

Unsafe products: responsibilities for notification



BY ALISON NEWSTEAD
partner,
Shook Hardy & Bacon
International

FACED WITH A POTENTIALLY UNSAFE product, the in-house lawyer has a critical role in ensuring that relevant notifications are made to appropriate authorities within set timeframes. Failure to comply with the General Product Safety Directive can make a difficult situation for the company even worse.

Where a safety problem arises with a consumer product within the European market, in-house lawyers will need to know the answers to the following questions:

- What are the obligations of the business?
- Who should the business notify about the unsafe product?
- Who should make the notification?
- How is a notification made?
- When should notification be made?
- What will happen after notification?
- What are the penalties for non-compliance?

Vehicles, pharmaceuticals, medical devices, food and animal feed have separate, specific, but similar, regimes within the EU.

BUSINESS OBLIGATIONS

Under the General Product Safety Directive (2001/95/EC), a 'producer' has an obligation to only place safe products on the market, ie products that do not pose any risk or only minimum risk compatible with the product's use. A producer is a manufacturer, first importer into the EU, 'own brander', or 'other professional in the supply chain insofar as their activities may affect the safety of a product'.

Producers are also obliged to provide information and warnings to consumers about any inherent risks that a product may pose, usually in the form of instruction booklets, warnings or labels.

In addition, producers must establish adequate systems to monitor and address any safety risks, and to take appropriate action such as issuing warnings or withdrawing or recalling the product from

the market should a safety problem arise. This usually involves sample testing and maintaining a carefully monitored register of complaints. Traceability of products is also required.

If your business is a distributor, it will still have an obligation to actively monitor product safety by passing information to producers and the authorities about product risks. It is important to maintain appropriate documentation so that unsafe products may be easily traced. You will also be required to co-operate with producers and competent authorities in the event of a product recall and should any redress action need to be taken.

NOTIFICATION AUTHORITIES

In each EU member state there is a national body that ensures compliance with the General Product Safety Directive and circulates information about safety risks to the European Commission. Other member states are also notified. Consumer product producers in the UK should contact their local Trading Standards Office should a potential safety issue arise.

When a producer or distributor has concerns that a product may be unsafe, the relevant authorities in each territory where the product is marketed should be notified immediately. Within the EU, if the product poses a 'serious' risk all other member states will be notified automatically through the RAPEX (rapid information exchange) system.

RESPONSIBILITY FOR MAKING THE NOTIFICATION

The General Product Safety Directive suggests that both the distributor and the producer should notify the national authority should a safety risk arise.

In practice, usually only the producer makes the notification for practical reasons. The distributor may have passed information to the producer about possible safety problems received via customer complaints, but it is unlikely to have necessary technical information to carry out the risk assessment and decide whether a notification is necessary.

The duplication of a notification is not necessary if you know that all relevant

'Directors could face severe criticism, and even criminal penalties, should a notification be unduly delayed. Such criticism is particularly likely if consumers are injured.'

information has been conveyed to the competent authority by another party, such as the producer if you are a distributor.

NOTIFICATION PROCESS

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 an option for EU businesses to use an online notification process called the Business Application.

In the event that a product poses a serious risk to health and safety, information given to the national authority must include:

- details of all 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;
- details of companies in the distribution chain; and
- a description of the corrective action undertaken to prevent risks to consumers.

TIMING OF NOTIFICATION

In the event of a product safety problem, all communications need to be handled with the utmost care. Co-ordination among the key management team is essential and the legal team will need to emphasise the importance of reporting duties, when other departments may be less keen to make information public.

Initially, a producer may have little information to commence a risk assessment and determine whether a product is unsafe and therefore know whether a notification is necessary.

The General Product Safety Directive states that notifications should be made 'immediately'. Guidance from the European

'In each EU member state there is a national body that ensures compliance with the General Product Safety Directive and circulates information about safety risks to the European Commission.'

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 ten days in any event'. The UK interpretation of this requirement is that a notification should be made 'forthwith'. One thing is certain: the drafting of the directive clearly suggests that investigations and notifications to competent authorities should not be unduly delayed.

Practices differ in each member state, but a producer may inform the national competent authority that a risk is being investigated and a decision to make a 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 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.

Directors could face severe criticism, and even criminal penalties, should a notification be unduly delayed. Such criticism is particularly likely if consumers are injured in the period during which investigations are being carried out and notification is not made.

Regulatory authorities should be informed of the problem prior to any corrective action being taken as you will want to ensure they agree with the action that is being proposed.

REMEDIAL ACTION POST-NOTIFICATION

Authorities, such as Trading Standards, have established procedures for co-operation and exchange of information with producers and distributors. There is usually a continuing dialogue after notification and monitoring of

the effectiveness of corrective action and enforcement actions.

The national authorities have wide-ranging powers to ensure that adequate measures are taken to address product safety risks, including 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.

While such powers exist, voluntary action is advocated. In practice, responsible producers commonly embark on voluntary corrective action and co-operate fully to ensure that remedial action is both proportionate and acceptable to the national authorities. It is usually only where producers fail to take any action, where action is not deemed to go far enough, or where producers cannot be identified, that national authorities call on these powers to deal directly with products posing a serious risk.

PENALTIES

The General Product Safety Directive is not prescriptive regarding the level of penalties for failure to comply. It is left for each member state to set out the penalties for infringement in national law. Nevertheless, the directive makes it clear that such penalties should be 'effective, proportionate and dissuasive'. The UK introduced both fines and prison sentences in response to this:

- a person who places an unsafe product on the market or a distributor who fails to ensure that an unsafe product is not placed on the market, for example by supplying it, can be convicted for up to 12 months or face a fine not exceeding £20,000, or both;
- a person who fails to provide consumers with relevant information to allow them

to assess risks and take precautions against these risks or who fails to undertake adequate monitoring shall be liable to a maximum penalty of a prison term of not exceeding three months and a potential fine of up to £5,000;

- if a person fails to make the requisite notification to the authorities, again the penalty is up to a three month prison term or a maximum £5,000 fine; and
- a person who contravenes a safety notice, such as a suspension notice, a requirement to mark, a requirement to warn, a withdrawal

‘Co-ordination among the key management team is essential and the legal team will need to emphasise the importance of reporting duties, when other departments may be less keen to make information public.’

notice or a recall notice, faces a maximum penalty of 12 months in prison or a fine not exceeding £20,000, or both.

The in-house lawyer may need to remind the board of these potential penalties in

order to keep the notification process on track.

*By Alison Newstead, partner,
Shook Hardy & Bacon International.
E-mail: anewstead@shb.com.*