonment for not more than three years or by a fine not exceeding 30 million won (article 26 of the Framework Act on Product Safety).

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

If the business fails to comply with the order for recall, the head of the central administrative agency can directly recall and destroy the relevant products, or prohibit the supply, and the expenses involved in such activities will be borne by the business (article 50(2) of the Framework Act on Consumers, article 38 of the Enforcement Decree of the same act, article 11(3) of the Framework Act on Product Safety). Upon giving an order for recall, the head of the central administrative agency can specifically decide the period and method of the recall (article 9 of the Enforcement Decree of the Framework Act on Product Safety).

20 Can the government authorities publish warnings or other information to users or suppliers?

The head of the central administrative agency can publicly announce the results of a product safety investigation or an incident report through newspapers, broadcast systems or product safety information networks (article 15-2 of the Framework Act on Product Safety and article 17-2 of the Enforcement Decree of the same act). Also, the director of the Consumer Safety Center can publicly announce the results of the investigation relating to the safety products (article 51(2)2 of the Framework Act on Consumers).

If the business that received the recommendation for recall refuses to comply with it without any justifiable reason, or if the business receives the order for recall, the head of the central administrative agency can publicly announce this (article 49(4) of the Framework Act on Consumers, articles 10(2) and 11(1) of the Framework Act on Product Safety).

Also, citizens can report any defective product or the relevant incident through the Safety Korea website or the Consumer Injury Surveillance System, and the reported contents are utilised for the investigation relating to recall measures.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

If the business fails to comply with the order for recall, the head of the central administrative agency can directly recall and destroy the relevant products, or take other necessary measures (article 50(2) of the Framework Act on Consumers, article 11(3) of the Framework Act on Product Safety). Also, if it is deemed that any defect causes or might cause any urgent and significant danger or injury to consumers' lives, bodies or property, and it is deemed to be avoidable in order to prevent the occurrence or spread of such danger or injury, the head of the central administrative agency can do so without going through the recall procedure (article 50(1) of the Framework Act on Consumers).

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

In cases where the head of the central administrative agency directly recalls the relevant products, the expenses involved in such measures will be borne by the business (article 50(4) of the Framework Act on Consumers, article 38(9) of the Enforcement Decree of the same act and article 11(3) of the Framework Act on Product Safety).

23 How may decisions of the authorities be challenged?

If a business that has been recommended to carry out a recall of products or that has received an order for recall seeks to challenge such recommendation or order, it can file an application for the cancellation of such recommendation or order in whole or in part with the head of the competent central administrative agency within 30 days from the date it becomes aware that such recommendation or order is given (article 12 of the Framework Act on Product Safety). Also, the business can file an administrative appeal or administrative litigation against the recall or the order for recall without filing an application for the cancellation of such recommendation or order (article 12(3) of the Framework Act on Product Safety).

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

Under the Product Liability Act in Korea, a manufacturer should compensate for damages to the life, body or property of a person caused by a defect of a product (excluding damages inflicted only to the relevant product) (article 3(1) of the Product Liability Act). In such a case, the plaintiff has to prove not only the defect of the product but also the causal relationship between the defect and the damages to his or her life, body or property. However, as it is difficult for consumers to prove the causal relationship between a defect and damages, the Supreme Court of Korea eases the burden of proof for customers by assuming the causal relationship once the customer provides prima facie evidence of the relevant defect and proves that the damages were caused even when he or she used the relevant product in a proper way, unless the manufacturer proves that the damages were caused by other causes (Supreme Court Judgment 2011Da88870, decided 26 September 2013).

In civil cases regarding liability for products, a safety warning or a product recall does not automatically prove the business's liability for defective products as the customer has to prove the defect of the product, and the causation between the defect and the damages. However, given the above ruling by the Supreme Court of Korea, there is a high probability that the defect of the product will be acknowledged when the customer submits in litigation the contents of the recall order, safety and the results of an incident investigation that are publicly announced.

Furthermore, there is a high probability that the business will bear liability for damages unless it proves that the recall order is improper, that there is no defect in the product, or that the damages were not caused by the alleged defect because the causal relationship between the defect and the damages will be assumed to be proven when the customer proves that he or she used the product in a proper manner.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Korea's Civil Procedure Act does not adopt the discovery system as it is in the common law system, and therefore there is no obligation to disclose internal information. However, under the Civil Procedure Act, courts can order the concerned parties to submit documents by giving an order for submission of documents (article 344 of the Civil Procedure Act).

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SEPLAW

General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

Safety requirements for general products in Mexico are governed by the Federal Consumer Protection Law and the Federal Standards Law. Also, the Federal Standards Act establishes that the safety requirements must comply with the Mexican Official Standards, called NOMs, which are technical rules issued by the Ministry of Economy and provide further details to the requirements of products on an industry-oriented basis.

Also, specific provisions apply regarding safety requirements of food and medicines, including the General Health Act and its rules.

2 What requirements exist for the traceability of products to facilitate recalls?

There are no specific requirements for the traceability of products.

3 What penalties may be imposed for non-compliance with these laws?

If a product does not meet the safety requirements, the Federal Consumer Agency can impose administrative sanctions and other measures, including issuing warnings and interim remedies, such as fines, temporary or permanent closures, administrative warrants for up to 36 hours of detention and, finally, the suspension or revocation of the relevant governmental licences.

Any affected consumer can file a claim before such Federal Consumer Agency, in which the manufacturer, distributor, importer or seller of the defective product must reimburse the consumer plus a bonus of up to 20 per cent of the product price.

Notwithstanding the above, any affected party can also file a civil or commercial claim regarding the defective products against the manufacturer. In such claims, the available remedies include indemnification of damages and lost profits, as well as moral damages.

Also, if the failure to comply with the relevant safety requirements of a product is the direct cause for harm or death of a person, criminal liability can also be claimed against the manufacturer.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

The Federal Consumer Protection Law provides that in cases where a product can harm or jeopardise the life of a consumer, the manufacturer must give notice to the Federal Consumer Protection Agency.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

There is no specific provision in the Federal Consumer Protection Law or in the Federal Standards Act governing the requirements for the notification or its time limits, however, we deem that such notification should be made as soon as possible and provide such agency with all the available data to coordinate a recall.

6 To which authority should notification be sent? Does this vary according to the product in question?

For products in general, the relevant authority is the Federal Consumer Protection Agency and, regarding drugs or food products, it must be sent to the Federal Commission for the Protection against Sanitary Risks.

7 What product information and other data should be provided in the notification to the competent authority?

There is no specific regulation regarding the contents of the notification, but we deem that said notification should provide all available data that helps to coordinate the recall of the products.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

The Federal Consumer Protection Agency can request any entity with the information about a product that may result in harm to the life or health of a consumer.

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

Administrative penalties include fines, temporary or permanent closure of establishments or businesses, administrative detention for up to 36 hours, suspension or revocation of the relevant governmental licences.

When determining the penalty to be imposed, the Federal Consumer Protection Agency must take into account the damages caused by the breach, if such action was intentional and if there were any previous incidents.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

Commercially sensitive information is considered confidential pursuant to article 113 of the Federal Law for Transparency of Public Information. As such, any authority has the legal obligation to safeguard the confidentiality of such information.

11 May information notified to the authorities be used in a criminal prosecution?

Yes, if the information provided to an administrative authority is related to a criminal action, the authority has the legal obligation to notify the public prosecutor, which has the legal capacity to use said information as evidence in a criminal prosecution.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

Although there is no specific provision governing the criteria for a product recall or corrective actions, if a product may harm or jeopardise the life of a consumer, a product recall will be required.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

Pursuant to the Federal Consumer Protection Law, the supplier or manufacturer must provide the consumers with the specific warnings in relation to any product that is considered dangerous. These warnings should include information on:

- the product's harmful characteristics;
- the product's recommended use or application; and
- the potential effects of the product's use or application outside the recommended guidelines.

14 Are there requirements or guidelines for the content of recall notices?

There are no specific guidelines for recall notices in Mexico.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The Federal Standards Act provides that, in the event of a defective product which may harm or jeopardise the life of a consumer, the Federal Consumer Protection Agency has the legal capacity to request the immediate diffusion of such information to any mass media entity.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There are no specific guidelines for recall notices in Mexico, however, we deem that the recall will last until all products considered harmful to a consumer are no longer in the market.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

Yes, pursuant to the Federal Consumer Protection Law, consumers are entitled to the substitution of the product or the return of the amount paid against the delivery of the product acquired and/or that the affected customer be reimbursed with the cost of the product, plus a bonus of at least 20 per cent of the product or service price.

18 What are the penalties for failure to undertake a recall or other corrective actions?

If a manufacturer doesn't recall a product or fails to take corrective actions, it will be subject to the administrative penalties described in question 3, as well as the civil liability derived from the breach of such an obligation.

Update and trends

The Mexican Constitution was amended in relation to civil and commercial proceedings and the Mexican General Congress will issue a new National Civil Procedures Code that will replace the civil procedures code of each Mexican state.

This new National Civil Procedures Code may introduce new remedies and change the civil liability regarding product recalls.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

The Federal Consumer Protection Agency may exercise the corrective measures set forth in article 25 of Federal Consumer Protection Law, which includes warning orders and fines; also, it has the legal capacity to order interim remedies such as:

- impoundment of containers, goods, product and transportations;
- seizure of goods or products;
- order the suspension of the marketing of the products; and
- placement of closure seals.

20 Can the government authorities publish warnings or other information to users or suppliers?

Yes, pursuant to article 98 Bis of the Federal Consumer Protection Law, the Federal Consumer Protection Agency has the legal capacity to order to inform consumers, either individually or collectively, including through mass media, the actions or omissions of the supplier that affect the interests or rights of consumers.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Yes, the Federal Consumer Protection Agency is required by law to issue and coordinate such recall if it has knowledge of any risks to the life or health of the consumers produced by a defective product.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Pursuant to article 57 of the Federal Standards Act, when a official notice has been issued forbidding to sell a defective product, the responsible party for breaching the relevant Mexican Official Standard is bound reimburse the value of the product, or provide a new product which complies with Mexican Law, as well as all costs made to treat, recycle, or dispose any hazardous product, according to the relevant laws.

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23 How may decisions of the authorities be challenged?

Administrative decisions can be challenged either through an administrative review which will be decided by the same authority or through a nullity claim filed before the Federal Administrative Justice Court (administrative court).

If the Federal Administrative Justice Court rules against the claimant, such resolution can also be challenged by means of an *amparo* (constitutional review process) filed before the federal judicial courts.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

No. In a civil proceeding, any confession must be made before the court, however, the civil court may take such publication as evidence of a possible breach of Mexican standards.

Notwithstanding the above, the claimant in a civil proceeding must also probe that such a breach was the direct cause for the alleged damage to be awarded with an indemnification.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

There is no discovery process in Mexico and although civil courts are entitled to request any relevant information or identifiable document to a party, civil courts don't have the legal capacity to order a search warrant.

The legal remedy if a party fails to present the requested document is to hold the rebel party as admitting the facts that the counterparty is trying to prove with the document.

South Africa

Evert van Eeden and Elzaan Rabie Van Eeden Rabie Inc
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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

In terms of the common law, liability for injury caused by a person may arise from culpable conduct (requiring proof of negligence) of the party who has caused the injury. In terms of section 61 of the Consumer Protection Act, Act No. 68 of 2008 (CPA) (www.thencc.gov.za/sites/default/files/consumer%20protection%20act%20final%20april%202009.pdf), a regime of modified strict liability was introduced in terms of which producers, importers, distributors or retailers of any goods are liable for harm caused, wholly or partly as a consequence of the supply of any unsafe goods, a product failure, defect or hazard in any goods, or inadequate instructions or warnings provided to the consumer pertaining to any hazard arising from, or associated with, the use of any goods. Liability in terms of section 61 arises irrespective of whether the harm resulted from any negligence on the part of the producer, importer, distributor or retailer. A person's liability in terms of section 61 is avoided where the defect only came into existence after that person supplied the goods to another person in the supply chain, the defect was wholly attributable to compliance by a person with instructions provided by a supplier of the goods to that person, or where the defect is wholly attributable to compliance with any public regulation.

The registration of products (medicine, scheduled substance or a cosmetic or foodstuff which contains a scheduled substance), medical devices or IVDs (in vitro diagnostic medical devices) is governed by the Medicines and Related Substances Act, Act No. 101 of 1965 (MRSA) (www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/legislations/acts/medicines_and_related_sub_act_101_of_1965.pdf). The MRSA was amended by the Medicines and Related Substances Amendment Act, Act No. 72 of 2008 on 1 June 2017 when the amendment came into operation. Products, medical devices and IVDs must be registered with the South African Health Products Regulatory Authority (SAHPRA) (previously the Medicines Control Council). The sale of unregistered medicines is an offence. In terms of the Foodstuffs, Cosmetics and Disinfectants Act, Act No. 54 of 1972 (FCDA) (www.nda.agric.za/doaDev/sideMenu/fisheries/03_areasofwork/Aquaculture/AquaPolGuidLeg/Legislation/FoodstuffsCosmeticsDisinfectantsAct54of1972.pdf), the sale, manufacture or importation for sale of certain specified foodstuffs, cosmetics and disinfectants is prohibited and contravention of the prohibition is a criminal offence.

The production, acquisition, disposal or importation of certain intrinsically hazardous or toxic substances is regulated by the Hazardous Substances Act, Act No. 15 of 1973 (HSA) (www.emergogroup.com/sites/default/files/file/south-africa-hazardous-substances-act-no-15-1973.pdf). Failure to comply with the HSA constitutes a criminal offence. The CPA applies to consumer protection issues in general, while more specific legislation such as the laws referred to above deal with specific industry-related questions.

In terms of regulations issued under the Occupational Health and Safety Act, Act No. 85 of 1993 (OHSA) (www.acts.co.za/occupational-health-and-/index.html), certain safety standards apply to escalators and elevators conveying passengers or goods. The aviation industry is extensively regulated. In terms of the National Regulator for Compulsory Specifications Act, Act No. 5 of 2008 (NRCSA) (www.nrcs.org.za/siteimgs/downloads/NRCS%20ACT%20Act%205%20of%202008.pdf) product specific specifications and standards apply to a broad range of products (eg, motor vehicles, electrical products and child restraints for use in motor vehicles, etc).

2 What requirements exist for the traceability of products to facilitate recalls?

In terms of the regulations issued under the FCDA, the label of any prepackaged foodstuff must contain the name and address of the manufacturer, importer or seller. Subject to certain exceptions the country of origin of a foodstuff must be indicated on the label thereof, the ingredients thereof and the date of manufacturing. Containers of foodstuffs must be marked in such a way that the specific batch is identifiable and traceable. Information related to the requirements in respect of the regulations must be kept on record by manufacturers, importers or sellers. In terms of the regulations issued under the MRSA, the immediate container of every medicine in which a medicine, intended for administration to humans, is sold must have a label attached to it with particulars that include the lot number of the medicine, the expiry date of the medicine and the name of the holder of a certificate of registration of the medicine. Medicines for human use must also contain package inserts indicating the name and business address of the holder of the certificate of registration of the medicine, or in the case of a parallel imported medicine, the name and business address of the holder of the parallel importer permit.

3 What penalties may be imposed for non-compliance with these laws?

Criminal penalties may be imposed in relation to contraventions of the FCDA, as well as the MRSA and the HSA. The CPA makes provision, in relation to conduct that is prohibited under the CPA, for the issue of compliance notices by the National Consumer Commission (NCC) and the imposition by the National Consumer Tribunal (NCT) of an administrative fine on application by the NCC. In certain circumstances, a court or the NCT may grant an order for interim relief in relation to conduct that is prohibited in terms of the CPA.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

The SAHPRA has issued guidelines (Guidelines: Reporting of ADRs) for the reporting of adverse drug events or experiences and adverse drug reactions (ADRs). The NCC has been tasked, by section 60(1) of the CPA, to develop and promote industry-wide codes of practice (codes of practice) making provision for the adoption and application of systems to deal with certain events relating to unsafe goods and product defects. Such systems should make provision for receiving notice of consumer complaints, reports of product failures, defects or hazards, and of goods returns because of product failures, defects or hazards. These systems should also make provision for monitoring and analysing information sources relating to such product events, conducting investigations concerning such events, which include investigations into the nature, causes, extent and degree of the risk to the public, and to notify consumers in relation thereto, and finally for

the recall of unsafe goods. The provisions of the CPA do not expressly require that suppliers must notify the NCC if defects are discovered in products or if incidents of personal injury or property damage occur arising from such defects.

No codes of practice have to date been implemented. The NCC has, however, issued Consumer Product Safety Recall Guidelines (the NCC Recall Guidelines). The NCC Recall Guidelines lay down recall procedures in general terms and urge suppliers to adopt recall policies. While it is submitted that the NCC Recall Guidelines are not currently legally enforceable, it is suggested that if a supplier encounters a situation where a product recall may be appropriate, it should report this to the NCC and carry out any recall reporting and implementation in close consultation with the NCC. It should also closely adhere to the procedures set out in the NCC Recall Guidelines.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

The CPA distinguishes between manufacturing defects, design defects, failures, hazard and unsafe goods. Goods are 'unsafe' when particular goods present an extreme risk of personal injury or property damage to the consumer or to another person. 'Defects' include both manufacturing defects (when a material imperfection in the manufacture of the goods or components renders the goods less acceptable than persons generally would be reasonably entitled to expect in the circumstances) and design defects (when any characteristic of the goods or components renders it less useful, practicable or safe than persons generally would be reasonably entitled to expect in the circumstances). A 'failure' means the inability of the goods to perform in the intended manner or to the intended effect.

At the time of writing, all notification to the NCC and recalls subject to the CPA can be described as 'voluntary'. In terms of the NCC Recall Guidelines, a supplier should, as soon as it becomes aware of a possible safety hazard (the term 'safety hazard' is not defined) in a consumer product that may cause injury to a person, conduct an assessment comprising:

- gathering and assessing the reliability of all available information about the potential hazard;
- identifying how the problem occurred;
- conducting a comprehensive risk analysis; and
- examining means of addressing the safety-related hazard and deciding whether the product can be repaired or modified.

The NCC requires a supplier to contact it when commencing with such an assessment, even though the notification to the NCC is not currently a legal requirement. However, it is nevertheless submitted that when a supplier becomes aware that product defects or failures may be connected with or result in death of, injury to, illness, loss of or physical damage to property, or any resulting economic loss, a supplier should initiate a review of the available information with a view to identifying the possible 'safety hazard', bearing in mind the guideline that the NCC should be contacted when such process of identification becomes an 'assessment'. The requirement that the NCC should be contacted when the assessment is 'commenced' implies that the NCC should become involved at a very early stage of the detection and consideration of product safety concerns, even if such concerns were to turn out to be unfounded.

6 To which authority should notification be sent? Does this vary according to the product in question?

Notification with regard to product recalls generally must be addressed to the NCC. The supplier has the prime responsibility for implementing a recall. A recall should be implemented in accordance with the supplier's recall policy and after consultation with the NCC. In order for the NCC to be assured that a product safety risk will be effectively mitigated, it requires that the supplier undertakes the following actions:

- notify the NCC of the recall, which includes providing details of other entities within the supply chain that have been notified of the recall;
- prepare and submit to the NCC a recall strategy;
- retrieve the affected product from consumers and from within the supply chain; and
- report on the recall to the NCC.

A supplier's recall strategy should include:

- an explanation of the problem, including the hazard associated with the product and the supplier's assessment of the risk posed by the product;
- the number of units supplied in the market;
- information about any known injuries, the proposed communication with consumers, complaint handling procedures, the manner in which the recalled product will be collected, destroyed or rectified; and
- relevant contact details.

In the case of foodstuffs, cosmetics, disinfectants and medicines, notifications should be addressed to the Department of Health. ADRs must be reported to the SAHPRA. If a pharmaceutical company receives a report of a suspected adverse reaction to a medicine marketed by another applicant for the registration of that medicine, such report should, in terms of the Guidelines: Reporting of ADRs, be forwarded to the applicant for the registration of that medicine.

7 What product information and other data should be provided in the notification to the competent authority?

In terms of the Guidelines: Reporting of ADRs, an adverse drug reaction report form (ADR Form) is available from the National Adverse Drug Event Monitoring Centre (NADEMC). Applicants may also use their in-house report forms, if such forms include all the necessary data elements in a readable format. Applicants should submit not only the minimum information required for a report but all the relevant information available at the time of initial notification of an adverse drug reaction report. Applicants are encouraged to attach discharge summaries, post-mortem reports, relevant laboratory data and other additional clinical data. The applicant must submit the name (or initials), address, telephone number and qualification of the initial reporter on the ADR Form.

In terms of the NCC Recall Guidelines, notification to the NCC may be effected through use of a Recall Notification Form (RN Form) supplied by the NCC. The RN Form must state that goods are subject to a recall. The nature of the problem or non-compliance must be stated in the RN Form if the goods contain a defect, have a dangerous characteristic, or do not comply with a prescribed consumer product safety standard. Use of the RN Form is regarded as fulfilling the NCC's notification requirement, although use of such form is not expressly required by the NCC Recall Guidelines. The RN Form requires information regarding the product, identifying numbers relating to the product, points of sale and periods of sale, the life span of the product, the supplier, elements of the marketing chain such as details of the manufacturer and the country of origin, the nature of the defects and hazards, what consumers should do and advertising relating to the recall.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

In respect of medicines, summary reports must be submitted annually to the NADEMC by applicants for the registration of medicine. These reports must, inter alia, include:

- the local usage of each formulation for the review period;
- a concise critical analysis of the reported ADRs for each medicine;
- the actions taken or to be taken (including actions taken by any other regulatory authority or marketing authorisation holder);
- a simple risk-benefit statement for ongoing use and monitoring of the medicine; and
- a line listing which includes the source, patient gender and age, formulation, daily dose, treatment dates and duration or time to onset, adverse reactions, seriousness, outcome and comment.

Owners of food-handling enterprises are required, in terms of the regulations issued under the FCDA, to implement 'HACCP systems'. This is a hazard analysis and critical point system that identifies, evaluates and controls hazards that are significant for food safety. HACCP systems must comply with the principles as provided for by the Joint Food and Agricultural Organization/World Health Organization Food Standards Programme Codex Alimentarius Guidelines. In terms of the NCC Recall Guidelines, a supplier must furnish the NCC with regular progress reports.

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

Penalties in terms of the CPA are mainly administrative, although a failure to comply with a compliance notice issued by the NCC constitutes an offence. Failure to comply with the FCDA is punishable by a fine or imprisonment and forfeiture of any foodstuff, cosmetic, disinfectant, appliance, product, material, substance or other object in respect of which the offence has been committed. Failure to comply with the MRSA may constitute an offence or result in the compulsory return of undesirable medicines to a manufacturer or importer or the disposal thereof, or in the suspension or revocation of certain dispensing, wholesaling, manufacturing, import or export licences. As noted above, recalls in terms of the CPA are currently voluntary. It is nevertheless suggested that any recalls falling within the domain of the CPA should be conducted on the basis of the NCC Recall Guidelines.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

There are three main sources of potential protection against disclosure of information disclosed to the NCC in terms of the NCC Recall Guidelines: the CPA itself, other statutes such as the Promotion of Access to Information Act, Act 2 of 2000 (www.justice.gov.za/legislation/acts/2000-002.pdf), and the rules of legal professional privilege in terms of the common law. It is submitted that the rules of legal professional privilege will not apply in respect of information furnished to the NCC in terms of the NCC Recall Guidelines.

A person may, when submitting information in terms of the CPA to the NCC, NCT, or an inspector or investigator appointed in terms of the CPA, claim that all or part of that information is confidential (confidentiality claim). This confidentiality protection arguably does not apply to information supplied to the NCC on a voluntary basis. Any confidentiality claim must be supported by a written statement explaining why the information is confidential. The NCC, NCT, an inspector or investigator, as the case may be, must consider any confidentiality claim and must notify the claimant whether or not the information claimed to be confidential will be treated as such. When making any ruling, decision or order in terms of the CPA, the NCC or NCT may take into account any information that has been the subject of a confidentiality claim. If any reasons for a decision in terms of the CPA would reveal any information that has been the subject of a confidentiality claim, the NCC or NCT, as the case may be, must provide a copy of the proposed reasons to the party claiming confidentiality at least five business days before publishing those reasons.

A party may apply to a court for an appropriate order to protect the confidentiality of the relevant information within five business days after receiving a notice or a copy of proposed reasons regarding a confidentiality claim. Rule 12 of the NCC Rules deals with processes for the disclosure of 'restricted information'. In terms of section 107(1) of the CPA it is an offence to disclose any personal or confidential information concerning the affairs of a person obtained in carrying out any function in terms of the CPA or as a result of initiating a complaint or participating in any proceedings in terms of the CPA. Section 107(1) does not apply to information that is imparted to the NCC for the purposes of the NCC Recall Guidelines, and such information also does not qualify as 'restricted information'.

11 May information notified to the authorities be used in a criminal prosecution?

Section 34 of the MRSA provides that no person may, except for the purpose of the exercise of his or her powers or the performance of his or her functions under the MRSA, for the purpose of legal proceedings under the MRSA, when required to do so by any competent court or under any law, or with the written authority of the Director General, disclose to any other person any information acquired by him or her in the exercise of his powers or the performance of his functions under the MRSA and relating to the business or affairs of any person. Section 32 of the NRCSA permits any person who was concerned in the performance of any function in terms of the NRCSA, to disclose any information which he or she obtained in the performance of such a function, if such information is required in terms of any law or as evidence in any court of law, or to any competent authority that requires it for the institution, or an investigation with a view to the institution, of any criminal prosecution. The FCDA does not contain comparable provisions. The NCC may refer alleged offences in terms of the CPA to the National Prosecuting Authority and may disclose personal or confidential information concerning the affairs of any person obtained in carrying out any function under the CPA for the purpose of the proper administration or enforcement of the CPA or the administration of justice.

The court has a discretion, both in civil and criminal proceedings, to allow evidence despite the fact that it had been obtained through violation of the constitutional rights of the accused person (*FEDICS Group (Pty) Ltd and another v Matus and others*; *FEDICS Group (Pty) Ltd and another v Murphy and others* 1997 4 All SA 14 (C)).

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

The NCC requires a supplier to contact it when deciding about the most appropriate strategy to deal with a prospective recall. It is required by the NCC Recall Guidelines that a supplier should notify the NCC when the supplier decides to undertake any one of the following actions to mitigate a product safety-related hazard:

- calling back or withdrawing products from the market or distribution chain;
- requesting consumers or other suppliers to return products for refund, replacement or modification, or to contact the supplier to arrange for a replacement product or part to be sent to the consumer;
- sending a service agent to a person's home or place of business to repair or modify a product; or
- making arrangements for a service agent to repair or modify a product when it is next presented for servicing.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

In terms of section 58 of the CPA, the supplier of any activity or facility that is subject to any risk that could result in serious injury or death must specifically draw the fact, nature and potential effect of that risk to the attention of consumers in a form and manner that meets certain standards including the use of plain language. This obligation also applies to a supplier of any risk or facility that is subject to any risk of an unusual character or nature, or risk of which a consumer could not reasonably be expected to be aware of, or which an ordinarily alert consumer could not reasonably be expected to contemplate, in the circumstances.

A person who packages any hazardous or unsafe goods for supply to consumers must, in terms of section 58(2) of the CPA, display on or within that packaging a notice that meets certain standards, including the plain language and transparency requirements of section 22 of the CPA, and any other prescribed standards, providing the consumer with adequate instructions for the safe handling and use of those goods. A person who installs any hazardous goods for a consumer, or supplies any such goods to a consumer in conjunction with the performance of any services, must give the consumer the original copy of any document required in terms of section 58(2), or any similar document applied to those goods in terms of another public regulation.

In terms of the NCC Recall Guidelines, a supplier undertaking a voluntary or compulsory safety-related recall is also responsible for goods supplied outside South Africa and should, therefore, notify in writing any person outside South Africa to whom the supplier has supplied goods, that the goods are subject to a recall. The notification must draw attention to the recall and a defect or dangerous characteristic in the goods or the failure thereof to comply with a prescribed consumer product safety standard. Where a supplier has complied with the notification requirements under section 60(1) of the CPA (ie, in terms of any applicable industry-wide code of practice), it must provide a copy of the notice to the NCC within 10 days of providing the notice.

14 Are there requirements or guidelines for the content of recall notices?

According to the NCC Recall Guidelines, a product-related communication to consumers must include a clear product description, including the name, make and model, any distinguishing features, batch or serial numbers and the dates when the product was available for sale;

a picture of the product; a description of the defect; a statement of the hazard; a section explaining what immediate action the consumer is to take; and relevant contact details. A recall notice should not contain the words 'voluntary recall'.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The NCC Recall Guidelines are not prescriptive as to any particular communication methods, but a supplier should place information relating to a product recall prominently on its website. In terms of the NCC Recall Guidelines, it is important to match the communication to the consumer and communications regarding a recall should, therefore, be directed to the particular consumer demographic for the recalled product using an appropriate communication method.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There is at this stage no provision prescribing a specific target or period after which a recall is deemed to be satisfactory. The NCC, however, requires that it be furnished with progress reports on the recall. In terms of the NCC Recall Guidelines, a recall can be closed and a final report submitted to the NCC 'when a supplier has taken all reasonable steps to effectively mitigate the risk posed by the unsafe product'. The regulatory oversight by the NCC ceases and the supplier is no longer required to promote the recall.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

In terms of sections 55 and 56 of the CPA, the consumer may, within six months of the delivery of the goods, require the supplier to repair the goods or may return to the supplier goods that are not reasonably suitable for the purposes for which they are generally intended, are not of good quality, in good working order or free of defects, or will not be usable and durable for a reasonable period of time. To the extent that recalled products fail to comply with the provisions of sections 55 and 56, a producer or other supplier can be required to repair or replace recalled products.

18 What are the penalties for failure to undertake a recall or other corrective actions?

Save for the powers of recall granted to the Chief Executive Officer of the board of the National Regulator for Compulsory Specifications (Chief Executive Officer NRCS) arrangements in terms of the CPA are currently voluntary. The authorities can also resort to the powers discussed in question 3.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

If the NCC has 'reasonable grounds' to believe that any goods may be unsafe, or that there is a potential risk to the public from the continued use of or exposure to the goods, and the producer or importer of those goods has not taken any steps required by an applicable code of practice, it may, by written notice, require that producer to conduct an investigation into the nature, causes, extent and degree of the risk to the public, or to carry out a recall programme on any terms required by the NCC (mandatory recall). These powers relate only in respect of codes of practice, none of which have been adopted to date. Product recalls in terms of the CPA are therefore for the time being voluntary. The Chief Executive Officer NRCS may, if certain commodities or products do not conform to a prescribed compulsory specification, take action to ensure the recall of the commodity or product.

In terms of the amended section 23 of the MRSA the SAHPRA has the authority, if it is of the opinion that it is not in the public interest that any product, medical device or IVD shall be made available to the public, to direct a person by notice in writing transmitted by registered post or by notice in the Government Gazette, to return any quantity of such product, medical device or IVD which he or she has in his or her possession to the manufacturer thereof or (in the case of any imported medicine) to the importer concerned or to deliver or send it to any other person designated by the council. The SAHPRA may direct that such product, medical device or IVD be dealt with or disposed of in such manner as it may determine. It is an offence for any person to sell any medicine that is the subject of such a notice (unless the notice has been set aside on appeal).

20 Can the government authorities publish warnings or other information to users or suppliers?

In terms of section 29 of the NRCSA, the Chief Executive Officer NRCS may, if it is necessary in the public interest, reveal any information which he or she considers necessary to prevent the public from being misled concerning any aspect regulated by the NRCSA, the fact that a commodity is not in compliance with a compulsory specification, or the name of a person who does not comply with or does not comply fully with a provision of the NRCSA. This can include the disclosure of the trade name and trademark of a non-compliant commodity or product or details regarding the supplier or retailer of the non-compliant product. The NRCSA issues alerts and orders recalls regarding non-compliant goods which are distributed to the media and posted on the NRCS's website (www.nrcs.org.za). The NCC publishes consumer alerts (www.thencc.gov.za/consumer-alerts).

In terms of section 22B of the MRSA, the SAHPRA may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a product, medical device or IVD. The Director-General may publish this information or release it to the public in a manner which he or she thinks fit. This information is generally published on the SAHPRA's website (www.sahpra.org.za/) in the form of 'safety-alerts'.

Neither the NRCS's nor the SAHPRA's websites make provision for the public to post remarks or reports of incidents online.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

A wide range of goods are subject to the NRCSA. In relation to these commodities, the Chief Executive Officer NRCS may, if it is suspected on reasonable grounds that a consignment or batch of a commodity or product does not conform with a compulsory specification, issue a directive requiring any person who is in possession or control of the commodity or product, consignment or batch, to keep it in his or her possession or control and to refrain from tampering therewith or disposing thereof, for as long as the directive remains in force. The National Regulator may take action to ensure the recall of a commodity or product and may also direct in writing that the importer of the consignment returns it to its country of origin. The National Regulator also has the power to direct that the consignment or batch of the article concerned be confiscated, destroyed or otherwise dealt with. See question 19. The NCC may, if it has reasonable grounds to believe that any goods may be unsafe, or that there is a potential risk to the public from the continued use of or exposure to the goods, in terms of section 60(2) of the CPA, by written notice:

- require the producer to conduct an investigation in terms of the applicable code of practice; or
- carry out a recall programme on any terms required by the NCC, a mandatory recall.

A producer or importer affected by a notice to carry out a mandatory recall may apply to the NCT to set aside the notice. It should be noted that the powers provided for by section 60 only apply in respect of implemented codes of practice. Currently, no such codes of practice are in existence.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Costs are generally not recoverable from the producer or another responsible party by the government authorities in relation to product safety issues or product recalls.

23 How may decisions of the authorities be challenged?

Regulatory legislation may typically make provision for some form of internal review. Decisions of the authorities are, in addition, generally subject to the principles of administrative law. These include principles

such as legality, reasonableness, the giving of reasons and principles regarding the abuse of discretion.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

The question of whether a safety warning or product recall will be viewed by the courts as an admission of liability for defective products will depend on the express wording of the safety warning or the established reasons for the recall.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

After the close of pleadings, any party to any action may require any other party thereto, by notice in writing, to make discovery of all documents and tape recordings relating to any matter in question in such action that are or have at any time been in the possession or under the control of such other party. Such notice may, with the leave of a judge, be given before the close of pleadings. It is possible that documents that have been furnished to an authority such as the NCC, in terms of the NCC Recall Guidelines, will constitute documents relating to a matter in question in an action, for example a product liability action in terms of section 61 of the CPA.

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

General regulations

EU law

- Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products;
  Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products;
- Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Directive 2001/95);
- 2004/905/EC: Commission Decision of 14 December laying down guidelines for the notification of dangerous consumer products to the competent authorities of the member states by producers and distributors, in accordance with article 5(3) of Directive 2001/95/EC of the European Parliament and of the Council (Commission Decision 2004/905); and
- Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93.

National law

- Act No. 39/2015, of 1 October, on the common administrative procedure of the public administration;
- Act No. 40/2015, of 1 October, on the legal system of the public sector;
- Act No. 14/1986, of 25 April, on the general health system (Act 14/1986);
- Act No. 21/1992, of 26 June, on industry;
- Royal Decree-Law No. 1/2007, of 16 November, which approves the consolidated general law on the defence and protection of consumers and users (Consumers General Act);
- Royal Decree No. 1801/2003, of 26 December, on general product safety, which transposes Directive 2001/95/EC (RD 1801/2003); and
- Act No. 7/2017, of 2 November, Incorporating to the Spanish legislation the Directive 2013/11/EU, of the European Parliament and of the Council, of 21 May 2013, regarding consumer alternative dispute resolution

Main specific regulations (among others)

Food products

- Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April on the hygiene of foodstuffs;
- Royal Decree No. 640/2006, of 26 May, which regulates certain conditions from the European regulations on hygiene in the production and commercialisation of foodstuffs; and
- Royal Decree No. 19/2014, of 17 January, which lays down the legal statute of the Spanish Consumer, Food Safety and Nutrition Agency (RD 19/2014).

Medicines and sanitary products

- Directive 2001/83/EC, of 6 November, on the Community code relating to medicinal products for human use;
- Regulation (EC) No. 726/2004, of the European Parliament and of the Council, of 31 March, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- Act No. 29/2006, of 26 July, on Medicine (partly repealed by Royal Decree 1/2015, of 24 July, of the Law on guarantees and rational use of medicines);
- Royal Decree No. 1591/2009, of 16 October, on sanitary products;
- Act No. 10/2013, of 24 July, on the modification of the Act 29/2006, of 26 July, on guarantees and rational use of medicines and sanitary products; and
- Regulation (EU) 2017/745 of the European Parliament and of the Council, of 5 April 2017, on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Cosmetics

- Royal Decree No. 1599/1997, of 17 October, on cosmetic products; and
- Royal Decree No. 85/2018, of 23 February, on cosmetic products.

Toys

- Directive No. 2009/48/EC of the European Parliament and of the Council, of 18 June, on the safety of toys; and
- Royal Decree No. 1205/2011, of 26 August, on the safety of toys.

Machinery

- Directive No. 2006/42/EC, of 17 May, on machinery, and amending Directive 95/16/EC;
- Royal Decree No. 1435/1992, of 27 November, which transposes Directive No. 2006/42/EC, on machinery; and
- Royal Decree No. 1644/2008, of 10 October, which lays down the regulation for commercialisation and implementation of machinery.

2 What requirements exist for the traceability of products to facilitate recalls?

There is no specific regulation for traceability purposes. However, there are references in the general and specific regulations for products and regulations on how a lack of traceability in products may be penalised.

RD 1801/2003 is the general regulation on product safety, and its applicability is subsidiary. If there is a specific regulation (as in the areas of medicines, food, etc) to ensure the traceability of a certain product, this specific regulation will apply in the first place and all the issues that are not foreseen will fall under RD 1801/2003.

RD 1801/2003 uses very general terms and gives the administration high levels of discretion to ensure that traceability is guaranteed. Therefore, the requirements of traceability may vary depending on the product.

Regarding the manufacturers, they must indicate on the product or its container the name of the company, the reference of the product and if appropriate they must also mention the manufacturing batch number. This information, irrespective of the product, ought to be retained for three years.

As an exception to the rule of three years' retention, RD 1801/2003 foresees a term of only one year of preservation of the information if the products are perishable, namely products that have a recommended consumption deadline or expiry date.

As for distributors, they must maintain and provide to the authorities, if requested, all the necessary documentation to ascertain the origin of the products, especially the identity of the suppliers; moreover, if they are not retailers, they must keep information about the destination of the product. This information must be kept for three years from the date the product leaves the distributor.

Both producers and distributors must cooperate within their areas of competence with the administration to prevent hazards that products may cause.

Regarding toys and machinery, it is notable that the manufacturer guarantees the conformity of products with the EU legislation by means of the 'CE' mark; therefore it or its representative must retain the documents and information concerning the procedure of manufacture and its conformity with the EU legislation, as well as the copies of it when filing before the competent administration, the address and place of manufacture and storage.

Under articles 87 and 15.4 of Act 29/2006, among other information regarding the use and components of the medicine, the packaging of all medicines must contain information regarding the medicine's national code, batch and unit that allows its mechanical, electronic or computer identification.

3 What penalties may be imposed for non-compliance with these laws?

The general regulation, namely RD 1801/2003, refers to the administrative penalties established in the Consumers General Act or Act 14/1986, depending on the nature of the non-compliance.

According to the above-mentioned acts, there may be three kinds of infringements against consumers' interests or health, depending on the level of risk to the health of the consumer, the position of infringer within the market, the amount of profit obtained, the grade of intentionality, the severity of the social alteration, the generalisation of the infraction and any recurrence of the infringement.

According to these criteria, the infringement and consequent penalties may be considered as follows:

- minor infringement: up to €3,005.06;
- serious infringement: between €3,005.06 and €15,025.31 (the fine imposed may exceed those quantities until it reaches five times the value of the products that were the object of the infringement); and
- major infringement: between €15,025.31 and €601,012.10 (the fine imposed may exceed those quantities until it reaches five times the value of the products that were the object of the infringement). In this case the authority could also close the factory for a maximum of five years.

It is also remarkable that Spanish law, introducing EU law, has recently raised the possibility of disqualifying chemists and labs neglecting the law on medicines for a period of between three months and one year.

As accessory penalties, the authority is entitled to confiscate the defective or hazardous products and to make public the penalty, factory's name and its general information, to be identified by consumers and users.

It is important to emphasise that the expenses arising from the confiscation of the product, its transportation, distribution and destruction will be the responsibility and charge of the party that neglected to follow the law.

The differing criteria are established in Act 29/2006, regarding medicines. Taking this as a basis, there are three kinds of infringements (minor, serious and major) for which the penalties may be imposed in different degrees (from minimum to maximum). According to article 102 of the above-mentioned Act, the fines may arise as follows:

- minor infringement:
  - minimum degree: up to €6,000;
  - medium degree: between €6,001 and €18,000;
  - maximum degree: between €18,001 and €30,000;
- serious infringement:
  - minimum degree: between €30,001 and €60,000;
  - medium degree: between €60,001 and €78,000;
  - maximum degree: between €78,001 and €90,000;
- major infringement:
  - minimum degree: between €90,001 and €300,000;
  - medium degree: between €300,001 and €600,000;
  - maximum degree: between €600,001 and €1 million (the fine imposed may exceed those quantities until it reaches five times the value of the products that were the object of the

All these punitive measures have an administrative scope. In principle, the imposition of these kind of fines does not necessarily imply civil liability. If criminal charges are brought, the administration must refrain from any kind of punitive measure, since criminal liability supersedes administrative liability.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

RD 1801/2003 foresees two kinds of notification to the competent authorities, depending on the seriousness of the risk found.

Article 6 of the above-mentioned regulation provides the ordinary procedure for notifying a defective product. In such a case, producers and distributors that have knowledge or should have had knowledge about a product incompatible with the general safety regulation must notify the competent administrative authority, as soon as they have such knowledge. The communication must contain at least the following:

- information to precisely identify the product or batch of products;
- complete description of the risk that the products represent;
- all useful information to locate the product; and
- a description of the actions taken to prevent risks to consumers.

The notification should be sent pursuant to the form established by the National Consumption Institute, the National Medicine Agency or the Spanish Consumer, Food Safety and Nutrition Agency, depending on the product.

With the exception of food and medicines, there is also a fast notification procedure to the authorities (RAPEX) for all dangerous consumer products if there is a serious hazard to consumers. This system allows a fast transfer of information about dangerous products identified in EU member states. In such a case, besides the above-mentioned information, the person who notifies must justify the results of the analysis to evaluate the risk and the use of this procedure.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

Pursuant to Directive 95/2001 and Commission Decision 2004/905, the European Commission defines these criteria:

- the product must be within the remit of Directive 95/2001, which means that the product must be directed to consumers or that it could be used by consumers within the frame of a commercial activity;
- the product is on the market;
- the manufacturer or distributor has evidence of the product being dangerous or lacking compliance with the legal requirements for safety; and
- the product should not remain on the market due to the risk (to determine whether a product is hazardous, the manufacturer or distributor should analyse the severity of damage, predictability of damage, type of consumer, and in the case of no vulnerable adults, whether the product is accompanied by accurate warnings).

Consequently, there are some circumstances in which the law understands that society accepts more risks than others and, therefore, the notification duty is at a lower level. An example of an unacceptable high level of risk would be toy regulation, since children would be considered a vulnerable subject.

6 To which authority should notification be sent? Does this vary according to the product in question?

The notification of any hazard or defective product should be sent to the competent authority within the affected autonomous community. This may vary if that the product has been already supplied to consumers in more than one autonomous community.

In general, according to RD 1801/2003, the notification should be made to the competent body equivalent to the National Institute of Consumption in each autonomous community. If the risk has taken place in more than one autonomous community, the manufacturer or distributor should notify the competent authority of the autonomous community where it has its general headquarters. The competent body will inform the National Institute of Consumption.

If the hazard is related to food, the competent authority will be the equivalent to the Spanish Consumer, Food Safety and Nutrition Agency in each autonomous community. If it is related to medicines, sanitary products or cosmetics, the competent authority will be equivalent to the National Medicine Agency.

7 What product information and other data should be provided in the notification to the competent authority?

To simplify the procedure of notification to producers and distributors, the European Commission created the 'Guidelines for the notification of dangerous consumer products to the competent authorities of the member states by producers and distributors in accordance with of Directive 2001/95/EC', which provide guidance regarding the determination of the preconditions for a notification as well as the practical aspects of the procedure. In addition, this guide establishes the content of the notification and includes the standard form that must be submitted to the competent authorities of each country. Regarding the notification, the following information should be provided:

- the authority or company receiving the notification form – the person filling in the form is requested to identify the authority and the company that will be receiving the notification and the role that these companies have in the marketing of the product;
- the producer or distributor completing the notification form – the person filling in the form must provide complete details of their identity, that of the company and its role in the marketing of the product;
- the product involved – a precise identification of the product is required, including its brand, model, etc, supported by pictures in order to avoid confusion;
- the hazard (type and nature) including accidents and health and safety effects and conclusions of the risk estimation and evaluation that has been carried out;
- corrective actions that have been taken or that are planned to reduce or eliminate the risk to consumers, such as recall or withdrawal, modification, informing consumers, among others, and of the company responsible for them; and
- all companies in the supply chain that hold affected products and reference to the approximate number of products in the hands of businesses as well as of consumers (this section applies in cases of serious risk or when the producer or distributor opts to submit the notification only to the authority of the member state in which it is established).

The form may be downloaded from the European Commission's website, https://webgate.ec.europa.eu/gpsd-ba/.

In the case of medicines, healthcare professionals shall, as soon as possible, notify the competent authorities in the drug supervision committee, which is a part of the National Medicine Agency.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Under RD 1801/2003, and in general, manufacturers and distributors have an obligation to cooperate with the authorities, providing all the information required, including information that is protected by industrial and commercial secrecy.

The manufacturers and distributors have five days to answer the enquiries of the administration. However, the authority is entitled to reduce this period due to the urgency of a specific case.

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

RD 1801/2003 sets forth administrative measures without penalties to provide for warranties and restore the safety of the products.

Even though the royal decree has no penalties but merely administrative measures, in addition to those measures, Act 14/1986 and the Consumers General Act are applicable with regard to the administrative punishment as stated in question 3.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

Information protected by commercial or industrial secrecy will not be used for any other purpose except where its request is justified.

In practice, although users and consumers are granted a right of access to the information on the defective product and should be informed by the administration in accordance with the specific case, the administrative body must implement the appropriate measures to prevent its employees from disclosing information protected by commercial or industrial secrecy that has been obtained for legal established purposes, under articles 6.4 and 17.3 of RD 1801/2003.

11 May information notified to the authorities be used in a criminal prosecution?

The administrative measures arising from notification of a defective product will not presume either criminal or administrative liability of the parties subject to those measures.

If the information provided shows that the actions of the manufacturer or distributor or any other agent may constitute an administrative or criminal infringement, the authorities are obliged to communicate this fact to the corresponding competent administrative or judicial authorities, to ensure that the neglectful party is guaranteed the appropriate legal protection during each procedure.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

Article 8 of RD 1801/2003, in relation to the Consumers General Act, states the general principle according to which the applied corrective measures must be congruent with the causes that originated them, as well as proportionally related to the risk that is faced. Once these requirements are covered, it is necessary to apply measures that are less restrictive of the free circulation of merchandise, liberty of enterprise and whatsoever affected right regarding these matters.

However, the administration is granted, in general, a high degree of discretion to take measures it may consider appropriate to the current case.

Among the corrective actions likely to be applied, besides recall, there is the possibility for sealing and preventing further movement of the product, recovery of the product from consumers, destruction of the product, and suspension of activities, selling and special offers.

Nevertheless, article 10 of RD 1801/2003 foresees special cases where specific measures should be taken:

- if there are signs of defects, the product supply should temporarily be suspended until, according to the respective evaluation, there is certainty of the safety of the product;
- if the risk of the product could be avoided by certain modifications and express warnings to consumers, before it is introduced in the market, the administrative request would specify what kind of warning should be added to the product and only then will it be able to circulate in the market; and
- regarding the recall: the regulation only states that when a product does not comply with the definition of 'safe product' and it has been introduced in the market, will it be subject to recall, recovery or destruction.

For the purpose of the previous points, it is convenient to bear in mind that the definition of 'safe product' is, according to article 2 of RD 1801/2003, any product that in normal and rationally predictable conditions of use does not entail any risk to people's health and safety.

Moreover, in Spain, a product will be deemed safe when it fulfils the requirements of health and safety as set out in specific regulations or, if it is not specifically regulated, it is at least supposed to be in accordance with technical national rules that harmonise European rules, UNE rules (the Spanish quality and standardisation rules), good practice codes and the current status of technical knowledge.

There is also a presumption of defective products, which basically comprises a lack of administrative authorisations for the product and a lack of information with which to identify the producer, and where the product belongs to a group of products where one of them was deemed defective. In such cases, the product may be deemed defective, irrespective of its actual state, according to article 3 of RD 1801/2003.

In the case of medicines, the specific regulations are more restrictive, since article 99 of Act No. 29/2006 states that upon the suspicion of the existence of an imminent and serious risk to health, the competent authorities may take the following measures:

- quarantine, recall from the market and prohibition of use of the medicines and suspension of activities and advertising, as well as the closing of premises, which means the automatic blocking of the circulation of the products; and
- suspension of the manufacture, prescription, sale and supply of the medicines.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

The general requirements that producers or distributors should comply with to implement a measure to warn consumers and protect consumers from the defective product will be specified in the request made by the administrative authority for those who do not fully comply with the safety of products.

Such enquiry will include the time or deadline producers or distributors have to carry out the warning and a recommendation for corrective actions, but also grants freedom to the producer or distributor to act as it deems appropriate (unless it is expressly regulated in a specific case), according to article 9 of RD 1801/2003.

Moreover, to adopt the measures previously listed, it is necessary to carry out the administrative procedure referred to in Act No. 39/2015. However, it will not be necessary to complete every single phase of the procedure, such as certain hearings and proof phases, as long as the hearing and evidence have been carried out before another administration of an autonomous community.

During the proceedings, the technical commission for product safety (or similar autonomous institutions) has been required to issue a report and those have already provided the corresponding hearings, and their ruling does not substantially differ from that report.

Furthermore, Royal Decree No. 85/2018, of 23 February, on cosmetic products determines a specific procedure of communication and transmission of unwanted serious risks and effects particular for cosmetics and establishes a Spanish system of cosmetic surveillance.

14 Are there requirements or guidelines for the content of recall notices?

As stated in question 13, according to article 9 of RD 1801/2003, the enquiry from the administration will specify:

- the result intended from the request;
- a deadline for fulfilling the request;
- the monitoring of the procedure; and
- the administration may recommend measures to take to obtain the result, but the entity subject to such enquiry may take other measures that lead to the intended result.

If the petitioning party does not take the necessary measures or the measures taken are insufficient, the administration may implement the measures listed in article 10 of RD 1801/2003 (see question 12).

Moreover, there is a guideline document for manufacturers and distributors or suppliers provided by various European health ministries that offers information about how to proceed when they have knowledge of an imminent risk presented by a certain product. These guidelines may be found on the following websites:

- www.prosafe.org; and
- www.aecosan.msssi.gob.es/AECOSAN/docs/documentos/consumo/seguridad_productos/guia.pdf.

Update and trends

The hot topics in Spain regarding product recall litigation concern the liability for products in the fields of artificial intelligence and robotics. In this sense, the fifth report on the application of the Directive 85/374/EEC concerning liability for defective products (2018); the Staff Working Document: Liability for emerging digital technologies; and the Communication, 'Artificial Intelligence for Europe', have created high expectations and have been a matter of discussion in Spain.

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

In general, according to what has been stated, the petitioning party may choose which media it prefers to use to communicate the warning or recall to users and suppliers. If the administration considers that the measures taken are not sufficient, it may implement measures according to article 10 of RD 1801/2003.

However, regarding medicines, regulations that state that the National Medicine Agency will publish, by means of the appropriate media, the methods undertaken to let all the potentially affected persons know about these measures.

Concerning food products, the president of the Spanish Consumer, Food Safety and Nutrition Agency will evaluate the risk before creating crisis and emergency committees, which will carry out the due procedures according to articles 34 and 35 of RD 19/2014.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

As mentioned above, regarding the measures to be taken, the competent authority will first be the administration from the autonomous communities that have responsibility – whose actions must always be reasonable and justified – to impose the measures for a reasonable period, always considering the right of free business and the interests at stake.

However, according to article 11.6 of RD 1801/2003, when the competent authority is the central administration, the measures taken must not exceed six months.

Act 29/2006, regarding defective or hazardous medicines, foresees that measures taken may be subject to further extensions if the nature of the risk justifies it.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

The recall of products is an administrative measure to prevent further damage to consumers. Moreover, all regulations that establish recall measures foresee that those measures may be taken without prejudice to eventual civil or criminal actions.

This means that if, according to the General Consumers Act and the Civil or Commercial Codes, the consumer or the purchaser of the affected goods can prove that he or she has suffered damage arising from the measure, such consumer or purchaser might be entitled to claim for the damage suffered.

These measures are also foreseen in article 12.5 of RD 1801/2003, in general, and article 100 of Act 29/2006 for medicines.

18 What are the penalties for failure to undertake a recall or other corrective actions?

When the public authorities deem that the entities that caused the infraction are not duly cooperating, they can proceed to perform the necessary actions themselves or with other entities' collaboration.

The fines that the administration may impose for a lack of collaboration with the measures taken (ie, the recall of the product or any other corrective measure) will be those stated in the General Consumers Act, Act 14/1986 or Act 29/2006, depending on the nature of the infringement, in the terms set out in question 3.

In general, this infringement will be considered as a minor infringement. However, depending on the nature of the risk and the interests at stake, the law allows the administration to deem the infringement serious or even major.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

As stated above, producers or distributors should be granted a determined period to correct the risk or defect of the product. Once this time has elapsed with no positive result, the administration may carry out either of the administrative measures that are stipulated in article 10 of RD 1801/2003 (see question 12), even the recall in the case of products that are already in circulation on the market.

The competent authority must ensure the full effectiveness of the corrective action being performed, which may be enforced or even directly undertaken by the authority itself.

20 Can the government authorities publish warnings or other information to users or suppliers?

According to article 17 of RD 1801/2003, considering the nature of the risk and interests at stake, the authorities will be entitled to inform users and consumers who are potentially endangered about the risks or irregularities in the products. This information may be displayed by the most appropriate means and will be related to the existing hazards and defects of the product, its identification, the corrective measures that have been taken, as well as measures consumers must take to protect themselves.

Alternatively, citizens also have the right to access the general information that is in the possession of the authority as long as this information is not restricted due to control or investigation activity.

Similar measures are foreseen for medicines, under article 99 of Act 29/2006, which states that the National Medicine Agency will give notice of the measures taken through the most appropriate means.

Regarding food emergencies, apart from the RAPEX, which allows rapid information exchange between autonomous communities and, if applicable, member states facing a food emergency, the Spanish Consumer, Food Safety and Nutrition Agency may inform the population through its own Communication and Institutional Coordination Unit, which is entitled to choose from official notices, electronic means or the mass media, according to article 39 of RD 19/2014.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

As explained previously, if a negligent party does not take the measures proposed by the administration or the competent authority deems that the producer or the distributor has not satisfactorily completed the proposed measure to prevent the hazard, it is entitled to enforce any corrective action including product recalls (see questions 13, 19 and 24).

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

Under article 12.5 of RD 1801/2003 and article 99.5 of Act 29/2006, all the measures taken to prevent the hazards from affecting, or at least further affecting, consumers, even those that the administration takes by itself, will be at the expense of the negligent party.

23 How may decisions of the authorities be challenged?

According to the general administrative procedure Act (Act No. 39/2015), any precautionary injunction must be followed by the initiation of administrative proceedings within the term of 15 days, in order to determine the potential liabilities of the different agents. At any moment, either the administration ex officio or upon request of the affected persons may lift such measures if there is a change or reconsideration on the urgency and risk situation.

Regarding medicines, article 99 of Act No. 29/2006 establishes the concrete procedure on quarantine and suspension of the commercialisation of medicines, and therefore the procedure to follow will not be the ordinary administrative procedure.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

As stated above, administrative actions are always without prejudice to further civil or criminal actions. In this regard, it must be borne in mind that each procedure (civil, criminal and administrative) grants the defendant different kinds of guarantees and defence possibilities.

Therefore, the initiation of an administrative file, and the information about the product defects gathered may be used as evidence in other proceedings, and the publication of a safety warning will not be viewed automatically as an admission of liability.

If an affected consumer or purchaser of defective products has suffered damages that may entail civil or criminal liability, he or she will have to prove the damage and the liability of the defendant, according to the Civil or Criminal Procedure Laws.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

If the reports, investigations or communications evidence that the activity of the negligent party entails criminal liability, the administrative procedure would be automatically suspended and the party would be brought before and dealt with by the competent judicial authority.

For medicines, article 100 of Act 29/2006 foresees that all the measures taken by the administration aimed at preserving the safety and health of the population may be maintained until the judge issues a ruling about their appropriateness.

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Alternatively, the initiation of a civil procedure does not interrupt the administrative proceedings. If the claimant has had access to the reports, communications or investigations that had taken place within those proceedings, such claimant may use them as evidence to reinforce his or her arguments against the defendant.

Sweden

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

The general product safety requirements are regulated by the Product Safety Act (2004:451), implementing the provisions of Directive 2001/95/EC into Swedish law. The Product Safety Act applies to goods and services that are supplied commercially and also to goods that are supplied in the course of public activities, provided that the goods are intended for consumers or likely to be used by consumers. The Product Safety Act does not apply to second-hand goods that are supplied as antiques. Neither does the Product Safety Act apply to goods that have to be repaired or reconditioned before they can be put into use.

Since the provisions of the said law are, in principle, general and abstract, manufacturers of products may demonstrate compliance with product safety legislation (and benefit from the presumption of safety) by complying with Swedish standards that implement a European standard. A product that complies with such standards is presumed to be safe.

In addition to the general rules of the Product Safety Act, there are special laws in Sweden, most of them implementing the provisions of relevant EU directives, regulating a variety of particular products. For instance, such laws are the Supplementary Rules to EU Regulation on Personal Protective Equipment (2018:125), the Act on Toy Safety (2011:579), the Act on Medical Devices (1993:584) or the Regulation on Electrical Safety (2017:218).

Safety requirements are not only set by direct rules of the above-mentioned laws, but also indirectly, by means of liability regimes. Such liability provisions are enshrined in the Product Liability Act (1992:18), the Tort Liability Act (1972:207), the Consumer Sales Act (1990:932) and the Sales of Goods Act (1990:931).

2 What requirements exist for the traceability of products to facilitate recalls?

The Product Safety Act obliges producers to label the goods or the packaging of the goods, indicating the name and address of the producer together with a reference to the goods or the consignment of goods to which they belong (unless such labelling is obviously unnecessary). The producers are also obliged to review and keep record of received complaints relating to product safety. The distributors are obliged under the Product Safety Act to communicate all information to the producer relating to the risks of injury from the goods (unless obviously unnecessary) and to maintain documentation that is necessary to trace the origin of the goods. Such documentation has to be preserved for the term of five years from the end of the fiscal year in which the relevant goods were acquired. The Product Safety Act sets forth the said obligations as injury prevention measures.

3 What penalties may be imposed for non-compliance with these laws?

According to the Product Safety Act, the supervisory authority may issue orders and injunctions (including export prohibitions) that are subject to default fines. Such default fines are administrative by nature. The Product Safety Act sets out the possibility to impose sanction fees in the event of breach of certain provisions of the act, conducted intentionally or by neglect. Such fees may also be imposed pursuant to the specific laws regulating particular products if certain provisions of the said acts are infringed. The fee may range between 5,000 and 5 million kronor; however, it may not exceed 10 per cent of the fined undertaking's annual turnover. The imposition of the fee is decided by an administrative court upon application by the competent supervisory authority.

There are no criminal sanctions in the Product Safety Act or Product Liability Act. Non-compliance with product safety rules may indirectly lead to liability for damages under the relevant liability regimes, most notably pursuant to the Product Liability Act.

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

Under the Product Safety Act, undertakings (ie, a natural or legal person acting for purposes relating to their own business operation) have notification obligations towards the supervisory authority. Such a notification obligation is to be fulfilled immediately when the undertaking becomes aware that the goods that it provides or has provided are dangerous. The undertakings are also required to notify the supervisory authority about the measures that have been implemented in order to prevent the occurrence of an accident.

Additional provisions regarding the notification obligation may apply pursuant to the specific laws as mentioned under question 1. For instance, under the Toy Safety Act, an economic operator considering a toy to entail any risks pursuant to the act must notify the relevant supervisory authorities within the EU member states where the toy was made available or offered.

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

The notification has to be made immediately when it becomes apparent to the undertaking that the provided goods are dangerous. Under the Product Safety Act, the supervisory authority does not have to be notified if it is manifestly clear that such notification would be of no importance. However, certain product safety regimes do not allow for such exception, for instance, the Toy Safety Act.

6 To which authority should notification be sent? Does this vary according to the product in question?

Notification under the Product Safety Act relating to products not falling under the special sectoral laws is required to be submitted to the Swedish Consumer Agency. Moreover, the Swedish Consumer Agency has competency with respect to notifications pursuant to the Supplementary Rules to EU Regulation on Personal Protective Equipment and the Toy Safety Act. In addition to the general competency of the Swedish Consumer Agency, with respect to certain categories of goods, other supervisory authorities may have competence, such as the Swedish Work Environment Authority, the Swedish Board of Agriculture, the Medical Products Agency and the Swedish Chemicals Agency.

7 What product information and other data should be provided in the notification to the competent authority?

According to the Product Safety Regulation (2004:469), the written notification should include information allowing for the identification of the dangerous product, together with a full description of the risks associated with such dangerous product. The written notification must also include all available information that may be necessary in order to trace the product and a description of the measures implemented in order to prevent risks that may occur to consumers. In addition to these essential requirements, the supervisory authorities may require further information or may regulate notification proceedings.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

Undertakings, including producers and distributors, are obliged to inform and to cooperate with each other and with the supervisory authority in order to avoid risks associated with products. Moreover, the supervisory authority may set up oversight programmes in which undertakings are required to cooperate by providing updates. The notification obligation pertains to all information relating to risks (see also question 7) including updated information. If the supervisory authority requests information, the conditions set forth in such individual request will apply.

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

Non-compliance with the notification obligation may serve as a ground for an administrative fine to be imposed under the Product Safety Act, as discussed in question 3.

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

The Product Safety Act prohibits any person in private practice who dealt with a case involving supervision under the act to, without authorisation, disclose or utilise any information that has been acquired regarding any party's business or operational circumstances.

For authorities confidentially applies in certain supervision matters in relation to information about the business of a party or financial information if it can be assumed that disclosure would lead to damage (the Public Access to Information and Secrecy Act (2009:400)).

11 May information notified to the authorities be used in a criminal prosecution?

Yes. Under the Swedish procedural rules, the principle of free evidence applies. A party is free to disclose any information it has available as evidence.

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

As discussed above, the Product Safety Act obliges the undertaking to notify the supervisory authority if the provided goods are dangerous. Moreover, according to the Product Safety Act, the producer has to without delay provide warning information or recall supplied goods when it becomes apparent that the goods are dangerous, if it is necessary to prevent the occurrence of an accident. The producer is obliged to arrange the immediate destruction of the goods (or to make the goods otherwise harmless) if they are particularly dangerous.

The goods are dangerous if they do not meet the requirements of safety that are enshrined in the Product Safety Act. According to the Product Safety Act, a product is safe if, upon normal or reasonably foreseeable use and lifespan, it does not entail any risks to the health or safety of natural persons, or only a low risk. This risk, however, must be acceptable considering how the goods or services are used; and it should be consistent with a high level of protection with respect to the health and safety of persons. Thus, in general, the harmfulness of the product has to be unexpected, meaning that the risks have to occur contrary to what the consumer may expect from the particular product.

The assessment of the risk must be carried out with the following factors taken into account:

- the characteristics of the product, such as its composition and packaging and the instructions for assembly, installation and maintenance;
- other information provided concerning the product by means of labelling, warnings, user instructions, instructions for disposal, among others;
- the effect of the product concerned on other products, if it can be assumed that it will be used together with other products; and
- the risks that the product may entail for certain categories of consumers, in particular for children and older persons.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

The producers, under the Product Safety Act, are obliged to provide safety information that is necessary in order to enable the consumers to assess the risks that the goods may entail and to protect themselves against these risks. The obligation to provide consumers with safety information does not only cover high risks of damage, but also any information that is necessary with respect to risks, as this obligation is not preconditioned upon whether the product is dangerous or not as defined by the Product Safety Act.

However, safety information is not required to be provided if the risk is obvious. According to the Product Safety Regulation, the safety information is required to be marked on the product or to be included in the manual of the product, or in another form at the point of sale, in advertisements or in any other form that the consumer requests. According to the Swedish Consumer Agency the information must be in Swedish. Furthermore, if the product is sold over the internet, the information must be available to the consumer before purchase (www.konsumentverket.se/for-foretag/produktsakerhet/).

The Product Safety Act imposes on producers the obligation of providing warning information if the supplied goods are dangerous (as discussed in question 12). The producer should provide, without delay, warning information about the risk of injury and the manner in which an injury can be avoided, where it is necessary in order to prevent the occurrence of an accident. The warning information has to be provided to the extent that is reasonable considering the need to prevent the occurrence of any accidents.

In addition to the above (question 12) discussed requirements regarding product recall, the producers are obliged to recall the dangerous goods from the distributors. If this measure is insufficient in order to prevent the occurrence of an accident, the producers should recall the dangerous goods directly from the consumers who possess the goods. The recall is required to take place to the extent that is reasonable considering the need to prevent the occurrence of any accidents.

14 Are there requirements or guidelines for the content of recall notices?

The recall notice should include information regarding the risks of damage. Such information should facilitate the purpose of preventing accidents. The producer should, in the recall notice, offer rectification, replacement or rescission (see question 17), and provide information on the conditions of such offer. According to the Swedish Consumer Agency, the information must state that the product is not safe and why. The recall notice must be easy for the consumer to understand (ie, what needs to be done to ensure the product is safe – eg, repair, etc). The revocation must be valid for a reasonable period and the recall must occur without significant costs or inconvenience for the consumer (www.konsumentverket.se/for-foretag/produktsakerhet/salt-farlig-vara/).

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

The warning information should be addressed directly to the persons in whose possession the dangerous goods are, for instance, by means of direct notices, advertisements or other means of communication that the producer uses in its marketing. The same applies to the recall notice. While warning information placed on the package of a product may serve the purpose of preventing injuries and accidents in cases where the product entails danger only for certain consumers (eg, children), a notice concerning the recall of highly dangerous products addressed directly to consumers might require the use of widespread

media, such as advertisements on television, or in newspapers and online news sites. According to Swedish Consumer Agency, a recall notice should be published in newspapers, on the company's website or on an appraisal at the store and preferably on the relevant market surveillance authority's website.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

There are no such provisions in the law as a recall is satisfactory if it effectively prevents the occurrence of any injuries. According to the Swedish Consumer Agency, the recall period must be reasonable but there are no guidelines for the length of the period.

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

The producer is required to offer rectification of the defect associated with the risk of injury, or replace the product with a defect-free version of the same or corresponding type, or take the product back and provide compensation therefor.

18 What are the penalties for failure to undertake a recall or other corrective actions?

The omission of providing safety information or warning information as well as failure to carry out a product recall may be sanctioned by the imposition of a fine. Moreover, non-fulfilment of the order of the supervisory authority concerning a recall or other corrective measures may lead to the imposition of the conditional fine set forth in the order. Non-compliance with the injury prevention measures (see question 2) may also lead to fines.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

The supervisory authority has wide powers to ensure compliance with the Product Safety Act and the related laws and regulations. The supervisory authority may order an undertaking to provide information, documents, product samples and such like. The supervisory powers include the entitlement to access the premises or spaces other than residences where goods are handled. The supervisory authority may issue orders or injunctions, suspend the supply or exhibition of goods for the duration of an investigation and prohibit the export of particularly dangerous products. Such orders and injunctions may be addressed to each of the undertakings that provide or have provided, take into or have in their possession a dangerous product. The fulfilment of the supervisory authority's orders and injunctions, as discussed previously, may be enforced by conditional fines.

The supervisory authority should commence negotiations with undertakings to voluntarily undertake measures in order to avoid the occurrence of an accident, unless the circumstances of the case do not allow for such solution (eg, due to urgency). It is also in the power of the supervisory authority to publish warning information, if an order cannot be issued concerning warning information or product recall because there is no undertaking to oblige. Finally, the supervisory authority may file, with the competent administrative court, an application for the imposition of a fine.

20 Can the government authorities publish warnings or other information to users or suppliers?

Yes, the supervisory authority is obliged to carry out monitoring programmes, about which it has to inform the public. Moreover, consumers can report incidents concerning products entailing risks or danger via the website of the Swedish Consumer Agency.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

The supervisory authority is not entitled to organise a product recall, however, it may commence negotiations with undertakings to voluntarily carry out a product recall or may order undertakings to recall dangerous products. If there is no undertaking that could be obliged to publish warning information or to recall dangerous products, the supervisory authority should publish warning information.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

The Product Safety Act provides for compensation for the costs of samples or tests of goods requested by the supervisory authority if there are special reasons for compensation.

23 How may decisions of the authorities be challenged?

Decisions of the supervisory authority concerning orders or injunctions (see question 19) and compensation (see question 22) may be appealed before an administrative court. However, a supervisory authority may render its decision concerning an order or injunction to enter into force immediately, in order to ensure high-level consumer safety. The decision of a general administrative court may be appealed to the Administrative Court of Appeal if a leave to appeal is granted.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

The publication of warning information or the recall of products cannot be deemed, per se, as an admission of liability under the Product Liability Act. Publication of warning information or a product recall is required to be applied if the goods are dangerous pursuant to the Product Safety Act. Product liability may arise if a defective

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product causes damage (meaning personal injury or damage to consumer property).

Product liability may be established if the injured person furnishes evidence that a defective product has caused damage and the producer (or supplier or distributor) cannot exonerate itself by means of the exhaustive list of applicable defences. A product is defective pursuant to the Product Liability Act if it does not provide the safety that is reasonable to expect from such a product, taking the following into account:

- the expected use of the product;
- how the product has been presented and marketed;
- manuals and other instructions issued with the product; and
- the time when the product was put into circulation and other relevant circumstances.

Since the notions 'dangerous product' under the Product Safety Act and 'defective product' under the Product Liability Act are similar, a product recall may contribute to finding the product defective under the Product Safety Act. However, in addition to establishing the defect of the product, the injured person is also required to prove the damage and the causality between the defect and the damage.

25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

A party in an ongoing court procedure can request disclosure of documents that are located with the counterparty or a third party. The request for disclosure will be tried by the court and may be granted if the documents are sufficiently identified and relevant as evidence in the case. For an authority, it will also have to take into account the legislation on confidentiality.

United States

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General product obligations

1 What are the basic laws governing the safety requirements that products must meet?

In the United States, product safety is largely regulated by federal agencies. Each federal agency regulates a specific category of products, with occasional overlapping authority among agencies with respect to a particular product.

Given the breadth and diversity of products regulated by the federal government, this chapter focuses on the following three agencies: the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA) and the National Highway Traffic Safety Administration (NHTSA). These three agencies regulate tens of thousands of different types of products, from prescription drugs and medical devices, to automobiles and more than 15,000 types of consumer goods. The products regulated by these agencies are often involved in the most well-publicised safety recalls and are at the centre of much of the product liability litigation in the United States. The three primary product safety laws administered by these agencies are the Consumer Product Safety Act (CPSA), title 15 of the United States Code (USC) sections 2051 to 2089, the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 USC sections 301 to 399(f), and the Motor Vehicle Safety Act (MVSA), 49 USC sections 30101 to 30183.

The CPSA applies to a broad range of consumer products defined generally as any product distributed for sale to a consumer for personal use in or around a home, school or in recreation. In addition to the CPSA, the CPSC administers a variety of other product safety statutes including: the Federal Hazardous Substances Act (FHSA), 15 USC sections 1261–78(a), the Flammable Fabrics Act (FFA), 15 USC sections 1191 to 1204, the Poison Prevention Packaging Act (PPPA), 15 USC sections 1471 to 1477, and the Refrigerator Safety Act (RSA), 15 USC sections 1211 to 1214. The FFDCA regulates foods, drugs and devices intended for human or animal use, as well as any cosmetic or biologics intended for human use. While most foods (and food additives) are covered under the FDA's jurisdiction through the FFDCA, certain foods, such as meat, poultry and egg products, are regulated separately under the United States Department of Agriculture Food Safety and Inspection Service. For reference, the laws governing these specific food products include the Federal Meat Inspection Act (FMIA), 21 USC sections 601 to 695, and the Poultry Products Inspection Act (PPIA), 21 USC sections 451 to 472. Finally, the MVSA regulates motor vehicles and items of motor vehicle equipment. Through the MVSA, the National Highway Traffic Safety Administration establishes various federal motor vehicle safety standards.

2 What requirements exist for the traceability of products to facilitate recalls?

As a practical matter, the ability for a firm to trace its product at the various levels in the distribution chain is essential to effectively implement a recall. That said, there are few specific requirements regarding the traceability of a product with regard to a recall. Depending on the agency, however, there may be more generally applicable traceability requirements with which the firm must comply. The FDA, as part of its quality system regulation scheme, requires that a manufacturer 'establish and maintain procedures for identifying the product during all stages of receipt, production, distribution, and installation to prevent mixups' (21 Code of Federal Regulations (CFR) section 820.60). Additionally, the manufacturer of a device intended for surgical implantation into the body must maintain procedures to identify finished devices and components, if the failure of such device or component could cause significant injury (21 CFR section 820.65). The CPSA requires tracking labels for certain children's products in order to 'facilitate ascertaining the specific source of the [children's] product' (15 USC section 2063, as amended by section 103 of the Consumer Product Safety Improvement Act of 2008 (CPSIA)). The CPSC has authority to grant exclusions to these tracking requirements where it determines that compliance would be impracticable.

3 What penalties may be imposed for non-compliance with these laws?

Both the CPSA and FFDCA provide for civil and criminal penalties. Criminal penalties are typically imposed only after repeated, intentional and fraudulent violations of the statutes. Civil penalties under both statutes may include a fine, administrative action or both. The CPSC said in its 2017 annual report, for example, that it had negotiated out-of-court settlements totalling US$29.4 million in civil penalties paid to the US Treasury. Two other significant administrative penalties include seizure and injunction. Under the CPSA and FFDCA, a violative product, which has been distributed in interstate commerce, may be seized by the agency, an injunction may be entered preventing sale of the product or both (eg, 15 USC section 2071 and 21 USC section 334).

In addition to administrative penalties, both statutes provide for fines and incarceration for violating a statutory or regulatory provision. Under the CPSIA, the maximum civil penalty per violation is US$100,000. The maximum civil penalty for a related series of violations is US$15 million (15 USC section 2069). Criminal penalties can be up to five years' maximum imprisonment for a knowing and willing violation. A criminal violation of a CPSC-enforced regulation may also result in forfeiture of the assets associated with the violation (15 USC section 2070). Under the FFDCA, the specific penalty available will be determined based on the alleged violation and violative product. Penalties can range from US$1,000 to US$1 million and one to 20 years' imprisonment. Penalties under the FFDCA are more severe if the violation was undertaken knowingly and if death resulted based on a violation (21 USC section 333).

Reporting requirements for defective products

4 What requirements are there to notify government authorities (or other bodies) of defects discovered in products, or known incidents of personal injury or property damage?

A manufacturer of regulated products must notify the applicable regulating authority regarding substantial safety deficiencies in its products. Although each agency maintains different thresholds and reporting requirements, all agencies rely, in large part, on the self-reporting of firms in determining product safety issues.

Under the CPSA, for example, there are two basic reporting requirements. First, a manufacturer, importer, distributor or retailer of a consumer product is required to report under section 15(b) when a product does not comply with a safety rule issued under the CPSA, contains a defect that could create a substantial product hazard to

consumers, or creates an unreasonable risk of serious injury or death. Second, under section 37, a manufacturer of consumer products must report information about lawsuits or settlements if:

- a particular model of the product is the subject of at least three civil actions filed in a federal or state court within a 24-month period;
- each suit alleges death or grievous bodily injury; and
- at least three of the suits result in final settlement or judgment in favour of the plaintiff.

The FDA also requires regulated companies to notify the agency immediately once the company becomes aware that the company's product is violative of a statute or regulation enforced by the FDA. Food manufacturers, processors, packagers and holders are required to notify the FDA as soon as they become aware that there is a reasonable probability that an article of food is 'reportable'. An article of food is considered 'reportable' if there 'is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals' (21 USC section 350f(a)). The FDA also requires that companies report serious and unexpected adverse events associated with new drugs, approved drugs, non-prescription drugs and dietary supplements as soon as possible, 'but no later than 15 calendar days from initial receipt of the information' (21 CFR section 314.80(c) and 21 CFR section 310.305(c)).

Finally, under 49 USC section 30118(c), a manufacturer of a motor vehicle or an item of original or replacement equipment must report to the NHTSA within five working days from determining that a safety defect or non-compliance exists in the manufacturer's product (49 CFR section 573.6).

5 What criteria apply for determining when a matter requires notification and what are the time limits for notification?

A firm's reporting obligations typically begin once the firm becomes aware that its product poses a risk to the safety of a user or consumer, or is otherwise in violation of a statutory or regulatory requirement, such as a safety standard. The specific reporting criteria and requirements, including when the information must be reported, depend on the product at issue and corresponding agency's regulations.

For example, under section 15 of the CPSA, a firm must immediately report after obtaining information that reasonably supports the conclusion that a product does not comply with a safety rule issued under the CPSA, contains a defect that could create a substantial product hazard to consumers, or presents an unreasonable risk of injury or death. According to CPSC guidance documents, 'immediately' means 'within 24 hours'. The obligation to report commences upon receipt of the reportable information, although the CPSC does allow 10 days for the company to conduct 'expeditious investigation' in order to evaluate whether the information is reportable. Likewise, the FDA's reporting obligation for drugs, non-prescription drugs for human use, and dietary supplements arises upon notice of a 'serious adverse event'. Title 21 USC section 379aa(a) defines a serious adverse event as an adverse event that results in a life-threatening experience, death, hospitalisation, disability, birth defect or requires medical or surgical intervention to prevent death, disability or birth defects. A report of a serious adverse event must be made to the FDA no later than 15 business days after the report is received by the company. Facilities responsible for the production or packaging of food are required to notify the FDA 'as soon as practicable, but in no case later than 24 hours after a responsible party determines that an article of food is a reportable food' (21 USC section 350f(d)).

The specific regulating agency for particular classes of products is discussed in question 6.

6 To which authority should notification be sent? Does this vary according to the product in question?

The particular authority to which notification should be sent – as well as the kind of information to be reported as part of the notification – depends on the kind of product at issue. A list of general product types and the corresponding regulating federal agency is listed below. Additional information about the specific types of products regulated by each agency can be located at the agency's website.

- Aircraft: Federal Aviation Administration: www.faa.gov.
- Alcohol: Alcohol and Tobacco Tax and Trade Bureau: www.ttb.gov.
- Boats: US Coast Guard: www.uscgboating.org.
- Consumer products: Consumer Product Safety Commission: www.cpsc.gov.
- Cosmetics: Food and Drug Administration: www.fda.gov.
- Drugs and medical devices: Food and Drug Administration: www.accessdata.fda.gov/scripts/medwatch/.
- Industrial, commercial or farm products: Occupational Safety and Health Administration: www.osha.gov/dep/index.html.
- Firearms and ammunition: Bureau of Alcohol, Tobacco, and Firearms: www.atf.gov.
- Food (meat, poultry and processed eggs): Department of Agriculture: www.fsis.usda.gov/wps/portal/fsis/home.
- Food (except meat, poultry and processed eggs): Food and Drug Administration: www.fda.gov.
- Motor vehicles (including tyres, car seats and parts): National Highway Traffic Safety Administration: www.safercar.gov.
- Pesticides, rodenticides and fungicides: Environmental Protection Agency: www.epa.gov.
- Tobacco and tobacco products: Alcohol and Tobacco Tax and Trade Bureau: www.ttb.gov.

7 What product information and other data should be provided in the notification to the competent authority?

Each regulatory agency will have its own requirements for what specific product information must be reported and what forms need to be completed as part of the notification process.

For example, the CPSC provides an online 'initial report' that companies can use to report potentially defective or hazardous products pursuant to section 15 of the CPSA. The initial report can be completed at www.saferproducts.gov/CPSRMSpublic/Section15/. The reporting should be done by a person with knowledge of the product and the reporting requirements of section 15. The initial report should include the following information:

- description of the product;
- name and address of the company and whether it is a manufacturer, distributor, importer or retailer;
- nature and extent of the possible product defect or unreasonable risk of serious injury or death;
- nature and extent of injury or possible injury associated with the product; and
- contact information for the person informing the commission.

Following the filing of an initial report, a 'full report', is required to be submitted by the reporting firm. The full report requires more detailed product information than the initial report, including, but not limited to, such information as technical drawings, test results and schematics; a chronological account of facts and events leading up to the report; and model numbers, serial numbers and data codes of the affected products. The complete list of information required by the full report is set forth in 16 CFR section 1115.13(d)(1)–(15).

The FDA requires that serious and unexpected adverse events be reported using FDA Form 3500A, which is available at www.accessdata.fda.gov/scripts/medwatch/. This form provides the required information necessary for the mandatory submission of serious adverse events. Some of the information required includes: name of the suspected product; description of the adverse event; relevant history associated with the specific adverse event; and other information regarding manufacturers, importers and users of the product. Reports regarding serious adverse health consequences or death from articles of food should include information concerning date and nature of food adulteration; product information found on packaging; contact information at the reporting facility; and the contact information for parties 'directly linked in the supply chain' for the reportable food (21 USC section 350f(e)).

Finally, the NHTSA requires a manufacturer to complete a 'defect and non-compliance information report' (also known as a '573 Report') once it determines there is a defect in its product (49 CFR section 573.6). Information that must be provided in this document includes, at a minimum: the manufacturer's name; identification of the product containing the defect with a description of the manufacturer's determination of the population subject to the defect; and a description of the defect or non-compliance, including a brief summary and a detailed description of the defect (49 CFR section 573.6(c)). The regulations recognise additional information that a manufacturer should submit as it becomes available.

8 What obligations are there to provide authorities with updated information about risks, or respond to their enquiries?

In order to ensure the adequate completion of recalls and other safety notifications, most regulating agencies require firms to submit various reporting documents regarding the status of the recall and the ongoing risks presented by the violative product. The ongoing reporting requirements and obligations will vary depending on the agency and product involved. The NHTSA, for example, requires that a recalling manufacturer submit quarterly recall reports under 49 CFR section 573.7. The specific information submitted in these reports includes, but is not limited to:

- notification campaign number assigned by NHTSA;
- date the notification campaign began and was completed;
- the number of vehicles or items involved in the campaign;
- the number of vehicles inspected; and
- the number of vehicles determined to be unreachable for inspection.

These quarterly reports are due on or before the 30th day of each month following the end of each calendar quarter (ie, 30 April, 30 July, 30 October and 30 January) (49 CFR section 537.7(d)). The FDA typically requests recall status reports every two to four weeks that include specific categories of information from which the FDA can determine the effectiveness of the current recall procedures (21 CFR section 7.53). The CPSC monitors all consumer product recalls. This typically includes submission of monthly progress reports, recall verification inspections, and retail visits conducted by CPSC field staff and state investigators to confirm receipt of recall notification and assure that recalled products are no longer being sold. This monitoring can continue as long as the CPSC deems necessary for a particular product recall.

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

The failure to comply with reporting obligations is typically considered a prohibited act and may subject the firm to civil penalties, criminal penalties or both (see, for example 15 USC sections 2069–72). A firm that intentionally fails to comply with the statutory reporting obligations may be deemed to 'knowingly' commit a prohibited act and be subject to more severe penalties under the appropriate regulatory framework. A motor vehicle manufacturer that fails to comply with the reporting requirements imposed by the MVSA can be fined up to US$105 million (49 USC section 30165(a)(1)). In addition to civil and criminal penalties, a drug manufacturer that fails to comply with its reporting requirements also risks having FDA approval of its drug withdrawn (21 CFR section 314.150 (b)).

10 Is commercially sensitive information that has been notified to the authorities protected from public disclosure?

The Freedom of Information Act (FOIA) allows for members of the public to access information controlled by the US government. A firm may seek to protect information submitted to a regulatory agency from the reach of the FOIA. For example, firms reporting under both the CPSA and FFDCA are, in certain situations, provided with protection from FOIA requests.

The CPSA prevents the public disclosure of proprietary and confidential information. However, information included in a section 15(b) report can otherwise be made available to the public, through an FOIA request, after remedial action is requested or if the submitting firm consents. The commission must notify the company prior to the release of any information to the public and allow the submitting company an opportunity to object. The CPSIA recently reduced the time within which a company may object to the release of information from 30 days to 15 days. Additionally, the CPSIA allowed for the CPSC to further shorten this period if it determines that 'the public health and safety requires public disclosure with a lesser period of notice' (15 USC section 2055).

A firm reporting under the FFDCA is protected from the disclosure of trade secrets and confidential commercial information (21 CFR section 20.61(d)). If the FDA disagrees with a firm's classification of the information as confidential, the FDA may determine that disclosure is appropriate. In such cases, the FDA will provide the submitting entity notice of the request and the opportunity to object to disclosure. The firm will have five working days from receiving the notice to object to the disclosure under these regulations (21 CFR section 20.61(e)(1)–(2)).

11 May information notified to the authorities be used in a criminal prosecution?

Generally no distinction is made between disclosure of information based on civil or criminal proceedings. The CPSC, however, expressly provides that information submitted pursuant to section 37 will be immune from disclosure except for an action brought against the manufacturer for failure to provide information required by section 37 (15 USC section 2055(e)(2)). Therefore such information could be used against the manufacturer in a suit brought against it by the commission (15 USC section 2070).

Product recall requirements

12 What criteria apply for determining when a matter requires a product recall or other corrective actions?

The criteria for initiating a recall or other corrective action vary according to the governing statutes, regulations and agency. Generally, once a firm becomes aware that its product is in violation of a statutory or regulatory provision of the agency, presents a threat to safety or creates a substantial risk of injury to the public even though it is not in violation of any applicable rule, the implementation of a corrective action should be considered (see, for example, 15 USC section 2064). The decision to recall a product is an important one and can be made voluntarily, at the request of the regulating agency or both. If, however, the regulatory agency requests the product be recalled as an alternative to other administrative action, a firm should consider undertaking such action so as to avoid incurring harsher administrative penalties. To encourage prompt recalls of potentially dangerous products, the CPSA allows manufacturers to elect a 'fast-track' recall procedure that, if satisfactory to the CPSC, avoids the need for a formal determination by the CPSC that the product contains a defect that creates a substantial product hazard (www.cpsc.gov/en/Business-Manufacturing/Recall-Guidance/CPSC-Fast-Track-Recall-Program/). This approach should be a serious consideration for firms seeking to minimise potential litigation or prolonged CPSC action.

13 What are the legal requirements to publish warnings or other information to product users or to suppliers regarding product defects and associated hazards, or to recall defective products from the market?

The requirements regarding publication of warnings and other information about a defective or dangerous product vary. For some products, statutes mandate that the manufacturer make specific notifications to all owners, purchasers and dealers of the product (see, for example 49 USC section 30118(b)). Most agencies provide guidance documents or product recall handbooks outlining suggested media for publishing such information. See also the discussion in questions 7 and 14. The CPSC is required by law to maintain a public online database containing any reports made by consumers or entities of harm or risks of harm related to products covered under the CPSA (CPSIA at section 212).

14 Are there requirements or guidelines for the content of recall notices?

All agencies provide guidelines regarding the content of recall notices and communications concerning products under their jurisdiction. Most recall or safety communications include information such as:

- the name of the recalling firm;
- the firm's contact information;
- the name of the product being recalled;
- a general description of the danger posed by the product; and
- specific instructions on what should be done with respect to the recalled product.

Additional information such as model numbers, photographs or line drawings may be helpful or required depending on the particular product and media used for the notification (15 USC section 2064(i)). The MVSA specifically mandates seven elements that must be included in notices for motor vehicle recalls (49 USC section 30119). The FDA requires that recall notifications be in writing, contain specific categories of information about the product and the reason for the recall,

Update and trends

There has been a significant number of outbreaks of illness and well-publicised food recalls in 2018. In April, the Center for Disease Control reported an E. coli outbreak that was eventually tied to romaine lettuce grown in the Yuma, Arizona region. More than 200 people from 36 states were infected in the outbreak, and five deaths were reported. In May, McDonald's stopped selling pre-made salads at 3,000 locations in 14 states owing to a cyclospora outbreak. In June, pre-cut watermelon, honeydew and cantaloupe were recalled in 26 states because of a salmonella outbreak that resulted in more than 75 illnesses. In July, various snack foods including Swiss Rolls, Ritz Bitz and Goldfish crackers were recalled because of the risk that the whey ingredient used to make these foods may have been contaminated with salmonella.

These well-publicised, multi-state recalls grabbed the attention of national media outlets, which noted the rise in food-related recalls and questioned the safety of the US food supply. In a report published in April 2018, the United States Department of Agriculture (USDA) looked at the trends in food recalls from 2004 to 2013 (Trends in Food Recalls: 2004-13, EUB-191, US Department of Agriculture, Economic Research Service, April 2018). It found that between 2004 and 2008, food recalls averaged 304 a year; between 2009 and 2013 that number had more than doubled to 676.

The USDA cautioned, however, that 'this upward trend should not be interpreted to mean that foods are becoming riskier'. Instead, the USDA attributed the rise in recalls to multiple factors, including 'an increasingly complex food supply system, improvements in health risk detection, increased regulatory oversight and enforcement, and the passing of two major food policy laws'. The report highlighted two important trends in particular.

First, a recall of an upstream ingredient – such as the whey used in the snack food recall – can have an exponential impact on downstream products that use the ingredient. Between 2004 and 2013, more than 22 per cent of recalls were the result of an upstream-ingredient recall. Second, undeclared allergens were the leading cause of recalls between 2004 and 2013, a trend likely caused by the passage of the Food Allergen Labeling and Consumer Protection Act (FALCPA). FALCPA came into effect in 2006 and requires that all the major food allergens (wheat, eggs, peanuts, milk, tree nuts, soybeans, fish, and crustacean shellfish) be properly declared on food products.

These food recalls have a significant financial impact on companies and the economy as a whole. More than 80 per cent of surveyed companies described the financial impact of a recall as either 'significant' or 'catastrophic' (Capturing Recall Costs: Measuring and Recovering the Losses, Grocery Manufacturers Association, October 2011). The direct costs of a recall include notifying consumers, regulatory agencies and the supply chain; product retrieval, storage, and destruction; and lost sales and profitability from the unusable product.

The indirect – but potentially more significant – costs include post-recall litigation, lost future sales, and negative impact to the company's market value and image. Given the massive expense of recalls and the fact that many could be prevented with an accurate label declaring all allergens, USDA suggests that companies implement procedures that will ensure compliance with all laws and regulations.

specific instructions on what should be done with respect to recalled products, a ready means for recipient of communication to report to recalling firm and not contain any promotional or irrelevant materials (21 CFR section 7.49).

15 What media must be used to publish or otherwise communicate warnings or recalls to users or suppliers?

No specific requirements exist as to the exact media that must be used in communicating warning or recall information to ultimate users or suppliers. Each regulatory agency provides its own guidelines and review of sent and proposed communications. However, a press release (submitted jointly or independently by the firm) is usually considered an initial step in communicating information to a wide range of consumers. Depending on the product, the degree of the risk posed and the specific distribution chain, other forms of media may also be appropriate or required, ranging from publication of notices in newspapers to direct contact with consumers via mailings, email or telephone.

16 Do laws, regulation or guidelines specify targets or a period after which a recall is deemed to be satisfactory?

In most product recalls, the number of products that must be retrieved and the time period for which the recall must be conducted is a subjective fact-specific determination made on a case-by-case basis by the appropriate regulatory agency.

For example, in a recall involving a CPSC-regulated product, the recalling firm may submit a final progress report and request that the file be closed once it has determined that its corrective action plan has been implemented to the best of its ability and as many of the recalled products as possible have been removed from the marketplace. The CPSC will then review the firm's progress and decide whether the file should be closed. If the CPSC determines the plan has not been effective, it may request that the firm implement broader corrective action measures.

Likewise, the FDA will terminate a recall when it 'determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product' (21 CFR section 7.55(a)). A firm may request that the FDA make such a determination by submitting to the district office a statement in writing that the recall has achieved the articulated goals and including the most recent recall status report (21 CFR section 7.55(b)).

17 Must a producer or other supplier repair or replace recalled products, or offer other compensation?

Although not always mandatory, nearly all product recalls in the United States include some form of replacement, repair or other compensation mechanism. For example, the CPSC may not approve a firm's proposed corrective action plan without some form of consumer remedy. Similarly, the FDA has authority to order a manufacturer, importer or any distributor of a device intended for human use, which the FDA determines presents 'an unreasonable risk of substantial harm to the public health' to undertake the repair, replacement or refund of the device or a combination of all three (21 USC section 360h(b)). Before issuing such an order, the FDA must provide the firm with an opportunity for an informal hearing at which time the firm may object to the classification of the FDA. Finally, it should be noted that providing a consumer remedy, even when not required by statute, may help achieve the appropriate level of consumer participation required by the administrative agency. By contrast, the MVSA specifically mandates that motor vehicle manufacturers remedy any defects without charge to the consumer (49 USC section 30120).

18 What are the penalties for failure to undertake a recall or other corrective actions?

Most product recalls are conducted voluntarily by firms, which may obviate more burdensome administrative procedures provided by statute (eg, seizure, detention and injunction). Therefore, a firm that fails to voluntarily initiate a product recall, or does not undertake a requested recall, may run the risk of being subjected to these harsher penalties.

Authorities' powers

19 What powers do the authorities have to compel manufacturers or others in the supply chain to undertake a recall or to take other corrective actions?

The authority to compel recalls or take other corrective action varies by product and agency. In most cases, manufacturers voluntarily initiate recalls and the agency merely provides oversight and assistance with developing a recall plan. However, in some instances, the regulating agency can override a manufacturer's decision regarding the need for a recall, and take corrective action of its own.

For example, the secretary of the NHTSA can issue recall orders to motor vehicle manufacturers requiring them to give notice to all owners, purchasers and dealers as well as remedy the defect (49 USC section 30118(b)). Additionally, the FDA has the power to initiate

recalls in four limited contexts: medical devices intended for human use (21 USC 360h(a)), biological products intended for human use (42 USC section 262), human tissue intended for transplantation (21 CFR section 1271.440) and misbranded or adulterated infant formula and interstate milk shipments (21 USC section 350a(e) to (g)). Furthermore, even where the FDA cannot otherwise compel a manufacturer to recall its drug, it may suspend or withdraw approval of the drug upon finding the drug presents an imminent hazard to public health (21 USC section 355(e)).

For most consumer products, the agency seeking to compel a recall must resort to filing an action in federal court for either an injunction or seizure of the defective products (16 CFR section 1115.21). The CPSA also authorises such actions to be brought by the attorneys general for states in which a defective product is sold (15 USC section 2073(b)).

20 Can the government authorities publish warnings or other information to users or suppliers?

In most situations, the administrative agency works with the recalling firm in drafting and approving all product safety or recall communications. The agency will then post recall notices or other pertinent safety information on the agency's website or specific recall websites such as www.recalls.gov. For example, the FDA publishes a weekly 'Enforcement Report' regarding recently initiated recalls. The Enforcement Report communicates the particular recall classification, whether the recall was voluntary or requested by the FDA and the action being taken by the recalling firm (21 CFR section 7.50). If an agency feels the recalling firm is lacking in its recall efforts, the agency may choose to publish information to consumers directly that is critical of the recalling firm and generally unfavourable. Under the provisions of the CSPIA, the CPSC is required to maintain a public online database for product incident reports. When a report is received, the CPSC transmits notice to the manufacturer of the product at issue. The manufacturer then has 10 days to challenge the accuracy of the report before it is made public. If material inaccuracies can be established, the CPSC is granted an additional five days to investigate before publishing the report (15 USC section 2055a). Both the FDA and CPSC have the authority to issue public health notices and other public warnings related to products within their jurisdiction, and they are more likely to issue such warnings when they perceive that the firm responsible for the products has failed to take sufficient action on its own.

21 Can the government authorities organise a product recall where a producer or other responsible party has not already done so?

Generally, product recalls are undertaken voluntarily by a firm, with the respective agency lacking authority to initiate a recall. Firms often choose to voluntarily conduct a recall that may obviate other possible administrative actions available under the respective agency's statutes, such as seizure or injunction. As discussed in question 19, there are certain products for which Congress has provided explicit recall authority. As a practical matter, even where an administrative agency lacks the specific authority to initiate a recall, a firm requested to do so should consider complying with this request in order to avoid the statutory alternatives.

22 Are any costs incurred by the government authorities in relation to product safety issues or product recalls recoverable from the producer or other responsible party?

A firm will usually not be responsible for costs relating to the government's actions regarding a safety issue or product recall. However, a court could, upon conviction, order payment of the agency's cost of investigation (28 USC section 1918(b)).

23 How may decisions of the authorities be challenged?

The decision by a firm to recall a product, in most cases, is voluntary and is undertaken with the assistance and input of the applicable regulatory agency. Many of the agency's decisions during the recall process are negotiated between the agency and the recalling firm. However, in situations where the agency may seek to pursue statutory remedies such as seizure or detention, a regulated firm may desire to challenge the decision of the regulating authority. In such situations, the firm will typically have a limited opportunity to present evidence that the product in fact complies with (or does not violate) the applicable statutes, standards or regulations. The regulatory authority will review the evidence and make a determination.

Implications for product liability claims

24 Is the publication of a safety warning or a product recall likely to be viewed by the civil courts as an admission of liability for defective products?

When determining tort liability, the publication of a safety warning or the initiation of a product recall is generally not considered a per se legal admission that the product at issue is defective. The CPSA, for example, expressly recognises that the use and definition of 'defect' are 'not intended to apply to any other area of the law' (16 CFR section 1115.4). Likewise, the FFDCA has a similar provision that states that information submitted in connection with the safety of a product 'shall not be construed to reflect a conclusion by the [reporting firm] that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness' (21 USC section 379v).

It should also be noted that, in practice, lay jurors may find it difficult to grasp the concept that a product that was recalled or labelled defective by the governing regulatory authority should not, in turn, also be considered 'defective' or as a basis for liability under the applicable state law. To that end, companies do have the benefit of limited legal safeguards, such as pretrial in limine motions (which can be used to attempt to exclude or limit evidence of the recall) and proposed jury instructions (which can be used to focus the jurors on the correct legal standards).

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25 Can communications, internal reports, investigations into defects or planned corrective actions be disclosed through court discovery processes to claimants in product liability actions?

Companies can expect that evidence such as internal reports or planned corrective actions will be disclosed to an adverse party during the pretrial discovery process. There are, however, certain categories of potentially relevant evidence that may – depending on the situation – be protected from disclosure. These include: communications between client and counsel, attorney work product and documents created in anticipation of litigation. In such situations, the company will have to state the basis for its non-disclosure, which can then be challenged by the adverse party. It should be noted that information or documents disclosed, or testimony given during the pretrial process will not necessarily be admissible at trial. For example, documents and other evidence of the company's subsequent remedial measures may be considered 'discoverable' but not ultimately 'admissible' in court. Conversely, courts are likely to admit evidence that a product was recalled, but may impose certain limitations on the use of this evidence at trial.

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