

Notes on Product Recall
Seminar for York EMC Club
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Tuesday 1st July 2003

General Product Safety

Introduction

General product safety is of fundamental importance to every business. In the worst case scenario, the very viability of a business can be at stake.

The Electromagnetic Compatibility directive, the Lift Safety directive and the Machine Safety directive all have one thing in common, they stem from the so-called "new approach" directives of the European Union. All the "new approach" directives are structured in the same general way: -

- They place an obligation upon manufacturers or suppliers to build a product to the appropriate standards.
- They require the manufacturer to "self certify" i.e. It is generally the manufacture who determines whether the obligations set out in the legislation have been met.
- They require the "CE Marking" to be placed on the product once the product has complied with the legislation.
- They are all backed up by the sanction of Criminal Law if they are not complied with.

The Directives all require that the product should be built to the appropriate European standards. Where there are no European standards, then local standards may be used.

A further feature of all this legislation is that it is safety-related. In each case, one main justification for the legislation being passed is the need to ensure that safety is not used as an artificial barrier to trade through the European Union. Without the legislation, it would be possible for a member state to prevent goods being imported into that state, on the pretext of having a higher safety standard than in other states.

However, these "new approach" directives are for the most part product orientated (for example, the Simple Pressure Vessels directive) or subject specific (for example, the Toy Safety directive). The European Union therefore decided that having a directive to act as a piece of "sweeping up" legislation was appropriate. This directive, the General Product Safety Directive (Council Directive 92/59/EEC of 29 June 1992 on General Product Safety) applies to any safety-related aspects of the design, manufacture and construction of a product that are not covered by one of these product-specific or subject-specific directives. The Directive is enacted in the United Kingdom by the General Product Safety Regulations 1994 (statutory instrument 1994 no. 2328). This Directive is

replaced by General Product Safety Directive (Council Directive 2001/95/EC of 3 December 2001) (OJ L 11/4 of 15 January 2002) which Member States of the European Economic Area must enact locally before 15 January 2004.

The General Product Safety legislation applies in addition to the Product Liability legislation. The general product safety legislation applies only to products that are supplied for consumers or likely to be used by consumers. Note, however, that this would include for example, a vehicle, such as a van, primarily designed for commercial use but equipped with an additional seat. It is likely that in many circumstances the spare seat could be occupied by a “consumer”. The term “consumer” is not defined in the General Product Safety legislation.

There is now a general duty on all manufacturers, and in most cases on distributors also, to ensure that the products they place on the market are safe. If they are not safe, both a company and its individual directors will suffer criminal penalties. In the United Kingdom, for example, they can be fined up to £5,000 or sent to prison for up to three months.

The standard of safety under the general product safety law is not as high as the standard of "no defects" required under product liability legislation. In general product safety, "safety" means that the risks associated with the use of the product must only be those minimum risks compatible with a high level of protection for the health and safety of people.

This is different from the obligations under product liability legislation, where products may be considered defective if, for example, they are liable (only) to damage personal property. Personal property could for instance include the fishing rights in a river "owned" by an individual, so that a product could be considered as “unsafe” under product liability legislation if it were likely to cause pollution to the river.

In applying this test for general product safety, only the normal and foreseeable use of the product needs to be considered and only the health and safety of people needs to be considered. The following points are also relevant when considering whether a product is safe under the directive:

- the characteristics and composition of the product
- the effects on other products
- the presentation of the product
- the labeling of the product
- the instructions for the use of the product
- the categories of consumer at risk (for example: children)

Under the general product safety legislation, distributors must also plan carefully to manage their responsibilities. For instance, even where a distributor possesses an unsafe product intending to supply it, the distributor can commit a criminal offence under the general product safety legislation.

However, any other business which is involved in the supply chain can also be liable. For example, if a transport company fails to ensure that the product remains safe while it is in its possession, the transport company will also be committing an offence under the regulations. This could occur, for example, where a transport company fails to keep a product within the temperature range stated by the manufacturer, and the product thereby becomes "unsafe". While the most obvious examples of this lie in the food industry, the reality with many other products: from cosmetics to sophisticated microprocessor - based products is that they also need to be kept within certain temperature ranges to prevent degradation.

There are defences available (at least under UK law) where the company or person who is prosecuted can show that he or she took **all** reasonable steps and exercised **all** due diligence to avoid committing the offence.

Similarly, (in United Kingdom law) if the company or person prosecuted can show that he or she relied on information from another person, he may have a defence. However, to take advantage of this defence, the defendant will need to show that relying upon the information supplied by the other person was reasonable in all the circumstances. So, for example, if a distributor can see that the packaging of the product has been damaged he is effectively under a duty to verify that the contents of the package are undamaged. If he does not, he will be liable under the new legislation should the contents be damaged and unsafe to use and he would not be able to use this defence of "reliance on others".

Other Provisions of the General Product Safety Regulations

The general product safety regulations also provide additional obligations on a manufacturer, most of which deal with the provision of information by the manufacturer. Perhaps the most radical, however, is that the manufacturer **must** have plans for a product recall campaign, just in case that eventuality might arise.

Under the new legislation, there is no absolute obligation for a manufacturer to hold a product recall. Probably the only circumstances where the manufacturer must hold one would be where it would amount to gross negligence if the manufacturer did not, thereby exposing the manufacturer to a charge of gross negligence if he did not hold a product recall. The new legislation does however require the manufacturer to take "appropriate action" including :

- avoiding the risk e.g. by tracking down the offending products and repairing them;
- effectively warning consumers against the risks associated with the products e.g. by issuing a press notice or writing to known purchasers or users of the product;
- withdrawing the product from sale;
- holding a product recall.

The 2001 legislation expressly states that the last remedy of holding a full product recall is to be considered as a "last resort". Further, the 2001 Directive provides that the appropriate authorities

can order the producer to take any of these remedies. There is no express guidance as to when the authorities are to intervene other than to state that those authorities are to have regard to the “precautionary principle”. This means that, at least in theory, the authorities could order a product recall where there is only a suspicion of a danger. No doubt if this did occur a legal challenge would be possible, and may even be probable, not least under the human rights legislation.

The manufacturer is also required to consider marking products and batches of products so that they can be subsequently identified. He must test samples of the products he places on the market. He also needs to investigate complaints and to inform distributors should a product recall be necessary. Of course, all good manufacturers have already been taking these steps for a long time.

A distributor is also now under a positive duty to help a manufacturer to ensure that unsafe products are not placed on the market. For example, a distributor must inform the manufacturer of any risks the distributor identifies in relation to products. So, for example if a customer return goods with a safety-related fault, the distributor must pass on details of that fault to the manufacturer. A distributor is also now under a positive obligation to help a manufacturer in dealing with product recalls and related issues.

Product Safety : Conclusions

There are several key areas where the product safety legislation imposes significant additional burdens on a manufacturer. For example, the general product safety legislation clearly applies to reconditioned and used goods. For example a person who reconditions or supplies second hand industrial equipment and then supplies that equipment into the consumer market will be obliged to comply with the General Product Safety Regulations. That person is under a duty to ensure that those products are safe (within the meaning of the General Product Safety legislation) before he places them on the market.

Manufacturers in particular should take heed of the product safety law as it is backed up by criminal offences. Distributors also have new obligations including a positive obligation to help manufacturers.

Product Recall

Product recall is for the public the ultimate solution, but is a solution of which a producer could justifiably be in fear of. However, fear of the consequences of product recall must not be allowed to outweigh the producer’s duty to the public. The consequences of a prosecution or civil action may well be far higher than those involved in product recall.

The General Product Safety legislation carries with it a principal of product recall. Specific obligations under the General Product Safety legislation include a requirement that a manufacturer must have plans for product recall, in case a product recall is ever required. Accordingly, a

manufacturer must plan in advance and should mark products or batches of products so that they can readily be identified. The manufacturer must test samples of products it puts on the market. The manufacturer must also investigate complaints and inform distributors should a product recall be necessary.

The manufacturer retains a continuing duty to warn of new problems with its products. Once a manufacturer has established the nature and extent of its problem, it must decide the appropriate level of response. This may take all or some of the following steps :

- no action;
- a press release
- discontinuation from sale of further items of a particular batch or class
- recalling the product from dealers
- writing to known purchasers and recalling the products from them
- a press-based full product recall

Practically, when a manufacturer selects a course of action it should be actioned immediately. Preparations therefore need to have been made in advance. Manufacturers **must** have contingency plans for defective products and in particular a strategy for recall. Writing to the ultimate consumers (or even the original purchasers) of a product will always be more effective than press advertising. Product recall is a painful business and will invariably tarnish a company's image : at least in the short term. However, openness has to be the key to minimise even greater damage to a company's image.

A manufacturer also needs to consider who should advise him should a product recall prove necessary: the team should include his lawyer, his publicity agent, his insurer (or insurance broker) and a technical expert. Ideally, the first three should also have some technical expertise in the type of product manufactured.

As has been stated, ideally, the manufacturer should contact all persons who have purchased the products. In the usual case where a complete customer list is unavailable the newspaper advertisements need to be considered. These should clearly state:

- what product is being recalled (i.e. how to identify the product);
- why the product is being recalled; and
- how to contact the manufacturer and return the product for repair or replacement.

The advertisement should clearly state that the recall is being undertaken for **safety** reasons.

Manufacturers should also consider the availability of insurance cover, as standard product liability policies exclude recall costs. It is possible, though expensive, to obtain product recall insurance cover, as an extension of a product guarantee policy. These policies are designed to cover the costs of recalling defective products, but will not cover malicious tampering for which separate cover must be obtained. In addition, insurance cover will not usually compensate for the manufacturer's

greatest potential loss - that of its reputation! The cost usually equates to a premium of about 2.5% annually of the cover i.e. cover of £1,000,000 would require an annual premium of about £25,000.

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Practical Summary

- 1 All manufacturers and producers should consider whether they are potentially liable under the product liability legislation and if so, in relation to which products.
- 2 The liability arising under the product liability legislation between producers and end-users, cannot be avoided. However, consideration ought to be given about whom among the various parties ought ultimately to bear the responsibility for compensation under the product liability legislation. This can be achieved by an indemnity being granted by one producer in favour of the next producer. For example, a chain of indemnities will often arise, which may have the result of putting the ultimate burden of liability for defects in a component on the producer of that component. It should be noted that this does not prejudice whom the injured party may sue, only who will ultimately end up with the expense of compensating the injured party.

Parties should not rely on implied indemnities or warranties, for example those contained in the sale of goods legislation, since these are not of clear applicability and their scope is open to question. The best advice is to have express indemnities or express exclusions of indemnities in contracts between producers. For example an indemnity should be contained in a contract between an own-brand retailer and the manufacturer of the product, or between the manufacturer of a product and the manufacturer of a component.

- 3 Manufacturers should consider carefully the instructions that they give to the producers of components. Where instructions are given, the component producer should ensure that those instructions are complete. Where the instructions are complete and the component producer follows them faithfully, he can escape liability under the product liability legislation for defects "wholly attributable" to following such instructions. Ensuring that those instructions are given or recorded in writing would be advisable, as would ensuring that any amendments to those instructions are also given in writing.
- 4 All producers should keep accurate records of their component suppliers. For instance, the manufacturer of an end-product may need to trace back a defect in a component to the actual manufacturer of that specific component - particularly where he has planned well and obtained indemnities from all his component suppliers. This may mean having to decide

who, of several suppliers of similar components, has supplied the specific defective unit in question.

- 5 Manufacturers may wish to impose rigorous testing requirements on component producers in their contracts. This would give a manufacturer some comfort that his finished product may not then contain a defect. If the contract is subsequently breached because testing has not occurred, and a defect has therefore been incorporated into the product, the manufacturer would then have a right to be indemnified under the contract. This is also important for own-brand retailers who have liability under the legislation.
- 6 Producers should ask their insurers what the nature of their existing cover is. If appropriate, a full or partial risk analysis and assessment should be undertaken. Insurance should then be taken out to meet the residual liability that a manufacturer has for defective products under the product liability legislation. Even if a producer, such as an own-brand retailer, has obtained a complete indemnity, insurance is still necessary since the party paying the indemnity may not be solvent when the time comes to rely on that indemnity.

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Dai is now a full time consultant with national law firm Nabarro Nathanson. Dai advises clients on intellectual property, computer and technology law subjects including such topical matters as E-Commerce issues. He is primarily a non-contentious lawyer, specialising in advising on commercial agreements relating to software and technology products. He also has considerable experience advising companies and consultants on product liability and product safety issues. Dai is a regular contributor to legal and technology journals and is a member of the editorial panel of World eBusiness Law Reports.

Dai is a Fellow of the Royal Society for the encouragement of Arts, Manufactures and Commerce. Dai is the convenor of the International Electro-technical Committee TC56 - Legal Advisory Working Group (IEC TC56 being the organisation which is responsible for drafting international maintainability and dependability standards). He sits on the Executive Committee of the IEE Management Professional Network.

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