GETTING THE DEAL THROUGH

Product Recall

in 26 jurisdictions worldwide

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European Overview

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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), (the 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) No. 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 chapter deals primarily with the regime as it applies to non-food consumer products.

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.*

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 allows 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.

In order that producers are kept adequately informed of the risks that their products may pose, they are also 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.

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.

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 territories where the product has been marketed.

Notifications are usually made by way of a standard format and are commonly sent to national authorities by e-mail, fax or post. There is also now 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. While the obligation is to notify the authority in each member state where the product has been marketed, this is not necessary if the product poses a serious risk. All other member states will be notified through the RAPEX information system in any event.

The Commission's outline notification form can be found on the European Commission's website. Each national authority will specify the exact information that they require 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 which is used by member states to make notifications to the European Commission. Producers should be aware of 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 the notification form online and send it 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, e-mail 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. In practice, notification is something that is commonly handled by the producer who has the necessary 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 they are 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 which 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.

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'.

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 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 30 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) No. 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 medicines 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 key words 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), which 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 new 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 new guidelines are 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 2011 Annual Report highlights a number of key trends:

- Between 2004 and 2010 the total number of notifications saw a continual upward trend, rising from 139 notifications in 2003 to 2,244 notifications in 2010. 2011 saw a decrease of 20 per cent in notifications to 1,803.
- The most notified product categories in 2011 were clothing, textiles and fashion (27 per cent), followed by toys (21 per cent), then motor vehicles (11 per cent), followed by electrical appliances and equipment (10 per cent), cosmetics (7 per cent) and others (24 per cent).
- The most common notified risks were injuries, chemical risks, strangulation, choking and electric shock.
- The most frequently notifying countries were Spain (12 per cent), Bulgaria (10 per cent), Hungary (10 per cent), Germany (8 per cent) and the UK (7 per cent).
- 54 per cent of all notifications through the RAPEX system in 2011 related to products originating from China.
- Only 19 per cent of notifications related to products of EU or EEA/EFTA origin.

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. China is currently the greatest source of unsafe consumer products on the EU market. A memorandum of understanding signed between the European Commission and the Chinese product safety regulator, AQSIQ, in 2006 (and revised in 2008), 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. AQSIQ reports to the Commission on a quarterly basis as to follow-up action which is taken as a result of these notifications. As part of the ongoing work in this area, a recent Consumer Product Roundtable took place and considered the best ways to promote awareness of EU and US product safety standards to those involved in design, manufacturing and export of products in China.

Bilateral cooperation also exists between the European regulators and the regulators in the US and Japan. Trilateral discussions and initiatives between Europe, US and China also exist with a view to ensuring the protection of consumers on a global basis.

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