Unsafe products: identifying serious risks and notifying the relevant authorities

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IN THE EVENT THAT A SAFETY PROBLEM IS identified with one of your products, you will need to undertake a risk assessment to comply with the General Product Safety Directive.

Our previous article outlined the reporting obligations under the directive. In this article, Alison Newstead of Shook, Hardy & Bacon International examines how businesses and regulatory authorities determine whether a non-food consumer or professional product poses a 'serious' risk and how information is then disseminated throughout the EU via the RAPEX system. This article does not cover food, animal feed, medical devices or pharmaceuticals; all of which have their own particular regimes.

WHAT IS THE RAPEX SYSTEM?

The RAPEX system (the community rapid information system for non-food products) was set up under Article 12 of the General Product Safety Directive (2001/95/EC) to ensure that information about dangerous products found in one member state was rapidly circulated to other member states and the European Commission. This ensures that effective corrective action is taken on a community-wide basis and that European consumers can be assured that the products they are purchasing are safe.

The system, which incorporates specific notification obligations, also ensures that businesses can easily take steps across European markets, should a potential safety issue arise.

EU UNSAFE PRODUCT TRENDS

Each year, the European Commission publishes an annual report, *Keeping European Consumers Safe*, outlining key statistics on product safety trends in the EU. This is based on the information provided through the RAPEX system. Of the 1,803 reported cases in 2011, the most notified product categories were clothing, textiles and fashion (27%); followed by toys (21%); then motor vehicles (11%); electrical appliances and equipment (10%); cosmetics (7%); and others (24%). The most commonly notified risks were injuries, chemical risks, strangulation, choking and electric shock.

The most frequently notifying EU countries were Spain (12%), Bulgaria (10%), Hungary (10%), Germany (8%) and the UK (7%). Of all notifications through the RAPEX system in 2011, 54% related to products originating from China and 19% of notifications related to products of EU or European Economic Area/European Free Trade Association origin.

IDENTIFICATION OF SAFETY RISKS – EU GUIDELINES FOR BUSINESS

In 2010, the European Commission published guidelines for the management of the RAPEX system, including detailing a standard approach to carrying out risk assessments in respect of potentially unsafe products and determining whether they pose a serious risk to 'the public interest', including health and safety, the environment, energy efficiency, and public security. Previous methodologies varied both within and across countries and produced differing results, which were difficult to compare.

The primary aim of the revised risk assessment method was to assist market surveillance authorities (and businesses) to take a uniform approach to risk assessment and provide a standard approach to addressing the questions of hazard probability and risk. While the guidelines are directed at national authorities to assist them in making a decision about whether or not a product poses a serious risk, in practice it is advisable for businesses to adopt the same procedures.

By working through the guidance, a business can justify why it considers a product may, or may not, pose a serious risk and why a particular course of corrective action has been adopted. A 'serious risk' is defined as one which requires rapid intervention by the public authorities, even though it may concern risks whose effects are not immediate. Other risk methodologies may still be used by businesses, but a reasoned explanation will have to be given to the relevant authority as to why the business has departed from the Commission's recommended guidelines.

The guidelines are an invaluable tool for your business, providing a step-by-step evaluation process with questions to be asked in order to build up a comprehensive

risk assessment of the product. Key areas to examine include:

- the product itself, its identification, description, life expectancy and packaging;
- the hazard posed by the product;
- the category of consumers likely to be affected (in particular vulnerable consumers such as children);
- injury scenarios and the severity of injuries;
- the probability of injury; and
- a determination of risk.

The guidelines are helpful in that they describe who is likely to fall into the categories of 'very vulnerable' and 'vulnerable' customers. They provide guidance in tabular form as to hazards, typical injury scenarios and typical injuries, as well as how to distinguish between four recognised categories of severity of injury.

This guidance also helps businesses to determine the level of risk and decide what corrective action is appropriate to address the risks identified. Although the guidelines do not always suit different complex scenarios, they provide a useful starting point for any assessment undertaken.

The guidelines specifically state that 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'.

An indication should also be given for any uncertainties that were encountered and be prepared in a 'reasonable worst case' scenario; 'not too pessimistic on every factor, but certainly not too optimistic'. In documenting how the risk assessment is carried out and any shortcomings to the process, your business should be able to give a reasoned explanation of the level of risk the product poses and justify the corrective action proposed.

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Documenting your approach and following the guidelines may help you to challenge a different conclusion which is reached by a national authority, via their own risk assessment investigations.

Failure to keep an accurate record of the approach adopted and the corrective action undertaken, if any, could lead to criticism by the national authority.

HOW WILL NOTIFICATION BE CIRCULATED THROUGH THE RAPEX SYSTEM?

On receipt of any notification of an unsafe product from a business, the national authority will also work through the risk assessment procedure to assess whether the product poses a serious risk, whether a RAPEX notification is necessary and what corrective action they consider producers should take. When your business (or indeed the national authority) takes steps to prevent or restrict the marketing of a product posing a serious risk, the relevant RAPEX contact point within the member state submits information about the product, the risks it poses, corrective action and distribution channels to the European Commission. The Commission will then review the notification, validate it and, if necessary, circulate information regarding the product to all the RAPEX contact points. The RAPEX contact points then forward the information to their respective national authorities who will take appropriate action, if the product is on their market.

National authorities are not bound to accept your business's own risk assessment and they may come to a different conclusion. There will usually be a dialogue between your business and the national authority to ensure that the most appropriate corrective action is being taken on a voluntary basis. In exceptional cases where appropriate action cannot be agreed voluntarily, the national authority has the ability to dictate what steps must be taken, such as withdrawal or a recall.

Products that pose a serious risk and have been notified to the Commission are published each week on the Commission's website (http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm). The weekly notifications set out:

- reference for each notification;
- details of 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.

This provides a full picture of where the risk can be found and assures consumers that steps are being taken to address that risk, wherever it may arise, throughout the EU.

For the European Commission, consumer confidence in the safety of EU products is key.

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REPORTING OF NON-SERIOUS PRODUCT RISKS TO THE EU

Information about unsafe consumer products that do not pose a serious risk is exchanged between national enforcement authorities and the European Commission by way of the 'notification procedure'. As these risks are not classified as serious they do not necessitate the employment of the RAPEX system.

In the case of non-serious risks, the national competent authorities are required to notify the European Commission of the steps that are being taken in their territory, and the reasoning behind the particular action being adopted. The authorities must also tell the Commission to forward the information contained in the notifications to the other national authorities as appropriate.

SAFETY PROBLEMS RESTRICTED TO THE PRODUCER'S OWN COUNTRY

A safety programme may only be concerned with one particular member state, although this is increasingly rare. For example, different voltages in the UK compared to other parts of Europe may produce this result.

In such circumstances, the European Commission will only need to be contacted if there is information that they may consider to be of interest to the Commission from a safety point of view or if it is a new type of risk that the Commission may not have previously come across.

Last year in the UK, there has been some discussion about the emergence of risk to children from eating brightly coloured washing machine liquid tablets. It may be this type of emerging risk in that the Commission may be interested to follow.

SUMMARY

It is important that your business understands how to evaluate the risks that a product may pose. The seriousness of the risk directly affects how information about the problem will be disseminated throughout the EU. In-house lawyers should be familiar with the Commission's risk assessment guidelines as the business will need to work through these quickly and methodically once a potential problem arises.

The recall trends show that particular caution has to be taken when sourcing products or components from China. However, there should be no complacency with products manufactured in the EU, which have also been shown to be significant contributors to the recall statistics.

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