



Is your product safe? New guidance published by the European Commission

A recent European Commission Decision sets out new guidelines on how to assess the risks associated with non-food consumer products under the General Product Safety (GPS) regime. Companies deciding whether to take corrective action (including whether to recall products) and whether to notify regulators about a safety issue need to know what the guidelines say. We have talked to the European Commission and have obtained further guidance on the new rules, which is outlined in this briefing.

Why the new guidance matters

On 26 January 2010, the European Commission (the Commission) published new guidelines on the operation of the EU's rapid safety alert system for non-food consumer products (RAPEX). Although primarily addressed to the member states, an appendix to Commission Decision 2010/15/EU sets out guidance on how the level of risk posed by non-food consumer products should be assessed for the purposes of the EU's General Product Safety (GPS) regime. (See inset box, 'The General Product Safety regime'). The answer to that question is an important one. When a problem does arise with such a product, this risk assessment process will help determine:

- whether the producer, retailer or other distributor of the product needs to notify regulators about the problem;
- what corrective action, up to and including recall, needs to be taken; and
- whether the issue will be communicated across Europe and beyond via the RAPEX network.

The guidelines themselves are intended for member states rather than industry and their main objective is to encourage more consistent, science-based risk assessment by national authorities when deciding whether they should themselves escalate an issue via RAPEX. This move reflects previous criticism from industry that some national authorities do not seem to be clear about how to classify risks and how to ensure consistency in enforcement. (See our guide, *Getting*

it right: product recall in the EU, page 20 available at www.freshfields.com/publications/pdfs/2008/mar10/21238.pdf). The new guidelines are stated to represent the 'best possible practice' for assessing consumer product risks.

However, the Commission has confirmed to us that businesses 'can' also use the new guidelines to determine the risks associated with their products, although it has also emphasised that this is not an end in itself: rather 'it is... the responsibility of businesses to determine the action they deem appropriate at any level of risk'. Our contact also told us that the previous risk assessment methodology (see inset box, 'The General Product Safety regime') has been 'superseded'. Our view is that, since regulators will use the new guidance in their future decision-making, it would be prudent for industry to do likewise.

What the new guidance says

The new guidance takes a far more sophisticated approach to risk assessment than the criteria contained in previous guidelines.

Under the old regime, businesses and regulators had to:

- identify the hazard posed by the product in question;
- estimate the level of risk (based on a combination of the severity of possible injury and the probability of that injury occurring); and
- factor in issues such as the obviousness of the risk and the vulnerability of consumers likely to use the product.

The General Product Safety regime

The revised GPS Directive (2001/95/EC), which came into force across the EU in January 2004, deals with the safety of non-food consumer products. It requires producers (including own-branders, EU importers and EU-based representatives of overseas manufacturers) to take appropriate 'corrective action' where a product safety issue is discovered. Distributors (including retailers) have complementary obligations.

The specific corrective action required depends on the seriousness of the issue and the location of affected products in the supply chain. Recalling products from consumers is described in the Directive as a 'last resort'. The new risk assessment guidelines described in this bulletin change the methodology for determining the seriousness of such an issue. The previous methodology was set out in guidance such as:

- a June 2004 guide, *Product Safety in Europe – A guide to corrective actions including recalls*, published by PROSAFE, Unice, EuroCommerce and BEUC; and
- the Commission's own *Guidelines for the notification of dangerous consumer products to the competent authorities of the member states by producers and distributors*, appended to European Commission Decision 2004/905/EC.

The GPS regime also requires producers and distributors who become aware of a safety issue 'immediately' to notify national authorities. Recently, a new 'business application' has been launched, allowing web-based notifications to be filed centrally. Notifications that concern risks classified as 'serious' under the previous methodology will then be escalated to the Commission by the appropriate member state, and by the Commission to other member states and partners such as the US and China, via RAPEX.

The GPS regime is supplemented by a number of category-specific directives that set out additional requirements for products such as toys, cosmetics and motor vehicles. Food and drink is covered by a separate, but similar, regime.

In 2008, we published an in-depth report into how the GPS regime was working, based on interviews with business carried out by Ipsos MORI. The conclusions of our report included:

- higher levels of recall were primarily attributable to stricter legal requirements, tougher enforcement of the law and increased consumer awareness of product risks;
- product recalls and safety issues could have serious reputational and financial impacts;
- businesses generally felt they were well prepared to handle such issues, although ensuring supply chain traceability remained a challenge; and
- cross-border recalls were particularly problematic, with a quarter of respondents identifying inconsistencies in the interpretation and enforcement of the GPS regime by national authorities.

Findings on these issues would be input into a simple (some would say 'simplistic') risk assessment table. This gave an overall risk assessment of whether the risk was:

- 'serious' (requiring rapid action/notification);
- 'moderate' (requiring some action and notification); or
- 'low' (not generally requiring action for products in the market, and often not requiring notification).

Our experience of working through this former methodology with clients is that it was often too blunt a tool. For example, in the case of a product intended for use by 'very vulnerable' consumers, corrective action would need to be taken and regulators notified in the event of any potential safety risk being uncovered – even if there was only a one in a billion chance of that risk actually eventuating. Similarly, in cases of design defects (ie where a specific problem affects all units of a product series), corrective action was almost always required, even if the chances of the risk materialising were in fact very low.

The new guidance is more nuanced. For example, it suggests drawing up various 'injury scenarios' depending on how the product can be used, the categories of users and the individual hazards a product may display. It further requires the determination of risk level for each injury scenario to be checked for plausibility in order to establish whether an injury scenario might possibly lead to a risk requiring action. Such a plausibility check may involve considerations as to whether a certain injury scenario is at all possible given the state of the scientific and technical knowledge at the time, as well as practical evidence, for example, from product testing and accident reports (see also inset box, 'Nine steps to preparing a risk assessment under the new guidelines').

The guidance also gives far more detailed recommendations on injury scenarios and on the classification of the severity of potential injury than its predecessor. It caters much better for situations where a single product poses multiple possible risks (eg a wiring problem in an electronic device would pose the risk of electrocution as well as fire), emphasising that such risks should not simply be added together to reach an overall risk assessment.

The most significant development is probably the introduction of a new category of 'high' risk (one below 'serious' risk) as a possible outcome of the risk assessment process. The effect is to introduce more flexibility into the regime. It may also reduce the number of safety issues that are classified as serious and which therefore require urgent notification, the most stringent

corrective action and urgent escalation via RAPEX. The Commission has told us that there is anecdotal evidence from trials of the new guidelines by PROSAFE (the association of EU product safety regulators) that the application of the new guidelines may lead to fewer classifications of ‘serious’ risk, but that only time will tell whether this (or the opposite) is true in practice.

What will change?

It is early days, but our first thoughts on the impact of the new guidance are as follows.

- The guidance will be of interest and use to industry. Those responsible for managing product safety incidents should familiarise themselves with it. Existing incident-management plans may need to be adjusted.
- EU member states will also need to update their own existing guidelines for industry. It will take time for national regulators to get to know the new guidance, particularly given its complexity.
- If used properly, the guidance will enable more sensitive assessment of the risks associated with a product. Product risks that were previously classified as ‘serious’ may, as noted, sometimes now receive a lower classification.
- The new methodology is more technically complex than the previous rules. It relies on a high level of technical and traceability information being available to the business or the regulator very early on. The new guidelines once again reinforce the need for preparedness. Where time permits, they may also indicate a greater role than previously for expert incident-management advice (from technical and other consultants).
- A key aim of introducing the new risk assessment guidelines is to ensure consistent risk assessments across member states on the basis of appropriate scientific and technical information basis. As well as encouraging good practice, the new guidelines may offer business operators the opportunity to challenge poor regulatory decision-making, such as a decision to escalate an issue via RAPEX in circumstances where these guidelines have not been properly followed – perhaps even in court.
- The publication of the guidance has, however, introduced uncertainty as to the status of existing Commission guidance based on the previous risk assessment methodology (see inset box,

Nine steps to preparing a risk assessment under the new guidelines

1. Describe the product and its hazard.
2. Identify the type of consumer to be included in the injury scenario.
3. Describe the injury scenario in which the identified product hazard(s) or adverse health effects might affect the identified consumer.
4. Determine the severity of the possible injury to the consumer.
5. Determine the probability of the injury scenario arising.
6. Determine the risk level.
7. Check whether this risk level is plausible.
8. Repeat the above to determine other injury scenarios and to identify the highest risk posed by the product – classify the risk as ‘low’, ‘medium’, ‘high’ or ‘serious’.
9. Document and pass on your risk assessment.

‘The General Product Safety regime’). For example, the Commission’s notification guidance for industry states that companies must inform national authorities immediately upon becoming aware of an issue, but in any event within 10 days of discovering a non-serious risk and three days of discovering a serious risk. The new guidance uses different risk classifications and is silent on the question of the timing of notifications by industry. Do the old time limits still apply?

Further information

A copy of Decision 2010/15/EU can be downloaded here: www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:022:0001:0064:EN:PDF. The guidelines appear at Appendix 5.

For further information on any of the issues discussed in this bulletin, or on the firm’s consumer products and retail work and its product risk and liability capabilities, please contact

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