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Products liability in Europe

– where the buck stops

Aspen Opinion

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Where the buck stops

Introduction

The growth of world trade has thrown up an array of problems in terms of products liability for goods imported into the European Community, especially if they are then transferred between member states. The surge of manufactured goods from the Far East and China, some of them counterfeit and dangerous, has highlighted concerns about the rights of the end-user consumer and of the position of the importers / distributors who may have legal liability to that consumer. The Sudan 1 crisis is a good example. This Aspen Opinion looks at:

- The European Directives
- The trend of court decisions
- The Sudan 1 crisis
- Counterfeit cigarettes
- The cornerstones of UK product liability law
- Practical advice to 'producers' of products and
- The role of contracts and insurance cover



The legal background

For over one hundred years, the United Kingdom has protected consumers against shoddy goods through the Sale of Goods Act 1893 as updated by the Supply and Sale of Goods Act 1994. These statutory remedies, while sound, are based on contract and so only open to those who had bought the product. Others with no contractual nexus may have suffered from the product. Thus seventy years ago the law of negligence developed from the case of the decomposing snail allegedly found in a bottle of ginger beer consumed by a non-purchaser.

This provided a new broader cause of action, but the burden of proving negligence often proved to be too great. Nowhere has this been more apparent than with pharmaceutical drugs. The thalidomide disaster, some forty years ago, exposed the shortcomings of the law in Europe when innocent victims of the drug's side-effects were unable to prove a case against the manufacturers. Reform was essential to introduce strict liability without proof of blame. It took time.

Products Liability Directive 1986

The European Union eventually agreed a Products Liability Directive in 1986. A Directive is an order from the European Commission to all Member States to incorporate its provisions into domestic law. By this means, a broadly uniform framework of law has been created throughout the Community. However, the United Kingdom, in passing the Consumer Protection Act 1987, did not precisely implement the Directive and incorporated a development risks defence. Yet the Government resisted a court challenge by the European Commission that it had diluted the strict liability concept. Other European nations also implemented the legislation with slight differences, so that the grand design of an entirely uniform law has not been met.

Critics of the development risks defence felt that the Government had bent over to assist the pharmaceutical and motor industries so as to encourage these giants to develop their drugs and new cars in the UK rather than abroad. The inter-reaction between the Directive and the 1987 Act has now been well explored in later products liability cases discussed below.

Community reviews of the 1986 Products Liability Directive

The first Directive was updated in 1999. Primary agricultural produce was added to the products originally covered – a result of the mad cow problems in Europe. Animals, grain, fruit and vegetables are now included. Since 1999, the law has also been reviewed by external lawyers hired by the European Commission, who advised that there was no pressing need for reform as the Directives had led to a reasonably fair balance between consumers and producers. Despite this advice, there remains a wide body of consumer activist concern in the UK that the 1987 Act has not worked as effectively as expected where establishing blame has been as tough as proving negligence. Examples are given below.



Consumer Protection Act 1987

The Consumer Protection Act 1987 applies to England, Wales, Scotland and Northern Ireland. Without inhibiting existing laws, it added new rights to the consumer to win cases against producers without proving negligence. The contractual remedies for buying defective goods (those of *unsatisfactory quality*) still remain under the Sale and Supply of Goods Act 1994.

Section 2 of the 1987 Act sets out the general principle of the law which can be summarised as follows:

Where (1) any **damage** is (2) **caused** by a (3) **defect** in a (4) **product** (5) every **producer** shall be liable unless a (6) **defence** applies.

The burden of proof is on the plaintiff to establish that the product is covered under the Act. *Product* now includes primary food and consumer products including those used in the workplace. Motor vehicles and pharmaceuticals are included. A building is not a product, though the bricks themselves would be. Written instructions *with* a product *are* covered as a product but in general printed matter providing information is not. The claimant must prove damage caused by a defect in that product, a serious hurdle, especially in pharmaceutical claims. Only then does the burden shift to the defence.

A claimant can sue more than one defendant and liability is joint and several. Contracting out of liability is not possible. However, as emphasised below, astute contracts may pass the ultimate financial burden.

What is a *defect*? - public expectation

Under s3, liability can be established where the safety of the product is not such that persons generally are entitled to expect – an objective test. In considering this, regard has to be taken of how the product was marketed and what instructions and warnings were supplied - if any.

Producer

As defined, a *producer* is far wider than merely the manufacturer. It means:

- Any participant in the production process
- The importer
- Any person putting their name, trademark or other distinguishing feature on the product (an own-brand) or
- Any person supplying a product whose producer cannot be identified

If a product from China is imported into Spain but then distributed in the UK, the liability rests with the first importer as the producer rather than the distributor into the UK. The final seller to the consumer remains liable. However, if the original producer cannot be identified, then even the middlemen like distributors can be liable.



Defences under the Act

- The liability of a producer may be reduced if the injured person was also to blame
- Liability can be avoided if the relevant defect came into being after the product was put into circulation
- Liability can be avoided if the product was not manufactured or distributed in the course of business
- Liability can be avoided if the product was not manufactured for profit-making sale
- Liability can be avoided if the state of scientific or technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered. This is the controversial development risks defence
- Liability can be avoided if the defect is due to compliance with mandatory regulations
- Liability can be avoided if in the case of a manufacturer of a component of the final product, the effect is attributable to the design of the product or the instructions given by the product manufacturer

Meaning of damage

Put simply, damage means death or personal injury or any loss or damage to any property including land. For small claims not involving injury, there is a minimum claim value that varies with inflation.

Limitation periods

The action must be commenced within three years of injury or if later, the date when knowledge of a claim against a defendant arose subject to an end-stop of ten years.

Criminal liability

Besides easing the path to civil claims, the Act introduced criminal liability usually to be enforced by Trading Standards.



Fireworks and cigarettes

The first importer's liability provision can give rise to serious problems – e.g.: for someone selling goods such as the often illicitly imported Chinese fireworks or cigarettes where the manufacturer cannot be traced. Middlemen can be liable if the original producer cannot be traced – and many would say: serve them right! They should have obligations to consumers if they profit from their role. The European Commission is looking at whether any reform is needed to provide a better balance concerning liability of suppliers.

A surge of fake but authentic looking cigarettes sold on the cheap and coming from Eastern Europe and China contain lead and arsenic and are particularly carcinogenic. The first importer into the European Community would be liable and in a hot seat because of the difficulty in proving source of supply. The pub or corner shop owners who buy them for cash cheaply can be liable were it possible to prove damage to health. It would not be necessary for the shop owner to know that the cigarettes were particularly dangerous.

Also exposed to liability can be wholesalers or retailers BUT only if they fail to identify the producer, importer or own-brand. Both middleman supplier and the original importer may be shadowy figures and impossible to trace or sue. If a consumer buys these cigarettes on the cheap, he may have an award reduced because of his own negligence, but primary liability against the seller should be established. The quality of the appearance and packaging may be material. However, if he had been told they were cheap because they were damaged goods or "smuggled in by me" from Calais, then the reduction may not be much. If the consumer bought them at full price reasonably believing them to be the genuine item, then it is hard to see how he can be blamed or have an award reduced.

General Product Safety Regulations 1994

These Regulations flowed from the EU General Product Safety Directive of 1992. The UK created a framework of safety standards and rules for different products including toys, fireworks, food and drink, chemicals and pesticides. A revised General Product Safety Directive from the European Commission came into effect in January 2004, but the UK and several other States have yet to implement the provisions. The UK intends to do so in 2005 at the end of an ongoing consultation process.

Where the 2004 Directive *has* been implemented, State Governments have cherry-picked so that the intended EU-wide effect will not be achieved. Perhaps the most important new element is an obligation on producers or distributors to own up when a product poses a serious risk to consumers. But what is a *serious risk*? A drug designed for arthritis relief may be highly effective for most but have serious side-effects for others. It would seem likely that under this Directive, management will have to be very open about negatives in their research or face criminal liability - a welcome step based on past manufacturer reluctance to blow the whistle on themselves by recall.



Product recall

Manufacturers dislike recalls because they are costly and because they open up an awareness of a problem in a disproportionate manner that may cause mass-tort litigation. The European Commission has taken action on this to ensure that defective products are recalled promptly.

The Consumer Protection Act in operation

The recent scandal of Sudan 1 dye in the international food chain has the potential to give clear guidance of the Act in operation if issues go to trial. Since July 2003, EC Regulations have required that all dried and crushed or ground chilli being imported must be certified as free from a colouring substance called Sudan 1. This was because it has carcinogenic implications.

Despite this, there was Sudan 1 in chilli powder imported into the UK from India which eventually made its way into myriad products - primarily from Worcester Sauce, something then used in many food products and not just in the UK. Once use of Sudan 1 was spotted, there had to be an expensive product recall with all the legal ramifications.

From a civil law viewpoint, the complex and still unproven facts make it difficult to give any opinion about where legal liabilities may rest. The manufacturers of the Worcester Sauce were not the original importers and so scrutiny of all companies involved in the chain from India is essential. Any consumer in the EC suffering proven ill-health from the carcinogenic product can claim against the place of purchase or consumption or against the manufacturer of the product. Consumers in theory might turn to the stores or restaurants or to the food manufacturer for compensation. Happily, it seems that the risk of any individual suffering from the low level dosage is remote. Proving ill-health will be a formidable burden.

Supermarket chains are not consumers and so contractual laws rather than the Act apply against their suppliers. Such retail outlets will check to see with whom they were in contract – perhaps manufacturers or other middlemen / distributors. They will establish what losses, if any, are claimable under the contract. They will also review their own insurance policies to see what rights they have for an indemnity from Recall Insurance cover.

The Sudan 1 incident is an excellent example of why all these companies needed public and products liability insurance coverage and for Product Recall costs. Unsubstantiated figures of £100 million have been mentioned as the estimated cost of the recall. It is fortunate that Sudan 1 in low dosage is arguably unlikely to cause any provable health effects. However, somewhere around will be another product that might give rise to a major product recall, to legal liability and to countless thousands of bodily injury claims with provable adverse health consequences.

Whoever is liable, the potentially costly implications serve as a warning to any company involved in selling or distribution of products, whether food or otherwise, to get early advice on their potential liability exposures and to have insurance protection, especially to cover a Product Recall. Besides, civil law implications, prosecutions could follow and again companies need to ensure that their policy covers the cost of legal defence.



Some leading cases

[Relph v Yamaha & Others 1996 – unreported](#)

The claimant was seriously injured when his 3-wheeler All Terrain Vehicle (ATV) overturned. He was a total novice yet he sued using the 1987 Act. There was a warning that the rider had to be experienced and the claimant had read this. His claim against all defendants under the Act failed. His claim alleging negligence failed as well.

[Worsley v Tambrands Limited \(2000\) PIQR95](#)

The claimant had read the warning on tampon packets of toxic shock syndrome but still used the products and ended up hospitalised when she did not recognise that TSS was the cause of her ill-health. The court barely distinguished between liability at common law and under the 1987 Act, and simply found that the warnings were a fair disclosure of the risk and it was irrelevant that better warnings were provided in the USA.

[Richardson v LRC Products Limited \(2001\) 59BMLR185](#)

The claimant alleged a condom had split during intercourse. She sued the manufacturer but failed because, due to the weight of evidence regarding the manufacturing process, she had not established existence of any manufacturing defect. It was not enough to prove a defect – it was necessary to prove the cause of the defect. The judge commented that the product exceeded British Safety Standards, but it is doubtful if this case lays down the principle that British Safety Standards equate to the norm expected by the general public. That would not be satisfactory. Such standards often lag behind the state of the art. This case was not approved or followed in the blood transfusion cases below.

[Foster v Biosil \(Central London CC 18th April 2000\)](#)

This was a County Court decision in which the Recorder was influenced by the Richardson condom decision. The claimant's breast implants were alleged to be defective. The right one was found by the judge to be satisfactory but the left one had leaked. The Recorder accepted this was not caused by the surgeon who did the implant. She decided that the left implant was unsafe, but that the claimant's case still failed because she could not prove by evidence the cause of the defect. Failure alone was not enough. In effect, despite the support of the Act, the claimant was being relegated to the old negligence standards and required to produce scientific evidence to establish what had gone wrong. This does not appear to be what the European Directive intended. The claimant was no better off than the original thalidomide victims.

[Abouzaid v Mothercare \(UK\) Limited \(Times Feb 20th 2001\)](#)

A child fixing an elasticated strap on a baby seat suffered an eye injury and sued at common law for negligence and under the Consumer Protection Act 1987. The Court of Appeal rejected the claim in negligence but found liability under the 1987 Act, though commenting that the case was on the border of failure. Expert testimony suggested that at date of manufacture, the state of expert knowledge would not have considered the design defective, but would have done when the accident occurred years later. The court held that an objective view of safety was required (the public expectation test) and meant that it was not relevant that there had been no recorded other accidents. The product had been defective from the outset and no warnings of the dangers had been given.



[A & Others v National Blood Authority \(2001\) 3 All ER289](#)

This was a vital definitive decision that gave the Act some teeth. The claimants had all been injected with infected blood and contracted Hepatitis C. Blood was a product within the 1987 Act. The judge decided that to see its purpose, the Act had to be read in the context of the Directive and by reference to the Articles of the Directive rather than just by reference to the UK Act. He decided that the blood was defective and that there was no defence open to resist liability. In reference to the case against the UK by the European Commission for not implementing the Directive because of the development risks defence, the judge determined that if a producer is faced with a known risk (being one which was known or ought to have been known), then continued supply is at own risk. The objective of the Directive was to prevent injury and facilitate compensation and Article 7(e) should not derogate from that.

[XYZ v Schering Health Care Limited and Others \(2002\) EWHC 1420 \(QB\)](#)

The claimants sued three drug companies alleging that the third generation of contraceptive pills caused cardio-vascular injuries. Reliance was placed on the 1987 Act but the claims failed. There was a mass of contradictory expert evidence and the claimants failed to establish that there was any increased relative risk of venous-thrombo-embolism.

[Bogle v McDonalds Restaurants Limited \(2002\) EWHC490 \(QB\)](#)

This was the UK's attempt to make the defendants liable for serving scalding coffee that caused injury when spilled. The USA case had succeeded amidst an outcry, but it was a much misunderstood decision that was sounder in law than the headlines suggested. The issue as far as concerns the 1987 Act was whether there was a duty to warn of the temperature and danger. Did the temperature make the coffee defective? The judge robustly rejected the claims. The fact that hot coffee was a danger if spilled was self-evident and no warning was needed. The cups and lids were safely designed.

[Leahy v Kinnarps AB – unreported](#)

The claimant sat down on a sofa in an insurance office. It gave way and the man was injured. The lawsuit was against the Swedish manufacturers under the 1987 Act and was settled for £80,000. Liability had been admitted subject to the issue of causation.

Summary of Case Law

The 1987 Act has not been a total success. The earlier decisions were consistent with the judiciary struggling with causation and the new concept of strict liability, not helped by the inclusion of the development risks defence. This defence while found to comply with the 1986 Directive was interpreted in the early decisions in a manner that negated the strict liability purpose of the Directive. Claimants found themselves mired in conflicting scientific testimony just as if proving negligence. However, the Mothercare and Hepatitis C decisions reflected a more mature approach with the court never losing sight of the Directive and its intent. Neither the ATV nor McDonalds cases were strong enough to add support to the complaints that the Act has failed. It is unfortunate that no decisions have reached the House of Lords. The conflicting decisions, without clear appellate guidance, make it a bold solicitor who will, at his own financial risk, take a products claim against a major company well able to finance a defence itself or through insurers. This is not what Brussels intended in 1986.



Practical advice to manufacturers to avoid a products disaster

- Evaluate the products liability risk
- Know your own suppliers and check that they are supplying products that are safe and lawful
- Be pro-active to counter that risk in-house or by shifting the burden to others by contract
- Check what regulations may apply to the product and ensure compliance
- Ensure that there is no reasonably available safer design
- Ensure that effective contracts are available so that even if it is not possible to contract out of liability, indemnity can be obtained from others
- Ensure others in the liability chain have insurance cover
- Maintain accurate records of research that shows what has been done to ensure that the product is state of the art
- Incorporate effective quality control to include raw materials to be used
- Check finished products
- Provide all needed warnings and instructions in clear language
- Check available insurance cover for liability or recall costs to include proper geographic coverage – see a disaster story below
- Keep records so as to make a recall easier
- Maintain records of all products complaints with details of actions taken or changes or improvements made
- Have a prepared procedure for effective action in the event of claims developing including recall procedures
- Know which agencies may require immediate notification in the event of a material claim – such as the Stock Exchange, Food Standards Agency or as otherwise required under the revised General Product Safety Directive
- Ensure appropriate public relations announcements will be made



James Budgett Sugars Limited v Norwich Union Insurance Limited (2002) All ER 222

The claimant was a sugar trader insured by the defendant. It had the benefit of a commercial public and products policy that covered loss but the issue was whether it covered direct and indirect liability from an Event. Sugar was sold to a food manufacturer who used it in mincemeat. The sugar was tainted by magnetite and so the mincemeat was withdrawn from sale and the buyer claimed, inter alia, for business interruption as it lost two customers. The claimant sought a court ruling on policy interpretation. The Judge commented that as the policy had not been negotiated but had been "off the shelf" in its terminology, there was no external evidence to determine what the parties had intended. He read the terms as not covering the buyer's claim as the customers had not backed off because of the physical damage to the mincemeat (claimable under the policy) but due to the breach of contract and so was not claimable.

The lesson is to ensure that the policy is bespoke, reflecting the precise risks to be covered.

Insurance aspects

Besides protecting against ultimate liability by indemnity clauses in contracts, producers and those in the supply chain should consider having the following insurance protection available to protect against joint and several liability:

- Public and products liability cover
- Middlemen / Suppliers should have similar cover, especially against the risk that the liability will solely be borne by them because the original producer may not be found or may be under or uninsured
- Product Recall Cover



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